The University of North Carolina at Greensboro

Procedures for Human Research Protection



Spring 2013

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1 Mission

The University of North Carolina at Greensboro (UNCG) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. In the review and conduct of research, actions by UNCG will be guided by the principles (respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Participants of Research*** (often referred to as the [Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)) and will be performed in accordance with the Department of Health and Human Services (HHS) policy, and regulations of [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) (also known as the “Common Rule”)[[1]](#footnote-1). The actions of UNCG will also conform to all other applicable federal, State, and local laws and regulations.

The University maintains an Institutional Review Board (IRB) to review research protocols involving human participants and to evaluate both risk and the protection against risk for participants. It is the function of the IRB to 1) determine and certify that all projects reviewed by the IRB conform to the policies and procedures in this document and the regulations and policies set forth under the Common Rule regarding the health, welfare, safety, rights, and privileges of human participants 2) assist investigators in complying with federal and state regulations and 3) ensure that research meets the universities ethical standard of “academic freedom” which the university is committed to.

1.1 Introduction

The UNCG ***Procedures for Human Research Protection*** details policies, regulations governing research with human participants, and the requirements for submitting research protocols for review by the UNCG Institutional Review Board. These policies and procedures apply to all research involving human participants, regardless of sponsorship and performance site, if UNCG faculty, staff, students, or facilities are involved.

UNCG is guided by the ethical principles regarding all research involving humans as set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research titled ***Ethical Principles and Guidelines for the Protection of Human Participants of Research***, often referred to as the [Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm), (National Commissions for the Protection of Human Participants of Biomedical and Behavioral Research, April 1979).

All institutional and non-institutional performance sites for UNCG, domestic or foreign, will be obligated by UNCG to conform to ethical principles which are at least equivalent to those of UNCG, as cited in the previous paragraph or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

In many cases, procedures required by UNCG are identical to those required or recommended by various federal agencies including the Office of Human Research Protections. Within the **UNCG Procedures for Human Research Protection,** text color is used to indicate wording that is from documents developed and distributed by such agencies. Blue text indicates wording from the Common Rule (45 CFR 46). Red text indicates wording from other relevant documents in which cases the source of the text appears in parentheses directly below the section in question.

1.2 Ethical Principles: The Belmont Report

**The Belmont Report**

It is the duty of UNCG Institutional Review Board to review and make decisions regarding all protocols for research involving human participants. The primary responsibility of the IRB is the protection of research participants from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of **three principles**, which are the touchstones of ethical research:

(1) that voluntary participation by the participants, indicated by free and informed consent, is assured;

(2) that an appropriate balance exists between the potential benefits of the research to the participants or to society and the risks assumed by the participants; and

(3) that there are fair procedures and outcomes in the selection of research participants.

These principles are referred to as **respect for persons**, **beneficence**, and **justice.**

**Respect for Persons: Voluntary Participation and Informed Consent.**

One of the most important elements in any research involving human research participants is the assurance of voluntary informed consent. Any person who is to be a research participant, whether that research is designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the associated potential risks and benefits are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB at UNCG strives to ensure voluntary informed consent of research participants through careful review of the recruitment and consent processes, and of the consent form or information sheet to be used with participants.

The informed consent concept is extended to those studies in which participants are not able to give personal consent for themselves. In such cases, the consent document is addressed to those who have been designated as responsible for the research participants’ well-being (e.g. parents of children). The IRB’s concern is to verify that the consent process and document are likely to assist these persons in making informed decisions which are in the best interest of the research participants. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme, there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential participants. The IRB must exercise special care when considering participants whose ability to give free and informed consent may be compromised in any way.

**Beneficence: The Risk-Benefit Ratio.**

The IRB is charged with deciding, for any proposed activity which falls under its jurisdiction, whether: “The risks to the participant are so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks” (Federal Register, May 30, 1974).

Assessment of the risk/benefit relation is a complex task. Risks of injury or discomfort to the individual can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. When reviewing applications, the IRB must carefully assess the types and degrees of both risks and benefits for a given participant population, as well as the investigator’s communication of these risks and benefits in the consent process and form. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research participant at risk, however minimal. Thus the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

**Justice: The Fair Selection of Research Participants.**

Both the risks and the potential benefits of research should be spread fairly among potential individual research participants and groups of individuals participating in research. Study design and selection of participants should avoid bias for or against particular social, racial, sexual, or ethnic groups.

**Sharing Research Risks**. The guiding principle in the ethical selection of research participant groups is that any risks of the research should fall upon the groups that might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus participant recruitment on vulnerable or disadvantaged groups (e.g. institutionalized people or prisoners, patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate. An undue share of research risks should not also burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the groups that might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the research participant population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations.

**Sharing Research Benefits**. In recent years, increasing attention has been paid to the rights of various groups to be included in research. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focus primarily on White middle-class research participant groups, the results of some trials have been of questionable value for members of other social, racial, sexual, and ethnic groups. As a result, both the National Institutes of Health and the Food and Drug Administration now require that study design include as broad a range of research participants as feasible and data be analyzed to uncover responses that differ between groups. Whereas women of child-bearing potential and pregnant and nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

2 Definitions

**Human Participant Research** – For the purposes of this policy research involving “human participant research” is defined as an activity that meets the definition of “research” and involves “human participants” as defined by 45 CFR 46.102(d)&(f).

**Research** – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

For the purposes of this policy, a **“systematic investigation”** is an activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question. Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study sample), inform policy, or generalize findings.

**Human participant** - a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through interventiona or interactionb with the individual, or
2. identifiable private informationc.

[aIntervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the subject's environment that are performed for research purposes.

bInteraction includes communication or interpersonal contact between investigator and subject.

cPrivate information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.]

**IRB** - an Institutional Review Board established in accord with and for the purposes expressed in this policy.

**IRB approval** - the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

**Minimal risk** - that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Certification**- the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human participants has been reviewed and approved by an IRB in accordance with an approved assurance.

**Moderate Exercise -** When evaluating participant safety during exercise testing or training, intensity (how hard the activity is—whether it is mild, moderate or vigorous) is not and should not be the primary issue. The primary issue is the level of cardiovascular, cerebrovascular, or musculoskeletal risk to be experienced by the person who is going to engage in a given intensity of exercise. The most important aspect of keeping individuals safe is to screen them properly prior to exercise participation. Some individuals who possess high levels of fitness along with satisfactory health histories and no serious personal risk factors are able to participate in very high intensity exercise testing or training and are at minimal risk for a serious medical event as a result of this activity. Their risk as associated with testing or training is close to the risk present in normal, everyday activities. This is in comparison to other individuals who have significant heart disease with symptoms and who should not participate in even mild/moderate exercise testing or training without American College of Sports Medicine (ACSM) certified personnel (or other properly certified personnel) directly supervising all aspects of the activity with a physician in close proximity.

**Agent of the University** – is anyone who has proper authority to make official representations on behalf of the University and/or bind the university to agreements.

**Engaged in Research** – when an UNCG employee or agent either intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes.

3 Institutional Authority

The Chancellor of UNCG has designated the Vice Chancellor for Research and Economic Development as the Institutional Official. The Director of the Office of Research Integrity is supported by the Vice Chancellor and both are responsible for carrying out the University’s human research protections program.

The UNCG IRB has jurisdiction over all human participants research (as defined above) conducted under the auspices of UNCG. Research under the auspices of UNCG includes research conducted at UNCG, conducted by or under the direction of any employee or agent of UNCG (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of UNCG using any property or facility of UNCG, or involving the use of UNCG’s non-public information to identify or contact human participants.

3.1 Assurance of Compliance

UNCG holds a Federalwide Assurance (FWA; Number 00000216). A FWA is an assurance of compliance with the federal regulations for the protection of human participants in research that is federally funded. The FWA is also approved by OHRP for Federalwide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support. UNCG maintains these same standards for all research involving human participants regardless of funding status.

3.2 UNCG ORI

The UNCG ORI reports directly to the Director of the Office of Research Integrity (“Director”) and is supervised by the Vice Chancellor for Research and Economic Development. The Vice Chancellor for Research and Economic Development is the Institutional Official and the Signatory Official on the Federalwide Assurance. The Director has expert knowledge in regulatory issues regarding human participants and has delegated authority for some signatory privileges on behalf of the Institutional Official. The Director supervises the Assistant Director who serves as the Human Protections Administrator, the primary point of contact and reviewer at UNCG for the Office for Human Research Protections, Department of Health and Human Services.

This office is staffed by other appropriate and knowledgeable individuals whose duties and responsibilities are found in their respective job descriptions, and whose performance is evaluated on an annual basis by the Director in accordance with UNCG Human Resource Standards.

3.3 North Carolina Law

UNCG and the UNCG IRB rely on the guidance of University Counsel for the interpretation and application ofNorth Carolina law and the laws of any other jurisdiction where research is conducted as they apply to human participants research. University Counsel has indicated that currently there are no specific state laws that apply directly/solely to research.

4 UNCG Institutional Review Board

The UNCG IRB is an administrative body established to protect the rights and welfare of human research participants recruited to participate in research activities conducted under the auspices of this institution.

The Director of ORI and Vice Chancellor for Research and Economic Development will review the activity of the IRB on an annual basis and make a determination as to the appropriate number of IRBs for the institution.

4.1 Authority of the IRB

The UNCG IRB reviews all research conducted under the auspices of UNCG and has the authority to approve, require modifications in, or disapprove such research. The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research participants [45 CFR 46.111]. In fulfilling these responsibilities, the IRB is expected to review all research documents and activities that bear directly on the rights and welfare of potential participants in proposed research. The research protocol and consent/assent document(s) are examples of information/materials that the IRB should review. The IRB should also review the methods and materials that investigators propose to use to recruit participants.

Before any human participant is involved in research conducted under the auspices of UNCG, the UNCG IRB will give proper consideration to:

1. the potential risks to participants
2. the anticipated benefits to participants, others, and society
3. the importance of the knowledge that may reasonably be expected to result from the research
4. the informed consent process to be employed

The IRB has the authority to suspend, place restrictions on, or terminate approval of research activities that fall under its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected adverse events. The IRB has the authority to observe or have a third party observe the consent process and the research if the IRB determines it to be indicated.

4.2 Jurisdiction of the IRB

The IRB jurisdiction extends to ALL research (funded and not funded) involving human participants conducted at UNCG, as well as research conducted elsewhere by UNCG faculty, staff, and students.

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the Director or Vice Chancellor for Research and Economic Development, depending on the circumstances. The institution will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

4.3 IRB Relationships

The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human participants are adequately protected. The IRB has review jurisdiction over all research involving human participants conducted, supported, or otherwise participant to regulation by any federal department or agency that has adopted the human participants regulations.

The Research Advisory Commission (RAC) ensures a dialogue is maintained between the various compliance entities at the University. The committee will act in an advisory capacity to the Vice Chancellor for Research and Economic Development, monitoring the effectiveness of existing integrity programs, developing new or revised policies as changes in requirements occur, and disseminating updated compliance information to the research community.

Institutional officials may NOT approve research if it has been disapproved by the IRB.

**Relationships with other institutions:** UNCG may choose, on a case-by-case basis, to provide human research protection oversight for another institution or allow that institution to provide oversight over a study at UNCG. In order for a University to provide this oversight, a formal relationship must be established between the University and the other institution through either a Cooperative Agreement or a Memorandum of Understanding. This relationship must be formalized before the University will accept any human research proposals from the other institution.

In the conduct of cooperative research projects, UNCG acknowledges that each institution is responsible for safeguarding the rights and welfare of human participants and for complying with applicable federal regulations. When a cooperative agreement exists, UNCG may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

* When UNCG relies on another IRB, the Director will review the policies and procedures of that IRB to ensure that they meet UNCG standards. If the other IRB is part of an accredited Human Research Protections Policy (HRPP), then it will be assumed that the UNCG standards are being met.
* When UNCG reviews research to be conducted at another institution, the particular characteristics of each institution’s local research context must be considered, either (i) through knowledge of its local research context by the UNCG IRB or (ii) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other IRB members.
* When UNCG is the coordinating center for a multi-center protocol, the IRB will require the UNCG PI to ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. At the time of initial review, the IRB will assess the procedures for dissemination of protocol information (e.g. unanticipated problems involving risks to participants or others, protocol modifications, interim findings) to all participating sites.
* Multi-site studies submitted to IRB by UNCG Faculty

Because cooperative or reliance agreements are on a case-by-case basis, all UNCG faculty research should be on file with the UNCG IRB if they are collaborating with another institution so that there is a record maintained at each site. IRB approval from that site, if applicable, should also be submitted to the IRB at the time it is received.

**Research at Cone Health**

Cone Health System IRB has signed Authorization Agreements to rely on the IRBs at the University of North Carolina located at Greensboro, NC and Chapel Hill, NC (UNC School Systems) for review of research proposals in which investigators at UNC School Systems plan to collaborate with the Cone Health System (CHS).

Cone Health System asks that the UNC-A-01 IRB form be completed for studies using this Authorization Agreement. This form is located under the “Forms” link on the CHS IRB website: <http://www.mosescone.com/IRB>. Cone Health System would like to receive notification of annual renewals, closure notices, and SAEs/Unanticipated Problems for all Cone Health System patients. These submissions will be reviewed and placed in the appropriate file.

4.4 Roles and Responsibilities

4.4.1 Chairperson of the IRB

The Director, on behalf of the Institutional Official, recommends individuals to the Vice Chancellor for Research and Economic Development to serve as Chairperson of the IRB. The Associate Provost, in consultation with the Provost for Academic Affairs and approval of the Chancellor, appoints a Chair of the IRB to serve for renewable two-year terms. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chair should be a highly-respected individual from within or outside the University fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair and the Director of the ORI. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair is a voting member of the IRB and counts toward quorum. The IRB Chair is responsible for conducting IRB meetings and is a signatory for correspondence generated by the IRB. The Assistant Director of the ORI will serve as co-Chair if the Chair is unavailable to Chair an IRB meeting.

The IRB Chair may designate other IRB members (e.g., the Past Chair, ORI Director and, specific IRB members) to perform duties as deemed appropriate including reviewing and protocols with signature authority.

The IRB Chair advises the Director of the ORI about IRB member performance and competence.

The performance of IRB Chair will be evaluated on an annual basis by the Director and the Vice Chancellor for Research and Economic Development. If the Chair is not acting in accordance with the IRB’s mission, following these policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair, a recommendation for removal may be made by the Vice Chancellor for Research and Economic Development to the Chancellor.

### 4.4.2 Subcommittees of the IRB

The Chair, in consultation with the Director, may designate one or more other IRB members (i.e., a subcommittee) to perform duties as deemed appropriate including reviewing protocols with signature authority, and other IRB functions.

**Duties of a subcommittee** may include the following:

1. Serve as designees by the IRB Chair for the **expedited review** of new or continuing protocols and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB and must be matched as closely as possible with the field of expertise for the study. This individual is usually the Assistant Director to the ORI but at the discretion of the IRB Chair can appoint any IRB member with deemed capable in review of the type of research being conducted.
2. **Review and approve revisions requiring only simple concurrence** submitted by investigators for a protocol given provisional approval, i.e. deferred for minor changes, by the convened IRB.
3. **Conduct an inquiry.** A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to conduct an inquiry into allegations of IRB non-compliance. Such a subcommittee will be given charges by the IRB, which may include any or all of the following:
4. Review of the protocol(s) in question;
5. Review of any relevant documentation, including consent documents and investigational files, etc. as they relate to the investigator's execution of the relevant research involving human participants;
6. Interview of appropriate personnel;
7. Preparation of either a written or oral report of findings to be presented to the full IRB at its next meeting;
8. Recommendation actions.
9. **Conduct on-site review.** Determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing particularly risky research, an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, or a project/investigator whose initial application or modification application has raised concerns in the eyes of the IRB may be subject to on-site review by an IRB subcommittee. Such a review might occur, or approval might be subject to an audit of study performance, after a few months of enrollment or after enrollment of the first several participants.

4.5 Resources for IRB

The Vice Chancellor for Research and Economic Development provides resources to the IRB and the ORI, including adequate meeting and office space and staff for conducting IRB business. Office equipment and supplies including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources provided for the IRB and the ORI will be reviewed during the annual budget review process

4.6 Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation

The ORI staff will conduct investigations and audits of ongoing research when the IRB directs an audit be conducted or a complaint or allegation of non-compliance is received. In addition, the staff will conduct “for cause” and “not for cause” audits of research. (See Section 11 for a detailed discussion of investigations and audits.)

The ORI will conduct an annual survey of all active researchers and committee members to evaluate the IRB’s performance. The survey will be conducted at the beginning of each academic year.

5 IRB Membership

**5.1 Composition of the IRB**

* 1. The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
	2. The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

# In addition to possessing the professional competence necessary to review specific research activities, The IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

# If the IRB regularly reviews research that involves a vulnerable category of participants (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB, who are knowledgeable about and experienced in working with these participants. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants (see Section 5.3).

1. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.
2. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
3. The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
4. One member may satisfy more than one membership category.
	1. Appointment of Members to the IRB

The IRB Chair and the Director of the ORI identify needs for new or replacement members, or alternate members. Department Chairs and other UNCG administrators may forward IRB nominations to the Director, the Vice Chancellor for Research and Economic Development, the ORI, or the IRB Chairperson.

In replacing faculty members on the IRB, the Director will consult with the current IRB members to request a recommendation for replacement. The Director will then contact the nominee to discuss his or her interest and/or qualifications. If there are no nominees, then appropriate Department Chairs or Program Directors will be contacted in writing by the Vice Chancellor for Research and Economic Development or the Director concerning the vacancies and nominees will be solicited from the Department Chairs or Program Directors.

The final decision in selecting new members is made by the Vice Chancellor for Research and Economic Development and the Director.

Appointments are made for a renewable three-year period of service. Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the Chair.

On an annual basis, the IRB Chair and the Director review the membership and composition of the IRB to determine if it continues to meet regulatory and institutional requirements.

**Alternate members:** The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member.

The IRB roster identifies the primary member for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an alternate member replaces a primary member. Alternate IRB members should be individuals who have formerly served as regular IRB members so as to ensure their knowledge, ability and familiarity with UNCG IRB policies and procedures and relevant federal documents governing IRB operations.

5.3 Use of Consultants (Outside Reviewers)

When necessary, the IRB Chair or the Director may solicit individuals from the University or the community with competence in special areas to assist in the review of issues or protocols which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. For full reviews, the need for an outside reviewer will be determined in advance of the IRB meeting in which the review will occur by the Director or the Chair by reviewing the protocols scheduled to be reviewed at the convened meeting. The ORI will ensure that all relevant materials, including the protocol, are provided to the outside reviewer prior to the convened meeting. For expedited or exempt reviews, the need for an outside reviewer will be determined by the Director or the Chair by reviewing the protocol itself. The ORI will ensure that all relevant materials are provided to the outside reviewer as soon as he or she is identified.

Prior to committing to review, consultants will be informed of the IRB conflict of interest policy either by telephone or letter from the Director. Consultants must verbally confirm to the Director that they do not have a conflict of interest prior to review. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

In the case of full reviews, the consultant’s findings may be presented to the IRB for consideration in person. If in attendance, these individuals will provide consultation but will not participate in the vote. The consultant may be asked to participate in the IRB’s deliberations at the IRB’s discretion. In the case of expedited or full reviews, consultants will be asked to provide written documentation concerning their findings. Written statements of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes.

Ad hoc or informal consultations requested by individual members (rather than the full board) will be provided in a manner that protects the researcher’s confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

5.4 Duties of IRB Members

IRB Members have many responsibilities inclusive of initial protocol and modification review, attending committee meetings, assisting in procedure development, and possibly serving on subcommittees.

In preparation for convened meetings, IRB members are provided the following information: the agenda and submission materials including protocols, proposed informed consent forms, and other appropriate documents. These are distributed to members prior to the convened meetings at which the research is scheduled to be discussed. Members receive the materials at least one week before each meeting in order to participate fully in the review of each proposed project. IRB members will treat the research proposals, protocols, and supporting data confidentially. All copies of the protocols and supporting material are returned to the IRB staff at the conclusion of the review for document destruction.

5.5 Attendance Requirements

Members should attend all scheduled IRB meetings. Given that IRB meetings are scheduled at a standard time and location, individuals should not be appointed to the IRB unless they have indicated their willingness and ability to attend meetings as scheduled. Members should not miss more than 25% of scheduled meetings. If a member is unable to attend a scheduled meeting, he or she should inform the IRB Chair or an ORI staff member. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the Director. This is vital to ensure that quorum can be met at all meetings.

If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate (See Section 7.5.2), the alternate may serve during the primary member’s absence, provided the IRB has been notified in advance.

5.6 Training / Ongoing Education of Chair and IRB Members in Regulations, Procedures

A vital component of a comprehensive human research protection program is an education program for the IRB Chair and the IRB members. UNCG is committed to providing training and an ongoing educational process for IRB members and the staff of the ORI related to ethical concerns and regulatory and institutional requirements for the protection of human participants.

**Orientation**

New IRB members, including alternate members, will meet with the IRB Chair and Director for an informal orientation session. At the session, the new member will be given an IRB Handbook (binder) that includes:

* A copy of the Belmont Report;
* UNCG Policies and Procedures for the Protection of Human Participants;
* An IRB Member Handbook;
* Federal regulations 45 CFR 46
* An Investigator 101 CD
* CITI UNCG IRB Group Modules

New members are required to complete the Initial Education requirement for IRB members before they may serve as Primary Reviewers. New members must also sign a Confidentiality Statement to be kept on file at the ORI.

**Initial Education**

In addition to the orientation meeting described above, IRB members will complete the following online tutorials and review all reference documents listed:

* Review UNCG Conflict of Interest policy
* Review UNCG Misconduct and Integrity policy
* Review UNCG Human Research Participant policy
* View Investigator 101 CD
* Complete CITI IRB Group modules

ORI staff will complete the following:

* View Investigator 101 CD
* Review UNCG Conflict of Interest policy
* Review UNCG Misconduct and Integrity policy
* Review UNCG Human Research Participant policy
* Review UNCG Confidentiality Agreement
* Review HIPAA guidance
* Review Data Safety guidance
* Review 45 CFR 46
* Review OHRP guidebook
* Review PRIM&R conference proceedings
* Complete CITI Behavioral Social Science modules

**Continuing Education**

To ensure that oversight of human research is ethically grounded and that decisions made by the IRB are consistent with current regulations and policies, training will be ongoing for IRB members throughout their service on the IRB. Ongoing educational activities will include, but are not limited to:

* In-service training at IRB meetings
* Reviewing copies of appropriate publications
* Identification and dissemination by the Director of new information that might have affected the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues distributed to IRB members via email, mail, or during IRB meetings
* Access to the ORI resource library.
* Completion of CITI

The Vice Chancellor for Research and Economic Development will provide support for the Chair and as many members of the ORI/IRB staff as possible to attend the annual PRIM&R conference on human research protections.

5.7 Liability Coverage for IRB Members

All University employees and authorized volunteers at UNCG are covered by the Defense of State Employees Act and the UNC System excess liability insurance policy in case of a lawsuit claiming that the employee or volunteer injured another's person or property. In order to qualify for that coverage, the employee or volunteer must have been acting within the course and scope of his or her job or volunteer duties and must not have violated laws, regulations, or University policies. Intentional acts of wrong doing are also excluded. The coverage provides for free legal defense by the Attorney General's office and, if a judgment is entered against the employee or volunteer, the judgment will be paid up to the limits of coverage (currently $5,000,000). All UNCG IRB members will be covered under the conditions described here. More information can be found at: <http://www.uncg.edu/ucn/faq/liability.html>

5.8 Performance of IRB Members

The performance of IRB members will be discussed on an annual basis by the Director, the IRB Chair, and the Vice Chancellor for Research and Economic Development. Members who are not acting in accordance with the IRB’s mission, following these policies and procedures, have an undue number of absences (more than 25%), or are not fulfilling the responsibilities of an IRB member may be recommended for removal by the Vice Chancellor for Research and Economic Development to the Chancellor.

6 IRB Records

The IRB must prepare and maintain adequate documentation of the IRB’s activities including copies of all items reviewed including, but not limited to, research protocols, recruitment materials, scientific evaluations (if any) that accompany protocols, approved consent documents, DHHS approved sample consent documents when they exist, any proposed amendments and the IRB action on each amendment, progress reports submitted by investigators, reports of injuries to participants and serious and unexpected adverse events, documentation of protocol violations, and documentation of non-compliance with applicable regulations.

Documentation of verified exemptions will consist of the reviewer’s written concurrence that the activity described in the investigator’s request satisfies the conditions of the cited exemption category.

IRB records for initial and continuing review by the expedited procedure must include the specific permissible category, a description of action taken by the reviewer, and any determinations required by the regulations and protocol-specific findings supporting those determinations.

IRB records must document any determinations required by the regulations and protocol-specific findings supporting those determinations.

IRB records must also include continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to participants. Such information must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

All IRB records, including protocols, are covered under the North Carolina Public Records Act and must be made available to requesting North Carolina residents upon request. Exceptions to this requirement include data and information protected under HIPAA and proprietary information.

6.1 Minutes of an IRB Meeting

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. Once approved by the members at a subsequent IRB meeting, the minutes must not be altered by anyone including a higher authority. Minutes of IRB meetings must contain sufficient detail to show:

1. The presence of a quorum when official business is conducted;
2. Attendance at the meetings including those members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions;
3. Alternate members attending the meeting and the members for whom they are substituting;
4. Actions taken by the IRB including those involving full review. The IRB must use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be exempt from IRB review (on a quarterly basis);
5. Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;
6. Documentation that the research reviewed meets the required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent;
7. Documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived;
8. When approving research that involves populations covered by section 10, the minutes will document the IRB’s justifications and findings regarding the determinations stated in the Subparts or the IRB’s agreement with the findings and justifications as presented by the investigator on IRB forms.
9. The vote on actions, including the number of members voting for, against, and abstaining;
10. A note indicating that when an IRB member has a real or potential conflict of interest, as defined by University policy (see Section 7.5.9), relative to the proposal under consideration the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained);
11. The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs;
12. A written summary of the discussion of controversial issues and their resolution;
13. Review of additional safeguards to protect vulnerable populations if entered as study participants when this is not otherwise documented in IRB records;
14. The determination of the level of risk, if not recorded elsewhere in IRB records;
15. The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;
16. Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization;
17. Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.
18. Note the justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS approved sample consent document.
19. Note the rationale for significant risk/non-significant risks device determinations.

6.2 Membership Rosters

A membership list of IRB members must be maintained; it must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain information such as a member’s name, earned degrees, affiliated or non-affiliated status, member status as scientist (physician-scientist, other scientist, non-scientist, or social behavioral scientist); voting status, alternate status, or status as chairperson.

The ORI must keep IRB membership lists current.

The Director must promptly report changes in IRB membership to the Office for Human Research Protections, Departments of Health and Human Services.

6.3 Records Retention Requirements

The above detailed records must be stored securely in the ORI and must be retained for at least 3 years.

Records pertaining to research which is conducted must be stored securely in the ORI and must be retained for three years after the application is closed. After that time, the records will be destroyed or archived. All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

Any paper records will be maintained in secured storage rooms in locked file cabinets in the ORI and electronic records will be password protected. IRB records are available only to IRB members (including the Chair), ORI staff and authorized entities as specified above.

6.4 Written Procedures and Guidelines

The UNCG ***Procedures for Human Research Protection*** detail the regulations governing research with human participants and the requirements for submitting research proposals for review by the UNCG IRB.

These procedures also detail:

1. Written procedures which the IRB must follow for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution, determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, and ensuring prompt reporting to the IRB of proposed changes in a research activity and for ensuring that such changes in approved research during the period for which IRB approval has already been given may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.
2. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the federal Department or Agency head of any unanticipated problems involving risks to participants or others, or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB suspension or termination of IRB approval.

The procedures present the most current information for reference by potential investigators and their staff; however, this is not a static document. The procedures are subject to annual review and revision by the Director, the Institutional Review Board, and University counsel. The Vice Chancellor for Research and Economic Development, in consultation with the Director, will approve all revisions of the procedures. The Director will keep the University research community apprised of new information that may affect the human research protection program including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website and through campus electronic mailing lists. The procedures will be available on the UNCG IRB website and copies will be available upon request.

7 IRB Review Process

7.1 IRBIS Online Submission

In February of 2013, the Office of Research Integrity introduced an online submission system to the UNCG campus. This system allows Faculty and Student Researchers to submit their IRB proposal electronically as well as direct communication with the IRB reviewer. The system has a built-in, smart logic to help with the application process and guides the applicant through the process by addressing specific items in relation to the federal guidelines.

These procedures and guidelines apply to all research involving human participants, regardless of sponsorship and performance site, conducted under the auspices of UNCG. During the review process, PI’s are responsible for responding to the IRB’s inquiries within 60 days or the protocol will be administratively withdrawn.

7.2 Human Participants Research Determination

The responsibility for the initial determination as to whether an activity constitutes human participants research rests with the investigator, but can also be determined by the IRBIS online system and the IRB reviewer. The investigator is responsible for submitting an application to the IRB for review and should pursue this determination based on the definition of “human participant research” in Section 2. Since the University will hold them responsible if an IRB application was not submitted when it was required, investigators are urged to request a confirmation from the ORI that an activity does not constitute human participants research. If the request is verbal (by phone or in person) or by email, it is the investigator’s responsibility to maintain documentation of such a decision. If the investigator submits a formal submission, the request must include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file.

Examples of Research That Does Not Involve Human Participants:

* Research involves only analysis of data from a database that contains no individually identifying or private information (see SOP 15.8 for definition of private information).
* Research involves analysis of private information or specimens that were not collected specifically for the currently proposed research project through interaction or intervention with living individuals **and** the data is coded in such a way that the researcher cannot readily ascertain the identity of the individuals to whom the information pertains (SOP 15.8).

7.3 [Exempt Research](http://www.hhs.gov/ohrp/policy/exmpt-pb.html)

All research using human participants must be approved by the institution. Certain categories of research (i.e. “exempt research”) do not require convened IRB review and approval. Exempt research is subject to institutional review and must be reviewed by the initial reviewer and approved by ORI staff, IRB Chair, or the Director. Once the investigator completes the screening questions in IRBIS, the system will ask whether they would like to have their study considered for exemption. If the investigator responds “yes”, they will answer a series of questions to determine whether their study qualifies for exempt review. If the study does qualify, the investigator will be directed by the system to complete the exempt application. If the study does not qualify for exemption, the investigator will be directed by the system and or the IRB Reviewer to complete a full application.

There are no expiration dates on exempt research and the PI will be responsible for closing the study when research has been completed. Any modifications to an exempt protocol must be submitted for review to ensure that the study continues to meet exempt status. The IRB does ask that the PI notify the ORI when a study is complete by submitting a closure form or closing the study within the IRBIS system.

### 7.3.1 Categories of Research Permissible for Exemption

With the above exceptions, when the only involvement of human participants in a research study will be in one or more of the following categories that study is exempt from IRB review, but requires institutional review, at UNCG:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
	1. research on regular and special education instructional strategies, or
	2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

\*Informed consent is required. However, documentation can be waived at the discretion of the IRB.

Examples: Teacher Action research can fit into Category 1 if:

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
2. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants ; and
3. Any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

\*Informed consent is required. However, documentation can be waived at the discretion of the IRB

 Examples of Research that is eligible for exemption under category 2:

* Researcher conducts a mail or email survey that collects no individually identifying information from participants
* Researcher collects individually identifying information, but the nature of the information is such that possible disclosure of individual responses would not reasonably place participants at risk in the ways cited in 2b above.
* Researcher originally collected individually identifying information on participants, but has destroyed the key linking individuals to their information. This project would not have been eligible for exemption until the key was destroyed and the researcher could no longer link participants to their information. This exemption is often used once data collection is complete and only analysis and manuscript preparation are ongoing.
1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if:
2. the human participants are elected or appointed public officials or candidates for public office; or
3. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

\*Informed consent is required. However, documentation can be waived at the discretion of the IRB

1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

\*Informed consent is generally not required for this category of research. However, the IRB will make this determination and note if any waivers can be applied.

5. Taste and food quality evaluation and consumer acceptance studies,

1. if wholesome foods without additives are consumed; or
2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

\*Informed consent is required however; documentation and other elements can be waived at the discretion of the IRB.

### 7.3.2 Categories of Research NOT Permissible for Exemption

Vulnerable Populations:

* Children: Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. (See Section 10.1.1 for the definition of a child).
* Exemptions do NOT apply for Prisoners, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged.
* Pregnant women when engaging in physical activity are not eligible for exemption.

Impermissible Research

* Studies that involve deception are not eligible for exemption.
* Studies that involve techniques which expose the participants to discomfort or harassment beyond levels encountered in daily life are not eligible for exemption.
* Studies that involve review or obtaining sensitive information with or through identifiers linked to participants are not eligible for exemption.

### 7.3.3 Additional Protections

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report. The individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report.

7.4 Expedited Review of Research

The IRB may use the expedited review procedure to review either or both of the following:

1. some or all of the research appearing on the list of expedited review categories and found by the reviewer(s) to involve no more than minimal risk,
2. minor changes in previously approved research having received expedited review during the period (of one year or less) for which approval is authorized

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to participants, (ii) the research design or methodology, (iii) the number of participants enrolled in the research (no greater than 10% of the total requested), (iv) the qualifications of the research team, (v) all added procedures fall into categories (1)-(7) of research that could be reviewed using the expedited procedure, (vi) the facilities available to support safe conduct of the research, or (vii) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

Under an expedited review procedure, the final review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among members of the IRB. IRB members, who serve as designees by the IRB Chair for expedited review, will be experienced in terms of seniority on the IRB and will be matched as closely as possible to the field of expertise for the study. Alternate members will not be designated as expedited reviewers.

Once the online application is received by ORI, the IRB Chair and IRB member(s) will review the application and all accompanying documentation.

If stipulations are noted and modifications are required, the reviewer will inform the investigator via IRBIS and email. Once the PI has responded to the stipulations, they will re-submit the application to ORI via IRBIS. The IRB reviewer will ensure that all modifications have been made prior to forwarding the application to the IRB Chair for final review. If the reviewer(s) find that the research does not meet the criteria for expedited review or if they recommend review by the full IRB, the PI will be notified and the protocol will be placed on the agenda at an upcoming IRB meeting.

In the event that expedited review is carried out by more than one IRB member and the expedited reviewers disagree, the Director and/or IRB Chair may make a final determination. The protocol will be submitted to the IRB for full review at the discretion of the Director or IRB Chair.

In reviewing the research, the reviewers will follow the Review Procedures described in Section 7.5 and may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full review.

### 7.4.1 Categories of Research Eligible for Expedited Review

[63 FR 60364-60367, November 9, 1998]

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

* The categories in this list apply regardless of the age of participants, except as noted.
* The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
* The expedited review procedure may not be used for classified research involving human participants.
* The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

**Research Categories one (1) through seven (7) pertain to both initial and continuing IRB review:**

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children1, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. [1Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."][[45 CFR 46.402(a)](http://irb.mc.duke.edu/45cfr46.htm#46.402)]

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human participants. See Exempt Categories and 45 CFR 46 101(b)(4). This listing refers only to research that is not exempt.]

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human participants. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; *or*

(b) where no participants have been enrolled and no additional risks have been identified; *or*

(c) where the remaining research activities are limited to data analysis.

[Of note, category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no participants have been enrolled" is interpreted to mean that no participants have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

**Note**: if a research protocol has been initially approved through a full-board review procedure, the continuing review may **not** be done by the expedited review procedure unless it falls within Category 8 or 9, above.

### 7.5 Full Board Meetings

Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings (also known as **Full-Board meetings**) at which a **quorum** (see below) is present.

### 7.5.1 Schedule of IRB Meetings

The IRB meets on second and fourth Wednesdays on a regular basis throughout the academic year. The schedule for the IRB may vary due to holidays or lack of quorum.

### 7.5.2 Quorum

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. The IRB Chair, with the assistance of the IRB staff, will confirm that an appropriate quorum is present prior to initiating any discussion regarding the full review. The IRB Chair will be responsible for ensuring that the meetings remain appropriately convened.

ORI staff will monitor quorum and ensure that quorum is met prior to initiating any discussion regarding the full review. If a quorum is not maintained, the protocol must be tabled or the meeting must be terminated. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest (see below). In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

It is strongly recommended that IRB members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this case, the member must have received all pertinent materials prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, telephone, facsimile, or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

### 7.5.3 Pre-Meeting Distribution of Documents

The place and time of meetings will be set forth on the agenda cover sheet distributed to all IRB members. All materials for review must be submitted 7-10 days prior to the next scheduled meeting.

The agenda, along with all protocols and supporting documentation to be reviewed at the meeting, are provided to all IRB members approximately one week prior to each meeting through the IRB Zone.

### 7.5.4 Guests

The Principal Investigator (and students affiliated with faculty research) may be invited to the IRB meeting to answer questions about their proposed or ongoing research. The IRB must ensure compliance with the North Carolina Open Meetings Law. All IRB meetings may be attended by guests from the public who may also review IRB minutes. The IRB has the ability to go into closed session which must be done with a motion and vote during open session. This motion must state the reasons and authority for closing that portion of the meeting. Discussion during the closed session must be limited to the subject matter for which a closed meeting was authorized. Final action on closed session matters may be made in closed session and does not need to be repeated in open session. Closed sessions must also include minutes which would not be available for review by guests. Guests may not speak unless requested by the IRB.

### 7.5.5 Informing the IRB

All members of the IRB will be informed at the next scheduled meeting of all expedited review approvals by means of the agenda under a section entitled "Approved Expedited protocols” Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

### 7.5.6 Primary Reviewers for Full Review Applications

The ORI staff assigns a Primary Reviewer from the members of the IRB for all protocols requiring initial full review. In most cases, the primary reviewer will be ORI staff or the IRB member who represents the department or school from which the protocol originated. Reviewers are assigned protocols based on related expertise. When making reviewer assignments, IRB staff takes into consideration the vulnerable populations involved in the research and assigns the protocol to at least one individual who has experience with this population or research topic. If the IRB Staff cannot identify a primary reviewer with appropriate expertise, the IRB Chair or the Director may solicit consultants from the University or the community with competence in special areas to assist in the review of issues or protocols which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB (see “Use of Consultants,” Section 5.3).

Before the meeting, the protocol application (including background information, project protocol, IRB protocol review checklist, and informed consent and the DHHS-approved sample consent document when one existed) is carefully reviewed by the Primary Reviewer.

At the meeting, the **Primary Reviewer** presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators and leads the IRB through the completion of the criteria for approval appropriate for the type of review (initial, continuing, or modification). Problems identified by the Primary Reviewer or by other IRB members are discussed and suggestions for any necessary changes are agreed upon by the IRB. These issues are considered in the vote to decide IRB action. Length of discussion can vary from a few minutes to over an hour when investigators make formal presentations or information from outside experts is required.

### 7.5.7 IRB Required Information for Review by Full Board

The Protocol Application must, at a minimum, include enough information for reviewers to make determinations based upon the **Criteria for IRB approval of Research** [45 CFR 46.111]. Each application must include or address:

1. Title of the study
2. Purpose of the study
3. Sponsor of the study
4. Participants inclusion/exclusion criteria
5. Recruitment Procedures
6. The importance of the knowledge that might reasonably be expected, i.e., the scientific or scholarly validity.
7. Description of procedures to be performed
8. The possible/potential risks to the participants
9. Provisions for minimizing risks/managing adverse reactions
10. The anticipated benefits of the research
11. Circumstances surrounding the consent procedure
12. Setting
13. Participant autonomy concerns
14. Language difficulties
15. Vulnerable populations
16. Procedures for documenting informed consent
17. Obtaining assent from minors
18. Using witnesses and/or translators
19. Document storage
20. Compensation to participants for their participation
21. Compensation for injured research participants (for more than minimal risk studies)
22. Provisions for protection of participant’s privacy
23. Protocol-specific conflict of interest information

Assurances:

1. The PI must certify that
	* 1. the study has been designed to protect the human participants;
		2. the PI is responsible for the scientific conduct of the research and for providing all reports and information to the IRB as required;
		3. all members of the research team are appropriately credentialed to perform the work undertaken in the protocol; and
		4. the PI and the other co-investigators are not in violation of the university’s Conflict of Interest Policy while participating in the research.

### 7.5.8 Materials Received by the IRB

IRB members reviewing protocols receive a copy of the full application, IRB protocol review checklist and attachments (consent and assent forms, recruitment materials, certifications, etc.) as well as relevant correspondence between the PI and the IRB reviewer and/or IRB Chair.

All IRB protocols for research funded or proposed to be funded by any agency under the umbrella of DHHS must include as an attachment a copy of the full grant proposal, including budgets. DHHS requires that the IRB compare the IRB application and the grant proposal to be sure that they are consistent in all respects relevant to the protection of human research participants. To assist the IRB in making this determination, PIs are required to (1) sign a statement indicating that research described in the IRB application and research described in the grant proposal are identical in all respects, (2) use page numbers to reference specific sections of the grant proposal within the IRB application in an effort to demonstrate the identical nature of recruitment and data collection procedures described within each document, and (3) highlight such sections within the grant proposal to assist IRB reviewers in locating text and comparing across the two documents. PIs are NOT to cut and paste the complete methods section of the grant proposal into the IRB application, but rather are to present an abbreviated form of this information that can be compared to the information within the grant proposal.

The UNCG IRB requires that agency letters be included with IRB applications under either of the following two circumstances:

1. Under circumstances involving UNCG being “either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.” Under such circumstances, the UNCG investigator must attach to the IRB application such evidence which may take the form of an agency letter.
2. Under circumstances involving an agency, school, organization, or individual providing the researcher access to potential research participants or authorizing data collection at the location of the agency, school, or organization. Consistent with this requirement:
	1. When access to potential research participants involves use of organizational directories, mailing lists, etc., the agency letter is not required if the contact information is publicly available or can be purchased for the purpose of contacting potential research participants.
	2. In the case of listserves, agency letters are not required when an individual managing the listserve sends out the recruitment information (as such an action implies agreement of the managing individual/organization). If an individual who does not manage the listserve sends out the information (e.g., a listserve member), an agency letter or documentation explicitly stating that the listserve is available for recruitment of research participants must be attached to the application.
	3. Recruitment of participants from a UNCG class requires an agency letter from an instructor or department chair unaffiliated with the research project. This documentation should be kept on file by the PI, but is not required at submission.

NOTE: Agency letters are not required when an agency, school, organization, or individual will be made aware of the research project and asked to refer potential participants to the investigator to be provided additional information regarding participation.

### 7.5.9 IRB Member Meeting Conflicts of Interest

IRB members and consultants will not participate in any IRB action taken, including the initial and continuing review of any project, in which the member or consultant has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB staff who will re-assign the protocol for review.

An IRB member is considered to have a conflict of interest when the IRB member or an immediate family member of the IRB member:

1. Is involved in the design, conduct, or reporting of the research
2. Is the project director or other member of the research team
3. Has a financial interest in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research
4. Has a financial interest in the research with value that exceeds the specified monetary threshold in the University Conflict of Interest Policy
5. Has received or will receive any compensation whose value may be affected by the outcome of the study
6. Has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright, or licensing agreement)
7. Has received payments from the sponsor that exceed the specified monetary threshold in the University Conflict of Interest Policy in one year
8. Is an executive or director of the agency/company sponsoring the research
9. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol

Except when requested by the IRB to be present to provide information, IRB members will recuse themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. The Chair will allow for board discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

In accordance with UNCG policy, all IRB members who are UNCG faculty and staff will have submitted annual disclosure forms to the Conflict of Interest Committee.

If the Conflict of Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or Director.

### 7.5.10 Possible IRB Actions Taken by Vote (Full Review Protocols)

**Approval** - The study is approved as submitted.

**Minor stipulations-** The Committee will approve the submission pending adequate response to stipulated changes and/or clarifications as detailed in these minutes and in a response to the principal investigator for the requested changes. The Chair and another IRB member is authorized to grant final approval upon verifying a satisfactory response to the stipulated changes.

**Deferred**- The Committee requested further information or substantive changes as detailed in these minutes and in a memo to the principal investigator. Responses will be returned for consideration by the convened Committee

If the application is deferred for substantive issues, the following will occur:

1. The IRB Chair informs the investigator in writing of the IRB's decision, questions, and concerns.
2. The investigator's response is sent to the IRB Chair.
3. In order to receive approval for a deferred protocol, the protocol must be submitted for full IRB review at a subsequent convened meeting of the IRB. The ORI provides IRB members with the investigator’s response, the revised protocol, and the previously submitted protocol. The item is placed on the agenda for a subsequent IRB meeting.
4. The protocol application is given full IRB review again.
5. The outcome of the IRB's deliberations is once again communicated to the investigator in writing.
6. The IRB's determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

**Note**: Approval of the protocol application will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB or IRB designee(s).

**Disapproved** - The Committee disapproved the submission for reasons detailed in these minutes and in a memo to the principal investigator. The investigator will be given the option of appealing the decision. Any appeals or resubmissions will be returned for consideration by the convened Committee.

**Approval in Principle** [45 CFR 46.118]

There is one circumstance under which the IRB may grant approval without having reviewed all of the study procedures and consent documents: If study procedures are to be developed during the course of the research, but human participants’ approval is required by the sponsoring agency. The IRB may then grant approval without having reviewed the as yet undeveloped recruitment, consent, and intervention materials. However, if the proposal is funded, the Principal Investigator must submit such materials for approval at least 60 days before recruiting human participants into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human participants.

### 7.5.11 Reporting IRB Actions

All IRB actions are communicated to the Principal Investigator (PI) in writing within ten (10) working days after final determination by the ORI and/or the Chair of the IRB via a template letter prepared by the IRB staff and signed by the IRB Chair or Director. For an approval, a copy of the approved consent form containing the stamped approval with the dates of the approval on each sheet will be sent to the investigator with written notification of approval. Special situations or conditions of approval will be indicated within the notification. For a disapproval, termination, or suspension, the notification will include the basis for making that decision.

The IRB reports its findings and actions to the institution in the form of its minutes which are distributed to the UNCG Institutional Official, (the Director of the ORI) and are stored permanently and securely in the ORI.

### 7.5.12 Determination of Risk

At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with research protocols. Risks associated with the research will be classified as either “minimal” or “greater than minimal.”

“Minimal risk” is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons ([45 CFR 46.303(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.303)).

Once the risks associated with the research have been identified, the process of categorizing the risks as *minimal* or *greater than minimal* may begin. Two characteristics influence the nature of the risk: 1) the probability of harm; 2) the magnitude of harm. The magnitude of harm can be related to the severity, duration and reversibility of a potential harm. The IRB reviewer should consider both the likelihood and magnitude of harm and whether they are greater than the ordinary daily life of a healthy person.

An aspect of risk assessment that is often overlooked is what protections are in place to minimize the harm. An IRB may diminish the risks to subjects by minimizing the probability and/or magnitude of harm to subjects. A greater than minimal risk may be reduced to minimal risk if protections are adequate to protect subjects.

An IRB reviewer identifies any risks involved with the study and classifies those risks as minimal or as greater than minimal risk, weighing the benefits of the study against those risks. The IRB reviewer then assesses whether the risk to participants are reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge that may reasonably be expected to result.

The meeting minutes will reflect the Committee’s determination regarding risk levels for full review protocols.

### 7.5.13 Period of Approval

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of research protocols. All protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. Under some circumstances, a shorter review interval (e.g. biannually, quarterly, or after accrual of a specific number of participants) may be required. The meeting minutes will reflect the IRB’s determination regarding review frequency for full review protocols.

### 7.5.14 Review More Often Than Annually

Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:

1. Significant risk to research participants (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;
2. The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
3. A history of serious or continuing non-compliance on the part of the principle investigator.

The following factors will also be considered when determining which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to participants.
2. The overall qualifications of the responsible Investigator and other members of the research team.
3. The specific experience of the Responsible Investigator and other members of the research team in conducting similar research.
4. The nature and frequency of adverse events observed in similar research at this and other institutions.
5. Characteristics of the research making unanticipated adverse events more likely.
6. Any other factors that the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of participants either studied or enrolled. If a maximum number of participants studied or enrolled is used to define the approval period, it is understood that the approval period in no case may exceed 1 year and that the number of participants studied or enrolled determines the approval period only when that number of participants is studied or enrolled in less than 1 year.

### 7.5.15 Independent Verification Regarding Material Changes

Protecting the rights and welfare of participants sometimes requires that the IRB verify independently, utilizing sources other than the investigator, information about various aspects of the study including but not limited to adverse event reporting, information in the scientific literature, and that no material changes occurred during the IRB-designated approval period.

The IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

1. Protocols for which concerns about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
2. Protocols conducted by Principal Investigators who have previously failed to comply with Federal regulations and/or the requirements or determinations of the IRB.
3. Protocols randomly selected for internal audit.
4. Whenever else the IRB deems verification from outside sources is relevant.

The following factors will also be considered when determining which studies require independent verification:

1. The probability and magnitude of anticipated risks to participants
2. The likely medical condition of proposed participants.
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, or may require such verification at any time during the approval period in the light of new information.

### 7.5.16 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence.

Such monitoring may be particularly warranted for cases in which the research presents significant risks to participants or if participants are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action when the IRB has identified problems associated with a particular investigator or research project. When monitoring is determined to be necessary there will be coordination with the investigator to determine how to have someone from the ORI participate in this phase of data collection.

### 7.5.17 Investigator Conflicts of Interest

It is the expectation of the University of North Carolina at Greensboro that all research be conducted following federal regulations, governing law, and that it meet the highest ethical standards. These expectations apply to everyone involved in the conduct of research involving human subjects, including: investigators and their staff, research sponsors, ORI staff, and IRB members.

#### 7.5.17.1 Conflict of Interest Management

All Investigators and key research personnel must follow the UNCG Conflict of Interest Policy. Key research personnel are those individuals who: 1) obtain consent from human participants; 2) recruit human participants, or 3) evaluate the responses of human participants

As part of its general financial disclosure procedures, the University will ask if any research being planned involves human participants. If this is determined to be the case, any conflict management plan which is developed will be forwarded to the IRB for review prior to approval.

The convened IRB will determine if the conflict will adversely affect the protection of human participants and if the management plan is adequate. The convened IRB has the final authority to decide whether the interest and its management, if any, allow the research to be approved. Based on the significance of the conflict and the potential for adverse effects on the protection of participants,

conflict management plans may include:

* Disclosure to participants through the consent process
* Modifications in the research plan
* Monitoring by independent reviewers
* Divestiture of financial interests
* Appointment of a non-conflicted Principal Investigator
* Prohibition of conduct of the research at the University

The IRB Chair (or designee) may

* 1. Accept the management plan and recommend approval
	2. Recommend changes in the management plan
	3. Refer the review to the full IRB

The IRB application asks protocol-specific questions regarding conflict of interest for the faculty investigators. As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human participants. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human participants in the protocol is in place.

A copy of the final, approved conflict management plan will filed in the ORI

#### 7.5.17.2 Protocol-Specific Conflict Management for the Full Board Review

The IRB application asks a protocol-specific question regarding conflict of interest for investigators and key personnel.

As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human participants. If the answer is yes and an approved conflict management plan exists, the IRB will review the plan to determine if it adequately protects the human participants in that protocol.

If no approved conflict management plan exists, the IRB will forward the conflict information to the ORI and an appropriate conflict management plan will be developed according to the procedures described above.

Review of conflict management plans are documented in the IRB minutes for full board reviews or in the protocol file for expedited review. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human participants in the protocol is in place.

If the conflict of interest status of an investigator changes during the course of a study, the individual is required to notify the ORI within ten working days of the change. The IRB will review the change as a modification to the protocol.

### 7.5.18 Other Committee Approvals

In the protocol application, the investigator will be asked specific questions to determine if the research requires approval from other pertinent research compliance committees (Radiation Safety Committee, Institutional Biosafety Committee, etc.). If the investigator answers yes to any of the questions, then he or she will be requested to provide documentation of approval from the other committees. Final approval from the IRB will be contingent on receipt of the required documentation.

**7.5.19 DXA Scanning**

When research is conducted with use of the DXA scanner in the Nutrition Laboratory Principal Investigators must follow the [Procedure for protecting human participants undergoing DXA scans in the Human Nutrition Laboratory](http://integrity.uncg.edu/wp-content/uploads/2013/06/Procedures-for-protection-of-human-participants-DXA-scans-Human-Nutrition-Laboratory-6-2013.docx), Stone Building, UNCG document.The IRB initial reviewer will ensure that individual named to conduct the scans for the study is named as a person trained to use the DXA prior to recommending approval for the study.

State law (§ 90-21.2) defines “treatment” sufficiently broadly to encompass the DXA scan even for research purposes, and the DXA scan would not qualify as the type of treatment that can be conducted on a minor without parental consent as described in § 90-21.1. When conducting studies that will include DXA scans of minors that the parental permission/consent for the DXA scan must be obtained.

State law (§ 90-21.5), however, provides that a minor can provide consent for, among other things, “diagnosis … pregnancy,” which means parental permission/consent is not required for the pregnancy test portion of the study. The general rule under HIPAA regarding control of a patient’s protected health information is that if state law does not require for treatment, then the minor controls the protected health information – which means the results of the study should go to the minor participant, not the parent/guardian, unless the minor participant provides consent. The parental permission/consent document cannot be misleading and should include a phrase similar to the following “pre-screening procedure for safety” will be conducted prior to the DXA scan taking place.

7.5.20 **Use of test articles in research: INDs or IDEs Investigational New Drug and Investigational Device Exemption studies**

An Investigational New Drug (IND) Application or Investigational Device Exemption (IDE) are exemptions from the law that otherwise requires that a drug, biologic, or device must be approved before it can be transported across state lines. Generally, one of these exemptions is required whenever a research study uses a drug, biologic or significant risk device that has not received FDA marketing approval. An IND may also be required for a drug that does have FDA marketing approval if the research study proposes a use of the drug that was not included in the existing FDA approval. (See the FDA Information Sheets on "Off-Label" and Investigational Use ofMarketed Drugs, Biologics, and Medical Devices"for additional requirements.)

IND and IDE research studies are subject to the same new and continuing review requirements as for human subjects research in general, but they also require FDA approval for the proposed research use.

Most IND and IDE studies at the UNCG are research protocols developed and sponsored by the commercial entity that is developing a drug or device pursuant to FDA regulations and is itself responsible for obtaining the IND or IDE approvals and for fulfilling all other FDA requirements for such a study. There are some IND or IDE studies for which the study protocol has been developed independently by a university investigator and for which that investigator is responsible for obtaining the IND or IDE and for fulfilling all FDA required filings and other documentation. Investigators should contact the Office of Clinical Trialsfor guidance and support regarding IND and IDE studies. Investigators will provide the IND or IDE number as a part of the IRB application; the IRB primary reviewer should verify that the IND or IDE number is valid by assuring consistency across documents (e.g., FDA letters, sponsor protocol).

The IRB is not required to monitor the investigator’s performance of required FDA paperwork. However, in reviewing the study, the IRB should be mindful that in this context, the IRB review should include a determination of whether an IND or IDE is required and may also require more intense IRB scrutiny of the protocol and related risks as well as more guidance to the investigator regarding the scientific design, subject safety parameters, informed consent process and other human subjects protection factors.

For emergency use of an investigational product, see SOP 20.0, Emergency Use of an Investigational or Unlicensed Test Article.

For non-emergency situations, prospective IRB approval is required. Single patient use allows a physician to obtain access to an investigational drug upon receiving approval from the IRB. This approval is granted for the treatment of a single patient. The treatment use may occur only after IRB approval is obtained.

7.5.20.1 **Compliance with IND regulations**

When research involves the use of a drug other than the use of a marketed drug in the course of normal medical practice, UNCG will confirm that:

* The drug has an IND; or
* The protocol meets one of the FDA exemptions from the requirement to have an IND

Exemption 1

* The drug product is lawfully marketed in the United States.
* The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
* If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
* The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
* The investigation will be conducted in compliance with 21 CFR 50 and 56.
* The investigation will be conducted in compliance with the requirements of 21 CFR 312.7.

Exemption 2

* A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
	+ Blood grouping serum.
	+ Reagent red blood cells.
	+ Anti human globulin.
* The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
* The diagnostic test will be shipped in compliance with 21 CFR 312.160.

Exemption 3

* A drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.

Exemption 4

* A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

7.5.20.2 **Compliance with IDE regulations**

* The device fulfilled the requirements for an abbreviated IDE:
* The device is not a banned device.
* The sponsor labels the device in accordance with 21 CFR 812.5.
* The sponsor will obtain IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval.
* The sponsor will ensure that each investigator participating in an investigation of the device obtains from each subject under the investigator’s care, consent under 21 CFR 50 and documents it, unless documentation is waived.
* The sponsor will comply with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
* The sponsor will maintain the records required under 21 CFR

* 812.140(b) (4) and (5) and report as required under 21
* CFR 812.150(b) (1) through (3) and (5) through (10);
* The sponsor will ensure that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and report as required under 812.150(a) (1), (2), (5), and (7); and
* The sponsor will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices; or
* The device fulfills one of the IDE exemption categories:
	+ A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
	+ A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that the FDA had determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
	+ A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
		- Is noninvasive.
		- Does not require an invasive sampling procedure that presents significant risk.
		- Does not by design or intention introduce energy into a participant.
		- Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
		- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.
		- A custom device as defined in 21 CFR 812.3(b), unless the device was being used to determine safety or effectiveness for commercial distribution.
			1. **IRB Determination of a Significant vs. Non-significant risk device:**

**What is a medical device?**

A **medical device** is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is 1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; 2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or 3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes (21 U.S.C. 321(h)).

**What is a significant risk (SR) device?**

Definition

* Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject
* Purported or represented for supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject
* Used for substantial importance in diagnosing, curing, mitigating, or treating disease and presents a potential for serious risk to the health, safety, or welfare of a subject
* Otherwise presents a potential for serious risk to health, safety, or welfare of a subject
* Examples: Dental lasers, embolization, devices for urological use, and collagen and bone replacements

**What is a non-significant risk (NSR) device?**

* One that does not meet the definition of a significant risk device
* Examples: External monitors for insulin reactions, general biliary catheters, MRI within specified parameters

**Who decides whether a device is SR or NSR?**

Sponsors

* Make the initial risk determination
* Presents the IRB with this information

IRB

* Required to determine whether the NSR device study involves a SR or NSR device

FDA

* Available to help
* Final arbiter

**Requirements in 21 CFR 812 for NSR device studies**

* Abbreviated requirements at 21CFR 812.2(b)
	+ Labeling, IRB approval, informed consent, monitoring, record keeping, reports, and prohibition against promotion.
* NSR studies are considered to have an approved IDE therefore no IDE to FDA
* Sponsors and IRBs do not have to advise FDA of NSR device studies
* IRBs must make a SR or NSR determination for every NSR study (21 CFR 812.66)

**The IRB will review the following information when making a NSR device determination:**

* IRBs must make a SR or NSR determination for every NSR study (21 CFR 812.66)
* Sponsor will provide the IRB with a brief explanation of why the device is not significant risk or provide a letter from FDA that FDA determined the device to be nonsignificant risk

Any other information requested by the IRB such as:

* Description of device
* Reports of prior investigations
* Proposed investigational plan
* Subject selection criteria

The IRB will make a SR or NSR determination by reviewing relevant information at a convened meeting

**When making the SR or NSR determination, the IRB will consider:**

What is the basis for the risk?

* Proposed use of the device

What is the nature of harm that may result from the use of the device?

Any additional procedures required for device use?

* Potential harm from procedures

**If the IRB determination of NSR agrees with the sponsor’s NSR:**

* IRB can review the study using criteria at 21 CFR 56.111 and 21 CFR 56.812.2(b)
* Non significant risks studies are considered to have an approved IDE, therefore no IDE to FDA
* Sponsors and IRBS do not have to advise the FDA of NSR device studies

**Documenting SR or NSR determination**

* Write the determination in the minutes
* The minutes will document the reason for the determination
* For Non-significant risk studies, all materials reviewed will be maintained

**If the IRB determination does not agree with the sponsor determination of NSR**

If the IRB determines that a NSR device study involves a significant risk device, the IRB will:

* Inform the clinical investigator and where appropriate, the sponsor
* The study cannot start until the sponsor obtains an IDE

Taken from: <http://www.fda.gov/downloads/Training/CDRHLearn/UCM176494.pdf>

7.6 Continuing Review of Active Protocols (Renewals)

Approved research is subject to continuing IRB review at least yearly through the IRBIS on-line system, or more frequently if specified by the IRB [45 CFR 46.109(e)], but not sooner than 30 days prior to the protocol termination (expiration) date. This review must take place **before the approval expiration date.** If continuing review is conducted earlier than 30 days prior to the approval expiration date (e.g., due to the scheduled IRB meeting date), the protocol will be assigned a new approval date: that of the early continuing review. The approval expiration date will be based upon the new approval date for the purposes of future continuing reviews.

The approval date and the termination (expiration) date are clearly noted on all IRB approval letters and stamped consent forms that are sent to the PI and must be strictly observed. Investigators should allow sufficient time for development and review of renewal submissions. Protocol renewals that are not submitted in time for the date of expiration will be allowed to expire. If a PI misses the expiration date, then all research must cease until that renewal is submitted and approved. The IRBIS on-line system will allow a PI to reactivate the research at any time, however it is considered noncompliance if research is continued on a study which has expired.

For each initial or continuing approval, the IRB will indicate an approval period with an approval expiration date specified. IRB approval is considered to have lapsed at midnight on the expiration date listed on the approval. For a study approved by the convened IRB, the approval period starts on the date that the IRB conducts its final review of the study; that is, the date that the convened IRB approved the research or the date the convened IRB deferred the research for non-substantive issues. For a study approved under expedited review, the approval period begins on the date the IRB Chair or IRB member(s) designated by the Chair gives final approval to the protocol.

The IRB will conduct continuing review of ongoing research at intervals that are appropriate to the level of risk for each research protocol, but not less than once per year. Continuing review must occur as long as the research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research must occur even when the remaining research activities are limited to the analysis of private identifiable information.

Continuing review and re-approval of a research project at least annually is required so long as the project continues to involve human subjects. OHRP considers a research project to continue to involve human subjects as long as the investigators conducting the research continue to obtain:

* Data about the subjects of the research through intervention or interaction with them; or
* Identifiable private information about the subjects of the research.

With respect to *obtaining identifiable private information*, OHRP considers this to include obtaining identifiable biological specimens originating from living individuals. *Furthermore, OHRP considers obtaining identifiable private information to include*:

* Collecting or receiving identifiable private information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator);
* Collecting identifiable private information by observing or recording private behavior without interacting or intervening with the human subjects; and
* Using, studying, or analyzing identifiable private information (including identifiable biological specimens), even if the information was already in the possession of the investigator before the research begins. This includes using, studying, or analyzing any of the following:
	+ Identifiable private information obtained by interacting or intervening with the human subjects;
	+ Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings provided to the investigators from any source;
	+ Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings already in the possession of the investigator before the research begins;
	+ Identifiable private information obtained about an individual by interviewing other people (e.g., an individual’s healthcare provider or teacher);
	+ Identifiable biological specimens provided to the investigators from any source; or
	+ Identifiable biological specimens already in the possession of the investigator before the research begins.

At UNCG, determination of the approval period and the need for additional supervision is made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing particularly risky research, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by a subcommittee of the IRB might occur or approval might be subject to an audit of study performance after a few months of enrollment or after enrollment of the first several participants.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur by midnight of the date on which IRB approval expires. If the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.

### 7.6.1 Continuing Review of Full Board Studies

To assist investigators the ORI staff will send out renewal notices to investigators two months and one month in advance of the expiration date; however, it is the investigator’s responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date and in time for the next scheduled IRB meeting. By federal regulation, no extension to that date can be granted.

For continuing review, investigators must submit a renewal through the IRBIS online system to the IRB reviewer. If there are anticipated changes to the protocol or consent forms, such changes can be submitted as attachments to the renewal. Some changes may be reviewed as expedited and approved by the IRB reviewer in the ORI and will not require full board review.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories). It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110 have changed or will change such that expedited IRB review would no longer be permitted for continuing review.

Continuing review of research not eligible for expedited review will occur at a scheduled IRB meeting. All IRB members are provided with the information contained in the IRB protocol file including: modification applications, the completed renewal form, and updated IRB application. At the IRB meeting, the Primary Reviewer will lead the IRB through the regulatory criteria for approval.

ORI staff attends the convened meetings and brings the complete protocol files or display the protocols via projection for each protocol on the agenda. The IRB staff will retrieve any additional related materials the IRB members request.

Review of currently approved or newly-proposed consent documents must occur during the scheduled continuing review of research by the IRB, but **informed consent documents should be reviewed whenever new information becomes available** that would require modification of information in the informed consent document.

### 7.6.2 Lapse in Continuing Review

The IRB and investigators must plan ahead to meet required continuing review dates. If the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, all research activities must stop, including recruitment (media advertisements must be pulled), enrollment, consent, interventions, interactions, and data collection, unless the IRB finds that it is in the best interests of individual participants to continue participating in the research interventions or interactions. **This will occur even if the investigator has provided the continuing information before the expiration date. Therefore, investigators must allow sufficient time for IRB review before the expiration date**.

As a courtesy, the ORI will send out renewal notices two months and one month before studies expire. However, it is ultimately the **investigator's responsibility** to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted. The IRB will accept an IRB renewal form for sixty (60) days after the expiration date of a protocol for review. Protocols that have been expired for more than sixty (60) days will be administratively terminated and will require submission of a new IRB protocol for review.

An expiration letter (or email) will be sent to investigators by the last date of the approval period.

Failure to submit continuing review information on time is non-compliance and will be handled according to the non-compliance policy (See Section 11.3).

The IRB Chair may review written requests by investigators to continue interactions with current participants for expired research protocols. The IRB Chair determines which participants, if any, may continue and what procedures may be performed because stopping those research procedures will harm them. The IRB Chair orally communicates the decision to investigators and also provides a written response. The IRB Chair may not permit the enrollment of new participants.

**7.6.3 Study Closure**

A study can be closed when all interaction with participants is complete (recruitment, enrollment, data collection), data has been analyzed, and all data has been deidentified *unless* there is a chance that participants will be re-contacted at a later date. According to the OHRP, a study may be closed if all data has been collected and deindentifed. Please see SOP 7.6 for further information on what meets the criteria for a study that should remain open and one which can be closed.

A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary.

The above criteria also fit in the case of a study which is merely awaiting publication, and all data has been analyzed and deidentified. Similarly, simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects’ research and thus does not require continuing review.

If a PI leaves the university to work at another institution, those active studies must be opened at the new site and all studies should be closed at UNCG once this has been done.

The PI can close any active study at any point in the study by notifying the ORI with the submission of a completed Closure forms or through the IRBIS online system. Completion of this form allows the IRB to appropriately close the file while ensuring that all regulatory requirements have been met.

**Student Research and Graduation/Departure**

In the case of student investigators, ORI recommends that a study be closed prior to or at the point of graduation if all of the previous criteria (SOP 7.6) from the OHRP have been met. If this is not done, the Faculty Advisor will assume responsibility for the study and all renewals. The Faculty Advisor will be required to store all deidentified data and consent forms until at least three years from the closure date as has been stated in the IRB application.

Faculty Advisors who renew protocols for students who have graduated, or wish to be associated with the study are fully responsible for the study and must be indicated as the primary investigator for the protocol. The former student must be removed from the study and may open their study at another institution in which they are affiliated, if the study is still considered to be in an active state. The Faculty Advisor must maintain the original research data including signed informed consent forms and confidentiality agreements or obtain such documents upon request from the IRB or ORI for Data Safety Monitoring auditing purposes. If the Faculty Advisor does not choose one of the two options above he or she is required to close the project. *See also* Study Closure 7.6.7. To assist investigators, the ORI staff will send out renewal notices to investigators two months and one month in advance of the expiration date; however, it is the Student and/or the Faculty Advisor’s responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date.

It is important to note that the location of the data will need to adhere to the University’s Data and Retention Policy and the ability to transfer data collected at UNCG as part of a research study may require an “Original Data Transfer Request” form may require a signature from UNCG if data from that study will need to be transferred to another institution.

Any lapse in approval will require that the research stop and, if the research is DHHS-sponsored, notification of the funding agency.

7.7 Modification of an Approved Protocol

Investigators may wish to modify or amend their approved applications. **Investigators must seek IRB approval before making any changes in approved research** - even though the changes are planned for the period for which IRB approval has already been given - unless the change is necessary to eliminate an immediate hazard to the participants (in which case the IRB must then be notified at once). Failure to obtain IRB approval before implementing changes (when there is no immediate hazard) may result in punitive actions or possible noncompliance from the IRB including, but not limited to, loss of IRB approval and closure of the study.

Modifications may be approved if they are within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study's purpose or study population may also be appropriate. If, however, the researcher wishes to add a population and revise study procedures, he or she will need to submit a new application for IRB approval, due to the change in the scope of the study. The PI will be informed by the IRB reviewer if this action is necessary.

Investigators must submit any modifications through the online IRBIS system to inform the IRB about the changes in the status of the study, including, but not necessarily limited to:

* Revised consent/parental permission/assent documents (if applicable) or other documentation that would be provided to participants when such information might relate to their willingness to continue to participate in the study
* Additional research staff or investigators
* Revised or additional recruitment materials
* Support letters from research sites not obtained by the time of IRB initial approval
* Any other relevant documents provided by the investigator

The IRB reviewer will determine whether the proposed changes may be approved through an expedited review process, if the changes are minor, or whether the modification warrants full board review. The reviewer(s) using the expedited procedure has the responsibility to determine that the proposed changes may be approved through the expedited review procedure and, if not, must refer the protocol for full board review.

### 7.7.1 Expedited review of Protocol Modifications

The IRB may use expedited review procedures to review minor or substantive changes in ongoing previously-approved research during the period for which approval is authorized. A minor (e.g. PI name change or adding another research site of the same caliber of currently approved sites) must also meet the both of the following criteria:

* All added procedures involve no more than minimal risk
* All added procedures fall into categories (1)-(7) of research that could be reviewed using the expedited procedure

If all of the above criteria are met the change may be reviewed and approved by the IRB initial reviewer.

Substantive (e.g. incorporating non-English speaking participants, addition of collecting blood samples) changes not greater than minimal risk may receive an expedited review carried out by the IRB initial reviewer and a member of the IRB modification subcommittee.

The IRB reviewer(s) complete the “Institutional Review Board - Protocol modification” checklist to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval.

### 7.7.2 Full Board Review of Protocol Modifications

When a proposed change in a research study is significant (e.g., procedures involving increased risk or discomfort are to be added or procedures involving a decrease in benefits or compensation for injury are removed), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research participants. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the participants' continued welfare. All IRB members are provided and review all documents provided by the investigator. At the meeting, the Primary IRB Reviewer presents an overview of the modifications and leads the IRB through the regulatory criteria for approval.

When the IRB reviews modifications to previously approved research, the IRB consider whether information about those modifications might relate to participants’ willingness to continue to take part in the research and, if so, whether to provide that information to participants.

**7.8 Data Safety Monitoring**

Data Safety Monitoring involves the oversight and monitoring of data collection, compliance with federal guidelines, UNCG policies, and that the procedures described within the application are being followed.

The investigator will disclose their plan to ensure the safety of research participants in the IRB protocol. This disclosure should also include a plan to terminate the research if warranted. The investigator must qualify/quantify how they will determine how they will terminate the study due to increased risk(s) to participants. These risks could include but are not limited to: students with a high probability of failing a class in which the curriculum is experimental, physical harm to participant, or overwhelming emotional/psychological trauma. The IRB will review the plans for data safety for protocols during initial review and at continuing review.

**Data Safety Monitoring Audits by the ORI**

The ORI will also conduct Annual Data Safety Monitoring Audits. Data Safety Monitoring is conducted to ensure that research is carried out according to the highest standards of scientific integrity and ethical behavior. The ORI will randomly select 5% of active nonexempt IRB protocols to be monitored.

Principal Investigators whose projects are selected for monitoring will be contacted by the ORI to schedule an appointment for the Assistant Director to review the selected protocols data. IRB members may accompany the Assistant Director on Data Safety Monitoring visits. Following the audit, a report will be drafted and forwarded to the Principal Investigator stating findings and corrective actions, if any.

Federal regulations regarding the conduct of Human Participants Research, as well as UNCG Policies and Procedures, change regularly. Accordingly, it is possible that a Data Safety Monitoring Audit may bring to light forms or procedures that were approved by the IRB in the past, but that would not be approved were the application to be submitted at the time of the Audit. In such cases, the following guidelines will be used to determine whether the PI will need make changes to forms or procedures:

* If Certificates of Training in the Protection of Human Research Participants have expired according to the current required renewal timeline, the PI will be required to update certificates according to current requirements.
* If Federal regulations have changed such that earlier approved procedures are now considered in violation of such regulations, the Director and IRB Chair will work with the PI to make changes to the project such that such violations are no longer present.
* If UNCG policies and procedures have changed (e.g., UNCG in now requiring additional elements of consent that were not required at the time of the approval) the investigator will generally not be required to make changes to the project. However, at such time that a new IRB application or renewal application for the project is submitted the new application will be required to conform to all current UNCG policies and procedures.

7.9 Unanticipated Problems Involving Risks to Participants or Others and Adverse Events

Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of unanticipated problems involving risks to participants or others to the IRB, appropriate institutional officials, and regulatory agencies. (NOTE: For simplicity, unanticipated problems involving risks to participants or others will be referred to as “unanticipated problems” in this policy).

Not all unanticipated problems involve direct harm to participants. Events can occur which are unexpected and result in new circumstances that increased the risk of harm to participants without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the participants, individuals with whom the participant may come in contact such as family members, research personnel, etc.) in addition to participants. In each case, while the event may not have caused any detectable harm or adverse effect to participants or others, it nevertheless represents an unanticipated problem and should be promptly reported.

Events which result in direct harm to participants are referred to as “Adverse Events”. Although adverse events occur most commonly in the context of biomedical research, adverse events may also occur in the context of social and behavioral research. Only unexpected adverse events that are related to the research need to be reported.

**Reporting Timetable**

1. Internal adverse events that are unexpected, fatal or life-threatening, and related to the research intervention must be reported to the IRB within 24 hours of the event.
2. Internal adverse events which are unanticipated problems (but not fatal or life threatening), shall be reported to the IRB within ten (10) working days of the investigator becoming aware of the event.
3. External adverse events (i.e., external sponsor generated safety reports) which are unanticipated problems shall be reported to the IRB within ten (10) working days of their receipt.
4. Unanticipated problems that are not related to adverse events must be reported to the IRB within ten (10) working days of the event.

### 7.9.1 Definitions

**Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem)**: Any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.

**Adverse event:** Any physical, psychological, or social harm to participants during the course of research and as a result of participation in the research.

**Unexpected:** An event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document.

**Related to the research:** An event is “related to the research procedures” if it was more likely than not to have been caused by the research procedures or if it is more likely that not that the event affected the rights and welfare of current participants.

### 7.9.2 Reporting

Principal investigators must report to the IRB as soon as possible, but in all cases within ten (10) working days any:

1. Adverse events which in the opinion of the principal investigator are both unexpected and related.
2. An unanticipated or unexpected event that involves risks to participants or others exposes individuals (e.g., research participants, investigators, research assistants, students, the public, etc.) and is more likely than not related to the research.
3. Information that indicates a change to the risks or potential benefits of the research. For example:
	1. An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
	2. A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
4. A breach of confidentiality.
5. Incarceration of a participant in a protocol not approved to enroll prisoners should the investigator intend to continue interactions with the participant while he or she is incarcerated.
6. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
7. Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
8. Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
9. Event that requires prompt reporting to the sponsor.
10. Sponsor imposed suspension for risk.
11. Proposed changes in a research activity and the premature completion of a study.

If the investigator is unsure whether the event should be reported, he or she should contact the ORI for consultation.

Principal investigators should report the above events using the IRB Unanticipated Problem/Adverse Problem Form or report the event through the IRBIS online system. Reports may be accepted by other means such as e-mail or by phone.

### 7.9.3 IRB Review of Reported Event

Upon receipt of an IRB Unanticipated Problem/Adverse Problem Form from a Principal Investigator, the ORI staff checks the form for completeness. If any applicable sections of the IRB Unanticipated Problem/Adverse Problem Form are incomplete or have been answered unsatisfactorily, the IRB staff contacts the investigator or the designated contact person to obtain additional information. Corrections are documented in the IRB file, indicating the date, the person spoken with, and the IRB staff making the correction.

The ORI staff submits the IRB Unanticipated Problem/Adverse Problem Form and all supporting documents provided by the investigator to the IRB Chair and Director for review.

Changes in approved research initiated without IRB approval to eliminate apparent immediate hazards to the participant have to be reviewed by the IRB to determine whether the change is consistent with ensuring the participants’ continued welfare.

Based on the information received from the investigator, the IRB Chair or Director may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or IRB Director must be reported to a meeting of the convened IRB.

If the IRB Chair and Director determine that either (1) the problem was foreseen OR (2) no participants or others were harmed AND participants or others are not at increased risk of harm, the IRB Chair or Director indicates on the form that the problem is not an unanticipated problem. The form is filed in the protocol record, the determination is communicated to the investigator, and no further action is taken.

If the IRB Chair and Director determine that the problem is an unanticipated problem, but that the risk is no more than minimal, the chair or designee will review:

1. The currently approved protocol
2. The currently approved consent document
3. Previous reports of unanticipated problems involving risks to participants or others for the project

After reviewing all of the materials, the chair or Director will take appropriate action depending on the nature of the risk involved including modification of the protocol or the consent form, if applicable. The results of the Chair or Director’s review will be recorded in the protocol record, communicated to the investigator, reported to the IRB, and referred to the ORI to be handled according the reporting procedures in Section 12.

All reported unanticipated problems in cases for which the risk is more than minimal will be reviewed at a convened IRB meeting. All IRB members are provided a copy of the IRB Adverse Problem Form and supporting documents provided by the investigator. At least one IRB member is provided:

1. The currently approved protocol
2. The currently approved consent document
3. Previous reports of unanticipated problems involving risks to participants or others for the project

If the IRB considers the event to not represent an unanticipated problem, the results of the review are recorded in the protocol record, communicated to the investigator, and no further action is taken.

If the IRB considers the event to represent an unanticipated problem, the IRB will consider the following actions:

1. Modification of the protocol
2. Modification of the information disclosed during the consent process
3. Providing additional information to current participants (This must be done whenever the information may relate to the participant’s willingness to continue participation)
4. Providing additional information to past participants
5. Requiring current participants to re-consent to participation
6. Alteration of the frequency of continuing review
7. Observation of the research or the consent process
8. Requiring additional training of the investigator
9. Notification of investigators at other sites
10. Termination or suspension of the research according to Section 11.4
11. Obtaining additional information

The results of the IRB review are recorded in the protocol record, communicated to the investigator, and referred to the ORI to be handled according the reporting procedures in Section 12.

7.10 Appeal of IRB Decisions

If a subcommittee of an IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator has 30 days from the date of the IRB decision to appeal, in writing, for review by the convened IRB.

If the convened IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the Chair of the IRB or the Director, taking care to explain, with new information not available to the IRB initially, the reasons for believing that the proposed procedures are in compliance with University policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the IRB, in writing. The IRB will reconsider the appeal based upon the new information provided and will continue to re-review protocols as long as the investigator wishes to appeal. Following the review of the investigators written request the IRB may request the investigators presence at the next scheduled IRB meeting for further discussion. Institutional officials may not approve research if it has not been approved by the UNCG IRB.

7.11 Sponsored Projects

1. Externally funded projects must be reviewed by the Office of Sponsored Programs:
	1. The Office of Sponsored Programs and the IRB will collaborate to ensure that the IRB protocol and the sponsored project as described in the sponsored programs application are consistent.
2. University funded projects (i.e. unit funds or research grants committees):
	1. The IRB may request a copy of any proposal submitted to a university program (such as a faculty grant) to ensure that the IRB protocol and funded project description are consistent.

3) The Office of Sponsored Programs reviews funded projects against institutional policy and informs the sponsor of university policy. In some cases this is done by signing assurance statement that accompanies sponsored projects award documents. When there is a discrepancy the Office of Sponsored Programs negotiates directly with the sponsor.

8 Criteria for IRB Approval of Research

In accordance with 45 CFR 46.111 in order to approve research, the IRB must determine that all of the following requirements are satisfied:

(1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

(2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with, and to the extent required by [§46.116](file:///D%3A%5CUSERS%5CECALLEN%5CDesktop%5CJeff%5CMy%20Documents%5C45CFR46.htm#46.116).

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](file:///D%3A%5CUSERS%5CECALLEN%5CDesktop%5CJeff%5CMy%20Documents%5C45CFR46.htm#46.117).

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

(7) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

(8) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

8.1 Risk/Benefit Assessment

The goal of the assessment is to ensure that the risks to research participants posed by participation in the research are justified by the anticipated benefits to the participants or society. Toward that end, the IRB must:

1. judge whether the anticipated benefit, either of new knowledge or of improved health for the research participants, justifies asking any person to undertake the risks;
2. disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research - one of the major responsibilities of the IRB - involves a series of steps:

1. **identify the risks** associated with the research, as distinguished from the risks of therapies the participants would receive even if not participating in research;
2. **determine whether the risks will be minimized** to the extent possible;
3. **identify the probable benefits** to be derived from the research;
4. **determine whether the risks are reasonable in relation to the benefits** to participants, if any, and assess the importance of the knowledge to be gained;
5. **ensure that potential participants will be provided with an accurate and fair description** of the risks or discomforts and the anticipated benefits;

Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

**Risks to participants are reasonable in relation to anticipated benefits**, if any, and to the importance of the knowledge that may reasonably be expected to result.

1. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research - as distinguished from risks and benefits of therapies participants would receive even if not participating in the research.
2. The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

### 8.1.1 Scientific Merit

In order to assess the risks and benefits of the proposed research, the IRB must determine that:

* The research uses procedures consistent with sound research design;
* The research design is sound enough to reasonably expect the research to answer its proposed question; and
* The knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review.

8.2 Selection of participants is equitable.

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of participants. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, pregnant women, human *in vitro* fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see Vulnerable Populations).

### 8.2.1 Recruitment of Participants

The investigator will provide the IRB with all recruiting materials to be used in identifying participants. The IRB must approve any and all advertisements and or recruitment scripts prior to posting, oral presentation, and/or distribution. The IRB will review:

1. The information contained in the advertisement.
2. The mode of its communication.
3. The final copy of printed advertisements.
4. The final audio/video taped advertisements.
5. The final website recruiting participants.
6. The final oral script

The criteria for advertisements are as follows:

* Do not state or imply a certainty of favorable outcome or other

benefits beyond what is outlined in the consent document and the

protocol.

* Do not include exculpatory language.
* Do not emphasize the payment or the amount to be paid, by such

means as larger or bold type.

* Do not promise “free treatment” when the intent is only to say

participants will not be charged for taking part in the investigation.

* Limit information to the prospective participants to assist them in

determining their eligibility and interest, such as:

* + The name and address of the investigator or research facility.
	+ The purpose of the research or the condition under study.
	+ In summary form, the criteria that will be used to determine

eligibility for the study.

* + A brief list of participation benefits, if any.
	+ The time or other commitment required of the participants.
	+ The location of the research and the person or office to contact

for further information.

If you are utilizing email recruitment, please be aware of the Survey Harassment policy (see section 11.2).

**8.2.1.1 Snowball Sample Recruitment**

“Snowball sampling” is a recruitment technique in which research participants are asked to assist researchers in identifying other potential subjects. The use of currently enrolled research participants to recruit additional research participants (sometimes referred to as “snowball sampling”) may be approved by the IRB under some circumstances. However, the protocol must include justification of the use of this method in the context of the study and target population. The method that minimizes risk would be the preferred choice. For example, a researcher seeking to study patterns of informal leadership in a community may ask individuals to name others who are influential in a community.

If the topic of the research is not sensitive or personal, it may be acceptable for subjects to provide researchers with names and contact information for people who might be interested in participation. If the topic is sensitive or personal, snowball sampling may be justified, but care should be taken to ensure that the potential subjects' privacy is not violated. For example, studies of networks of drug users or studies tracking sex partners require extreme caution with information gathered from one subject about another.

The steps taken to minimize the risk of violating an individual’s privacy should be articulated in the recruitment section of the protocol. Current participants cannot receive incentives or compensation for referrals.

Acceptable alternatives that reach the same potential subjects include:

* The study team member may provide information to subjects and encourage them to pass it on to others who may be interested or eligible. The information provided to enrolled subjects (fliers, letters of explanation, etc.) must be approved by the IRB. Interested prospective participants could then contact the project for more info and possible inclusion.
* The study team member may ask subjects to obtain permission from others prior to disclosing their contact information. In this scenario, the researcher would not directly contact the referred/potential subject without permission from the potential subject and would not have access to any information about a potential subject without permission from that individual.

This information should be submitted to the IRB with the initial application.

The IRB reviews the material to assure that the material is accurate and is not coercive or unduly optimistic, creating undue influence to the participant to participate.

Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest.

When participants are being paid, the IRB will review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence.

8.3 Informed Consent

The IRB will ensure that informed consent will be sought from each prospective participant or the participant’s legally authorized representative in accordance with and to the extent required by [45 CFR 46.116](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). In addition, the Committee will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by [45 CFR 46.117](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). See Section 9 below for detailed policies on informed consent.

8.4 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to **protect the privacy** of participants and to **maintain the confidentiality of the data**.

**Definitions**

* Privacy - having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
* Confidentiality - methods used to ensure that information obtained by researchers about their participants is not improperly divulged.

**Regulations**

46.102(f) Human participant means a living individual about whom an investigator conducting research obtains:

 (1) data through intervention or interaction with the individual,

 or

 (2) identifiable private information.

* Private information - information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
* Identifiable information – information where the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

**Privacy**

The IRB must determine whether the activities in the research constitute an invasion of privacy. In order to make that determination, the IRB must obtain information regarding how the investigators gain access to participants or participants’ information and the participants’ expectations of privacy in the situation. Investigators must have appropriate authorization from relevant agencies or organizations to access the participants or the participants’ information.

**Confidentiality**

Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the participants from the data, then the research is not anonymous and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure.

8.5 Vulnerable Populations

The IRB determines if appropriate **additional safeguards** are in place to protect the rights and welfare of participants if they are likely to be members of a vulnerable population (e.g., persons with diminished autonomy). See Section 10 below for detailed policies on vulnerable populations.

9 Informed Consent

9.1 Informed Consent Process

No investigator may involve a human being as a participant in research without obtaining the legally effective informed consent of the participant or the participant’s legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with Section 9.3 of this policy. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent for research participation. Tools or instruments such as the Mini Mental Exam can also be used to determine capability to consent. Investigators must obtain consent prior to entering a participant into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

Consent must always be sought under circumstances that:

* provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate; and
* minimize the possibility of coercion or undue influence.

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential participant understands of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.

The information that is given to the participant or the representative must be in language understandable to the participant or the representative.

No informed consent, whether oral or written, may include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights.

A person knowledgeable about the consenting process and the research (i.e., a member of the project’s research team) to be conducted must obtain the informed consent.

If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

9.2 Basic Elements of Informed Consent

Informed consent must be sought from each potential participant or the participant’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

**The basic elements of informed consent are:**

1. a statement that the **study involves research**, an explanation of the **purposes** of the research and the expected duration of the participant’s participation, a description of the **procedures** to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable **risks** or discomforts to the participant;
2. a description of any **benefits** to the participant or to others which may reasonably be expected from the research;
3. a disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the participant;
4. a statement describing the extent, if any, to which **confidentiality** of records identifying the participant must be maintained;
5. for research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of **research-related injury**, including who will pay for the treatment and whether other financial compensation is available;
6. an explanation of whom to **contact** for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury to the participant;
7. a statement that participation is **voluntary**, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
8. For research involving more than minimal risk, if medical treatments are available when injury occurred, an explanation as to what it consists of or where further information could be obtained.
9. When appropriate, the amount and schedule of payments.

**Additional elements of informed consent to be applied, as appropriate:**

1. a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
2. The consent form of a full committee review, considered a “more than minimal risk study” by the nature that is being reviewed by the full committee, does not need to state that the study is “more than minimal risk”, but merely state the risks of the study.
3. anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent;
4. any additional costs to the participant that may result from participation in the research;
5. the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant;
6. a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation must be provided to the participant;
7. the approximate number of participants involved in the study.

In addition to these federally mandated elements of informed consent UNCG requires that consent documents include the following:

1. If Identified data will be stored off UNCG campus this must be clearly stated on the informed consent document, and the location of data storage (e.g., student researcher’s home) must be specified.

UNCG also requires that participants sign a copy of the approved consent form that has been stamped as approved by the IRB Chair (or designee) or the ORI. Investigators who wish to have this requirement waived must make formal request for such a waiver through an IRB application or modification application.

9.3 Waiver of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement for informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration will not adversely affect the rights and welfare of the participants;
3. the research could not practicably be carried out without the waiver or alteration; **and**
4. whenever appropriate, the participants must be provided with additional pertinent information after participation;

**or**

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
	1. public benefit or service programs;
	2. procedures for obtaining benefits or services under those programs;
	3. possible changes in or alternatives to those programs or procedures; or
	4. possible changes in methods or levels of payment for benefits or services under those programs;

**and**

1. the research could not practicably be carried out without the waiver or alteration.

9.4 Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

1. Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the participant or the participant’s legally authorized representative at the time of consent.

2. A copy of the signed and dated consent form must be given to the person signing the form.

3. The consent form may be either of the following:

1. a **written consent document** that embodies the elements of informed consent may be read to the participant or the participant’s legally authorized representative, but the participant or representative must be given adequate opportunity to read it before it is signed; or
2. a **short form written consent document** stating that the elements of informed consent have been presented orally to the participant or the participant’s legally authorized representative.

When this method is used:

1. there must be a witness to the oral presentation; and
2. the IRB must approve a written summary of what is to be signed by the participant or representative; and
3. the witness must sign both the short form
4. the person actually obtaining consent must sign a copy of the oral script; and
5. a copy of the summary must be given to the participant or representative, in addition to a copy of the short form.

9.5 Waiver of Documentation of Informed Consent (Waiver of Signed Consent)

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either that the:

1. only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality, or
**Note:** Participants must be asked whether they want documentation linking them with the research, and their wishes must govern.
(Example: domestic violence research where the primary risk is discovery by the abuser that the participant is talking to researchers.)
2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. .

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of information to be communicated to the participant, including all elements of informed consent and the IRB will consider whether to require the investigator to provide participants with a written statement regarding the research or consent information

9.6 Review and Approval of the Informed Consent Form

The IRB is responsible for the review and approval of the informed consent form prepared by the investigator. The wording on the informed consent form must contain all of the required elements and meet all otherrequirements as described in this section. If the wording of the informed consent has been initially prepared by an external entity (e.g., a pharmaceutical company or a cooperative study group, including National Cancer Institute (NCI) groups) rather than by a University Principal Investigator, the IRB needs to ensure that the wording of the consent meets all the requirements of and has been reviewed by the appropriate University committees and subcommittees such as the Institutional Biosafety Committee. The form must meet all requirements of the UNCG IRB, even if it was initially developed and/or approved at another institution. IRB approval of the wording of the consent must be documented on each page through the use of a certification stamp indicating the date of the most recent IRB approval of the document. If the consent form is amended during the protocol approval period, the revised form must bear the approval date of the amendment. This documentation will be maintained in IRB files but need not appear on consent information distributed to participants.

9.7 Parental Permission and Assent

See Section 10.1.3.1 for policies on parental permission and assent in research involving children.

9.8 Surrogate Consent

The regulations generally require that the investigator obtain informed consent from participants. Under appropriate conditions, investigators also may obtain informed consent from a *legally authorized representative* of a participant (surrogate consent). Surrogate consent is approved at the discretion of the IRB in consultation with University Counsel. This definition only applies to research conducted in North Carolina and may not apply in research conducted outside of North Carolina. When research is conducted outside of NC it the responsibility of the investigator to comply with local/state laws regarding the age of majority and document this in their research files

**Definition**: *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant’s participation in the procedure(s) involved in the research [45 CFR 46.102(c)].

Investigators are responsible for providing a plan to the IRB which outlines how they will determine who the research participants legally authorized representative (LAR) is in accordance with the DHHS definition of LAR.

This policy is designed to protect human participants from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity.

Surrogate consent may be obtained from a court appointed guardian of the person **or** a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC). For example, a participant might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research.

Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person’s medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements:

1. The practitioner may determine after appropriate medical evaluation that the prospective research participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
2. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research participant lacks decision-making capacity is based on a diagnosis of mental illness.

The IRB will require investigators to conduct a **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective participants.

If feasible, the investigator must explain the proposed research to the prospective research participant even when the surrogate gives consent. Under no circumstances may a participant be forced or coerced to participate in a research study.

9.9 Consent and Language Barriers

It is imperative that all participants in research be able to access and understand consent forms and research materials. Researchers should be aware that barriers to access may be presented by language, illiteracy, or disability. The UNCG IRB requires that researchers consider whether consent forms and research materials will be accessible to all participants as they plan their research projects and include in IRB applications descriptions and rationales regarding procedures for ensuring accessibility and qualifications of translators/interpreters. The UNCG recognizes the unique nature of each research project with respect to accessibility of consent forms and materials and that procedures will vary across projects. However, researchers should attend to the following considerations when developing research protocols:

* Generally speaking, documents converted from English to a foreign language translated by a native speaker of the foreign language.
* Researchers who are conducting research in contexts in which participants (or parents/guardians consenting to children’s participation) may not read English should provide copies of consent forms in the language(s) of known non-English speakers or develop plans to be sure that such individuals will be able to access consent forms.
* It is **never** acceptable to use computer software to translate consent forms or research documents.
* Translators/interpreters should understand the context/meaning of the material being translated/interpreted.
* Translators/interpreters should sign statements of confidentiality to be kept on file by the investigator.
* If the translator is in any way engaged in the recruitment of participants, is information must be stated in the application as he/she may require additional training in human subjects protection. The ORI can provide these resources.
* Investigators should attend to the qualifications of translators/interpreters with respect to certification by an appropriate organization (e.g., Department of Social and Health Services, American Translators Association) and adherence to an appropriate ethical code (e.g., National Code of Ethics for Interpreters in Health Care).

Researchers should submit with the IRB application both English language and translated consent forms for proposals that include non-English-speaking participants. If necessary, the IRB may consult with language experts or require a "back-translation" into English. The investigator should provide documentation to verify the accuracy of the translation and back-translation.

If a non-English-speaking participant is enrolled unexpectedly, researchers may rely on an oral translation of the English language consent form, but should take extra care in the informed consent process to ensure that the participant has understood the project. A statement in the research records (and on the English language consent form) should indicate that the translation took place, identify the translator, and document the translator's belief that the participant understood the study and the consent process. If the participant is a patient, a note about the translation should be made in the patient's research records as well. Researchers should try to provide a written translation of the vital emergency contact information.

Sometimes a participant understands English but does not read or write English. In such cases, an oral presentation of the consent form is acceptable. Again, an impartial witness should document that the participant understands the research and the consent process and consented to participate.

10 Vulnerable Populations

When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence, the IRB should include additional safeguards to protect the rights and welfare of these participants. Some of the vulnerable populations that might be involved in research include children, pregnant women, fetuses, neonates, and prisoners, adults who lack the ability to consent, students, employees, or homeless persons.

In cases in which the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the review process must include one or more individuals who are knowledgeable about or experienced in working with these participants. For example, an IRB should include one or more individuals who are knowledgeable about or experienced in working with children, prisoners, or adults with limited decision-making capacity when reviewing research that involves individuals from these populations. IRBs should examine their local context for other vulnerable populations that should be represented on the IRB.

45 CFR 46 has additional subparts designed to provide extra protections for vulnerable populations which also have additional requirements for IRBs.

* Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
* Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Participants
* Subpart D - Additional Protections for Children Involved as Participants in Research

DHHS-funded research that involves any of these populations must comply with the requirements of the relevant subparts. Research funded by other federal agencies may or may not be covered by the subparts. Researchers must check with the IRB to determine applicability of the subparts.

The following policies and procedures, which are based on the subparts, apply to both federally funded research and non-federally funded research.

10.1 Research Involving Children

### 10.1.1 Definitions

**Children** - persons who have not attained the legal age of majority (18) to consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

**Investigators are responsible for providing a plan/documentation that potential participants in the research meet the DHHS definition of children. This is to be provided when research will be conducted outside of North Carolina.**

**North Carolina Law defines guardian as listed below**

A person lawfully invested with the power, and charged with the duty, of taking care of the person and managing the property and rights of another person, who, for defect of age, understanding, or self-control, is considered incapable of administering his own affairs. One who legally has responsibility for the care and management of the person, or the estate, or both, of a child during its minority.

**NOTE: Research conducted in jurisdictions including international settings and states other than North Carolina, the must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The University Counsel’s Office will provide assistance with regard to laws in other jurisdictions.**

**Assent** - a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

**Permission** - the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

**Parent** - a child's biological or adoptive parent.

**Guardian** – an individual with responsibility of both the estate and the person.

**Guardian of the person** - an individual appointed solely for the purpose of performing duties relating to the care, custody, and control of a ward.

### 10.1.2 Allowable Categories

Research on children must be reviewed and categorized by the IRB into one of the following groups:

1. Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., **minimal risk**). [45 CFR 46.404]
	* The IRB may find that the permission of one parent is sufficient.
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant. [45 CFR 46.405]
* The risk is justified by the anticipated benefit to the participants;
* The IRB may find that the permission of one parent is sufficient;
* Requires assent of the child.
1. Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual participant, but likely to yield generalizable knowledge about the participant’s disorder or condition. [45 CFR 46.406]
* The risk represents a minor increase over minimal risk;
* The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
* **Permission of either both parents, or legal guardian, is required- unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child;**
* Requires assent of the child.
1. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. [45 CFR 46.407]
* Federally-funded research in this category must be approved by the Secretary of Health and Human Services, requires consent of either both parents, or legal guardian, and 45 CFR 46 Subpart D will be applied.
* For non-federally-funded research, IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:
	+ 1. That the research in fact satisfies the conditions of the previous categories, as applicable; or
		2. The following:
1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
2. The research will be conducted in accord with sound ethical principles; and
3. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

### 10.1.3 Parental Permission and Assent

#### 10.1.3.1 Parental Permission

In accordance with [45 CFR 46.408(b)](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) the IRB must determine that adequate provisions have been made for soliciting the permission of each child’s parent or guardian.

Parents or guardians must be provided with the basic elements of consent as stated in [45 CFR 46.116(a)(1-8)](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under [45 CFR 46.404 or 45 CFR 46.405](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). The IRB’s determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under [45 CFR 46.406](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) and [45 CFR 46.407](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) unless

* One parent is deceased, unknown, incompetent, or not reasonably available; or
* When only one parent has legal responsibility for the care and custody of the child.

The IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

* The research meets the provisions for waiver in [45 CFR 46.116(d)(1-4)](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm) and if the IRB determines that the research protocol is designed for conditions or a participant population for which parental or guardian permission is not a reasonable requirements to protect the participants (for example, neglected or abused children).
* An appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and that the waiver is not inconsistent with Federal State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

Permission from parents or legal guardians must be documented in accordance with and to the extent required by [45 CFR 46.117](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm).

#### 10.1.3.2 Assent from Children

Because “assent” means a child’s affirmative agreement to participate in research, (45 CFR 46.402(b), the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective participants. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity levels limit their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the children to understand, to the degree they are capable, what their participation in research would involve.

The IRB presumes that children approximately age 5 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script should be obtained from children 5 - 11 years of age. Written assent using a written document for the children to sign may be sought for older children 12-17. However the IRB can determine if assent is required regardless of the child’s age. As children approach age 18 and/or become increasingly cognitively competent, the written assent document should increasingly resemble the informed consent document.

At times there may be inconsistency between parent consent and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child cannot decide to be in research over the objections of a parent. Obviously, there are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life threatening disease is being considered). The general idea, however, is that children should not be forced to be research participants, even when their parents consent to it.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even when the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the Waiver of Informed Consent section of this manual.

**The Assent Form**

Researchers should try to draft a form that is age appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1. explain why the research is being conducted;
2. describe what will happen and for how long or how often;
3. state that it is up to the child to participate and that it's okay to say no;
4. explain if it will hurt and if so for how long and how often;
5. state what the child's other choices are;
6. describe any good things that might happen;
7. state whether there is any compensation for participating; and
8. ask if they have questions.

For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents should include more information and may use more complex language.

#### 10.1.3.3 Children Who are Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition, **only if such research** is:

1. related to their status as wards; or
2. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *loco parentis.*

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

The IRB is provided with a copy of the regulations in hard/soft form in order to make the appropriate decision under these circumstances.

10.2 Research Involving Pregnant Women, Human Fetuses and Neonates

For research not funded by DHHS, no additional safeguards are required and there are no restrictions on the involvement of pregnant women in research where the risk to the fetus is no more than minimal (see 45 CFR 46 Subpart B for restrictions on DHHS-funded research). For research that involves more than minimal risk to fetuses or which involves neonates, the following apply.

### 10.2.1 Definitions

**Dead fetus** - a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

**Delivery** - complete separation of the fetus from the woman by expulsion or extraction or any other means.

**Fetus** - the product of conception from implantation until delivery.

**Neonate** - a newborn.

**Nonviable neonate** - a neonate after delivery that, although living, is not viable.

**Pregnancy** encompasses the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**Viable**, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

### 10.2.2 Research Involving Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research involving more than minimal risk to fetuses if all of the following conditions are met:

1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under paragraph 4. or 5. of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

### 10.2.3 Research involving neonates

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this section) have been met as applicable.

**Neonates of Uncertain Viability.** Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

The IRB determines that:

1. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
2. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
3. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

**Nonviable Neonates.** After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.
6. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

**Viable Neonates.** A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of IRB Review Process and Research Involving Children.

### 10.2.4 Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material

1. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
2. If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent sections of this manual are applicable.

### 10.2.5 Research Not Otherwise Approvable

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:

1. That the research in fact satisfies the conditions of Section 10.2.2, as applicable; or
2. The following:
	1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
	2. The research will be conducted in accord with sound ethical principles; and
	3. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

Additionally if the project is funded by DHHS 45 CFR 46 Subpart B will be applied

10.3 Research Involving Prisoners

Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules protecting them. In the past, prisoners were viewed as a convenient research population. They are housed in a single location, constitute a large and relatively stable population, and live a routine life. Unfortunately, all the things that make a prison and prisoners a convenient research population also make prisoners ripe for exploitation.

The concerns articulated in Subpart C and the policy based on Subpart C attempt to address whether prisoners have any real choice concerning participation in research or whether incarceration prohibits free choice

### 10.3.1 Applicability

This policy applies to all research conducted under the auspices of UNCG involving prisoners as participants. Even though a University IRB may approve a research protocol involving prisoners as participants according to this policy, investigators are still subject to the Administrative Regulations of the North Carolina Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

### 10.3.2 Purpose

Because prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as participants in research, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities to which this subpart is applicable. [45 CFR 46.302]

### 10.3.3 Definitions

[According to 45 CFR 46.303]

**Prisoner** – any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Minimal Risk** – the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

### 10.3.4 Composition of the IRB

[45 CFR 46.304]

In addition to satisfying the general requirements detailed in the IRB section of this manual, when reviewing research involving prisoners, the IRB must also meet the following requirements:

1. A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.
2. At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

### 10.3.5 Additional Duties of the IRB

[45 CFR 46.305]

In addition to all other responsibilities prescribed for IRB in the UNCG Institutional Review Board and IRB Review Processsections of this manual, the IRB will review research involving prisoners and approve such research only if it finds that:

1. the research falls into one of the following **permitted categories** [45 CFR 46.306]:
	1. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
	2. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
	3. research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults);
	4. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.
2. any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language which is understandable to the participant population;
6. adequate assurance exists that parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Additionally if the project is funded by DHHS 45 CFR 46 Subpart C will be applied

### 10.3.6 Waiver for Epidemiology Research

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(l) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

(1) In which the sole purposes are

(i) To describe the prevalence or incidence of a disease by identifying all

cases, or

(ii) To study potential risk factor associations for a disease, and

2) Where the IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that

(i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants, and

(ii) Prisoners are not a particular focus of the research.

The specific type of epidemiological research participant to the waiver involves no more than minimal risk and no more than inconvenience to the human participant participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the participants.

In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data.

**(http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf)**

10.4 Persons with Mental Disabilities or Persons with Impaired Decision-Making Capacity

Research involving participants who are mentally ill or participants with impaired decision-making capacity warrants special attention. Research involving these populations may present greater than minimal risk; may not offer direct medical benefit to the participant; and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion.

### 10.4.1 IRB Composition for Representation

The IRB membership must include at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the population, a family member of such a person, or a representative of an advocacy group for that population.

### 10.4.2 Approval Criteria

**Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:**

1. Only incompetent persons or persons with impaired decision making capacity are suitable as research participants. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants. Incompetent persons or persons with impaired decision-making capacity must not be participants in research simply because they are readily available.
2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be participants of research that imposes a risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.
3. Procedures have been devised to ensure that participant’s representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] or guardians, must be given descriptions of both proposed research studies and the obligations of the person’s representatives. They must be told that their obligation is to try to determine what the participant would do if competent, or if the participant’s wishes cannot be determined, what they think is in the incompetent person's best interest.

### 10.4.3 Additional Concerns

Both investigators and IRB members must be aware that for some participants decision-making capacity may fluctuate. For participants with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary. **It is the responsibility of investigators to monitor the decision-making capacity of participants enrolled in research studies and to determine if surrogate consent must be re-obtained.**

The IRB will require investigators to conduct a **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective participants.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may participants be forced or coerced to participate.

**(National Bioethics Advisory Committee)**

11 Complaints, Harassment, Non-compliance, and Suspension or Termination of IRB Approval of Research

11.1 Complaints

Complaints reported to the IRB will be evaluated as possible unanticipated problems involving risks to participants or others under Section 7.9. Additionally any individual that is participating in a research study and wants to discuss a problem, concern, or if they have a question and would like to talk to someone not involved in the research study should contact the Director at (336) 256-1482 or toll free at 855-251-2351. Participants may also contact this person to get more information on their rights as a research participant or to offer input.

The Chair of the IRB and the Director will promptly handle (or delegate staff to handle) and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research participants and others.

11.2 Survey/Contact Harassment

When conducting survey research online researchers may only contact the potential participant. This should include the initial contact and two follow ups. In all of the correspondence the Principal Investigator will need to have an opt-out option prominent in the correspondence that will cease all contact by the Principal Investigator.

11.3 Non-compliance

All members of the University community involved in human participant research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human participants.

11.3.1 Definitions

“Non-compliance” is defined as failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

“Serious non-compliance” is defined as failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. As a general rule, OHRP and UNCG both consider the collection of data for a non-exempt human participants research project without IRB review and approval to constitute serious noncompliance.

“Continuing non-compliance” is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

“Allegation of Non-Compliance” is defined as an unproved assertion of non-compliance.

“Finding of Non-Compliance” is defined as an allegation of non-compliance that is found to be true or a report of non-compliance that is clearly true. (For example, a finding on an audit of an unsigned consent document, or an admission of an investigator of that the protocol was willfully not followed would represent reports of non-compliance that would require no further action to determine their truth and would therefore represent findings of non-compliance.)

11.3.2 Review of Allegations of Non-compliance

All allegations of non-compliance will be reviewed by the IRB Chair and Director in accordance with 4.4.2. The IRB Chair and Director will review:

1. All documents relevant to the allegation;
2. The last approval letter from the IRB;
3. The last approved IRB application and protocol;
4. The last approved consent document.
5. The grant, if applicable; and
6. Any other pertinent information (e.g., questionnaires, DSMB reports, etc.).

The IRB Chair and Director will review the allegation and make a determination as to whether non-compliance had occurred. They may request additional information or an audit of the research in question.

If, in the judgment of the IRB Chair and Director, non-compliance has not occurred, no further action will be taken. If, in the judgment of the IRB Chair and Director, non-compliance has occurred, the non-compliance will be processed according to 11.3.3 Review of Findings of Non-compliance.

If, in the judgment of the IRB Chair and Director, any allegation or findings of non-compliance warrants suspension or termination of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair may terminate or suspend the research as described in below with subsequent review by the IRB.

### 11.3.3 Review of Findings of Non-compliance

If, in the judgment of the IRB Chair and Director, the reported finding of non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action is required and the IRB is informed at the next convened meeting. Documentation concerning the noncompliance and the proposed corrective action plan will be filed with the protocol. If, in the judgment of the IRB Chair and the ORI Director, the reported finding is serious or continuing, an inquiry will occur (11.3.4).

### 11.3.4 Inquiry Procedures

A determination may be made by the IRB Chair and Director that an inquiry is necessary based on several issues that may include but are not limited to:

1. Participants' complaint(s) that rights were violated;
2. Report(s) that investigator is not following the protocol as approved by the IRB;
3. Unusual and/or unexplained adverse events in a study;
4. Repeated failure of investigator to report required information to the IRB.
5. Data collected without IRB approval.

A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is given a charge, which can include any or all of the following:

1. Review of protocol(s) in question;
2. Review of sponsor audit report of the investigator, if appropriate;
3. Review of any relevant documentation, including consent documents, case report forms, participant’s investigational and/or medical files, etc. as they relate to the investigator's execution of her/his study involving human participants;
4. Interview of appropriate personnel if necessary;
5. Preparation of either a written report of the findings, which is presented to the full IRB at its next meeting;
6. Recommend actions if appropriate.

### 11.3.5 Final Review

The results of the inquiry will be reviewed at a convened IRB meeting. Prior to the meeting all IRB members will receive the full protocol, a copy of the current consent document and the noncompliance report to review. At the convened IRB meeting the IRB will receive a report from the subcommittee. If the results of the inquiry substantiate the finding of serious or continuing non-compliance, the IRB’s possible actions could include, but are not limited to:

1. Request a correction action plan from the investigator;
2. Verification that participant selection is appropriate and observation of the actual informed consent;
3. An increase in data and safety monitoring of the research activity;
4. Request a directed audit of targeted areas of concern;
5. Request a status report after each participant receives intervention;
6. Modify the continuing review cycle;
7. Request additional Investigator and staff education;
8. Notify current participants if the information about the non-compliance might affect their willingness to continue participation;
9. Modification of the protocol;
10. Modification of the information disclosed during the consent process;
11. Requiring current participants to re-consent to participation;
12. Destruction of data;
13. Keep data but never use to contribute to generalizable knowledge;
14. Keep data and may use to contribute generalizable knowledge BUT must inform journal that the data was collected without an approved protocol;
15. Required to attend human subjects use workshop;
16. Suspend the study (See below); or
17. Terminate the study (See below).

The investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. If the IRB determines that the non-compliance was serious or continuing, the results of the final review will be reported as described below in 11.5.

### 11.3.6 Additional Actions

A finding of serious or continuing non-compliance may also result in the following sanctions, among others:

1. Suspension or termination of IRB approval of specific research protocols or of all research involving human participants in which the investigator participates.
2. Sponsor actions. In making decisions about supporting or approving applications or proposals covered by this policy the Department of Health and Human Services or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been participant to a termination or suspension as described above, and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department of Health and Human Services or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human participants.
3. Institutional or individual action by the federal government OHRP. The OHRP may
* withhold approval of all new UNCG studies by the IRB;
* direct that no new participants be added to any ongoing studies;
* terminate all ongoing studies, except when doing so would endanger the participants; and/or
* notify relevant state, federal and other interested parties of the violations.
1. Individual **disciplinary action** of the investigator or other personnel involved in a study, up to and including dismissal, pursuant to University policies and procedures.

Failure to secure necessary UNCG IRB approval before commencing human participant research must be reported by the Director to the appropriate Department Chair/Unit Head, Dean, and Provost.

Investigators who are UNCG employees should also be aware that, in general, UNCG **indemnifies** them from liability for adverse events that may occur in UNCG studies approved by the UNCG IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator **personally liable** in such cases. This does not apply to individuals who are not UNCG employees.

11.4 Suspension or Termination

Suspension of IRB approval is a directive of the convened IRB or IRB Chair or Director to temporarily or permanently stop some or all previously approved research activities. Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

The IRB Chair or Director may suspend research to ensure protection of the rights and welfare of participants. Suspension directives made by the IRB Chair or Director must be reported to a meeting of the convened IRB.

Research may only be permanently terminated by the convened IRB.

When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to stopping all research activities, the convened IRB or individual ordering the suspension or termination may notify any participants currently participating that the study has been suspended or terminated. The convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled participants are necessary to protect their rights and welfare of participants. These procedures might include: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons.

If follow-up of participants for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require that the participants should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

11.5 Reporting

Serious or continuing noncompliance with regulations or the requirements or determinations of the IRB; and suspensions or terminations of IRB approval will be reported to the appropriate regulatory agencies and institutional officials according to the procedures in Section 12.

12 Reporting to Regulatory Agencies and Institutional Officials

1. The ORI will initiate the reporting procedures described here as soon as the IRB takes any of the following actions:
	1. Determines that an event may be considered an unanticipated problem involving risks to participants or others
	2. Determines that non-compliance was serious or continuing
	3. Suspends or terminates approval of research
2. The Director or designee prepares a letter that contains the following information:
	1. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research)
	2. Name of the institution conducting the research
	3. Title of the research project and/or grant proposal in which the problem occurred
	4. Name of the principal investigator on the protocol
	5. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
	6. A detailed description of the problem including the findings of the organization and the reasons for the IRB’s decision
	7. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants, etc.)
	8. Plans, if any, to send a follow-up or final report by the earlier of
		* 1. A specific date
			2. When an investigation has been completed or a corrective action plan has been implemented
3. The letter is reviewed by the IRB Chair and the Associate Provost Research and modified as needed
4. The Director signs the letter.
5. The ORI sends a copy of the report to:
	1. The IRB by including the letter in the next agenda packet as an information item
	2. The Vice Chancellor for Research and Economic Development
	3. OHRP, if the study is subject to DHHS regulations or subject to UNCG’s FWA
	4. If the study is conducted or funded by any Federal Agency other than DHHS that is participant to “The Common Rule,” the report is sent to OHRP or the head of the agency as required by the agency
		* Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
	5. Principal investigator
	6. Sponsor, if the study is sponsored
	7. Department Chair , Dean and other supervisors of the principal investigator
	8. Others as deemed appropriate by the Director

The Director ensures that all steps of this policy are completed within 15 days of the initiating action. For more serious actions, the Director will expedite reporting.

**(OHRP Guidance http://www.hhs.gov/ohrp/policy/incidreport.htm)**

# 13 Investigator Responsibilities

Principal Investigators are ultimately responsible for the conduct of research. Principal Investigators may delegate research responsibility. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

**In order to satisfy the requirements of this policy, investigators who conduct research involving human participants must:**

* develop and conduct research that is in accordance with the ethical principles in the Belmont Report, which is achieved through training courses and data safety monitoring
* develop a research plan that is scientifically sound and minimizes risk to the participants;
* have sufficient resources necessary to protect human participants, including supervision, a sufficient number of appropriately trained staff persons, and appropriate support services.
* protect the rights and welfare of prospective participants;
* have plans to monitor the data collected for the safety of research participants,
* have a procedure to receive complaints or requests for additional information from participants and respond appropriately,
* ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff;
* obtain and document informed consent as required by the IRB and ensure that no human participant is involved in the research prior to obtaining his or her consent;
* ensure that all research involving human participants receives IRB review and approval in writing before commencement of the research;
* comply with all IRB decisions, conditions, and requirements;
* ensure that protocols receive timely continuing IRB review and approval;
* report unanticipated problems involving risk to participants or other or adverse events to the IRB
* obtain IRB review and approval in writing before changes are made to approved protocols or consent forms
* seek IRB assistance when in doubt about whether proposed research requires IRB review

13.1 Research Personnel

**Principal Investigators**

At UNCG, **faculty or staff members with University-paid appointments** may serve as the Principal Investigator or as the Faculty Advisor on a research project involving human participants. Student researchers can also be listed as Principal Investigators as of February 2013 via the submission of an IRB application through the IRBIS system.

The IRB recognizes one Principal Investigator (PI) for each study. The PI has ultimate responsibility for the research activities, however in the case of the Student PI, the Faculty Advisor has the ultimate responsibility for the research activities pursued by the student.

Protocols that require skills beyond those held by the Principal Investigator must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-investigator(s).

**Student Researchers**

Students can list themselves as Principal Investigators at the point of IRBIS online submission; however, they must have a Faculty Advisor who fulfills the role as the responsible party for the student research. The Student must also make sure contact information allows for the ability of the ORI to reach them at a later date. The Faculty advisor will also be contacted in the case that a student’s research has lapsed in its renewal.

**Research Team**

The PI, Research Assistants, and other individuals, also known as key personnel, who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol.

13.2 Protocol Development

When developing a protocol, the Principal Investigator or a member of the protocol research team may contact the ORI for a determination regarding whether the proposed project constitutes human participants research and, if so, what level of review would be required. Contact with the ORI may be in the form of a telephone call, by letter, or by email and must include a brief description of the proposed research. The ORI will respond to the Principal investigator or member of the research team by telephone, letter, or email.

Using the IRB protocol application, the Principal Investigator must carefully develop a Description of Study (investigator/local research plan) and consent form(s), making sure that consent form information is consistent with the research plan.

The Protocol Application must, at a minimum, include enough information for reviewers to make determinations based upon the **Criteria for IRB approval of Research** [45 CFR 46.111].

If research is DHHS-sponsored, materials delivered to the departmental IRB reviewer must include the entire sponsoring application; if there is a significant variation between the DHHS application and the IRB protocol, the investigator must identify and justify the discordance.

**Note**: Investigators who have other individuals submit their protocols and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Principal Investigator (PI) or Faculty Advisor. It is incumbent upon these responsible parties to check all material that is submitted to the IRB for review.

13.3 Changes to Approved Research

Investigators must seek IRB approval before making any changes in approved research - even though the changes are planned for the period for which IRB approval has already been given - unless the change is necessary to eliminate an immediate hazard to the participant (in which case the IRB must then be notified at once).

A completed modification application should be sent directly to the ORI. The IRB Chair or designee or Director must sign and return a letter to indicate approval. Nonsubstantive changes (e.g., change in last name of PI) may be approved by signature of the ORI staff IRB reviewer alone. Major changes (e.g. changes that involve increased risk or discomfort) may require full board review. Substantive minor changes will be approved by the signature of the IRB reviewer and the IRB Chair or designee.

**Note**: IRB approved modifications to ongoing research do NOT extend the original approval expiration date.

13.4 Data Storage

The PI or Faculty Advisor is the primary custodian/steward of data generated in the context of a research study and has primary oversight for data security. By certifying an IRB submission, the PI or Faculty advisor accepts this role (see the UNCG [Access to and Retention of Research Data policy](http://policy.uncg.edu/research_data/)). The University supports the PI or Faculty Advisor by making available the infrastructure and expertise needed to ensure the security of data.

Responses to the series of questions in the online application trigger determination of the "level" of security risk for each study. For administrative data, UNCG defines two levels of data, "restricted" and "public". See the [Data Classification policy](http://policy.uncg.edu/data/) for more information. For research data, the governing policy is the [Research Data Policy](http://policy.uncg.edu/data/) which speaks to different data classification for types of research data. When prompted to certify each electronic IRB submission, the PI or Faculty Advisor is informed of the security level assigned to their study and is provided with recommended and/or required steps they must take to ensure data security.

### 13.5 Progress Reports

Investigators must report the **progress of the research** (including multi-site studies) to the IRB in the manner and frequency prescribed by the IRB, but no less than once a year. When reporting the progress of a multi-site study the PI is responsible for assuring the UNCG IRB that all associated sites have valid initial and continual IRB approval.

When an approved research project is completed, the investigator must promptly notify the IRB and file with the IRB a **final progress report**, which includes the information required for continuing review of protocols for the last research project period.

Once data collection has been completed and the research is closed at either the University or other sites, the Principal Investigator is not required to submit any further reports of the research to the IRB.

### 13.6 Investigator-Required Record Keeping

Investigators must retain copies of approved IRB documents and implement a system to comply with approval expiration dates. Storage of data in identifiable and de-identifiable states will likely differ. Identifiable data must be stored securely in a locked file cabinet or similar apparatus preferably on the UNCG campus, on a password protected/encrypted computer/flash drive, or according to other equivalent systems approved by the IRB.

In addition to providing a copy of the signed and dated consent form to each participant, a copy must be stored securely by the Principal Investigator (PI) and retained for a **minimum of 3 years after completion of the research. Completion of research is defined as the time at which IRB file for the project is closed. When the minimum retention period has been met, the PI must destroy all identifiable data (consent forms, video/audio tapes, key to identifiers, and etc.) according to measures approved in the IRB protocol.** Deidentified data may be kept indefinitely without the PI having an open IRB file for the project.

**Statements of Confidentiality and Human Subjects Training verification**

It is the responsibility of the PI or the Faculty Advisor to maintain on file copies of signed Statements of Confidentiality (for all persons who are not investigators or student researchers but have access to research data) and UNCG-accepted certificates of training in the protection of human research participants (for all persons who are not investigators or student researchers but who interact with research participants). Statements of confidentiality do not need to be submitted to the IRB, but kept on file with the researchers.

All Principal Investigators and Faculty advisors need to submit documentation verifying completion of Human subjects training at submission. Any research assistants added after initial approval in a modification are *not* required to submit documentation of human subjects research training, but it is expected that the PI maintain this verification as part of the study files.

**Biospecimen Storage**

When human specimens (e.g., blood/plasma) are collected they must be stored in accordance with OSHA regulated standards. Additionally, human specimens must be stored securely in a locked room with limited access, regardless of whether they are identified or deidentified.

13.7 Human Subjects Protection Training / Ongoing Education of Principal Investigator and Research Team

One component of a comprehensive human research protection program is an education program for all individuals involved with research participants. UNCG is committed to providing training and an on-going educational process for investigators and members of their research teams related to ethical concerns and regulatory and institutional requirements for the protection of human participants.

**Education**

The PI, student researcher(s), and all co-investigator(s) must submit with IRB applications certificates of training in the protection of human research participants dated no earlier than five years prior to the date of submission. UNCG’s IRB accepts only certificates of training from the following sources:

A Certificate of Completion from an ORI-sponsored training session.

Certificate of Completion for the **Researcher** module, and the required additional modules for a student researcher, in the CITI Course in the Protection of Human Research Participants indicating scores of a minimum of 80% of questions answered correctly for all included modules.

New research protocols and applications for continuing review will not be accepted from principal investigators who have not completed the education requirement or whose training has exceeded the valid certification period of five (5) years

While research protocols and applications for continuing review will be accepted and reviewed if the Principal Investigator holds a current certification of training, final approval will not be granted until all co-investigators have completed the initial education requirement.

Investigators who are also IRB Chair, IRB members, or ORI staff will satisfy the training requirements for IRB members and staff described in this policy under Section 5.6.

**Additional Resources**

Human research protection information will be made available on the ORI website on an ongoing basis to ensure that the University research community apprised of current regulatory and policy requirements and training opportunities.

13.8 Participant Recruitment

Investigators are responsible for recruiting research participants in a manner that is fair, ethical, and equitable. IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive.

**Online Survey Recruitment/Contact Harassment**

When conducting recruitment for an online research survey, researchers may only contact the potential participant a total of 3 times. This should include the initial contact and two follow ups. In all of the correspondence the Principal Investigator will need to have an opt-out option prominent in the correspondence that will cease all contact by the Principal Investigator.

13.9 Payment to Participants

Payment to research participants may be an incentive for participation or a way to reimburse a participant for travel and other experiences incurred due to participation. However, payment for participation is **not considered a research benefit**. Regardless of the form of remuneration,investigators must take care to avoid coercion of participants. **Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation.** The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.

Credit for payment should accrue and not be contingent upon the participant completing the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive. The IRB does not allow the entire payment to be contingent upon completion of the entire study.

The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence.

The consent form must describe the terms of payment and the conditions under which participants would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

If monies for payment are administered through the UNCG Controller’s Office, the PI must follow the procedures or requirements of that office. In the event the payment through UNCG Controller’s Office requires identification of the participant, this must be stated on the informed consent form.

It is prohibited for the following payments to occur:

* Payments to professionals in exchange for referrals of potential participants (“finder’s fees”).
* Payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”) unless they are judged not to interfere with providing prospective participants with sufficient opportunity to consider whether to participate and does not increase the possibility of coercion or undue influence on investigators or participants.

13.10 Investigator Concerns

Investigators who have concerns or suggestions regarding UNCG’s human research protection program should convey them to the Director or other responsible parties (e.g. Research Policy Committee) regarding the issue, when appropriate. The Director/Institutional Official will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB or the Director will be available to address investigators’ questions, concerns, and suggestions.

14 Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the creation of a Privacy Rule for identifiable health information. The resulting Privacy Rule, finalized in August 2002, set a compliance date of April 14, 2003. While the main impact of the Privacy Rule is on the routine provision of and billing for health care, the Rule also affects the conduct and oversight of research. Researchers, IRB staff and members, as well as research administration must be aware of these changes.

14.1 Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is an expansive federal law, part of which is intended to protect the privacy of health care information. Personal health information (PHI) referred to as protected health information, generally refers to demographic information, medical history, test and laboratory results, insurance information and other data that is collected by a health care professional to identify an individual and determine appropriate care. The final Privacy Rule regarding such information was published on August 14, 2002. See the [NIH HIPAA Privacy Rule Booklet for Research](http://privacyruleandresearch.nih.gov/pr_02.asp) and the [NIH fact sheet on Institutional Review Boards and HIPAA](http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp) for more information on how HIPPA applies to research. Under HIPAA, patients have certain new rights. These include the right to receive a Notice of Privacy Practices, the right to access, inspect, and receive a copy of one’s own PHI, the right to request an amendment to one’s own PHI, and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, payment and health care operations that have not been authorized.

UNCG as an institution is not a covered entity under HIPAA although some covered entities (e.g., clinics) do exist at UNCG. However, UNCG researchers who are working with “Protected Health Information” (PHI) from other institutions that are covered entities will need to comply with HIPAA rules.

14.2 HIPAA and Research

The final Privacy Rule published on August 14, 2002 included a number of changes in how the Rule applies to research. See the [NIH HIPAA Privacy Rule Booklet for Research](http://privacyruleandresearch.nih.gov/pr_02.asp) and the [NIH fact sheet on Institutional Review Boards and HIPAA](http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp) for more information on how HIPPA applies to research. See also [The HIPPA Privacy Rule: Lacks Patient Benefit, Impedes Research Growth](http://www.aahcdc.org/Portals/0/pdf/AAHC_HIPAA_Privacy_Rule_Impedes_Research_Growth.pdf).

The University of North Carolina at Greensboro is NOT a covered entity under HIPAA. However, researchers who are working with “Protected Health Information” (PHI) from other institutions that are covered entities will need to comply with the rules on HIPAA. UNCG does has four covered entities: the Psychology Clinic, Speech and Hearing Program (Gateway North), Speech and Hearing Clinic, and Student Health Services. These covered entities have established policies and procedures that researchers must follow.

**14.3 HIPAA and UNCG Documentation Requirements**

The IRB requires one of the following documents, and these are the *only* documents that would need to be submitted and reviewed: a HIPAA authorization form, a waiver of authorization form, or a de-identification form. These documents must be used whenever PHI from a covered entity is being utilized in the research. The covered entity should provide the researcher with their approved authorization form or waiver of authorization form. In the event that the covered entity does not have these documents the UNCG IRB will assist the researchers in developing them. A researcher who will use PHI must complete the application to use protected health information and submit it with the IRB protocol. The IRB does not require any information from a researcher regarding a Business Associate Agreement, as this item is obtained from the covered entity in the event that the covered entity is collaborating with the researcher and is sharing PHI within that study.

**14.4 HIPAA and Existing Studies**

Any research participant enrolled in a study that uses PHI from a covered entity must sign a HIPAA-compliant authorization form. This form is in addition to the existing Informed Consent document, and is federally required. In a few cases, the Informed Consent document may be combined with a HIPAA authorization.

**14.5** **Waivers to HIPAA consent form**

In some cases, an IRB may approve a waiver to use of the HIPPA authorization form. This may occur when the IRB finds that the research could not be practically done without the waiver, and not without access to and use of the PHI, and that disclosure poses minimal risk to privacy. This waiver would generally come from the IRB of the covered entity that has “ownership” of the PHI.

15 Special Topics

**15.1 NIH Certificate of Confidentiality**

**15.1.1 Statutory Basis for Protection**

Protection against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d):

"The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the participant of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. For more information, see the NIH Certificates of Confidentiality Kiosk.

Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision.

The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the participants).

Any investigator engaged in research in which sensitive information is gathered from human participants (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of:

* information about sexual attitudes, preferences, practices;
* information about personal use of alcohol, drugs, or other addictive products;
* information about illegal conduct;
* information that could damage an individual's financial standing, employability, or reputation within the community;
* information in a participant’s medical record that could lead to social stigmatization or discrimination; or
* information about a participant’s psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the ORI for help in applying for a certificate.

**(NIH Guidance, http://grants.nih.gov/grants/policy/coc/background.htm)**

The IRB may require investigators to apply for a Certificate of Confidentiality.

### 15.1.2 Limitations of a Certificate of Confidentiality

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research participants only from legally compelled disclosure of their identity. It does **not** restrict voluntary disclosures.

For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse, a participant’s threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form which research participants are asked to sign.

In addition, a Certificate of Confidentiality does **not** authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research participant if

* the participant (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
* authorized personnel of the Department of Health and Human Services (DHHS) request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
* information about a participant’s psychological well-being or mental health.

**(NIH Guidance, http://grants.nih.gov/grants/policy/coc/background.htm)**

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the ORI for help in applying for a certificate.

15.2 Mandatory Reporting

While preparing a research protocol, investigators must keep in mind that a specific professional group may have mandated reporting guidelines that will need to be followed. In addition, the state of North Carolina also has mandated reporting regulations. Guidance on these state regulations can be sought from university counsel. Investigators should consult appropriate sources to determine if potential participants should be advised of mandatory reporting requirements during the informed consent process.

15.3 UNCG Students and Employees as Participants

When UNCG students and/or employees are being recruited as potential participants, researchers must ensure that there are additional safeguards for these participants. Their participation must be voluntary and undue influence on their decision to participate. Researchers must emphasize to participants that neither their academic status or grades, nor their employment, will be affected by their participation decision.

To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in procedures that are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit participants through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes **other than their own**. When entering a classroom to recruit students and conduct research (e.g. administer a survey) investigators must do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

15.4 Psychology Department Participant Pool

The Psychology Department of UNCG employs the use of a “participant pool” for student-participants.

The Department of Psychology participant pool consists of all students enrolled in PSY 121 (General Psychology) during a given semester. As part of the course requirement, students are expected to earn 16 Research Participation Credits (RPCs; with each credit corresponding to 0.5 hours of research participation), unless otherwise arranged between the Department Head and the Instructor. There are two methods by which students can earn their 16 RPCs: 1) participating in 7.5 hours of IRB-approved research studies conducted under the supervision of Psychology faculty or 2) writing a research paper on a specified topic related to Psychology as an empirical science and its research methods. Students must earn all 16 RPCs in either one of these two methods (i.e., the research paper counts towards all 16 RPCs, so it is of no advantage to complete the research paper and participate in some experiments). RPCs are NOT graded assignments; if they are not satisfactorily completed, the student simply earns an Incomplete grade in the PSY 121 course until the requirement is completed. Students who complete 7 credits by the midterm of the semester receive a one credit bonus towards the total of 16 credits and only have to earn 15 RPCs through research participation

The Department of Psychology conducts all research and training in accordance with the ethical guidelines set forth by the American Psychological Association, and, as appropriate, with the approval of UNCG’s Institutional Review Board. Department policies governing the use and operation of the participant pool are reviewed, and revisions pertaining to research activities are submitted to IRB for approval. In addition the Department of Psychology follows the OHRP guidance on “Student Subject Pools and Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments.” <http://www.hhs.gov/ohrp/policy/correspond/OHRP20100108.html>

15.5 Student-led Research

Student-led research falls into three categories:

* ***Research.*** The purpose of the activity is to contribute to generalizable knowledge and data gathered may be shared with a research community or the public at large. This includes funded and unfunded projects as well as thesis/dissertations studies. When anticipated activities are research, IRB review and approval ***must*** be obtained prior to data collection.
* ***Classroom Project.*** The purpose of these types of activities is the education of an individual student or group of students through an inquiry or experiential approach to discover known principles or phenomena rather than generalizable knowledge. Data gathered may only be shared with the course professor or faculty sponsor, classmates, or in the case of an internship/practicum, the collaborating party. If the data gathered is intended to be presented in the classroom setting only, this does not contribute to generalizable knowledge, and is not considered research per the federal regulations.
* **Program Evaluati**on (see SOP Section 2, Definitions) Data gathered may ONLY be shared with the sponsor/client/requesting party and where appropriate, the faculty sponsor/professor, or used for internal decision making or informational purposes. It is not necessary to submit an IRB application. The primary distinction between “research” and program evaluations that in a program evaluation the study data and results may only be shared with the organization requesting the evaluation.

Faculty advisors must still be listed on the application and will also be fully responsible for that study.

15.5.1 Class Projects

The UNCG IRB recognizes that human participants may be harmed by unethical or careless activities resulting from evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice. As a board that values the protection of human participants and the conduct of ethical behavior, the IRB strongly disapproves of such unethical behavior. Class projects are generally conducted for educational purposes and not as research. While some require submission of an IRB application or a determination that IRB approval is not required, many class projects require neither. Instructors and departments are encouraged to contact the relevant IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent, and professional ethics when class projects are part of the course syllabus. IRB chairs and staff can share expertise related to managing risks of deductive disclosure, coercion-free recruiting, informed consent, and special considerations for projects that include potentially vulnerable individuals. These issues may still remain even when IRB approval is not required, in which case instructors, advisors, departments and schools play an even greater role in providing the appropriate guidance and oversight.

It is the responsibility of the Faculty member to determine, prior to assigning a project, whether the project is a classroom project or research. Faculty members are encouraged to consult with the ORI in making such a determination. Should a class project be conducted that meets the definition of research but does not receive IRB review and approval, the faculty member will be considered to have engaged in IRB noncompliance and may be personally liable. If a student research project is originally conducted as a course assignment but develops into disseminated research, IRB approval must be obtained immediately***.***  Data collected as a course assignment can be used for research purposes at a later date if the data has been deidentified and the study is submitted and approved as an Exempt study.

**All participants should be made aware of this activity as a class project.**

Research or class projects that involves vulnerable populations (see chart below) or deception should involve consultation with the IRB or Director of the Office of Research Integrity and may require IRB review. When a study involves deception a debriefing is mandatory following the study.

|  |
| --- |
| **Vulnerable Populations** |
| Children |
| Prisoners |
| Elderly |
| Mentally or physically challenged individuals |
| Pregnant women |
| Individuals in foreign country |
| Immigrants |

**The following class projects do not need to be submitted or reviewed by the IRB:**

1. **CLASS PROJECTS** involving **secondary data analyses** that are assigned and conducted as educational exercises, using data that are either publicly available data, de-identified or otherwise impossible to be linked to personal identities.
2. **CLASS PROJECTS** involving **secondary data analyses** that are assigned and conducted as educational exercises, and that use datasets that include private information and codes that link to identifiers, but the students do not have access to the identifiers.\*

\*IRB review *may* be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants. Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics*.*

Instructor provides information about the assignment for the students to distribute to people who participate in these class projects. List the instructor as the appropriate contact person should questions arise

1. **CLASS PROJECTS or PRACTICA** that involve **direct interaction** (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and **not** **research**. The project or practicum is not “research” even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site\*\*

**\*\*Exception:**

If a student decides *after* the completion of a practicum activity to pursue additional activities with the same information for dissemination (e.g., master’s project, conference paper, article), then an IRB application describing research use of secondary data should be submitted for approval, as above.

The following class project *would* need to be submitted and reviewed by the IRB:

**CLASS PROJECTS** **or PRACTICA** that **involve direct interaction** or **secondary analyses of sensitive, private identifiable data** and are undertaken as **both an educational experience and as research** (e.g., results of these activities will be presented publicly or otherwise disseminated, or the data will be stored and used by the students or others as research data).

**Submission Tip**:

Such projects may be very similar to one another. For example, each student may interview one or more persons for a group of oral histories, or conduct telephone surveys as part of a yearly poll, but all in the class follow the same general script or guidelines. If class projects follow different protocols, a table or chart can describe these more individualized activities, under the umbrella of a single IRB application.

**Program Evaluation** – This is defined as a funded or unfunded evaluation of a specific program (formative, outcome, needs assessment, cost analysis, etc.) where the data and results will **ONLY** be shared with the organization/sponsor/client/requesting party or used for internal decision making or informational purposes. In this case, the work would not be considered “research” for IRB purposes.

Example 1: A researcher is conducting a program evaluation for an agency, program, or other organization. The work may include drawing a sample or sampling the entire population affected by the program; data collection, data analysis, and a written report. The organization may also require the PI to present the results at meetings with stakeholders or constituents. The PI has no intention of presenting results from this evaluation in any academic or professional publication or presentation other than that required by the organization. The PI also has no control over what the funding organization may do with the written report. In this case, the work would *not* be considered “research” for IRB purposes. Although the results may be intended to be generalized beyond the specific study sample, findings are not intended to be used or presented as generalizable beyond the scope of the particular program that is being evaluated. In this situation, **no IRB application** would be required.

Example 2: The situation is the same as in Example 1. However, in addition to sharing results with the organization, the researcher also intends to present the findings in an academic or professional setting other than that required by the agency. Depending on the content of the project, it may be considered **“research”** rather than solely “program evaluation,” and **an IRB application *may* be required**.

Example 3: A faculty member collects data to evaluate an academic program. The data and results will only be used by faculty within the department or School for internal decision-making or information sharing regarding the specific program. In this situation the work **would not be considered “research”** for IRB purposes, and **no IRB application** would be required.

Example 4: The situation is the same as in Example 3. However, the faculty plan to share evaluation data and results with an accrediting body or present the results from this evaluation in an academic or professional publication or presentation. As above, depending on the content of the data gathered, the project may be considered **“research”** rather than solely “program evaluation,” and **an IRB application may be required**.

15.5.2 Independent Doctoral Studies and Cornerstone Projects

These research activities are considered to meet the federal definition of human participants research and must be independently submitted to the IRB by the student-researcher. However, when students conduct research as part of a course of study, *a faculty member ultimately is responsible for the protection of the participants*, even if the student is the primary researcher and actually directs the project. The Faculty Advisor is responsible for research that is conducted as part of a course.

Students may list themselves as Principal Investigators (PI) on an IRBIS online submission. They must have a Faculty Advisor who fulfills the role of oversight of all research activities with the student as the affiliated student on the project. If the research activity is at another site and/or part of another research study outside of UNCG, the student will need a PI at UNCG and to submit an application informing the IRB of their specific research question/study within the existing active study.

### 15.6 Oral History

OHRP has determined that generally oral history projects are not designed to contribute to generalizable knowledge and therefore do not usually constitute research and thus do not require IRB review. However, some projects involving oral history include additional components that do constitute research and should be reviewed by the IRB. In addition, the definition of oral history is very specific and not all projects that investigators initially identify as oral history meet this definition. Investigators who believe they are conducting oral history should submit an IRB application to the IRBIS online system to the ORI. Based on the information provided, the ORI may issue a letter to the Investigator stating that the described project meets the definition of oral history and need not receive IRB review and approval. Investigators are advised to consult with the ORI regarding whether their oral history project requires IRB review and to complete an IRB application to the IRBIS online system to avoid potential liability should their project constitute research and require IRB review and approval.

**15.7 Genetic Studies**

Although GINA (the Genetic Information Nondiscrimination Act) prohibits discrimination in health care coverage and employment based on genetic information, genetic research studies may create special risks to human participants and their relatives. These involve psychosocial, and economic risks, such as the possible loss of privacy, and insurability (i.e. life, disability or long-term care), change in immigration status, and limits on education options, and may create a social stigma. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members.

Investigators need to insure that they do not overstate the protections provided by GINA and specifically address the elements of informed consent related to; 1) description of any reasonably foreseeable risks or discomforts and 2) statements pertaining to the confidentiality of records. Investigators need to understand that GINA does not prohibit discrimination related to life insurance, disability insurance or long-term care insurance if information about the subject obtained as part of the research was disclosed to or sought by such insurers and investigators may want to state this if individual information will be given to subjects. In addition, GINA generally does not apply to employers with fewer than 15 employees and individuals who are or will be employed by such employers receive none of the GINA protections that prohibit discrimination in employment based on genetic information.

In studies involving genetic testing, several questions need to be addressed, including:

1. Will test results be given on an individual level? NIH supports not giving individual level results if no cure is available for the disease.
2. Will a change in a family relationship be disclosed, such as mistaken paternity?
3. Does the participant or family member have the option not to know the results? How will this decision be recorded?
4. Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
5. Is the participant permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?
6. Will disease risk be quantified, including the limits on certainty of the testing?

For DNA banking studies, several questions need to be addressed, including:

1. Will the stored DNA samples be de-identified? (see biospecimen section 15.??)
2. Will DNA be shared? If shared, will the participant’s identity be known by the new recipient investigator?
3. Will the participant be contacted in the future by the investigator to obtain updated clinical information?
	1. Are re-contact provisions included in the original IRB for future studies not related to the original purpose of the collected DNA samples? If yes, what are the specifics included in the re-contact provisions?
4. How can the participant opt out of any distribution or subsequent use of his/her genetic material?

**15.8 Research Involving Coded Private Information or Biological Specimens**

UNCG procedures are based on the OHRP guidance document entitled, **“Guidance on Research Involving Coded Private Information or Biological Specimens”** (August 10, 2004 http://www.hhs.gov/ohrp/policy/cdebiol.html. This document:

* Provides guidance as to when research involving coded private information or specimens is or is not research involving human participants, as defined under HHS regulations for the protection of human research participants (45 CFR part 46).
* Reaffirms OHRP policy that, under certain limited conditions, research involving **only** coded private information or specimens is not human participants research.
* Provides guidance on who should determine whether human participants are involved in research.

For purposes of this procedure document, *coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Under the definition of human participant in Section 2 of this policy, *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human participants research. *Obtaining* means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving **only** coded private information or specimens do **not** involve human participants if the following conditions are both met:

* 1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;

**and**

* 1. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
		1. the key to decipher the code is destroyed before the research begins;
		2. the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
		3. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
		4. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human participants. Unless this human participants research is determined to be exempt (See Section 7.2), IRB review of the research would be required. Informed consent of the participants also would be required unless the IRB approved a waiver of informed consent (See Section 9.3).

**(OHRP guidance document “Guidance on Research Involving Coded Private Information or Biological Specimens” (August 10, 2004 http://www.hhs.gov/ohrp/humanparticipants/guidance/cdebiol.pdf)**

### 15.8.1 Who Should Determine Whether Coded Private Information or Specimens Constitutes Human Participants Research?

The investigator will submit an IRB application via the IRBIS online system which asks specific information about the information they will be using. Additionally the system inquires about parameters of data use inclusive of written agreements between investigator and bearer of identifiable data/key. This will be submitted to the IRB reviewer who will determine if the research involving coded information or specimens requires IRB review. Formal documentation will be provided to the PI and a copy of the submitted materials and determination letter/email will be kept on file.

1. All research which is regulated by the US Food & Drug Administration (FDA) conducted under the auspices of UNCG will be submitted for review to Moses Cone Health Systems, a biomedical IRB with which UNCG has a reciprocal agreement. [↑](#footnote-ref-1)