1. **Can consent or parental permission ever be “passive” or “implied”?**
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6. **Is child assent always required when research involves children?**
7. **How should child assent be documented?**
8. **Can consent or parental permission ever be “passive” or “implied”?**

Terms such as “passive” or “implied” consent are not referenced in the federal regulations. However, federal government does reference altered or waived informed consent documents. These alteration or waivers include the requirement to document consent or parental permission has been waived.

The term “passive consent” is sometimes used in research with children to describe situations in which the investigator can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an opt out procedure, which is not consistent with the regulatory requirement for seeking and obtaining parental permission. If the IRB determines that the conditions for [waiver of parental permission](http://answers.hhs.gov/ohrp/questions/7268) can be met, then the IRB could waive the requirement for parental permission under [45 CFR 46.408(c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408) or [45 CFR 46.116(c) or (d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116). Even though not required by the regulations, an IRB may require that parents be given the opportunity to refuse permission even when the IRB has waived the regulatory requirement to obtain parental permission.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **When may a legally authorized representative provide consent on behalf of an adult with diminished decision-making capacity?**

The federal regulations in addition to the state laws in which the research is conducted should be consulted. As a general matter, if an adult lacks capacity to consent, for example, as a result of trauma, mental retardation, some forms of mental illness, or dementia whether temporary, progressive, or permanent only a [legally authorized representative](http://answers.hhs.gov/ohrp/questions/7264) for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB in accordance with the federal regulations. Should the subject regain or develop the capacity to consent, then his or her consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **What are the requirements for assent and parental permission in research with children?**

The IRB must determine, to the extent required by federal regulations on consent, that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent as well as the permission of the parents. In the United States the legal age of adulthood is a matter of state and local law. This means that who is legally considered a child may vary from state to state; in a large majority of states 18 years of age is the legal age of adulthood, but this is not true in every state, locality, or territory. Certain states provide a mechanism for the emancipation of minors, through which a child younger than the legal age of adulthood may gain certain civil rights, which might include the legal ability to consent to research participation.

Under the federal regulations the IRB may find that the permission of one parent is sufficient for research to be conducted. Where research is conducted at a higher risk with no direct benefit to the child, permission must be obtained from both parents 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.

Although the regulations state that children are unable to provide legally effective informed consent to participate in research, some might be able to give their assent. Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted regarding assent, 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 where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under [certain circumstances](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408) in accord with federal regulation on consent and the additional safeguards for research with children.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **May the requirement for obtaining informed consent or parental permission be altered or waived?**

Waiver or alteration of the requirements for obtaining informed consent from adult subjects can occur. Of the three provisions only one apply to the type of research conducted at UNCG:

1. Research in general: an IRB may waive or alter the requirement of informed consent under the federal regulations, provided that the IRB finds and documents that all of the following four conditions are met:
   1. the research involves no more than minimal risk to the subjects;
   2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
   3. the research could not practicably (mere convenience to the investigator does not constitute practicability) be carried out without the waiver or alteration; **and**
   4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

For research involving children, an IRB may waive the requirements for obtaining parental or guardian permission under any of the following four provisions:

1. The IRB makes and documents the required findings under the federal regulations for consent.
2. The IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and the following 2 additional criteria are also met:
   1. an appropriate mechanism is in place to protect the children, **and**
   2. the waiver is not inconsistent with federal, state, or local law ([45 CFR 46.408(c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408)). The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child’s age, maturity, status, and condition ([45 CFR 46.408(c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408)). Note that an IRB may waive the requirement for obtaining parental or guardian permission under [45 CFR 46.408(c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408) even if the research involves more than minimal risk to the child subjects.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **What is a waiver or alteration of informed consent or parental permission?**

The federal regulations allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under the federal rules on consent.

Waiving the requirement for obtaining informed consent or parental permission means that the IRB has determined that investigators need not obtain the subjects’ informed consent to participate in research. For example, some research about natural behavior may require that subjects be unaware that the research is taking place. Such research can only be approved by the IRB if the research meets the criteria for a waiver of informed consent under the federal regulations and for approving research according to federal regulations.

An IRB may approve research for which some or all of the elements of informed consent have been altered, or for which some elements have been left out. For example, some research designs require that subjects be left unaware of the particular purpose of the research, because the subjects’ responses might be biased if they know in advance what the investigators are seeking. Such research designs do not preclude offering potential subjects some information about the research and giving them the opportunity to decide whether to participate (debriefing). The IRB may approve such research in which investigators will leave out or alter elements of informed consent, so long as the research meets the criteria for approving research, and the research meets the criteria specified in the federal regulations for leaving out or altering those elements.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>t

When may the requirement for documentation of informed consent or parental permission be waived or altered?

When an IRB has not waived the requirement for seeking prospective informed consent of the subjects or the parental permission of children who are subjects, under the federal regulations, the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).

Some subjects might refuse a copy of the consent form once signed out of concern that their possession of the form could compromise their privacy. This is fully consistent with the idea behind one of the bases for a waiver of the requirements for documentation of informed consent that harm would result to the subject if his/her identity were compromised by the documentation itself. The investigator may document that the subject refused a copy of the informed consent document and still include the subject in the study.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or the parents of children who are subjects with a written statement regarding the research.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **Is child assent always required when research involves children?**

No. The IRB is responsible for deciding whether child assent is required in proposed research activities. At UNCG age 5 is when the IRB considers a child potentially capable of providing assent. Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Child assent is required, except in the following three circumstances described below:

1. the capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
3. the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the federal regulations for consent.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>

1. **How should child assent be documented?**

The federal regulations do not require documentation of assent. The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child’s age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent’s assent.

If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.

Full text can be found at <http://answers.hhs.gov/ohrp/categories/1566>