**Transition to Online Submission**

**When may I begin to submit online?**

The Office of Research Integrity is conducting a phased implementation of online submission. As of February 18, 2013, we will only accept **new** IRB submissions through IRBIS, the on-line system.

**What about Modification and Renewals?**

As of June 17, 2013, all modifications and renewals must be submitted via the IRBIS online system. Paper applications are no longer being accepted. Modification and renewal applications can be found on the investigator’s IRBIS homepage under “Create a New Submission”.

Any existing study (including those submitted on paper) that was previously entered into the IRBIS admin system has an electronic record in the online system.  A PI wanting to renew online a study that previously existed on paper should login, click My Studies in the left navigation bar, and then select the relevant study number and initiate a renewal.  Since only minimal electronic information exists for these studies (basic, identifying info), limited data is carried into this “new” online renewal application. Please not that nothing pre-populates beyond the General Information section and that data should be reviewed for accuracy by the PI at time of submission.

**How do I submit an online modification?**

To begin the online modification process, log in to the IRBIS online system and click "modification" in the upper left-hand corner. Please be specific when describing your modification and be sure to revise the applicable sections of the application.

Please note that the modification process may take longer for the first submission for those studies that were originally submitted on paper as the study information will need to be transferred to the electronic format. Once this process has been completed, future modifications will take less time.

**How do I submit an online renewal?**

To begin the online renewal process, log in to the IRBIS online system and click "renewal" in the upper left-hand corner. If your study is still open to enrollment, please be sure to submit the most recently approved consent form for stamping. If your renewal requires a modification, please begin the renewal process FIRST and respond "yes" when asked if the renewal involves a modification.

Please note that the renewal process may take longer for the first submission for those studies that were originally submitted on paper as the study information will need to be transferred to the electronic format. Once this process has been completed, future renewals will take less time.

**How do I submit an Unanticipated Event / Problem?**

**The unanticipated event form can be found on the IRBIS homepage under “Create New Submission”. Click on the Unanticipated Problem form to begin the application. Please note: You must “certify” the submission in order for it to be sent to the IRB for review. Once the application is complete, you will certify by going to “PI Certification” and completing the certification process as you would with any submission. .**

**Is training for using the new online submission system available?**

If your department is in need of training, please contact our office to set up a training session. Web based training modules and task-specific training aids are accessible by clicking [HELP](https://uncg.myresearchonline.org/irb/irb_faq.cfm) on the online application task bar, as well as at the ORI [website](http://compliance.uncg.edu/irbis-online-submission-training/). You may also request assistance from the Office of Research Integrity at 336.256.0253.

**Please keep in mind that this system is hosted by UNC-Chapel Hill, so there may be references to their campus in the training and instruction information.**

**ONLINE ROUTING AND CERTIFICATION**

**When I submit a study, where is it routed?**

**Once a study has been certified by a Principal Investigator and/or Faculty Member, it will be routed to the ORI for review. You may check the status of your application on your home page of the IRBIS system or under “My Dashboard”.**

**Who can certify an online submission for review?**

Only a Principal Investigator or Faculty Advisor can certify an online submission.

Prior to our online submission, a Student Investigator could not be listed as a Principal Investigator on an IRB application, however with online submission, students who are leading the research as a requirement of a school or programs (masters, dissertation, etc.) will need to assign themselves as Principal Investigator. Student Investigators will still require the assignment of a Faculty Advisor, who will be required to certify and submit the online application. As is our current policy, the Faculty Advisor will remain responsible for the conduct of the research as well as the storage of the data. We currently do NOT require departmental approval.

**Can I assign specific access to other people on a research protocol?**

Yes, this is part of the Project Personnel section of the application and all specific levels of access can also be assigned by the PI.

**ATTACHMENTS AND CONSENT FORMS**

**How do I submit my consent forms and attachments?**

You will need to download our consent templates and fill in the text as needed. Consent forms and other attachments will need to be saved and uploaded as attachments with your submitted application.

If there are any required changes, these will need to uploaded and titled as revised. We prefer the changes in Word with tracked changes for easy acceptance and quick review.

**Where can I find the required attachments and consent forms?**

Consent forms templates will be available on the IRBIS site when requested. Required attachments that may need to be completed and uploaded will be available on the [ORI IRB website](http://integrity.uncg.edu/institutional-review-board/).

**How will I receive the approved, stamped consent forms and any other documents if my study is approved?**

You will receive your approved consent forms and any other documents the way we currently send them. Once you get the email approval, we will scan and email the approved consent forms. You may also request a hard copy if you need one.

**Responding to IRB minor stipulations using the online system**

**How will I be notified of the completed IRB review and any stipulations that I need to address?**

You will be notified by email of any changes stipulated by the IRB. This same email will also be sent to all members of your study team whom you designate to receive IRB correspondence. The email will contain a link to the IRBIS [home page](https://uncg.myresearchonline.org/irb/) where all IRB correspondence requiring your attention is listed on your home page.

**May any member of my study team respond to IRB stipulations?**

Yes. Although the PI is responsible for the conduct of the study, he/she may delegate responsibility for responding to stipulations to others, as relevant. All research members will have editing access by default.

**How do I respond to stipulations?**

You can reply to stipulations about the application itself using an interactive webpage that will direct you to the exact location in the online application where the stipulation was noted. Through this interactive webpage, you will be able to respond to the IRB about this and other stipulations, eliminating the need for a point-by-point response memo. In addition, IRBIS also makes available to you pdf copies of your consent forms and attachments.

To view stipulations:

* Go to your IRBIS homepage
* Once on the homepage, you will see the studies that have stipulations
* Click on the reference ID number of the study which has the stipulations you would like to view
* Once you click on the reference ID, you will be directed to a new page
* Once on the new page, click “view stipulations” in the upper right hand corner.

Further information is available on the FAQ page in text and video and you can also call our office at 336.256.0253.

**Does my response to stipulations require faculty PI re-certification?**

No.

**Human subjects research ethics training and online submission**

**How do I indicate that my study team members who are employed by UNCG have completed CITI training?**

Currently, the system is not able to link in with CITI trainings or UNCG sponsored trainings, so the ORI will continue to verify your completion of these trainings through your attached training certificates or looking you up manually in CITI.

Please note that we are moving toward linking CITI with the IRBIS online submission system. When you complete CITI training, you are asked to provide your UNCG Employee/Student ID. If you do not include your correct UNCG ID, it will delay processing of your submission. If you do not know your employee/student ID number, please contact HR at 334-5009 if you are an employee and the Admissions Office at 334-5243 if you are a student.

**GRANT APPLICATION/FUNDING INFORMATION THROUGH RAMSES**

**DOES RAMSES INTERFACE WITH THE IRBIS ONLINE SUBMISSION SYSTEM?**

Yes, if your research involves human subjects, RAMSES will prompt you to submit an online application through IRBIS and each system should hold a record of the study.

**Data security and online submission**

**Who is responsible for ensuring data security for a study?**

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.

**What measures must be taken to secure 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/research_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.

**Will I still be responsible for keeping** [**Statements of Confidentiality**](http://integrity.uncg.edu/wp-content/uploads/2012/08/Confidentiality_agmt.doc) **on file for all research team embers with access to identifiable data?**

Yes, while we do not require you to upload these documents, you are required to keep the signed statement on file with your study in its secure location.

**EXPIRATION and REACTIVATION OF IRB PROTOCOLS**

The IRBIS system will continue, as it always has, to send out reminders for the expiration of studies 30 and 60 days ahead of that expiration date. Continuing to collect and work with data on an expired protocol can lead to issues of noncompliance, so all data must cease if it is discovered that a study has expired. Our online system, however does allow you to reactivate a study that has expired and you may follow the instructions provided in the system to accomplish this reactivation.

It is important to note a new ORI policy that any study determined as “Exempt” will be granted approval for the duration of the study. We ask that any modifications be submitted on Exempt protocols, but also that the study is closed when that research is complete.

Any minor stipulations issued by the IRB reviewer on a study will have due date. If these are not addressed and received by this date, the IRB reviewer may still withdraw that study and it can also be reactivated by the PI at a later date.

**ASSISTANCE WITH ANY ISSUES WITH THE IRBIS ONLINE SYSTEM**

If you need assistance or have questions about completing the online IRB application, please contact the Office of Research Integrity at 336-256-0253.

If you need technical assistance with user account login, access to IRBIS, bugs, or pages not saving correctly, etc., please contact the Office of Research and Economic Development IT support at 336-334-9702 or cifarrio@uncg.edu

The Office of Research Integrity IRB website <http://integrity.uncg.edu/institutional-review-board/> can also provide you with resources to assist you in the completion of your IRB application.

**Any comments and/or suggestions about the application should be sent to** **ori@uncg.edu****.**