COMMON QUESTIONS

TRANSITION TO ONLINE SUBMISSION

When may I begin to submit IRB submissions online?

September 6, 2016. After this date, new IRB submissions will only be accepted through IRBIS, the online system.

What about Stipulations for Approval, Modifications and Renewals?

NEW Studies: If you have submitted a new study through IRBIS, then all Stipulations, Modifications and Renewals for that study will also need to be submitted online.

EXISTING Studies:

- **New Protocol Numbers in IRBIS**: Numbers for all existing studies have been reformatted to reflect the new IRBIS numbering standard (i.e., YY-MM##).
  
  **NOTE**: The “##” designates the processing ‘identifier’ in IRBIS. For example, if the original study number was 15-06-01, the new number in IRBIS will simply be: 15-0601.

  **NOTE**: Information uploaded into IRBIS for existing studies includes only: study number, Investigator/co-investigator name(s) and department information and IRB approval date. It is the PIs’ responsibility to enter details from their original protocol document into the IRBIS application. **Do not copy and paste from the current protocol into IRBIS as this can cause problems with the IRBIS application.** Additional details on the steps needed will be available on the IRBIS website in the IRBIS Manual Existing Studies Renewal or IRBIS Manual Existing Studies Modification user manuals.

- Renewals due between September 6, 2016 and December 31, 2016 may be submitted using the current forms/process.

- **Beginning January 1, 2017**, renewals of existing studies must be submitted online. PIs will receive instructions from the Compliance Office as to the steps needed. PIs will need to allow sufficient time to develop their application and renewal information in IRBIS.

- **Modifications** of existing studies should be submitted using the current amendment form via paper or email until the next protocol renewal period. After the online Renewal, any future actions related to the study may be completed through IRBIS. The Compliance Office will provide details on the steps needed as part of the renewal notification reminders sent to Investigators by email.

- **Closure** of existing studies may be done using the current closure form. Please do not submit a closure through IRBIS. This is the case for all existing studies.

  All protocol actions will be submitted and managed through IRBIS by the end of 2017.

Will training on how to use the new online submission system be available?

Future training sessions will be posted on the IRBIS website. In addition, task-specific training aids are accessible by clicking the Online Submission Guide (upper right corner) within IRBIS as well as at the Compliance Office’s IRBIS webpage. You may also request assistance from the Office of Research Compliance (ORC) at 704-687-1871 or 607-687-8341 or uncc-irb@uncc.edu.
NOTE: The IRBIS system is hosted by UNC-Chapel Hill, so there may be references to their campus in the training and instruction information. However, the information being provided is still valid for UNC Charlotte’s version of IRBIS.

How do I submit a new study?

Log in to the IRBIS online system and click the “New Study” on the Dashboard under “Create New Submissions” in the upper left-hand corner of your IRBIS homepage.

See the IRBIS USER MANUALS available on the IRBIS website for specific information about submitting a new study and IRBIS features.

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 Responsible Faculty, it will be routed to ORC to begin the IRB review process. 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 and/or Responsible Faculty can certify an online submission.

As with our previous paper-submission process, a Student Investigator may be listed as a Principal Investigator (PI) on an IRB application if they are leading the research as a requirement of a school or program (e.g., thesis or dissertation, etc.). Student Investigators will need a Responsible Faculty to be designated on the submission.

The Responsible Faculty will be required to certify and submit the online application. The Responsible Faculty will remain responsible for the conduct of the research as well as the storage of the data just like in our current policy and process. We currently do NOT require departmental approval.

Student Investigators should not submit their application until both the student and the Responsible Faculty have finished editing the application. Once the application is submitted it will be locked for editing.

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

Yes. The PI can assign specific levels of access to anyone listed on the protocol in the Project Personnel section of the application. This includes Co-investigator, Faculty Advisor, Project Manager or Study Coordinator, Research Assistant, and Regulatory Associate who can edit or make changes to your protocol application. Otherwise, you may choose Other with Read-Only-Access and describe in the box the team member’s designation.

ATTACHMENTS AND CONSENT FORMS

How do I submit my consent forms and attachments?

Download the consent form template(s) you choose for your research project and fill in the text as needed. You may use the Consent Form Checklist to develop a consent document without using a template. Consent forms and other attachments will need to be saved as Microsoft Word documents and uploaded to IRBIS.

If any changes or modifications are required, you may revise/replace previously uploaded consent documents. Please include the word “Revised” in the file title any make changes to the document using the Microsoft Word “Track Changes” feature or otherwise indicated/highlight the changes for easy acceptance and quick review.
Where can I find the required attachments and consent forms?

Consent form templates will be available in IRBIS and on the Office of Research Compliance IRB website, specifically on the Informed Consent page. You may also use the Consent Checklist, also available on the ORC website, to create a consent form appropriate for your study and study population.

How will I receive the IRB-approved consent forms and any other documents if my study is approved?

You will receive your approval notification via email. Your IRB-approved consent forms will be available in IRBIS.

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 log in page. You may access all IRB correspondence requiring your attention from your IRBIS Home page after you log in.

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

Yes—By default, in IRBIS, ALL research members have editing access. **NOTE:** Although the PI is responsible for the conduct of the study, he/she may delegate responsibility for responding to stipulations to anyone else on the research team, as relevant.

How do I respond to stipulations?

You will use an interactive webpage to respond to stipulations in the application. You will be directed to the exact location in the online application where the stipulation was noted. The interactive webpage allows you to respond to the IRB about each specific stipulation, eliminating the need for a separate point-by-point response memo. However, in addition to responding to the stipulation you will need to update the actual application sections as well when responding to stipulations.

Further information is available in IRBIS user manuals and you may also call Office of Research Compliance at (704) 687-1871 or 704-687-8341.

As a Student Researcher, does my response to stipulations require my Responsible Faculty’s recertification?

No.

HUMAN SUBJECTS RESEARCH ETHICS TRAINING AND ONLINE SUBMISSION

What kind of documentation is required to show that study team members have completed CITI training?

Please upload PDFs of CITI completion reports and submit along with your online application through IRBIS. You and your study team members can access your CITI training completion reports by simply logging in to your personal CITI account at [http://www.citiprogram.org](http://www.citiprogram.org) and selecting “My Reports” in the main menu. If you need assistance with your CITI user name and password, use the CITI help options to retrieve this information.
GRANT APPLICATION/FUNDING INFORMATION THROUGH NORM

Does NORM interface with the IRBIS online submission system?

Yes. If your proposed research involves human subjects, NORM will ask you to provide information about your IRB-approved protocol or will prompt you to submit an online application through IRBIS. Subsequently, NORM and IRBIS 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 Responsible Faculty 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 Responsible Faculty accepts this role. See Information and Technology Services’ (ITS) Guideline for Data Handling and the End User Checklist for guidance and requirements, including information about data classification levels and associated data handling guidelines for each classification level.

Questions or concerns about compliance with the Guidelines for Data Handling should be directed to your College Data Security Officer.

EXPIRATION AND REACTIVATION OF IRB PROTOCOLS

Will I be notified that my protocol is about to expire?

Yes. The IRBIS system will send out reminders for the expiration of studies 30- and 60-days ahead of that expiration date.

NOTE: Continuing to collect and work with data on an expired protocol can lead to issues of noncompliance, so all data collection must cease if a study has expired.

Can an expired protocol be reactivated?

Our online system does allow you to reactivate a study that has expired. Our IRB will allow this as long as the reactivation is completed within 30 days of the expiration date. Follow the instructions provided in the system to accomplish this reactivation. If the expiration goes beyond 30 days, a new protocol must be submitted (i.e., at day 31, a new protocol is required).

It is important to note that the Compliance requires annual updates of studies fitting an Exempt category. A continuation of Exemption will be issued. Any modifications must be submitted on Exempt protocols as well.

Any minor stipulations issued by the IRB reviewer on a study will have a due date. If these are not addressed and received by the due 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 Compliance at 704-687-1871 or 704-687-8341.

If you need technical assistance with user account login or access to IRBIS, please contact the AURA team in the Office of Research and Economic Development at 704-687-1865 or aura-team@uncc.edu.
The OFFICE OF RESEARCH COMPLIANCE IRB website http://research.uncc.edu/departments/office-research-compliance-orc/human-subjects 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: uncc-irb@uncc.edu.