Investigator Responsibilities

The UNC Charlotte Institutional Review Board (IRB) has completed review of your IRB protocol and has approved it as indicated on your Certificate of Approval. While the IRB will oversee the conduct of your study from the prospective of the protection of human subjects, it is your responsibility to make certain that your research is conducted in accordance with the Federal regulations which govern research with human beings. This requirement applies to all UNC Charlotte faculty, staff and students.

Please be sure that you are aware of these regulations (Code of Federal Regulations, 45 CFR 46 which may be found at [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Investigator Responsibilities

Your interactions with the IRB throughout the course of your project will revolve around changes in your approved study protocol, study related materials, adverse events (should any occur), and project renewals and closure.

Study Changes

You must submit an amendment to the Office of Research Compliance for IRB approval for any changes to the procedures described in the original protocol or supporting materials. Any changes to the research team as well must be submitted to the IRB. The IRB Amendment Form can be found on the Compliance Office website under "Amending Your Protocol." Once the amendment has been approved, you may proceed with and implement the changes.

It is important to note that changes in a protocol might, in turn, require a change in the consent form(s) for your project as well. In which case, the amended consent forms must be submitted as well for IRB approval. Please mark any changes to the consent boldfaced, shaded, etc.) so that changes may be identified easily.

Remember to include the original protocol approval date on your updated and/or new consent form once the amendment is approved.

Adverse Events

Unanticipated problems or serious adverse events involving risk to human subjects must be reported to the IRB immediately and documented in your protocol file. A report detailing the problem(s) should be submitted to: Dixie Airey, Director, Office of Research Compliance, 320 Cameron Hall.

Annual Renewal

The IRB determines the period of time between the initial approval and the subsequent renewal date based on the complexity of the study and/or the risk to study participants. Most protocols are approved for continuing review on an annual basis. The term of approval for your study will be provided on the Certificate of Approval. Your protocol must be renewed with the IRB by the date stipulated by the IRB on the Certificate of Approval.

All protocol renewals must be submitted through IRBIS, the online application submission system.

Reminder notices will be sent as the end to the current IRB approval period approaches.

It is important to document your anniversary date, keep accurate records and copies of all protocol documents for submission with your Protocol Renewal Form. Plan your time accordingly!

FAILURE TO RENEW YOUR PROTOCOL BY YOUR ANNIVERSARY DATE WILL RESULT IN THE AUTOMATIC TERMINATION OF YOUR PROJECT.

Addition or Deletion of Personnel or Investigators

The Office of Research Compliance should be notified of the intention to add or delete personnel to the protocol. Both types of changes can be completed by submitting an Amendment to the approved protocol. The IRB Amendment Form can be found on the Office of Research Compliance website under "Amending Your Protocol."

If additional personnel become involved with your project, they must meet the human subjects educational requirement(s) in effect at the time they are brought into the study. New personnel cannot assume their roles in the study until they have completed the on-line IRB tutorial which can be accessed through the Office of Research Compliance website.
Record Keeping
In accordance with UNC Charlotte's Policy Statement #306, "Research Utilizing Human Subjects," (see http://legal.uncc.edu/policies/up-306) the Office of Research Compliance oversees the long term storage of original protocol applications and consent forms for a minimum of three (3) years.

In Policy Statement # 309, investigators (faculty or students) are encouraged to maintain their raw research data for a 'reasonable period' or five (5) years after publication.

More guidelines and standards which apply to post doctoral fellows and faculty can be found in UNC Charlotte's Policy Statement #309, "Guidelines for Research." Additional information can be found at the URL listed below. (See http://legal.uncc.edu/policies/up-309)

Questions
If you have any questions about the IRB status of your study or questions related to human subjects, please contact:

Barry Rowan, Associate Director
704-687-8270, browan1@uncc.edu
Cat Runden, IRB Program Manager
704-687-1871, crunden@uncc.edu
Marie Dilan, Protocol Coordinator
704-687-8341, mdilan@uncc.edu

Links of Interest
Office of Research Compliance
- http://research.uncc.edu/compliance-ethics/human-subjects

Code of Federal Regulations

UNC Charlotte’s Policy Statement #306: "Research Utilizing Human Subjects"
- http://legal.uncc.edu/policies/up-306

UNC Charlotte’s Policy Statement #309: "Ethical Conduct in Research, Scholarship, And Educational Activities"
- http://legal.uncc.edu/policies/up-309