Guidance for Faculty Points of Contact

This guidance is for those who will be listed as the “Faculty Point of Contact” on an IRB application. You can choose to be a Faculty Point of Contact for many reasons. These include (but are not limited to) serving as the lead PI on a research team or serving as an advisor to your students.

Regardless of why you are listed, you will have some responsibilities of which you should be aware. As the Faculty Point of Contact, you are responsible for the following:

The Thorough and Accurate Completion of the eIRB Application

- Answer all questions on all tabs of the application
- Upload all study materials such as recruitment, consent, instruments, and other needed/relevant information for your study
- Read through the entire application and work out the study design with your student/research team – you will be the only person who can actually “submit” the IRB application to the IRB office. You will have to click “submit” in order to send it to the IRB.
- Ensure that your “additional personnel” have their unity ID (beginning of @ncsu.edu email address) entered appropriately so that the appropriate people have access to the eIRB application.
  - Additional personnel includes the student or students that you are advising and other members of your research team (who have an NCSU email address) who need to access the protocol or create amendment/renewal requests.

Research Team/Advisee Training

- Have your research team take the CITI Human Subjects Training and the NC State e-Learning module online.
  - See the NC State IRB office website for this information.
  - See IRB site for articles and discussion questions regarding research ethics and compliance.
- Ensure all research personnel have been trained on the specific research protocol and methods associated with the study.
  - They should know what documents are to be used, how data are to be protected, and what to do in the field.
  - You should ensure that your team is familiar with the supporting documents that have been approved.
- Outline a plan for your research team regarding what to do if something goes wrong. Some of this will be outlined in your IRB application, and other procedures will be related to other issues raised in this document.

Implementation of Research “In the Field”

- Ensure that only “IRB Approved” Documents are the documents that are used for the research project.
- Have your entire team read the entire approved protocol before recruitment, consent, and data collection so that all on the team are familiar with the protocol.
- Engage in active and regular communication with your team members so that everyone is up to date and aware of what is happening with the research.

Data Protection through Collection, Storage, Analysis, and Disposition

- Understand how to implement the data protection plan outlined in your approved IRB protocol and you must ensure that all of your research team members understand how to properly implement the plan.
• Ensure all tools and software platforms remain up to date, password protected, and, when
required, that all data are encrypted or stored off any computer network, if such provisions are
included in the approved protocol.
• Know who your Departmental OIT contact is and how to get in touch with them to address any
technology problems, including actual or potential lapses in data security or breaches of privacy.
• Be familiar with NC State’s Data protection recommendations and how to implement them
properly.

Submission of Amendments and Renewals
• Remember when your study approval expires (if applicable) and when you need to submit for
Continuing Review Approval.
• Ensure that there is no lapse in approval, and that if there is, no work is done on the project
(including data analysis).
• Understand when an amendment request is required and do not implement changes until the IRB
has reviewed and approved the amendment request.
• Understand how to apply for an amendment request or a request for continuing review.

Participant Complaints, Adverse Events, Unanticipated Problems and Non-Compliance.
• Know how to identify when there is an issue or a problem that needs to be reported to the IRB. If in
doubt, ask the IRB staff!
• Have a plan for managing participant complaints and unexpected issues during data collection.
• Know what it means to be in non-compliance (see resources on IRB website)
• Know when to report non-compliance to the IRB office.
  • Report non-compliance to irb-director@ncsu.edu as soon as you are able.
  • Provide an overview of what happened, if it increased risks to participants and the
corrective actions you took (if any).
• Communicate with your team about non-compliance
  • Specifically, talk with your team about not deviating from the approved protocol as any
protocol deviation is considered non-compliance.
  • Understand what could increase risks to participants if the processes are not done correctly.
  • Understand and navigate ethical issues regarding your research; help prepare your team
and know when to report issues to the IRB office.

If you are serving as the Faculty Point of Contact for one of your students’ studies. you are
responsible for the human subjects aspects of this project.
• You are expected to work with your student on study design.
• You are expected to talk with your student about participant protections throughout all parts of the
study (design, recruitment, consent, data collection, data analysis, data protection,
reporting/publishing, and data disposition).
• You are expected to be aware of any conditions of IRB approval.
• You are expected to ensure that the study is implemented as described in the approved IRB
protocol.
• You are expected to read through the IRB application and all study materials to ensure continuity
and accuracy before documents are uploaded and before the application is submitted.
• You are responsible for training your student in issues related to research in practice, including
completing the IRB application.
• You are responsible for teaching your students about the IRB process, expectations related to a
“good” IRB application, and resources available on the IRB site.
  • The IRB application is not a learning process for your students where IRB staff are
expected to serve as their teachers, advisors, or committee members. You are expected to
fulfill these roles.
• You are expected to discuss IRB issues as related to pilot work.