

<b>Title:</b>	Faculty Points of Contact
<b>Last Approval Date:</b>	8-7-18
<b>Previous Approval Dates:</b>	None
<b>Policy and SOP:</b>	3

### **3.1 Executive Summary**

This policy addresses the policy and standard procedures for those listed as “Faculty Point of Contact” on an IRB protocol. In this document, you will find the IRB policy regarding the “Faculty Point of Contact” and any standard procedures that the Faculty Point of Contact is expected to complete. Please see supplemental guidance for Faculty Points of Contact for more information.

### **3.2. Policy**

NC State stakeholders listed as a “Faculty Point of Contact” on an IRB protocol are responsible for the completion of the IRB application, training of all research team members listed on the IRB protocol, and the maintenance of the IRB protocol and subsequent requirements of managing the study’s regulatory and ethical requirements.

### **3.3. Standard Operating Procedure (SOP)**

A faculty point of contact is selected/appointed by the research team based on experiences and role in the research. The Faculty Point of Contact has multiple responsibilities. These include:

1. The thorough and accurate completion of the IRB application through initial review, amendment requests, and continuing review approval requests.
2. Train and advise research team members on issues of compliance, research ethics, and protocol implementation.
3. Adherence to and maintenance of data security plans regarding approved protocol
4. Management of and communication around participant complaints, adverse events, unanticipated problems, and noncompliance.

#### **3.3.a. Completion and Maintenance of the IRB protocol**

1. All questions in IRB application must be addressed thoroughly.
2. All study materials (such as recruitment, consent, instruments, and other needed/relevant information for your study) must be uploaded into the IRB protocol.
3. IRB protocol must remain updated, including request and proper implementation of amendments and continuing review approval requests.

#### **3.3.b. Advising and Training of Research Team Members**

1. Train and advise research team members on issues of compliance, research ethics, and protocol implementation when in the field.
  - a. Only “IRB Approved” Documents are used for the research project in the field.
  - b. All research team members should be familiar with the approved protocol before recruitment, consent, and data collection.
  - c. Engage in active and regularly occurring communication with research team members so that the team remains up to date and aware of current issues with the research.
2. Have your research team take the Human Subjects Training
  - a. All trainings available can be found on the NC State University IRB website.
  - b. You are responsible for tracking your research team members’ completion of the training.
3. Train all research personnel on the IRB approved research protocol
4. Outline a plan for your research team regarding what to do if something goes wrong.

### **3.3.c. Adherence to and maintenance of data security plans regarding approved protocol**

1. All study protocols must adhere to the approved data security plan outlined in the IRB protocol.
2. The data security plan must be maintained by updating software and hardware and updating security as the landscape of data security needs change.
3. Know how to access the NC State's Data protection recommendations and how to implement them properly.
4. It is suggested (and sometimes required) that you work with your Department IT in order to create and implement a data security plan.
5. You are responsible for understanding what the data security plan entails. This includes communicating expectations to your research team.

### **3.3.d. Participant Complaints, Adverse Events, Unanticipated Problems and Non-Compliance.**

1. You are responsible for reporting issues or a problems that need to be reported to the IRB.
  - a. All research team members have this expectation.
2. Develop a plan for managing participant complaints and unexpected issues during data collection.
3. Report issues of noncompliance to the IRB office.
  - a. Report noncompliance to [irb-director@ncsu.edu](mailto:irb-director@ncsu.edu) as soon as you are able.
  - b. Provide an overview of what happened, if it increased risks to participants and the corrective actions you took (if any).
4. Communicate with your research team regarding issues of unanticipated problems, adverse events, and noncompliance
  - a. Discuss protocol deviations with research team including what they are and what the consequences of them could be
  - b. Plan for issues that could increase risks to participants if the processes are not implemented by the research team correctly.
  - c. Teach your research team how to identify issues of unanticipated problems, adverse events, and noncompliance as related to regulatory issues and research ethics.