Research Completed as Class Projects or Program Milestones
TimeLine and Process
Overview

The IRB office has a special process to help streamline IRB review and approval for all students who are completing research that is also for a class project, pilot work, second year project/thesis, or dissertation. This includes training on the application system and individual consultations with the IRB office.

If you would like to take advantage of priority review to ease your IRB approval process, you can! A priority review means that your study will be reviewed during a specific timeframe in order to speed up your review process. **In order to receive priority review/approval you must:**

- Complete the appropriate IRB training detailed in the "Student Information Sheet and Check List" section below.
    - Online pre-requisites
    - Then an in person training on completing the IRB application
- Submit IRB application during one of the "Option to Submit" Weeks noted below (M-Th only)
- Be available during the "Option to Submit" Week to quickly respond thoroughly to questions from the IRB office

This packet will provide you all the details needed in order to take advantage of this process.

Fall Semester

- September 10, 2019: In Person Training
    - 12:30p – 2:30pm
    - Administrative Services III, Room 220

- September: Option to Submit
    - Submit IRB Application to IRB Office by: 9/23/19 at 8am
    - IRB Office Prioritizes Class Project Submission from 9/23/19 - 9/26/19

- October 14, 2019: In Person Training
    - 12:30p – 2:30pm
    - Administrative Services III, Room 220

- November: Option to Submit
    - Submit IRB Application to IRB Office by: 11/04/19 at 8am
    - IRB Office Prioritizes Class Project Submission from 11/04/19 – 11/08/19

- November, 29, 2019: In Person Training
    - 1:30p – 3:30pm
    - Administrative Services III, Room 220
    - This session is intended to provide students the training needed so that they can use the time to work on their applications over the university closure. While the university is closed, no applications will be reviewed/approved as the IRB office is closed.

Spring and Summer Semesters

- January 15, 2020: In Person Training
    - 1:00p – 3:00pm
    - Administrative Services III, Room 110

- January: Option to Submit
    - Submit IRB Application to IRB Office by: 1/27/20 at 8am
    - IRB Office Prioritizes Class Project Submission from 1/27/20 – 1/01/20

- February: Option to Submit
    - Submit IRB Application to IRB Office by: 2/17/20 at 8am
    - IRB Office Prioritizes Class Project Submission from 2/17/20 – 2/20/20

- April 6, 2020: In Person Training
    - 1:00p – 3:00pm
    - Administrative Services III, Room 220

- April: Option to Submit
    - Submit IRB Application to IRB Office by: 4/20/20 at 8am
    - IRB Office Prioritizes Class Project Submission from 4/20/20 – 4/23/20

Academic Department Information Sheet and Check List

- Trainings to Complete: All students taking advantage of the priority review process must provide the IRB office with documentation of completed trainings. This documentation will be in the form of an e-mail from the IRB Office. Trainings that must be completed BEFORE receiving official documentation of training completion and submitting to the IRB Office for priority review include:

    o Online Training to Complete First: CITI Training:
        - Click Link above or go to the CITI Training Site.
        - Login through Institution and use NC State IDs to Login
        - Complete the 12 modules called "Social/Behavioral Research Course"
        - Complete the 8 modules called "CITI Responsible Conduct of Research"
        - Print certificates to bring to in person training

    o Online Training to Complete Second: NC State Reporter
        - Click Link above to go to the NC State REPORTER site/
        - Login using your NC State IDs
        - Complete the module called Institutional Review Board Overview - RES-COMPLI-IRB
        - Print proof of completion to bring to in person training

    o In Person Training to Complete Third: Completing the IRB Application
        - Sign up for the in person training here:
        - Attend the in person training
        - Bring proof of completion and certificates from online sessions
        - Within 3 days of completion, the IRB office will send you a "proof of completion" email that you can save as a PDF and upload with your IRB application when you submit the protocol.
        - Available training sessions are noted on the first page of this packet

- Completing the eIRB
    o Determine the project needs to be submitted to the IRB Office for review (this is determined for how the info from the project will be used, please see Appendix A)
    o The title of the application should begin with "Priority Review Request, <Insert Name of Study>
    o The email from the IRB confirming completion of training must be uploaded before submission.
    o All study materials including recruitment scripts/flyers, Consents, Assents, Parental Permission Forms, Study Instruments must be uploaded before clicking submit
    o Faculty Points of Contact are the only person who can submit the study to the IRB Office on the student's behalf. The Faculty must review the study to ensure they agree with what will occur and assert that all necessary information is in the application
    o The Faculty Point of Contact must click "Submit"

- Timing of Submission and Expiration of Priority
    o Students must submit their application within one of the "Option to Submit" weeks noted on the first page of this packet.
    o The earlier in the week the application is submitted, the better. No submissions should be submitted on Friday of that week with the expectation of priority.
    o Once you submit, you and your student must be ready and available to receive and address feedback form the IRB office ASAP. If you do not, we cannot prioritize the work.

- Reminders of University Closures and Availability
    o The IRB office is not open, nor will it process research when the University is closed.

Check List:
- ☐ Disseminate this information to all of the faculty in the Department.
- ☐ Faculty should disseminate this information to all students completing research as course projects, pilot work, second year projects, dissertations, and thesis.
- ☐ Discuss expectations with faculty regarding their role as Faculty Points of Contact
    o Guidance for them and review of NC State's policy regarding "Faculty Points of Contact"
    o Expectations of reviewing and clicking submit on the application

Student Information Sheet and Check List

- Trainings to Complete: All students taking advantage of the priority review process must provide the IRB office with documentation of completed trainings. This documentation will be in the form of an e-mail from the IRB Office. Trainings that must be completed BEFORE receiving official documentation of training completion and submitting to the IRB Office for priority review include:

    - Online Training to Complete First: CITI [Training]:
        - Click Link above or go to the CITI Training Site.
        - Login through Institution and use NC State IDs to Login
        - Complete the 12 modules called "Social/Behavioral Research Course"
        - Complete the 8 modules called "CITI Responsible Conduct of Research"
        - Print certificates to bring to in person training

    - Online Training to Complete Second: NC State [Reporter]
        - Click Link above to go to the NC State REPORTER site/
        - Login using your NC State IDs
        - Complete the module called Institutional Review Board Overview - RES-COMPLI-IRB
        - Print proof of completion to bring to in person training

    - In Person Training to Complete Third: Completing the IRB Application
        - Sign up for the in person training here:
        - Attend the in person training
        - Bring proof of completion and certificates from online sessions
        - Within 3 days of completion, the IRB office will send you a "proof of completion" email that you can save as a PDF and upload with your IRB application when you submit the protocol.
        - Available training sessions are noted on the first page of this packet

- Completing the eIRB
    - Determine the project needs to be submitted to the IRB Office for review (this is determined for how the info from the project will be used, please see Appendix A)
    - Your study title should being with "Priority Review Request, <Insert Name of Study>
    - Upload email from IRB office confirming completion of training (save the e-mail as a PDF and upload it).
    - Upload all study materials including recruitment scripts/flyers, Consents, Assents, Parental Permission Forms, Study Instruments
    - Work with your faculty point of contact as they are the only person who can submit the study to the IRB Office on your behalf.

- Timing of Submission and Expiration of Priority
    - You must submit your application within one of the "Option to Submit" weeks noted on the first page of this packet. Please note, if your study requires full board review, the review process will take longer.
    - The earlier in the week you submit it, the better. You cannot submit it on Friday of that week and expect it to be prioritized. Friday we will be wrapping up approvals for studies that were appropriately submitted and addressed by researchers
    - Once you submit, you must be ready and available to receive and address feedback form the IRB office ASAP. If you do not, we cannot prioritize your work.

- Reminders of University Closures and Availability
    - The IRB office is not open, nor will it process/review/approve research when the University is closed.

Check List
- ☐ Complete [CITI] SBER and CITI RCR Online Training and print completion certificate
- ☐ Complete Online Training in [Reporter] and print proof of completion. Complete the modules listed below:
    - Institutional Review Board Overview
- ☐ Sign up for "in person" IRB training for completing the IRB application. See dates on sheet titled *timeline and process*
- ☐ Attend "in person" IRB training for completing the IRB application, bring proof of completion information with you.
- ☐ Complete the IRB application, have faculty point of contact review it and click "submit" during the "Option to Submit" week for priority. Make sure to name it properly, upload education proof, and all study materials.
    - ☐ Use the Consent Form template on our website and apply it to your study.
- ☐ Be prepared to receive and respond to feedback from the IRB office ASAP
- ☐ Receive IRB approval and proceed with research project

<center>**Appendix A**</center>

To determine if you need to submit for IRB approval before you start your project, discuss these questions with your advisor/chair/faculty point of contact.

Is it Research?

Research is defined as a *systematic investigation*, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge.*

- Is the information from this project going to be used as data outside of the class project for things like pilot studies, method development, thesis, dissertation, publishing in peer reviewed journals, at conferences, contributing to the academic record in another way?

  - If yes – move onto the next question because you may need IRB approval.
  - If no – you do not need IRB approval.
  - If you are unsure – contact the IRB office at irb-coordinator-admin@ncsu.edu

Is it Human Subjects Research?

Human Subject is defined as: a *living* individual *about whom* an investigator conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens (this includes manipulation of environment) or Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- Is the information you are accessing or generating about a living individual?

  - If yes, proceed to the next question.
  - If no, you do not need IRB approval.

- Is the information you are accessing or generating about the individual's thoughts, feelings, opinions, behaviors, roles, responses, or reactions?

  - If yes, you need IRB approval.
  - If no, you do not need IRB approval.

- Accessing identifiable (or re-identifiable) information about a person and using that information for research purposes – counts as research with human subjects and you need IRB approval before accessing this data (information or specimens)