Advising a Student Researcher who is Conducting Human Subjects Research?

1. **IS THE PROJECT SUBJECT TO IRB REVIEW?** If you assign a class project to students, it might not be subject to IRB review. If the purpose of the project is only to fulfill a course requirement, and there is no possibility that the student will use the information to create or contribute to generalizable knowledge, the activity does not meet the IRB definition of “research.” Undergraduate projects generally do not rise to the level of human subjects research.

   "Research" as defined by the regulations that govern IRBs is a systematic investigation designed to develop or contribute to generalizable knowledge. “Systematic” means there is a cohesive approach to the project and analysis to address a question or test a hypothesis. “Generalizable knowledge” means that the results or outcomes of the project may be viewed in some way as relevant beyond the specific participant population.

   If you have assigned a project that does not meet the IRB definition of “research” best practice is to complete a brief “NHSR” (not human subjects research) application in IRBIS. You can do this in one of two ways. If you have assigned a standard project to all students, you can submit a single application in IRBIS to cover the entire class. If the projects are unique to each student, you should instruct the students to submit individual applications in IRBIS. Importantly, in order for IRBIS to generate the limited “NHSR” application form, the applicant must respond “No” to the screening question that asks if the project is “research.” There will be a few more questions to complete, then after submission and confirmation by IRB staff, you and/or the student will receive an email from the IRB confirming that the activity does not constitute human subjects research. You can retain this email for your records.

2. **REQUIRED TRAINING:** IF the project is subject to IRB review, please ensure that you, the student researcher, and any other members of the research team have completed the required human subjects training. Make sure they did not accidentally complete the Responsible Conduct of Research training. The IRB does not accept that course for human subjects research. To avoid completing the wrong course, the IRB strongly recommends to anyone completing the training that they follow the registration instructions outlined in a PDF document posted on the Human Subjects Research Compliance website: [http://uncw.edu/sparc/integrity/irb.html](http://uncw.edu/sparc/integrity/irb.html)

3. **INFORMATIONAL VIDEO:** The IRB has a new informational training video that we strongly encourage new applicants to review to help them create stronger applications in the IRBIS system. The video is about an hour long, reviews general concepts in human subject protections, and provides many tips on how to appropriately respond to application questions. Look for the video under the Resources column of the IRB website. Please refer your advisees to this video. We think they will find it helpful!
4. **CERTIFICATION:** When the research is led by a student, a faculty advisor must be listed in the personnel section of the IRBIS application. After the application is completed, the faculty advisor is required to certify that the application is ready for submission to the IRB. If the application is incomplete or deficient in any way, this is your opportunity to return the application to your advisee and coach him or her on how to improve the application. Please do not certify an incomplete application, as it creates unnecessary additional work for everyone. The application will be returned to you and your advisee with stipulations that must be addressed before the IRB will consider the application further.

Things to keep in mind as you review an advisee’s IRBIS application:
- Are methods for each step of the project (recruitment, consent, data collection, data analysis, etc.) clearly and thoroughly described?
- Has your advisee explained who the target population is and how they plan to contact them?
- Has your advisee explained the consent process, particularly if conducting interviews by Skype or if working with non-English speaking subjects?
- Does your advisee need permission to recruit or conduct research at a specific location, such as a public school or nursing home? If recruiting by email, how will email addresses be obtained?
- Has your advisee uploaded all appropriate supporting documents in the Attachments section, such as recruitment scripts or emails, data collection instruments (observation or focus group guides, surveys, etc.), letters of support, and consent forms?

5. **CONFLICTS OF INTEREST:** Make sure you have completed your annual conflicts of interest disclosure for the current academic year, and any external professional activities for pay (EPAP) reports, if applicable. Your advisee’s application may be delayed if your COI requirements have not been met. If your advisee’s research is externally funded, you and your advisee will also be required to submit a project-specific conflict of interest disclosure.

6. **FERPA:** If your advisee is trying to identify specific student populations at UNCW, a community college, or a public school, please be aware that they must do so in a way that does not violate FERPA (Family Educational Rights and Privacy Act) standards. Unless students consent beforehand to a release, schools are prohibited from disclosing anything other than basic “directory” information. So as an example, schools may not help your advisee identify potential subjects who are male students with GPAs of 3.0 or higher.

7. **CONTACT INFORMATION:** Don’t hesitate to ask questions if you are uncertain or confused! A quick question prior to completing the application can save all of us a lot of time!

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