12.4.1  Human Subject Research and Course Projects

Learning how to conduct ethical human subject research is an important part of a student’s educational experience. Research activities that are designed as part of a course requirement for purposes of learning experience only and are not “designed to develop or contribute to generalizable knowledge” may not require IRB review and approval if all of the following conditions are true:

- Results of the research are viewed only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes.
- Results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.).
- Research procedures are no more than minimal risk (research cannot include sensitive or controversial topic areas).
- Vulnerable populations are not targeted (e.g., children under age 18, prisoners, pregnant women, persons who are cognitively impaired, etc.).
- Data collected are recorded in such a manner that the subjects are not identifiable (images in videotapes and photographs and voices on audiotape are identifiable).
- When appropriate, an informed consent process is in place.

In the event that a student conducted course projects yielding results that warrants a full study or the student would like to use the data for other purposes, the student must then come to the IRB to request the use of secondary data. The IRB will then review the research to determine if the student might have some additional requirements in order to use the data or to continue the research for purposes other than classroom education; for example, possibly consenting or re-consenting subjects informing them of the new use.

Please note: If an individual conducts research without the appropriate IRB approval, it is possible that there would be a sanction in which the data could not be used. The IRB has the authority to determine whether the data collected without IRB approval can be used.

12.4.1.1  Responsibility of the Course Instructor

The course instructor is responsible for communicating to the students the ethics of human subject research, for ensuring the protection of human subjects (including a process is in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students’ progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:
• Understand the elements of informed consent;
• Develop appropriate consent documents;
• Plan appropriate strategies for recruiting subjects;
• Identify and minimize potential risks to subjects;
• Assess the risk-benefit ratio for the project;
• Establish and maintain strict guidelines for protecting privacy and confidentiality; and
• Allow sufficient time for IRB review (if necessary) and completion of the project.

In making a determination of whether or not a class research project requires IRB review, the instructor is encouraged to visit our website (https://research.shanghai.nyu.edu/resources/human-subjects) for more information or contact the IRB office (RCOinfo@nyu.edu) for assistance.

Course instructors are required to submit a “class project” protocol in which the specifics of the project are documented along with the parameters that students must maintain; i.e. only innocuous surveys, interviews in public areas, etc. As long as students conduct their class projects within those boundaries, no IRB review will be necessary.

12.4.1.2 Individual Research Projects Conducted by Students

Independent study projects, senior theses, undergraduate research projects, and advanced degree research, and similar exercises involving human subject research must be independently submitted for IRB review. It is important to keep in mind that any human subject research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects and collecting data. IRB review/approval cannot occur after a study has begun.

Students and advisors should contact the IRB Office (RCOinfo@nyu.edu) with any questions.

12.4.2 Independent Study, Theses and Dissertations

Those research activities that are considered to meet the federal definition of human subject research must be independently submitted to the IRB by the student-investigator. When students conduct research as part of a course of study, the faculty member is still ultimately responsible for the protection of the subjects, even if the student is the investigator and actually conducts the project. Faculty advisors assume the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

At NYU Shanghai, students may not serve as principal investigators. They must have a faculty sponsor who fulfills the principal investigator eligibility criteria (Please refer to section 11.1 “Investigator Classifications” of the NYU Shanghai Procedures for Human Subjects Research Protection and who will serve as principal investigator and faculty advisor on the study.

12.4.2.1 Roles and Responsibility of the Faculty advisor

What is the faculty advisors role in student-conducted research?

The faculty advisor shares with the student the responsibility for the ethical conduct of the research. The advisor is responsible for ensuring that research activities involving human subjects are reviewed and approved by the NYU Shanghai IRB before they are initiated. The faculty advisor is expected to take an active role in student research activities and provide supervision for the
duration of the project. The faculty advisor is responsible for all research activities and must review, approve and sign the submission to the IRB.

What are the responsibilities of the faculty advisor in student-conducted research?

1. **Be informed.** Contact the IRB Office to discuss policies and procedures for obtaining IRB review before the initiation of research activities. Faculty advisors are expected to be familiar with institutional requirements for the conduct of human subjects research. Familiarize yourself with the IRB website.

2. **Complete the CITI training** for human subjects research. Faculty advisors are expected to be familiar with ethical and regulatory requirements.

3. **Know what must be reviewed.** Determine when an undergraduate or graduate student project constitutes research with human subjects and requires review by the IRB Office and/or the IRB. If you are unsure about whether or not a planned activity constitutes research with human subjects it is your responsibility to contact the IRB Office for guidance.

4. **Assist students with protocol submission.** When proposed activities constitute research with human subjects, it is the responsibility of the faculty advisor to assist students in preparing and reviewing materials to be submitted to the NYU Shanghai IRB. Faculty advisors are responsible for reviewing the scientific integrity of the project, including evaluating the scientific rigor and merit of the study.

5. **Educate students** on the role of the NYU Shanghai IRB and the importance of research review. Students must complete the CITI training for human subjects research before submitting an application to the IRB.

6. **Maintain ethical standards.** Faculty advisors ensure that projects are conducted to the highest ethical standards and that students understand and implement these ethical standards in the conduct of their research.

7. **Help students navigate the IRB process.** Faculty advisors contact the IRB Office to determine what the requirements are for submission to the IRB and help students understand the NYU Shanghai IRB process.

8. **Take an active role** in the IRB review process and assist students when presented with questions and comments from the IRB and/or IRB staff.

9. **Meet regularly with the student** to review project, progress and any issues.

10. **Ensure data security and retention** as described in the approved IRB protocol.

11. **Oversee changes.** Ensure that before a change is implemented to an approved protocol, the change is approved by the IRB. All changes must be reviewed by the faculty mentor before submission to the IRB.

12. **Report any unanticipated problems** or other research-related problems to the IRB as soon as possible.

13. **Ensure that continuing review requirements** are satisfied when applicable.

14. **Ensure that the study is closed** at the conclusion of the study.