

SUNY Institute of Technology

SUBJECT – Institutional Review Board	EFFECTIVE DATE – 02 February 2013
TITLE – Student Research and Classroom Projects	APPROVED BY – IRB; Deborah Tyksinski, Associate Provost; Academic Affairs Committee

SCOPE – This policy applies to all faculty members, staff and students within the SUNYIT system conducting research involving human subjects, and to the Institutional Review Board that oversees the conduct of that research.

PURPOSE – To define and establish guidelines and responsibilities for ensuring the protection of human subjects involved in research conducted by students. The policy also defines responsibilities of faculty members conducting and / or overseeing classroom projects that do not require IRB review.

POLICY - All non-exempt research involving human subjects conducted by SUNYIT faculty members, staff and students is subject to federal regulations governing the protection of human subjects, and must be reviewed by the Institutional Review Board prior to initiation. While exempt research is not subject to the *Common Rule* (45 CFR 45) and generally does not require detailed IRB review, the rights and welfare of the participants of that research must still be protected.

GUIDANCE

Some student projects will be classified as research, as defined in 45 CFR 46 and will require IRB review. Other student projects are conducted for educational purposes only, are not research, and will not require IRB review.

All student research and classroom projects must be supervised by a faculty member. Faculty members are ultimately responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the research. Advisors shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

It is the responsibility of the faculty member to determine if a student project is research subject to IRB review, or if it is a classroom project not intended for the creation of generalizable knowledge or publication beyond the classroom, and not subject to IRB review. Faculty members are encouraged to consult with the IRB Coordinator or Chair when making this distinction.

To assist in determining whether a project constitutes human subject research, the following federal definitions apply:

Research – A systematic investigation, including research developments, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject – A living individual about whom an investigator, whether professional, faculty, staff or student, conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Intervention – Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction – Includes communication or interpersonal contact between investigator and subject.

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Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vulnerable Populations – Participants that may have compromised autonomy relating to decision-making. Although not an exhaustive list, examples include:

1. Children
2. Prisoners
3. Pregnant women and fetuses
4. Neonates
5. Mentally disabled
6. Economically, socially, physically or educationally disadvantaged
7. Non-English speaking persons

Private Information – Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (medical record). Private information must be individually identifiable (the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Classroom activity or project – Includes course assignments, projects or exercises designed to teach students about methods and procedures of research. These projects, though limited in scope, may involve observation, interview, or collection of data from human subjects, but, are not intended to create generalizable knowledge, and do not result in publication or data dissemination beyond the institution of SUNYIT. These projects conclude at the end of the semester, and any data collected should be destroyed at the completion of the assignment. Students are still expected to follow sound ethical principles in conducting their research, including procedures to maintain confidentiality and informed consent from each participant.

Classroom projects that involve human subjects need not be reviewed by the IRB provided **all of the following conditions are met:**

1. The project involves no more than minimal risk to subjects
2. The project does not involve sensitive topics or confidential information that could place participants at risk if disclosed. Examples of these include:
 - (a) Sex activity or sexuality
 - (b) Death or suicide
 - (c) Drug use of any type
 - (d) Consumption of alcohol
 - (e) Violence or violent acts
 - (f) Failure and / or inadequacy
 - (g) Depression
 - (h) Illegal activities
 - (i) Topics which could cause emotional distress
 - (j) Topics which could lead to civil or criminal liability

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3. The project does not involve persons from vulnerable populations as participants.
4. The results of the project will never be distributed outside the classroom and / or the institutional setting, or be used for publication, except for educational purposes as part of the class assignment.

IRB review and approval must be granted prospectively. The IRB cannot grant retroactive approval. Data collected without IRB approval cannot later be used for thesis, publications or other research. If it is subsequently determined that the work is appropriate for a research project, IRB approval must be obtained and the data recollected.

It is the responsibility of faculty members to ensure that students planning to conduct research involving human participants submit an application to the IRB, and to thoroughly review the application prior to the submission. Faculty members must also:

1. Monitor the progress of student projects and ensure confidentiality and minimal level of risks to participants.
2. Report unexpected adverse events, unanticipated problems or complaints involving human participants promptly to the IRB Chair.

Students must be attentive to the welfare of participants regardless of whether the project is classified as human subject research or as a classroom project.

Certification Requirements

All faculty members must be certified to conduct research involving human subjects, even if they are not currently conducting such research. Students who will conduct research or participate in classroom projects involving human subjects must also complete the training. Certification can be accomplished by completing the web-based training at <http://phrp.nihtraining.com/users>.

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Classroom Research Project Instructor Checklist

Instructions: *Instructors should use this checklist as an aid in assessing whether or not a classroom project may be excluded from review and approval of the SUNYT Institutional Review Board (IRB). ALL checklist items must be satisfied in order for the classroom project to proceed without IRB review. Please contact the IRB Office with questions at irb@sunyit.edu.*

- 1. The research project will be performed by students enrolled in a graduate or undergraduate course at SUNYIT as a requirement for completion of the course.
- 2. The primary purpose of the project is as a learning experience about research methods and procedures, **or to gather data for subsequent classroom activities.**
- 3. The faculty member is fully aware of all aspects of the research project and assumes responsibility for overseeing the project, and assuring that ethical principles are adhered to in the conduct of activities related to the research.
- 4. There is no intent of the faculty member or the student to produce generalizable knowledge, or to publish or disseminate the findings beyond the SUNYIT classroom setting or faculty presentation.
- 5. The project involves no more than minimal risk (*probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*).
- 6. The project does not involve sensitive topics or confidential information that could place participants at risks if disclosed.
- 7. The project does not involve persons from vulnerable populations as participants.
- 8. The project involves only the voluntary participation of individuals, absent any coercion or pressure, to participate in the research. Instructors and students have considered the need to obtain informed consent of participants.
- 9. The faculty member has completed the human subjects protection web-based training within the **previous five years**, and a certificate is on file in the Office of the IRB (it is the instructor's responsibility to verify the existence of the certificate). The faculty member will ensure that students complete the web-based training and certification prior to engaging in the project. Training can be found at <http://phrp.nihtraining.com/users>.

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Guidance When University Students Are Research Subjects

Students as research subjects should be of the age of majority in New York (18 years old). Research involving minors (under the age of 18) as subjects, generally requires a signed parental consent, as well as that of the student. Some types of research may qualify for a waiver of parental permission (46.408(c); 46.116(c); 46.116(d); 46.117(c)).

Generally, researchers may not access classroom performance evaluations, grades, and information in a student's records without prior written permission from the student, regardless of the access an investigator may have in his/her academic role.

When course credit or extra credit is given to students who participate in research as part of a course requirement, students should be offered other options for fulfilling the research component, for example: short papers, special projects, book reports, and brief quizzes on additional readings, research seminars, or completing a similar project. These projects should be comparable in terms of time, effort and educational benefit to participation as a research subject in order to ensure that students are not being coerced into becoming subjects. Alternatives offered to subjects need prior IRB approval.

Solicitation of volunteer student subjects for research must be done in a non-coercive manner. To avoid undue influence, subjects should be recruited by a general announcement, central posting or announcement mechanism, and should include a clearly written description of the project and a statement of the proposed student participation.

Whenever possible, researchers should avoid data collection during regular class meetings. When study participation consumes a significant portion of a class section, loss of instructional time for both participants and non-participants may be considered a loss of benefits. Also, when research participation is expected during the same session at which participation is invited, students may be unduly influenced to take part due to peer pressure, perceived stigmatization from nonparticipation, or a sense of having otherwise wasted time by attending the day's class.

The use of class time for research purposes must be justified. Submissions proposing the use of class time for research should include an explanation of the beneficence of the research to the students. Specifically, the researcher should explain how participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class.

Since there are special risks of confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks in the consenting of a student to participate. The plan for handling research data should also be designed to minimize the risk that confidentiality will be breached. When instruments call for the disclosure of information which participants may view as personal or sensitive, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

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Students must be allowed to withdraw from the study at any time. The informed consent statement should make clear the consequences of withdrawing from a project prior to completion. In general it is favorable to give credit if the subject withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.

If the research is one where data are collected from a group project or perhaps a videotape of the group interaction, each student's consent is necessary for the use of the data in the instructor's research. If one student does not consent, the data may be used only if the non-consenting student's data can be effectively excluded.

Students have the right to full disclosure as soon as possible. Whenever possible a teaching opportunity in the form of an "educational debriefing" should be employed. Students should know something about the rationale for the study, the process of data collection, and intent of the researcher. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the completion of data collection. In such cases, students must not be subjected to undue stress or embarrassment and must have the right to full disclosure of the purpose of the research study as soon as possible after the data have been collected. During the debriefing, students should be given an opportunity to decide whether the researchers can use the data collected.

Research conducted by graduate students in a class in which the researcher assists in the class or does any grading should be subject to the same restraints described above.

References

Most of this document is patterned after documents of the same subject at:

Boston University IRB - (<http://www.bu.edu/irb/>)

University of Kentucky IRB - (<http://www.research.uky.edu/ori/>)

University of Notre Dame - (<http://or.nd.edu/compliance/human-research/irb>)

University of Texas at Arlington (UTA) IRB

(<http://www.uta.edu/research/administration/policies-procedures/>)

Additional sources of information can be found in the following documents:

Bankert, E. A.; Amdur, R. J. (2006) *Institutional Review Board, Management and Function*, 2nd ed., Jones and Bartlett Publishers Inc., Sudbury, MA.

Code of Federal Regulations: Title 45 Part 46 (45 CFR 46)

Rutgers State University of New Jersey, IRB - <http://osrp.rutgers.edu>

Southern Utah University IRB - www.suu.edu/irb

SUNY Binghamton - <http://research.binghamton.edu/compliance/humansubjects>

SUNY University of Brockport - <http://www.brockport.edu/irb/>

University of Texas El Paso IRB – irb.orsp@utep.edu