Guidance for Enrolling University Students as Research Subjects

In some research situations, use of students is integral to a research protocol. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning.

An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary and based upon full and accurate information.

It is not acceptable to mandate student participation in research surveys. Nor should research surveys be disguised as mandatory quality improvement initiatives to improve response rates. Individual researchers are not positioned to directly affect institutional practice and bring about immediate change. Such initiatives should be conducted by and under the direction of Institutional Research, as it is in a position to coordinate efforts, prevent duplicative assessments, and aid the University in achieving strategic goals. See the UK ORI Research vs Quality Improvement guide for characteristics that differentiate and define the boundaries between these activities.

The student-teacher relationship raises the issue of volunteer participation. Students may volunteer to participate in the belief that doing so will place them in a favorable situation with faculty (e.g., better grade, good recommendation, employment possibilities), or that failure to participate will negatively affect their relationship with the investigator or faculty (e.g. lower grade, less favorable recommendation, being "uncooperative and not part of the scientific community).

Care should be taken to eliminate coercion or reduce undue influence when soliciting student participation in research.

In the social and behavioral sciences, course credit is commonly offered for research participation. The following guidelines are offered to assist faculty who engage in research projects in which students will be asked to be research subjects. Research conducted by graduate students in a class in which he/she teaches, assists, or does any grading are subject to the same restraints described below.

- Assess need: Prior to proposing research surveys, consider whether data is available from an
 existing public or institutional <u>common data set</u>. Repeated surveys with duplicative topics can
 contribute to survey fatigue resulting in declining response rates and data quality.
- Disclosure risks: If research may involve disclosure of potentially risky situations or harmful circumstances, researchers are responsible for taking appropriate action and providing referrals for care. Implement safeguards to minimize inherent risks to participation such as use of a certificate of confidentiality (CoC) to prohibit disclosure of information about illegal behaviors in response to legal demands; provision of counseling resources for research topics which may be distressing or upsetting; or referral for care in studies that inquire about suicide ideation or behavior (see UK ORI Suicide Guidance).
- Third-party consent & Independent Data Collection: To minimize undue influence, the instructor may arrange to have the consent process and/or data collected by an independent third party, so that the instructor does not know who participated and does not have access to the identifiable data or the identity of participants until grades have been assigned and entered. For instructors using pre- and post- tests to determine efficacy of a particular curriculum, a colleague or third party should obtain the consent forms and distribute the tests when the instructor is not present (a graduate teaching assistant in the class in which the student/subject is enrolled does not qualify as a third party for collecting the data on behalf of the instructor).
- Extra Credit: When course credit or extra credit is given to students who participate in research, students are to be given other alternatives for earning the research credit, for example; short papers, special projects, book reports, additional readings, research seminars, or completing a

similar project. This requirement applies for any study in which an academic incentive is offered. Courses which require students to earn credits in a research subject pool must also meet this requirement. If the subject pool does not offer equivalent non-research activities to earn credit, then the course instructor is obligated to offer an alternate activity credit option.

- Extra Credit Alternatives: These alternatives should be comparable in terms of time, effort and
 educational benefit to participation as a research subject to ensure that students are not being
 coerced into becoming subjects. Alternative options should not be graded so that full credit is
 given for completing the alternative. Likewise, penalties or deductions in credit may not be applied
 should an enrolled research subject choose to withdraw from a study (see OHRP determination
 letter). Alternatives offered to students need prior IRB approval, as do Department subject pools.
- Non-Coercive Recruitment: 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 or central posting/announcement mechanism and it should include a clearly written
 description of the project and statement of the proposed student participation. In addition to being
 provided with the traditional information and consent forms, students should also be provided with
 the name and contact information of a neutral third party to contact should they feel coerced at
 any time during the process.
- Age of Majority: Students should be of the age of majority in Kentucky (18 years old). Research
 involving minors (under 18 years of age) as subjects (including 17-year-old college students)
 generally requires a signed parental consent, as well as assent by the student. Some types of
 research may qualify for a Waiver of Parental permission.
- Medical Center Students: Prior to conducting any research involving Chandler Medical Center residents/house officers as subjects, the investigator must obtain the approval of the Graduate Medical Education (GME) Committee. Prior to conducting any research involving University of Kentucky College of Medicine students as subjects, the investigator must obtain the approval of the Office of Medical Education (OME).
- Permission to Access Student Information: Generally, researchers may not access classroom performance evaluations, grades, and/or 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. The FERPA) protects privacy and confidentiality of personally identifiable information contained within student education records. For guidance on obtaining permission to access student records for research, see the UK IRB FERPA Guidance and the <a href="FERPA | Office of the University Registrar (uky.edu). Find resources for obtaining informed consent to use the accessed information for research purposes on the ORI Informed Consent/Assent webpage.
- Data Collection During Class: 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 regularly scheduled class
 sessions, students may be unduly influenced to take part due to peer pressure, perceived
 stigmatization from non-participation, or a sense of having otherwise wasted time by attending that
 day's class.
- Confidentiality Risks: 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 in research. 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.

- **Right to Withdraw:** 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 withdrawal is immediate or there is evidence of bad faith on the part of the student.
- **Group Data Collection:** 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 that 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.
- Right to Disclosure: Students have the right to full disclosure of the research project 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(s). 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 study as soon as possible after the data have been collected. During the debrief, students should be given an opportunity to decide whether the researcher(s) can use the data collected from them.

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