

To: Campus Community

From: Elisabeth Sherwin, Chair IRB

Re: Changes, amendments and clarifications to the previously reviewed policies and procedures document

First, the IRB wishes to thank all those faculty, staff and students who came to the assorted meetings, who took the time to educate, explain, and debate with us about the nuances of the definitions and the implications of the policies. This was all done in the spirit of cooperation and for the betterment of the system – and we appreciate their commitment to the research endeavor.

Following are elaborations on issues that appeared to repeat across our campus-wide meetings.

1. **What is research:**

Research is defined as: any systematic investigation, including research development, testing, and evaluation, designed to **develop or contribute to generalizable knowledge**. The term ‘research’ designates an activity designed to **permit conclusions to be drawn**, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

Important in this definition are the words “designed to contribute to generalizable knowledge.” A study must be systematic and designed to contribute to generalizable or transferable knowledge in order to be considered research that must meet the requirements of the human subject regulations. Although publication is often viewed as evidence of research status, it is not the only criterion. “Systematic investigations” that result in published studies do not qualify as research if they were not designed to contribute to generalizable knowledge. In general, activities that contribute to generalizable knowledge are those that attempt to make comparisons or draw conclusions from the gathered data; attempt to identify generalizable principles of historical or social development; seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes; create general explanations about all that has happened in the past; or predict the future.

Generalizable knowledge is not limited to quantitative studies designed to produce generalizations. Qualitative studies may also contribute to generalizable knowledge through the use of focus groups, case studies, ethnographies, interviews, or other means to identify general themes that the reader can choose to transfer to another situation.

*If it is not research, it does not need to be reviewed, However, it then becomes the faculty member’s responsibility to ensure that he or she is not conducting research. It is*

recommended that the safer way is that the determination of status (yes/no research) be made by the IRB.

## 2. **What types of review are there?**

There are three types of reviews: Full Board, Expedited, and a request to qualify for an Exemption.

Irrespective of the type of review accorded to a protocol:

1. All data collected in the research must be stored for three years in a safe place.
2. The PI(s), and may be others, are required to have and keep current CITI training.

The type of research is determined by the degree of risk to the participant, and, or, the participant group involved (children, prisoners, pregnant women, the PI's own students etc.). Risk does not only mean physical harm. Often the risk is of coercion – That the participant is actually not free to decline, or feels that he or she is not free to decline to participate. Risk is not determined solely by the PI – it is primarily the participant's subjective view of perceived physical or psychological harm.

The bigger the risk the more reviewers it merits. So in great risk, the Full Board reviews the protocol. When there is the least risk, and the protocol meets one of the six categories which qualify for exemption, only one or two reviewers will process the protocol.

1. **Exemptions:** This is an unfortunate term. The federal publications use this term to refer to types of situations: projects that are exempt from any review as opposed that do. Also, they use it as a type of review, one of the three that IRB's conduct. This creates a lot of confusion.
2. UALR has chosen to assure the oversight authorities (Office of Human Research Protection) that it will abide by the most rigorous standards of review. This means that all human subjects research will be reviewed irrespective of funding sources. UALR has adopted "The Common Rule." This means UALR will hold all research to standards that exceed the federally mandated guidelines. This is the reason why the IRB Policies and Procedures surpass the bare minimum that is required by law.
3. The following will, we hope, clarify the matter:
  - a. All human subjects research must be reviewed, without exception:
    - i. However, not every collection of data is research!
    - ii. Not every research project is human subject research!
  - b. An Exemption does not mean the project is exempt from review. It means that there may be room to exempt a project from some of the federal guidelines that govern human subjects research A research project may qualify for an exemption for some of the federal guidelines established for human participant protection.
  - c. However, per Office of Human Research Protection (OHRP) policies that determination may not be made by the PI or any one affiliated with the research.
  - d. Moreover, the determination must be made by an individual(s) educated and well-versed in the federal guidelines and the institution's policy and

procedures. Therefore even if the project falls into one of the six categories which qualify for exemption, a request for exemption must be submitted.

### 3. **Time frames and review procedures:**

Once reviewers receive a protocol they have 10 business days to return feedback to the research compliance officer (RCO) who then disseminates it to the principal investigator (PI).

The protocol must be received by the RCO at least 10 business days prior to the Full Board meeting to ensure that the Board has sufficient time to review the protocol before the upcoming board meeting. The schedule of Full Board meetings is available on the IRB website.

The PI is always welcome to be present to receive in-person comments and feedback during the review session. Often this prevents lengthy cycles of rewriting and re-reviewing. In any case, a formal written summary of the IRB's decisions will be issued.

The initial reviewers remain with a protocol until its approval. However, if such a procedure might undermine a rapid review (illness or travel by one or both of the reviewers), there are alternate procedures.

### 4. **Appeals Procedure**

In response to faculty concerns, we have reviewed the matter with the OHRP, and the following policy has been developed:

The Institutional Official has the authority to overturn the IRB's CONSENT. That is, if the IRB approves a project, the Institutional Officer (IO) may revoke it if there is concern about the implications for the institution.

If a PI disagrees with the IRB's written decision, he/she is encouraged to contact the Office of Research Compliance and/or the IRB Chair and provide a written response detailing justification for the disagreement.

If the IRB reviewers do not approve a project, the following appeals procedures are available to the PI. Note that the procedure used for a project depends upon the degree of risk to participants inherent in the project

- a. If the disagreement is related to a substantive human protection issue and the protocol was reviewed by the full IRB, the protocol will be referred back to the full IRB.
  - i. An appeal of a disapproved research project must be reviewed at the next *Full Board* meeting.

- ii. If resolution of the disagreement requires direct interaction with the PI, the PI may attend a portion of the IRB meeting to address Board concerns.
  - iii. If the re-review process by full board does not satisfy the PI, the PI may choose to forward the matter to OHRP. In which case, the protocol, and all attendant documents and correspondence, will be forwarded to the IO, who will forward the matter to OHRP for resolution.
- b. If the disagreement does not represent a substantive human protection issue, the IRB Chair will seek a resolution.
- i. This may include two new reviewers to assess the protocol. The IRB Chair will serve as a third reviewer
  - ii. If the re-review process by FB does not satisfy the PI, the protocol, and all attendant documents and correspondence, will be forwarded to the FB and reviewed at the next FB meeting.
  - iii. If that re-review process by FB does not satisfy the PI, the PI may choose to forward the matter to OHRP. In which case, the protocol, and all attendant documents and correspondence, will be forwarded to the IO, who will forward the matter to OHRP for resolution

## 5. Student research

There are two types of research in which students may be involved: Research where the student serves as a PI (the student is largely independent as in an independent study or graduate project), and when the student is identified as the PI but the faculty member is active in the project (i.e., a research project conducted outside the classroom for a research methods class).

When the student is a PI, a faculty member must serve as principal investigator or faculty advisor and signatory on all student research.

All students conducting research requiring IRB review must complete CITI training prior to IRB approval of the research. This includes *research that qualifies for exemption*. (See Research Protection Program policy determination of exemption for further information.)

However, students participating in classroom projects that *do not* require IRB review are *not* required to complete CITI training.

However, colleges, departments, and instructors are encouraged to require all students enrolled in research methods classes (or research method-type classes) to complete CITI training.

### a. Student research projects that require IRB review:

- i. The IRB assumes that dissertations, theses and senior capstone conducted with humans constitute research. They therefore will probably require review. Thus they should be submitted to the IRB for a “Determination of Human Subjects Research” to identify whether further review (if any) is necessary.
- ii. Any student project that recruits or includes a protected class of participants
- iii. Any student project that may be disseminated outside the immediate classroom
- iv. The results will be shared with more than the other students in the class or the instructor of record. If there is even a remote chance that the data or the report/manuscript will be used in the future for a conference presentation, or a related research project, the research should go through IRB review.
- v. Research that involves direct human interaction or a manipulation of their environment (e.g., in person, or via mail, email, web survey, or telephone), or data from human subjects for which the researchers will have access to identifiers.
- vi. Research activities using departmental subject pools even when the activity is conducted for educational purposes as a class requirement.
- vii. Class projects or practicums’ that involve direct interaction or an intervention or secondary analyses of private identifiable data and are undertaken as both an educational experience and as research (e.g., results of these activities will be presented publicly or otherwise disseminated, or the data will be stored and used by the students or others as research data).

**b. Student research projects that may not require IRB review:**

- i. Research where the experience is for educational purposes only
  - 1. Class projects with the limited objective of teaching proficiency in performing certain tasks or using specific tools or methods
  - 2. Class projects or practicums that involve direct interaction (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and is not intended for research purposes. The project or practicum is not “research” even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.
  - 3. Class projects involving secondary data analyses that are assigned and conducted as educational exercises, and that use data sets that include private information and codes that link to identifiers, but the students do not have access to the

identifiers or the code key. Note - activity must be limited to class project use only.

**Faculty responsibility when IRB approval is not necessary:**

- a. Faculty members are responsible to discuss the guidelines and ethics for the protection of research subjects with their students and incorporate these into their methodology.
- a. Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics.
- b. The Instructor should provide information about the assignment for the students to distribute to people who participate in these class projects. The information should list the instructor as the appropriate contact person should questions arise.
- b. Particular emphasis should be placed on:
  - i. Developing an awareness of the types of risk subjects may be exposed to in various types of research projects, i.e., psychological, social, physical, economic, and legal.
  - ii. Obtaining voluntary informed consent to participate in a way that honestly informs subjects of the purpose and potential risks and benefits of the research.
  - iii. Management of potential risks to subjects.
  - iv. A risk/benefit analysis for all populations, with special consideration of vulnerable populations (children, pregnant women, fetuses, mentally disabled, institutionalized persons, prisoners, etc.).
  - v. Protection of privacy and confidentiality of the subjects.
  - vi. Identification of benefit to be derived from participation in the research.

**6. Non-compliance**

There are different types of non-compliance. The IRB focuses on non-compliance in research. It is defined as the failure to comply with any Health and Human Services regulations, and/or IRB requirements or policies and procedures.

Noncompliance may be assessed as non-serious, serious, or continuing.

When the IRB receives notice that an incident of non-compliance may have, or has, occurred:

1. The RCO will immediately inform the PI that an investigation will ensue.
  - a. All notifications will be in writing.
  - b. If the PI is a faculty or staff member then only the PI will be informed of the investigation.
  - c. If the PI is a student, the Faculty Advisor is notified.
  - d. The Faculty Advisor will notify the student.
  - e. The IRB may notify Computing Services to ensure that no material is erased from the computers of the parties involved.

- f. Funds associated with the protocol under investigation may be frozen.
- 2. The IRB will investigate and until a determination is made.
  - a. At that point parties involved will be notified in writing as to the dispensation of the matter and of IRB recommendations. The IRB makes its recommendations to the Chancellor and the Research Integrity Officer.

7. **Research with children as participants**

Children are considered a “protected class” and are entitled to special protection. However, the fact that the participants are children does not *a priori* indicate that they are at risk. Therefore, all protocols involving children will be reviewed in a manner commensurate with the risk associated within the specific research project. Depending on the project, the protocol may

- a. be reviewed by the Full Board
- b. be reviewed as an expedited protocol
- c. qualify for exemption

Another area of debate was the issue of **Child Assent** --- particularly in classroom settings, when the research is integrated into standard educational practices. Therefore the IRB has determined that in instances where the assent would be more disruptive or confusing to the child than any potential risk to their freedom to consent – assent may be waived. This is particularly true if the child is young.

In such instances, the PI should request a waiver and justify its request.