Is it Research?
Is It Research?

2 Elements

– The project involves a systematic investigation
– The design (meaning goal, purpose, or intent) of the investigation is to develop or contribute to generalizable knowledge.
It Is Research so Does It Involve Human Subjects?

• Definition: a living individual about whom an investigator conducting research obtains:
  – Data through intervention or interaction with the individual
    ➢ Intervention: physical procedures and manipulation of the subject or the environment for research purposes.
    ➢ Interaction: communication or interpersonal contact between investigator and subject.
It Is Research so Does It Involve Human Subjects?

• OR identifiable private information
  – Information about behavior in a context in which the individual can expect no recording.
  – Information that was made available for a specific purpose that would not be expected to be made public
Research vs. Education

• Academic publication is not necessarily research.
  – Sharing results with colleagues so they can benefit from information
  – Nonresearch can be published.
  – If identified as research it must go through IRB.

• The word research cannot be used in the publication otherwise.
Quality Improvement Is Not Research

• Key word: Intent
  – Goal of improving performance of institutional practice is quality improvement, not research
  – Should not be published as research
Other Examples of Nonresearch

• Quality Assessment – activities in line with established standards
• Quality Assurance – review, analysis, or evaluation of specific data for improvement
• Case Report – publication of a specific incidence, etc. If subject identifiable, must have subject’s permission.
Who Needs IRB Approval?

If

• the research is sponsored by the University
• the research is conducted by or under the direction of any University employee or agent (for example, faculty member, researcher, or student) in connection with his / her other institutional responsibilities, no matter where the research is conducted
• the research is conducted by or under the direction of any University employee or agent (for example, faculty member, researcher, or student) using any University property or facility
• the research involves the use of the University's nonpublic information to identify or contact human research subjects or prospective subjects to provide data for the research
• the research involves the use of the University's students, employees, or facilities.
Who Needs IRB Approval?

Examples of documents:

- Dissertations
- Masters' theses
- Pilot studies
- Class projects
- Faculty directed research
Certification to do Research
Who Needs It?
Do I Need Certification?

- The training requirement applies to all faculty, staff, students, visitors or any other individuals who work with human subjects in research or their data. Some examples include: individuals who obtain informed consent, administer study interventions such as surveys, or collect/analyze private or personal information from individuals.
Protecting Human Research Participants Certification

- The National Institutes of Health Office of Extramural Research
- Introduction
- FAQs
- Course Objectives
- Online and Offline access to study materials
Where do I find the forms?

Under the Academics tab of the UAFS home page.
Click on Institutional Review Board.
When Do I Submit the Forms?

- Submit the Application for Review to the UAFS IRB at the appropriate point in the research development process. Timing may be particularly important if external support is being sought for the project since most federal and many other sponsors require IRB approval as a condition of award.

- The UAFS IRB, therefore, strongly recommends that all researchers applying for external support submit an Application for Review to the UAFS IRB within 60 days after submission of the proposal for funding.
When Do I Submit the Forms?

- Do NOT begin your data collection before receiving IRB approval.
- Receive full approval from the UAFS IRB before initiating any research activities with human subjects and do only such work with human subjects as has been approved by the UAFS IRB.
Research Using the PI’s Students

• Maintaining student privacy is paramount in research of college students to prevent feelings of coercion.

• When using classroom for data collection, PI’s should
  – Have a colleague distribute and collect surveys that are distributed in the classroom.
  – All students should receive the packet and research assistant should state those who choose not to participate should put blank surveys in packet and seal to maintain confidentiality of those who participate and those who don’t.
Research Using the PI’s Students

– The PI should not be in the room.
– Signed consent forms are not necessary when using surveys. Completion of the survey indicates consent.
– When using a survey site, i.e. Survey Monkey, indicate that no IP addresses are to be returned to the PI.
Students Performing Research on Human Subjects
Procedure

- Work through your instructor when you decide what type of research you want to do
- Both you and your instructor must approach the Dean of your college about your research and gain his/her approval
- If your research does not involve human subjects and you feel it should be exempt, it does not have to come to the IRB; but, a specific form must be completed and signed by yourself, your instructor, and the Dean stating why it should be exempt.
• If your research involves working with human subjects, you must complete the “Request for Review of Human Subjects Research.” This completed form shall be emailed to Dr. Wallace, Provost, Dr. Timmons, and Dr. Fulbright, IRB Coordinator.

• The IRB will grant approval of your research once your request has been reviewed and all criteria have been met.
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