Frequently Asked Questions regarding the UCO Institutional Review Board

1. What is an IRB?

IRB stands for Institutional Review Board. The UCO IRB exists to review all research that directly or indirectly involves human participants as study subjects, and to develop institutional policies to oversee such research. The primary role of the IRB is to ensure the protection of human participants as subjects of research at UCO.

2. What is human subjects research?

The sort of research that falls under the review authority of the UCO IRB is defined as the systematic investigation, including development, testing, and evaluation of research, that is designed to develop or to contribute to generalizable knowledge.

Human subjects are living individuals about whom the investigator conducting research obtains data by direct intervention or interaction with that individual, or by obtaining identifiable private information from or about that individual.

Intervention can include either physical procedures by which data are gathered, such as manipulations of the subject or the investigation of the subject's environment, that are performed for research purposes. An example of this can be the stimulation of the subject's environment in order to obtain an immediate stimulus response. Interaction can include communication with or interpersonal contact between the investigator and the subject, such as a survey or an interview.

Private information may include information about behavior that occurs in a context where the subject can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by the subject and which they can reasonably expect will not be made public, such as a health record or accounts of personal behaviors.

3. **Do I have to submit a proposal to the IRB before I start my study?**

   Yes. All research projects that will involve human participants must be submitted for IRB review and approval **before** beginning the study. This includes research involving existing data, or any advertising or other recruitment procedures. Information about the application process may be found on the UCO Office of Research Integrity and Compliance website.

4. **Who can be an investigator?**

   At UCO, all full time faculty and staff, graduate students, and full time students, may act as investigators. However, per UCO policy, all students, graduate or undergraduate, who act as PIs must have an eligible full time faculty or staff member to act as a Co-Investigator ("Co-PI").

5. **Do I need any specific training to be an investigator?**

   Yes. All investigators are required to complete the Protecting Human Research Participants training. UCO offers this through Collaborative Institutional Training Initiative (CITI). This training is valid for two (3) years. Alternatively, UCO recognizes the training of collaborating researchers from outside UCO as long as that collaborating entity has federal wide assurance. Once training is completed, you must save the Certificate of Completion, and upload it with your IRB submission.

6. **Does a research project that is part of a class need IRB approval?**

   Yes, it might, if the project fits the definitions of "research" and "human participants" as described above.

7. **What kinds of IRB review are there?**

   There are three types of IRB review according to federal regulations (45 CFR 46.101(b)): full board, expedited, and exempt. Full board review is done by the full IRB committee at its monthly meeting. The IRB meet

regularly on the first Wednesday of each month during the school year. The IRB typically does not meet during the summer. Reasons for full board review can include the use of vulnerable populations as study subjects, projects that may involve deception, or that seek to obtain particularly sensitive information. This does not mean no other types of proposals will go before the full board, nor does it mean that all others may be either expedited or exempt. The Chair of the IRB makes the determination of the type of review. Expedited review means that the study does not have to be reviewed by the full board but is still subject to the same scrutiny regarding protecting human research subjects. **You may not begin any research activities until you have received written approval for the IRB.**

8. **What is meant by "exempt" research?**

Some human participant research proposals may be granted exempt status. This means that all of the research activities outlined in the proposal fall under one or more of the exemption categories specified by the federal regulations. There is a separate form for exempt research on the IRB Forms link. Being granted exempt status does not lessen the ethical obligations to human research subjects as articulated in the Belmont Report or in UCO IRB policies. You may consider your study to qualify as exempt and submit your proposal on the Exempt Short Form, but that does not mean your proposal will be granted exempt status; the IRB Chair will review all requests for exempt status and will notify you of the result of the review. If the Chair determines that your study does not qualify as exempt, you will have to submit the regular IRB application. Even if your proposal is exempt, you still have to submit all supporting documentation, **and you still are required to complete protecting human research participants training**.

9. **If my proposal requires full board review, does that mean I have to attend the IRB meeting?**

No. Full board review simply means that, for any number of reasons, the decision was made to have the full board take a look at your proposal. This does not mean there is anything wrong or improper; it could mean that the study seeks to investigate an issue with which the Chair is not familiar, and wishes the rest of the board to look at it. The IRB has very talented and knowledgeable members who are experts across a variety of disciplines.

It can sometimes happen that the board wants to talk to you about your study, usually to clarify some point or method. In such cases the ORIC staff will notify you to come to the IRB meeting, and will tell you why you are being asked to attend. If this occurs, **don't panic**; in nearly all cases we merely need some point to be clarified. Even if we do not ask you to attend, you are welcome to attend the IRB meeting when your study is being reviewed, but you must let the ORIC office know ahead of time. When you arrive we will invite you to come in to talk to us about your project, and you can ask the board any question you like. The only rules are that you keep confidential what is discussed, and you are not permitted to be present during deliberation or voting.

10. Can I make changes to my study after it has been approved?

Yes. There is a Modification/Amendment form that may be used for most purposes to make changes to an approved study. This form is found on the IRB Forms link. The IRB Chair must approve any changes made to an approved study **before** they are implemented.

11. What do I do when I am done with my study?

There is a closure form that must be submitted to the Office of Research Integrity and Compliance to officially close a study. Once you have received notification that the study is closed, you may not continue to recruit new study subjects or collect new data; however, you may continue to analyze already-obtained data and to prepare that analysis for presentation or publication.

12. My study involves deception. Are there any special considerations?

Yes. Deception in research is not prohibited by either the federal regulations or by UCO, and the use of deception in research can be very useful in obtaining data not possible otherwise. It also can be seen as a violation of the trust that the participant puts in the researcher, so it is important to be able to justify using deception. Investigators need to be able to describe to the IRB the method of the research, including a clear

statement that no non-deceptive study method would be able to yield equally valid data, and there must be a process for the study participants to be informed at the end of their participation that deception was a component of the study. Participants must be fully debriefed and it must be explained to them very clearly why it was necessary that they be deceived. Great care should be taken not only in crafting a study where deception is a component, but also in the debriefing of participants afterward. Usually, people do not take kindly to being intentionally deceived, so you must be very careful about how you inform your study participants that deception was a part of the study. A script of the debrief must be included with your IRB application, and the IRB will examine it with special attention.

13. **What is a vulnerable population? Are there special considerations for doing research with a vulnerable population?**

A vulnerable population refers to members of a group that may have a diminished capacity to give informed consent. Informed consent means that the subject is fully informed of and understands the purpose and method of the study, has been informed about all foreseeable benefits and risks, has been able to ask questions and been given answers regarding the study, is free to volunteer to participate or not, and is aware that they can discontinue their participation at any time without any penalty or loss of rights to which they might otherwise be entitled. Persons who cannot meet this standard of consent still may be study subjects, but because of their diminished capacity to give informed consent special considerations are necessary to ensure that receive the fullest protections possible. Federal regulations do not clearly specify all vulnerable groups. The UCO IRB views children (meaning, by law, anyone who is under the age of 18), prisoners, the mentally and/or cognitively challenged, subjects over the age of 65, and pregnant women, as requiring greater considerations. Ordinarily, studies involving vulnerable populations will require full board review; this is to ensure that the fullest protections are in place for their rights to be secured.

14. **What is "informed" consent? Why is it so important?**

Much of the justification for the existence of IRBs has to do with records of studies done where the participants were forced to participate, were not told what exactly was going to be done to them, were lied to about the

purpose of the study they were participating in, or were never told they were even subjects in a study. Examples include accounts of “medical” experiments done in Nazi and Japanese prisoner of war camps, and the Tuskegee Syphilis Study in the U.S. The need for medical studies using live human participants had to be balanced by issues of respect for the participants, the balance of risks and benefits, and simple justice regarding the selection of study subjects. These considerations were enshrined in a document that has become commonly known as the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). As a result of this report, legislation was passed requiring that all human subjects research undergo IRB review to ensure the fullest protections for the rights of the study participants.

All IRB-approved research, unless it is exempt, must include informed consent forms that the study participants must sign prior to the initiation of your study. Guidelines for obtaining informed consent are available on the IRB Forms link. There are separate forms for children (Assent) and for their parents/guardians (Parental Consent). All are available on the IRB site.

15. How do I obtain consent if my study is done online?

Informed consent is a standard, not a document. It can sometimes be the case that the recruitment, consent, and the study itself, all are designed to be done entirely online. The IRB application allows you to obtain consent without an actual written and signed document. There is a separate form called the “Waiver of Documentation of Informed Consent” which is used to allow for obtaining unsigned consent under certain circumstances; these can include implied and verbal consent. Consent will still be obtained from participants; the difference is that they will not be required to sign a physical document. Examples where the IRB may waive the requirement to obtain a signed consent form can be where the only record linking the research participant and the research would be the consent document itself, and the only risk would be potential harm resulting from a breach of confidentiality, or that the research presents no more than minimal risk of harm to participants.

16. **What is a "waiver" of informed consent? How is it different from a "waiver of documentation" of informed consent?**

    Basically, the difference is that when you request a waiver of informed consent, you are requesting to forego obtaining any kind of consent. Examples of types of studies in which some or all elements of consent have been waived include retrospective chart reviews or studies that involve no more than minimal risk and waiving consent will in no way affect the rights of the study subjects. A waiver of documentation of informed consent means that you still will be obtaining consent, but without a paper document signed by the participant. Some examples can be online surveys or studies where verbal consent is acceptable or necessary; the form for waiving documentation of informed consent has places where these instances are to be explained.

17. **So: I can do my research online?**

    Yes. You can solicit study participants, obtain consent, and conduct your research entirely online. There are provisions on the IRB application where you specify and explain the need to do online research. If you want to send out an email targeted at a specific population or an email "blast" to everyone on campus to recruit participants, you must submit your proposal to the UCO Office of Information Technology for approval. You can do this when you submit your application to the IRB. UCO employs several online platforms, such as SurveyMonkey and Qualtrics, to assist in your online research.

18. **I am not collecting any identifying information. Do I still need an informed consent form?**

    Yes. This can be done by relating all of the elements of consent to the study subject, but the signature line of the form is replaced with a statement informing the subject that completion and return of the study instrument(s) is considered to be tacit, or implied, consent. In other words, completing the survey or answering the investigator's questions by itself is a sufficient acknowledgement of the willingness of the subject to take part in the study. Obtaining consent in this manner must be explained on the IRB application.

19. What is "implied" consent?

Implied consent is the tacit agreement to participate in research by engaging in research activities. By completing the research activities, such as a survey or questionnaire, the subject has demonstrated that they have agreed to participate in the study. It is important to realize, though, that implied consent is still a form of informed consent, and the investigator is still obliged to ensure that consent is both informed and freely given.

20. Can I do research off campus? Does it require IRB approval?

Yes. If you are UCO faculty, staff, or student, and you are the Primary Investigator (PI), you will need UCO IRB approval to conduct your research, regardless of where the research takes place. If the study site has an IRB, or something like it, we may require that this other body send us their approval for you to do your study. If the site is a school, or other organization, we will require that they provide permission for you to be present to do your research on their site. Written permission is best, but an email that identifies the local authority usually will suffice.

21. If I have approval from another IRB, do I still need UCO IRB approval?

Investigators who wish to do collaborative research under the authority of another IRB may do so, but the UCO IRB must be informed. In cases where the other IRB recruits local study participants or Co-PIs, an Inter- institutional Authorization Agreement may be submitted; this effectively cedes control and responsibility for the oversight of the research and the researchers to the other IRB. The UCO participants and/or researchers are still obliged to abide by the ethical research guidelines of UCO, regardless of who is in charge of the study or where the study is conducted.

The UCO IRB will require documentation of the other IRB's approval of the study, and the approved IRB form from that institution; in some cases, The UCO IRB may require the completion of a UCO IRB form, regardless of the study being approved by another IRB. Such decisions are made by the UCO IRB Chair and may involve full board review and approval. In either case, no research activities by UCO personnel may begin until the UCO IRB has reviewed and approved the study.

22. Does the IRB provide any other training for investigators?

Yes. The IRB is a part of the Office of Research Integrity and Compliance (ORIC). The ORIC staff schedules training sessions at various locations around campus several times a year for students and for faculty. The Chair of the IRB is available to meet with individuals and classes, as requested, to do presentations on the IRB application process, as well as more general presentations about human subjects research. Contact the ORIC office at 974-5497 to schedule training or presentations.

23. What do I do if an unanticipated problem involving risks to participants or to others arises?

If a serious adverse event occurs, it must be reported to the ORIC office immediately, and the PI must submit a written report within 24 hours of the PI's becoming aware of the event. A serious adverse event usually means injury or death to a study subject or a researcher, even if the event was not directly related to the research itself. Though very rare, in such cases the research activities will be suspended until an investigation into the adverse event has been completed.

Less serious unanticipated problems, such as the loss of data security or violations of confidentiality, should be reported by the PI to the ORIC office within 7 days of first becoming aware of the problem, using the Unanticipated Problem Report form. In these cases, it is likely that research activities will be suspended, pending the outcome of an investigation. Prompt reporting is important, since unanticipated problems may require the modification of study procedures, protocols, and/or informed consent. As above (#9), any modifications require submitting the proper form and are subject to the review and approval of the IRB. [See IRB SOP 404]

24. How long can I keep my data?

As long as you want to, provide it is "de-identified." This means that all potentially personally identifiable information has been erased/deleted. This can include, names, dates of birth, addresses, hometown, high school attended, college major, identifying medical conditions; in short, you can only keep data results if they are stripped of anything that might identify any of the participants.

Data that contains identifiable information may only be kept for the approved duration of the study. If you want to keep it longer, this amounts to a continuation of the study itself, so you will have to fill out the Continuing Review form and specify why you want to keep your identifiable data longer.

By law, Informed Consent forms are to be kept under secure storage for a minimum of three years. Your closet at home does not constitute "secure storage," many PIs bring their signed Informed Consent forms to the Office of Research Integrity and Compliance immediately upon the completion of their study, and the ORIC will store them for the remainder of their three-year approval. Alternatively, faculty who are PIs sometimes keep the signed Informed Consent forms in the offices on campus. In either case, they must be accessible for review for three years. After three years we recommend that you bring the consent forms to the Office of Research Integrity and Compliance and the office staff will dispose of them properly.

For more information contact:

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