Office of Research Compliance Guidance for IRB Protocol Development

- You must **obtain IRB approval prior to conducting human subjects research**.

  The Institutional Review Board (IRB) is primarily responsible for protecting the rights, privacy, and welfare of human research participants. IRB approval is required before starting any aspect of your project that involves people, including recruitment and pilot testing.

- **Complete all applicable sections** of the form.

  The LEO electronic system is designed to allow you to submit for IRB consideration by entering text, and by use of check boxes and drop-down boxes. It enables you to upload documents such as consent forms, surveys, recruitment flyers, letters of support, etc. You must insert project specific details into each applicable section of the form, rather than stating, "See attached" in the online IRB protocol outline form fields. If something does not apply to your study, indicate "Not applicable" or "N/A" in the form field.

- If the Primary Investigator (PI) is a student, there must be an Ohio University (OU) faculty **advisor**.

  Whenever a student is listed as the primary investigator, an OU faculty advisor must be assigned. If more than one OU faculty member will be involved, you may only list one advisor. The other faculty member(s) may be listed as co-investigator(s) or research assistant(s). If the Corresponding Investigator (CI) is a student, they should consult their advisor prior to submitting the protocol and when responding to reviewer issues.

- Select the correct **review level**.

  If the probability and magnitude of harm or discomfort anticipated in your research are not greater in and of themselves than those ordinarily encountered in daily life or during the routine performance of physical or psychological examinations or tests, then your study may qualify for

Exemption or for Expedited review. Consider whether your proposed activities fit neatly within one or more of the defined categories listed for Exemption or Expedited review. If your study poses greater than minimal risk to research subjects, it must undergo Full Board review. If you have selected the wrong review level or category, the submission will come back to you for correction.

- Clearly define the **study population**.

  The IRB is responsible for ensuring that the subject population is appropriate for the research and that the PI has provided sufficient rationale for inclusions or exclusions. They are also responsible for ensuring that if vulnerable subjects are included (minors, pregnant women, or prisoners) there are appropriate safeguards in place.

- Detail your **recruitment methods**.

  One of the responsibilities of the IRB is to ensure that selection of participants is equitable and that safeguards are in place to ensure that there is no pressure or coercion to participate. If you will use a tool, such as a poster, newspaper ad, social media post, or flyer, to recruit participants, you must upload it for review by the IRB. If you will be providing verbal information to potential participants to recruit them, upload a document that includes what you plan to say to them. All recruitment material must indicate that the research is conducted under the auspice of Ohio University and include your IRB number.

- Provide a clear overview of your project in the **summary** section.

  Clearly articulate, in non-technical terms, why and how you plan to do your research project.

- Articulate the study **objectives/aims**.

Clearly state what you are hoping to achieve by doing the project, and what new information your study will contribute. Include background information and the significance for your proposed activities. If your project has more than one objective or aim, include a thorough description of each one. Provide citations for previous relevant or related research if available.

- Fully describe the **procedures** of the study.

  Clearly describe sequentially all the steps that will be followed with the participants. Provide a description of all aspects of the study, including recruitment, the consenting process, and study methodology. If your study involves more than one component (e.g. an online screening survey, followed by an individual interview, and a focus group session), describe each one.

- Identify all potential **risks/discomforts**, and the steps you will take to minimize them.

  Your research may pose more than one kind of risk or discomfort, such as physical, psychological, reputational, legal or financial risks. List all possible risks participants might encounter and provide the details of how you plan to decrease the chances or the impact of those risks. Ensure that you are not subjecting participants to any unnecessary risks or discomfort.

- Describe the societal/scientific **benefits**.

  While it is understood that not all research will provide benefit to the individual participant, there must be an anticipated benefit to society or to science in general to justify doing the study. The IRB must ensure that your research design and/or data analysis plan is likely to yield useful data. The potential benefits of the study must outweigh the potential risks.

- Describe **confidentiality** and privacy measures.

  Your submission should provide details about how you will protect participant privacy and/or confidentiality, particularly if you are collecting sensitive data. If your study will involve protected health information, HIPAA regulations

may apply. If your study will involve recordings or a master code list, the IRB will need to know how they will be securely stored and the month and year by which these will be destroyed. You may be asked to ensure that sensitive electronic data is stored on an encrypted device.

- Upload and describe all **instruments/questionnaires and** describe all **equipment/devices** that will be used in your project.

  If you plan to interview participants individually or in a focus group setting, upload the interview guide that you will follow. If you will use a researcher-developed survey or a standardized instrument, upload it for review. If you will utilize a piece of equipment or a device to obtain study data, describe how it will be utilized, maintained, calibrated, and/or cleansed before and between use on participants.

- Detail the **consenting process**.

  The consenting process involves providing information to potential participants about the study, answering any questions they may have, and obtaining their agreement to participate. The IRB will consider whether potential participants will be approached for informed consent in an appropriate manner and whether qualified study personnel will be obtaining their consent. All consent language, including written consent forms and verbal scripts, must be uploaded for review. It is strongly recommended that you use one of the consent form templates that are available on the Office of Research Compliance website when developing consent documents. Consent information must be presented to participants in language that is easy to understand. It is recommended that all consent language be written at an eighth-grade reading level.

  Parental or guardian consent must be obtained for research involving minors (those under the age of 18). In addition to parental consent, you will likely be required to obtain assent. Assent is a minor participant's affirmative agreement to participate in research. This should be an age appropriate

presentation to the minor, and depending on the age of the minor, it may be a written form or verbal script. The assent language must be uploaded for review.

The IRB will consider whether you have included these **required elements** in your proposed consent process:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts the participant may or will encounter;
3. A description of any benefits to subjects or others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. A future use statement for any research that involves the collection of
10. Identifiable private information or identifiable biospecimens.

Take your time to carefully proofread and review your submission before sending it for IRB consideration. If the Corresponding Investigator (CI) is a student, they should consult their advisor prior to submitting the protocol and when responding to reviewer issues.