Research Proposal Form

This form should be used for:
1) New Review (human subject research not currently approved by the IRB);
2) Continuing Review (research currently approved by the IRB with an expiration date; research proposals requesting re-approval must be submitted to the IRB 14 - 60 days before the expiration date);
3) Major Revision (research currently approved by the IRB but the PI is requesting significant changes to the protocol; examples of significant changes include altering the experience of the participants in the study, adding new measures or procedures, collecting data from a new or different sample or source, altering the consent or debriefing process, etc.)

Minor Revisions to a proposal can be submitted via email to irb@owu.edu. If you are unsure whether your changes constitute major or minor revisions, you may email irb@owu.edu for guidance.

STUDENT PROJECTS: For all student projects, the research advisor must serve as the PI.
REVIEW STATUS: If you're not sure whether your project meets the criteria for "human subject" or "research" according to the OWU HSR Policy, you are encouraged to email irb@owu.edu for guidance prior to completing this form.
RESEARCH DESCRIPTION: Your research overview should be concise and written for a general professional audience. Citation information is acceptable, but usually not necessary.
FILE UPLOADS: Research materials (e.g., surveys), consent form, debriefing script, and ethics training certification should be prepared in .doc or .pdf files to be uploaded into this form.
FORMAT & SUBMISSION: Proposals that fall into one of the three categories listed above must be submitted to the IRB using this form. All attachments for relevant appendices should also be uploaded to this form. Please do not email your attachments to the IRB unless requested to do so.

* Indicates required question

1. Email *

Part I: General Information

2. Research Title *

3. Type of Review *

Mark only one oval.

- New Review
- Continuing Review
- Major Revision

4. Principal Investigator (PI) name *

5. PI Status *

Mark only one oval.

- Faculty
- Staff
- Other:

6. PI Education *

Mark only one oval.

- ◯ BS/BA
- ◯ Masters
- ◯ PhD
- ◯ Other: _____

7. PI campus phone number *

_____

8. PI campus address *

_____

9. Co-Investigator(s) name *

_____

_____

_____

_____

_____

10. Preferred Start Date *

Mark only one oval.

- ◯ Immediately upon approval
- ◯ Other: _____

11. Name all sources of funding for this project *

12. If you have submitted similar proposals to the IRB previously, please provide the IRB number(s).

Part II: Determination of Review Status

13. Indicate the level of risk to participants that is associated with this research. *

Mark only one oval.

- The research is free of foreseeable risk to participants.
- The research presents no more than minimal risk to participants.
- The research presents more than minimal risk to participants.

14. Indicate whether each item applies to this research (each item must be checked yes or no). *

Check all that apply.

	Yes	No
The activities meet the HSR definition of "Human Subject" (Section II.A) (also see Interpreting the definition of "Human Subject" and "Research" in the HSR policy on the OWU IRB website)	☐	☐
The activities meet the HSR definition of "Research" (Section II.B) (also see Interpreting the definition of "Human Subject" and "Research" in the HSR policy on the OWU IRB website)	☐	☐
The research involves deception or incomplete disclosure (i.e., participants will not be informed	☐	☐

The research involves the collection or recording of behavior which, if known outside the research, could reasonably place participants at risk of criminal or civil liability or damaging to the participant's financial standing, employability, or reputation.	☐	☐
The research involves the collection of information regarding sensitive aspects of participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).	☐	☐
The research involves participants		

The research involves participants that are under 18 years old, prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.	☐	☐
Information will be collected anonymously (i.e., no identifying information will be collected and the identity of the participants will not be known to the investigator at any point).	☐	☐

Part III: Research Description

15. Provide a brief overview of the research project (designed for a general scientific audience). *

16. Describe how participants will be recruited. *

17. Indicate the expected age range and other relevant demographic characteristics. *

18. Describe any criteria that will be used to include or exclude participants from the initial sample. *

19. Indicate the number of participants you reasonably expect to include in your research. *

20. Briefly describe the research design. Be sure to describe any manipulation (e.g., of the environment) or intervention. *

21. Describe any data collection materials or instruments. *

22. Attach all materials related to data collection (e.g., surveys). PDF preferred.

Files submitted:

23. Describe the research procedures that are relevant to the participants' experiences. Be sure to indicate the typical duration of subject's participation. *

24. Described how informed consent will be obtained from participants or their legal representative. If deception or incomplete disclosure are used, provide a scientific justification for its use. If prospective agreement will be used in lieu of informed consent, provide a justification. *

25. Attach informed consent or prospective agreement document (if consent will be given orally, attach the script that will be read). PDF preferred. *

Files submitted:

26. Describe the debriefing procedures. If deception was used, be sure to specify how the deception will be undone during debriefing. *

27. Attach the debriefing document or script. PDF preferred. *

Files submitted:

28. Explain how the information obtained from participants will be stored and secured. If data will not be collected anonymously, describe the protocol that will be used to protect the confidentiality of all information obtained from participants during and after participation. *

29. Describe all potential risks (e.g., physical harm, psychological harm, stress, distress, or other risks) to participants during or after participation. Describe the actions that will be taken by investigators in the event of unforeseen risks or harms to participants. *

30. Describe any potential benefits (e.g., improved health for participants) of the research. Describe any incentives for participation, such as money or course credit. *

31. Briefly describe any relationship that participants might have with the investigators. If any relationship exists, describe the precautions that will be taken to protect participants from being coerced to provide informed consent, or to continue their participation. *

32. Describe the role of co-investigators in this research (e.g., will all the above information apply, or will their contact with participants or with participants' information be limited in any way). *

33. For all PIs (on all research proposals) and all co-investigators (on Expedited or Full review proposals), attach a certificate of completion for the NIH Protecting Human Research Participants course or similar ethics training. PDF preferred. *

Files submitted:

34. Research Assurances *

Check all that apply.

	Yes
By checking this box, the PI gives assurance that 1) the statements herein are accurate and not misleading, 2) participants will be afforded all protections set forth in the Belmont Report unless specified above, and 3) all investigators will abide by the OWU HSR policy, including obtaining informed consent or prospective agreement and informing the IRB of any proposed changes to the research during the approval period.	☐
By checking this box, the PI gives assurance that noncompliance	☐

and unanticipated problems related to this research will be reported to the IRB in a timely fashion. See the OHRP guidance on these issues for more details.