OBERLIN COLLEGE
REQUEST FOR IRB REVIEW OF
USE OF HUMAN PARTICIPANTS IN RESEARCH

For use by IRB Administrator only
Proposal No:
Date Received:
Date Approved:
Expiration Date:
☐ Exempt (Category:)
☐ Expedited (Reviewers:)
☐ Full Committee
Notification Sent:
Signature:

Submit a completed copy of your application and all supporting materials to **ocirb@oberlin.edu**. Please do not send Google docs. Review of protocols cannot begin until the IRB has received all materials in the required formats. To ensure expeditious review of this project, be as specific and complete as possible in responses and provide all necessary supporting materials (e.g., recruitment text, consent forms, letters of support from participating organizations, surveys, interview questions, and, if relevant, debriefing).

All investigators must sign forms before submitting and **student protocols** must have the faculty supervisor's signature at the end of this document.

Today's Date:
Principal Investigator (PI):
PI T# (Students Only):
PI Telephone:
PI Email:

List all **other investigators/team members** who will participate in the consent process, interact with subjects, analyze data, or contribute to the project.

Name: **Role on project:** **Email:**
Name: **Role on project:** **Email:**
Name: **Role on project:** **Email:**

If the Principal Investigator is a **student**, please list the faculty supervisor's name and email. The supervisor's signature must also appear at the end of this form.

Name of faculty supervisor: **Email:**

What is the **Project Title?**

Which of the following does this **Project Involve?**

☐ **Faculty research**
☐ **Student course-based research (in a faculty taught course)**
☐ **Student independent research (Honors, or other independent study)**
☐ **Other** (please specify):

What is the **Anticipated Start Date?**

What is the **Anticipated End Date?**

Please Note: The anticipated start date cannot predate IRB approval. NO RESEARCH may be done before IRB approval of your protocol.

A. NATURE OF THE PROJECT

A1. In 250 words or less, briefly **summarize your proposed research project** in terms suitable for a general audience. What are the study objectives? What is the population or sample size? What is the basic methodology? How do the benefits of the research justify any possible risks that might be incurred by the participants in the study?

Enter Text:

A2. Specify the procedures that will be used in the study. This section should include the following:

(a) a description of your **methods**, including rationale for the method(s), details of data collection including how you will record the information: if you use a data sheet, include the sheet. If multiple experiments are to be done, describe each separately. Include all interventions, experimental manipulations, data collection procedures, and measurements;

(b) a description of how you will **recruit** your subjects;

(c) all verbal/written **statements** that will be made to participants, particularly any statements that might be misleading or deceptive, as well as statements during the debriefing period;

(d) all **written materials**, including questionnaires, surveys, or tests, to be given to or served online to participants during the course of the study. If your methods involve conducting "open-ended" interviews or focus groups, you should submit an outline of the areas you will cover and basic questions that will be asked to guide the subjects. (All supporting materials should be sent as MS Word files via email to ocirb@oberlin.edu at the same time you submit the application.)

Enter Text:

A3. Where will your research take place (i.e., geographic location and/or performance site)? If outside

the U.S., please discuss the country's research regulations and any possible added risks for your subjects. Projects dealing with advocacy, history, minorities, politics, religion, refugees, roots or sexuality may not be welcome in the host country. See International Research for information. Investigators should have a resource person in the country where the research will be carried out.

Enter Text:

A4. Which of the following **data collection methods** are used in this study? (Indicate all that apply.)

☐ **Survey**
☐ **Social Media**
☐ **Observation**
☐ **Interview**
☐ **Focus Groups**
☐ **Video Recording**
☐ **Audio Recording**
☐ **Photographs**
☐ **Scientific or Technological Devices (ex. EEG, biometrics, etc.)**
☐ **Other** (please describe):

A5. If your project includes an **online survey,** please attach a PDF and describe any security measures to maintain anonymity and confidentiality. A copy of the survey must be sent to the IRB before the proposal can be reviewed and approved.

Enter Text:

Enter Survey Link:

A6. If your project involves **observation**, describe what behaviors/interactions you will be observing and how you will record the data.

Enter Text:

A7. What is the **anticipated product** of this research project? (Indicate all that might apply.) Please note that additional use or presentation of the research that is not listed here will require an amendment request to IRB.

☐ **Course paper**
☐ **Web page**
☐ **Public presentation**
☐ **Honors thesis**
☐ **Publication**
☐ **Other** (please describe):

A8. Is the Project currently funded? If yes, by whom? Is funding is being sought for the project? If yes, from

whom?

Enter Text:

A9. Does this research project engage in **Community Based Research** or **Community Based Participatory Research** (i.e., a collaborative approach that involves engaging community members, researchers, and organizational representatives as equal partners in the research)? If no, write "no." If yes, please explain.

Enter Text:

A10. Does this research potentially qualify as **Exempt Research**? (See sections J for Exempt Categories.) If no, write "no." If yes, please explain and list the possible category numbers (1-8).

Enter Text:

B. PI TRAINING

B1. All Oberlin College student researchers involved with human subjects research must complete one of the prescribed, CITI Human Subjects online training courses. (All CITI completion records are automatically sent to the IRB Chair.) If you are confused about which course or learner group to sign up for, visit the IRB website or email ocirb@oberlin.edu.

☐ I have successfully completed a CITI **Human Subjects** course (either Social & Behavioral Research Investigators **OR** students conducting no more than minimal risk research).

Certificate #:

☐ All other members of my research team have completed a CITI course.

Names and Certificate #: (Include a separate document if the list is extensive.)

B2. If you are a student, please describe your **training and preparation for this project** (e.g., a methods course, work on previous research projects).

Enter Text:

B3. If applicable, please describe how you will **train your research team members.**

Enter Text:

C. PARTICIPANT POPULATION

C1. What **type of participants** will be involved in your research? (Indicate all that apply.) Please note that research involving Minors requires an assent process in addition to parental consent and that some Oberlin Students may not be 18 years old and may not participate in research without parental consent. Plan consent and assent procedures or your consent form should say, "you must be 18 years old to participate."

☐ **Adults**
☐ **Minors** (under 18 years old)
☐ **Oberlin Students**
☐ **Other Vulnerable Populations** (e.g., institutionalized persons, persons with diminished capacity) (please specify)
☐ **Other:** (please specify)

C2. Does your research involve any **Institutional Affiliations?** (Indicate all that apply). Please note that research involving off-campus institutions such as hospitals, schools, prisons, or other social service agencies requires approval from that institution's IRB or comparable research review board or agency official. Documentation of approval from external agencies is required and should be submitted along with this application. If you plan to work with other institutions, please describe who you are working with (name, contact info) within the organization/agency and any procedures or review process that you have been asked to follow.

☐ **No institutional affiliation outside of Oberlin College is involved**
☐ **Schools** (please specify)
☐ **Hospitals** (please specify)
☐ **Other** (please specify)

Enter Text:

C3. How will the participants be **solicited or contacted** (e.g., ads, telephone, letter, announcements made in courses, M-TURK, etc.)? Include all materials, texts, scripts that will used with participants with your application.

Enter Text (or attach a copy):

C4. Will any participants need to have documents (invitation, recruitment, consent, directions) or verbal interactions **translated?** If no, write "no." If yes, please explain who will translate and include any translated materials with your application.

Enter Text:

C5. Will any **incentives** (ex. payment, course credit, etc.) be offered to the participants? If no, write "no." If yes, please explain the nature and amount of incentive and how any monetary payments are being funded.

Enter Text:

C6. How long will it take a participant to complete all study procedures (e.g., 2 hours, 15 minutes)? Please be

specific.

Enter Text:

D. RISKS and BENEFITS

D1. Will participants incur any psychological, social, physical, or legal **risk**? This includes any psychological distress associated with experimental manipulations. If no, write "no." If yes, please explain the nature of the risk.

Enter Text:

D2. Will the participants be **deceived or misled** in any way? If no, write "no." If yes, please explain the nature of the deception.

Enter Text:

D3. Will there be any probing (either verbal or in written form) for information that participants might consider to be **personal or sensitive**? If no, write "no." If yes, please explain the nature of the information.

Enter Text:

D4. Will participants be presented with materials, or be exposed to social interactions, that they might consider to be **offensive, threatening, or degrading**? If no, write "no." If yes, please explain the nature of the materials or social interactions.

Enter Text:

D5. Will participants be **recorded** in any of the following ways? (Indicate all that apply.) If you answer "yes" to any of the options, please describe the devise and/or program and how/when these records will be used, protected, archived or destroyed. If you are recording, filming or photographing participants, your consent process/documents must include a statement that recording/photographic devices will be used. You must also state what will be done with the recordings/pictures upon completion of the study (published, destroyed, erased, archived, kept for future studies, etc.). Please provide a separate line on the consent form for the subjects to agree to be photographed, filmed or recorded.

☐ **Audio Recorded**
☐ **Video Recorded**
☐ **Filmed**
☐ **Photographed**

Enter Text:

D6. If you answered "yes" to any of the questions in this section, please explain how you will minimize any risks. Include a description of the Data Protection methods/programs that will be used.

Enter Text:

D7. How might a subject **benefit** from participating in this research?

Enter Text:

E. CONFIDENTIALITY

E1. Will data be collected that **identifies individuals** or that will be recorded in a way that allows observations to be linked to individuals? Please note that too many demographic data points may allow unintended identification of subjects. If no, write "no." If yes, please explain the nature of the information and the manner in which it will be disseminated.

Enter Text:

What types of **demographic data** will be collected? (Please indicate all that apply.)

- ☐ **Names of People**
- ☐ **Ethnicity**
- ☐ **Names of Employers**
- ☐ **Addresses**
- ☐ **Marital Status**
- ☐ **Types of Employees**
- ☐ **Phone Numbers**
- ☐ **Gender Identification**
- ☐ **Income**
- ☐ **Social Security Number**
- ☐ **Age**
- ☐ **Job Title**
- ☐ **Religious Affiliation**
- ☐ **Membership** (team, group, club, political party, etc.)
- ☐ **Other unique information** (explain)

E2. Will any personal data be drawn from **institutional files or archives** (e.g., school files)? If no, write "no." If yes, please explain the source and nature of such data, and who will give you permission and access to these records.

Enter Text:

E3. Who will have access to **raw data** (e.g., PI, Research Assistant, Faculty Adviser, staff, public, funder)?

Enter Text:

E4. What steps will be taken to insure **confidentiality of personal data?** Please be specific. Will research personnel (including students) be informed of their responsibilities in maintaining confidentiality? How will confidentiality be preserved as data are collected, stored, analyzed and published? When will data identifying individual participants be destroyed?

Enter Text:

F. DATA STORAGE/DISPOSITION

F1. Describe how will you keep your **data secure and maintain confidentiality** during the course of your project.

Enter Text:

F2. Describe how will you ultimately **dispose of your data** (notes, drafts, lists of subjects, photographic records, tapes, computer disks, etc.) after you have completed your research (e.g. shredding, burning). Please note that all research records must be maintained for at least three years after the completion of the research, including consent forms, flyers, etc. If you do not plan to destroy research data, please provide a justification for maintaining the data for an indefinite period of time and how you will ensure confidentiality.

Enter Text:

G. VOLUNTARY PARTICIPATION/INFORMED CONSENT

The information below should be included in an informed consent document, that should be submitted with this protocol. Include with your application a copy of the consent form or alternate information form/text if you have requested a waiver. The form you submit should be the **exact form** that you will use with your subjects.

Federal law requires that, except in special circumstances, informed consent must be obtained. In brief, consent forms must include (1) a statement explaining the purpose, procedures, and duration of the project, (2) a description of benefits to the participant and others, (3) a statement describing the manner in which confidentiality will be maintained (4), a statement of any risks involved (5), contact information should questions arise in the future, and (6) a statement that participation is completely voluntary.

If a consent form is not to be used, the researcher must provide a justification, for instance in the case of web-based surveys where consent can be implied by participants accessing a web-site. In addition, researchers must provide participants with contact information for a person affiliated with the project and for the IRB should questions arise. Include the following: "Should you have questions regarding your rights as a research participant, please contact the Oberlin College Institutional Review Board, Cox 101, (440-775-8410) or email:

ocirb@oberlin.edu." Sample consent forms may be viewed and downloaded from the Oberlin College IRB forms web page.

G1. What steps will you take to ensure that participation is **voluntary**? Be sure to provide the script for information provided by research personnel or written materials to be given to the participant.

Enter Text:

G2. How will **information about the study** be provided to potential participants? If it is necessary to obtain participation without informing participants of the true nature of the study, include a script for information that will be provided by research personnel or written material that will be given to participants. If participants are to be debriefed after participating, include debriefing script or materials.

Enter Text:

G3. If research involves **participant observation**, how will the researcher's role be explained to other participants in observed activities?

Enter Text:

G4. If participants are **minors** (under 18 years old), will parents' or guardians' consent be obtained? If not applicable, write "not applicable." If no, please explain. If yes, please explain and include a copy of the consent and assent forms with the application.

Enter Text:

H. LEVEL OF REVIEW: IRB Committee Use Only

☐ Exempt (*check off all categories that apply*)

☐ Expedited

☐ Full Committee

Protocols MUST be received by the IRB at least 2 weeks before the next scheduled IRB meeting. See **schedule**. Send application and any/all additional documents as email attachments to ocirb@oberlin.edu. Please remember to keep copies of all materials submitted to the IRB. If you need help, please call 440-775-8410 or email ocirb@oberlin.edu

I. ASSURANCE STATEMENT

I confirm that the procedures described above are accurate and will be followed in the course of the research project. I will notify the IRB of any changes to procedures and if unanticipated problems arise during the

research process.

Printed Name of Researcher: **Date**:

Students: This form **MUST** be reviewed and submitted via email by your faculty supervisor

Printed Name of Faculty Supervisor: **Date**:

Faculty Supervisors/Advisors: Please initial below, indicating you have performed the duties listed for **Faculty Advisors**

Initials:

J. Exemption Categories: IRB Committee Use Only

☐ (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ (3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the

subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels

of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

☐ (6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ (7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

☐ (8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.