

Application for Exempt Status for Human Subjects Research

University of Hawaii - Human Studies Program

1960 East-West Road, Biomedical Building B-104, Honolulu, HI 96822, (808) 956-5007, uhirb@hawaii.edu

Aloha! Most research involving human subjects at the University of Hawaii must be approved by the UH Human Studies Program. Some research may be exempt from certain Federal requirements. Please read and follow all instructions carefully when filling out this application. For more information, please go to the Human Studies Program website at www.hawaii.edu/irb or contact our office with any questions. Underlined words are defined in the Glossary on page 5.

I. Is Your Project “Research”?

To determine if your project qualifies as research, please answer the question below.

If you answer “Yes” to the following question, your project meets the federal definition of research. Please answer Section II to determine if your project is <u>human subjects</u> research. If you answer “No”, your project does not meet the federal definition of research. No application is required.	
1. Is your project a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to <u>generalizable knowledge</u> ? (Underlined words are defined in the Glossary on page 5.)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

II. Is Your Project “Human Subjects” Research?

To determine if your project qualifies as human subjects research, please answer the questions below.

If you answer “Yes” to either of the following 2 questions, your project does not require Human Studies Program review and approval and you do not need to complete or submit this application.	
1. Does your project involve only the analysis of publicly available data? Examples include census data, large public survey data sets with no individual identifiers, and public information available on the internet.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2. Is this a UH class project (whether individual or group) from which the data will only be submitted to your instructor for a class grade and will not be published, presented at an academic conference, given to an agency as a formal report, and will not be used in future research or to qualify for a graduate degree (e.g. Master’s or Doctoral dissertation)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If your answer to the following questions is “Yes” for both 1 and 2, or both 1 and 3, please complete Section III of this form. If you answer “No” for 1, 2, and 3 below, your project does not require Human Studies Program review and approval and you do not need to complete or submit this application.	
1. Does your research involve obtaining information about living individuals?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2. Will the information be obtained through intervention or interaction with these individuals?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. Will your research involve access to <u>private information</u> from which individuals can be identified directly or indirectly through a link or code? This includes access to existing data that identifies individuals but these individuals will not be contacted in your research project.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

III. Categories of Exemption

Complete all the categories below that apply to your research. If a category does not apply to your study, check “Not Applicable” (N/A). If your research does not meet the requirements for any of the six categories below, please complete and submit the standard Application for a New Study available on the Human Studies Program website at www.hawaii.edu/irb under “Forms”.

Research on Educational Practices (Federal Category 1)	<input type="checkbox"/> N/A
Your research will take place in an established or commonly accepted <u>educational setting</u> , involving normal <u>educational practices</u> .	<input checked="" type="checkbox"/> Yes
If Yes, complete Section IV and Section V of this application.	

Research Involving Surveys or Interviews (Federal Category 2)	<input checked="" type="checkbox"/> N/A
1. Your research will involve the use of educational tests, surveys or interviews for participants ages 18 and older. (educational tests may include cognitive, diagnostic, aptitude, and achievement tests)	<input type="checkbox"/> Yes
2. Your survey/interview research will involve only adult participants (18 and older) who would not be considered part of a <u>vulnerable</u> population. (for definitions, see Glossary on page 5)	<input type="checkbox"/> Yes
3. The research data that you collect (including field notes) will be recorded in such a manner that if participants can be identified, they would not be at risk of damage to their reputation, financial standing, employability, or criminal and civil liability or this data will be recorded anonymously (so that participants cannot be identified, either directly or through identifiers linked to them).	<input type="checkbox"/> Yes
If you answered "Yes" to 1, 2 and 3, complete Section IV and Section V of this application.	

Research Involving Public Observation (Federal Category 2)	<input checked="" type="checkbox"/> N/A
Your research will involve observation of human subjects in a public setting where there is no expectation of privacy.	<input type="checkbox"/> Yes
If Yes, complete Section IV of this application.	

Research Involving Public Officials (Federal Category 3)	<input checked="" type="checkbox"/> N/A
Your research will involve surveying or interviewing elected or appointed public officials (or candidates for public office).	<input type="checkbox"/> Yes
If Yes, complete Section IV and Section V of this application.	

Research Involving the Use of Existing Data (Federal Category 4)	<input checked="" type="checkbox"/> N/A
1. Your research will involve the study of <u>existing data</u> , documents, records, pathological specimens, or diagnostic specimens.	<input type="checkbox"/> Yes
2. You will record the information in such a manner that participants cannot be identified either directly or through identifiers linked to the participants, or the sources of these data are publicly available.	<input type="checkbox"/> Yes
If you answered Yes to 1 and 2, complete Section IV of this application.	

Research Involving Public Benefit or Service Program Evaluation (Federal Category 5)	<input checked="" type="checkbox"/> N/A
Your research will evaluate, study or otherwise examine a <u>public benefit or service program</u> at the request of a department or agency head. (IRB approval is required to perform research under this category.)	<input type="checkbox"/> Yes
If Yes, complete Section IV and Section V of this application.	

Research Involving Taste and Food Quality (Federal Category 6)	<input checked="" type="checkbox"/> N/A
Your research will involve an evaluation of taste and food quality, or a consumer acceptance assessment.	<input type="checkbox"/> Yes
If Yes, Complete Section IV and Section V of this application.	

IV. Description of Project

Please attach 1-2 typed pages answering questions 1 through 6.
(Do **not** attach a master's proposal or contract/grant.)

1. Briefly describe the purpose and objectives of your research in non-technical language.
2. Briefly describe your research design and methods.
3. For research being conducted as "educational practice," describe how the activity being studied is part of "normal" educational practice.
4. If you are using existing data, describe the source(s), the extent to which individuals are identified, and how you have access to the data.

5. If your research will be observational, describe how the observations will be recorded (e.g., audio, video, field notes). If you are planning to audio or videotape the participants, please see Section V. If videotaping, please explain how you plan to use and store the videotape(s). In most cases, if your project involves videotaping, it will not qualify as exempt.
6. Describe your participant population (e.g., age, as special needs, etc...). How will you identify, contact and recruit participants? How many participants do you intend to involve in your research? How will you explain your research to participants?

V. Attachments

1. Please provide a consent form to be given to research participants. Examples can be found on the Human Studies Program website under "Sample Consents".
 - a. If audio or video recordings will be a part of the research records, there must be a clear description in the consent form of: 1) how the recordings will be used, including any uses beyond this research project; 2) how the recordings will be stored; and 3) what will be done with the recordings when the project is complete. A separate consent form, or yes/no checkbox on the main consent form must be provided so that participants can agree or refuse to be recorded.
 - b. As applicable, include language in the consent form that describes how the data or recordings are likely to be used for future research purposes.
2. For research involving minors (ages 17 and younger), you must provide the following:
 - a. A parent/guardian consent form for their child to participate in research that includes space for a signature and date.
 - b. A way of obtaining assent or refusal to participate from the child(ren) that is understandable to them. If the participants are 5 to 11 years old, please provide an oral assent script with an explanation of how you will explain the project to them and obtain their assent or refusal to participate. If the participants are 12 to 17 years old, please provide a written assent form that includes space for a signature and date.
3. Attach a copy of all survey instruments and interview guides. If you are using recruitment flyers, or advertisements, please provide copies of these as well. If draft instruments are submitted, final drafts must be submitted for final Human Studies Program approval before use.

Approval of this Exempt Application is valid for the entire life of the research project and does not need to be renewed annually. However, any changes in the procedures or instruments must be prospectively approved by the Human Studies Program, a process which can occur via email for Exempt projects. Once the study is complete, please notify the Human Studies Program.

If you have questions, or you are unsure whether your research project is Exempt, please call the Human Studies Program office at (808) 956-5007, or send an inquiry by email to uhirb@hawaii.edu.

VI. How to Submit Your Application:

Please provide the Human Studies Program with this application (typed and signed on page 4), a description of the project, and all relevant documents listed in Section V.

- **Mail or Deliver:** Send/provide 2 copies of all materials (collated) with original signatures to UH Human Studies Program, 1960 East-West Road, Biomedical Building B-104, Honolulu, HI 96822.
- **Email to:** uhirb@hawaii.edu. Subject line: "Exempt Application". A signed application is required. To convert your signed application to an e-file, please scan.
- **Fax to:** (808) 956-8683. Applications must be signed and dated.

VII. Glossary

Assent A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Application Form (these forms are found on the Human Studies Program website under "Forms" at www.hawaii.edu/irb).

- **Application for Exempt Status for Human Subjects Research** Use this application to determine if and to apply for Human Studies Program approval as an exempt study.
- **Application for New Approval of a Study Involving Human Subjects** Use this application for research that is not exempt.

Consent Form A document which explains a research study (including a description of any procedures, the potential benefits and risks of participation, etc.) to potential research participants. Most consent forms require a signature and date of the participant. By signing the consent form, a participant asserts his or her voluntary agreement to participate in a study. Examples of consent forms are available on the Human Studies Program website at www.hawaii.edu/irb.

Educational Practices Includes teaching, curriculum development and other activities consistent with the process of formal education.

Educational Setting A school, classroom, and other locations where formal education is typically conducted.

Exempt Research Under federal regulations, specific categories of research can be designated as exempt from certain regulatory requirements as well as initial and continuing review by the IRB. Research at UH must be approved as exempt by the UH Human Studies Program.

Existing Data Data that has been previously compiled for research or non-research purposes, such as school records or census information. Existing data may include data sets, interview notes or audio or video tapes.

Generalizable Knowledge When study results are intended to answer a research question, to draw conclusions about a specific premise (or hypothesis), or to apply study results beyond the specific focus of the research (the research data or study participants), they are considered to be generalizable. Study results that will be published (in a scholarly journal, book, or on-line), placed in a library (such as a master's or doctoral dissertation), or presented at an academic meeting are considered to be generalizable.

Human Subject A human subject is a living individual about whom a researcher, whether professional or student, obtains data through intervention or interaction, or obtains identifiable private information about them.

Informed Consent The process by which a person voluntarily agrees to participate in research based on adequate knowledge and understanding of the research project.

Identifiable Data Data that can be used to identify individual research participants. Identifiers include but are not limited to names, addresses, phone numbers, social security numbers, geocodes, and images (but not voices). Identifiers may also include codes that can be used to link an individual's identity with information about them.

Private Information Information that an individual would reasonably expect to not be shared without the individual's permission. Private information may also refer to observed behavior about a person in a setting in which the person would not expect to be observed for research purposes without permission.

Public Benefit or Service Program A government agency or program established to provide services to eligible members of the public (e.g. WIC, Veterans Affairs, etc.) Research must be supervised by the agency in charge of the public benefit or service program. Please contact the Human Studies Program office if you believe your project may qualify under this category.

Vulnerable populations Children, prisoners, pregnant women, physically or mentally disabled persons, or economically or educationally disadvantaged persons.