

Exempt Research

The Committee for the Protection of Human Subjects (CHS) provides this form to investigators who plan to conduct "exempt" research involving human subjects. Use this form to determine whether your intended research involves human subjects and is exempt, and also to make a formal declaration of its status. This declaration helps both CHS and investigators in the task of separating research involving human subjects into two categories: 1) exempt research, which is not subject to regulation but which must be reported to the CHS nevertheless, and 2) non-exempt research, which must be submitted for full review and approval by the Committee before it begins.

Please follow all instructions carefully in making your declaration of exemption. This declaration will be checked for completeness and consistency, and incomplete or inconsistent forms will be returned to investigators.

IMPORTANT NOTICE: It is CHS and University policy that all research involving human subjects, whether exempt or non-exempt, funded or not, must be reported to the Committee. This rule has been instituted to protect both research subjects and investigators. Exempt research is not subject to regulation by the Committee (although it must still be reported). Non-exempt research, on the other hand, must be reviewed and approved by the CHS before it begins. Failure to report and receive Committee approval prior to the conduct of non-exempt research involving human subjects is a violation of University policy and, in some cases, federal law. By filling out this form and submitting it to CHS for verification prior to beginning your exempt research, you protect your own best interests as an investigator.

Step 1. CONFIRM THAT THE RESEARCH INVOLVES HUMAN SUBJECTS.

Does the research in question involve a living individual about whom an investigator (whether professional or student) conducting research activities obtains either:

- (1) Data through intervention or interaction with the individual (Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.) or
- (2) Identifiable, private information? (Identifiable in this context implies that the identity of the subject is or may readily be ascertained by the investigator or associated with the information obtained as part of the research. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

YES NO

If 'YES', you must either: (1) complete and submit this form if you believe that the research is exempt, or (2) submit a full protocol for review and approval by the CHS (please consult the Committee's Guidelines).

If 'NO', then the research does not involve human subjects, and there is no need to complete this form or to notify the CHS about the research, except in research that will involve the use of human blood, tissue or other pathological specimen. Such research requires CHS review and approval but may qualify for exemption if anonymous and pre-existing (see exemption category #6 for this, if applicable).

NOTE: It is possible to conduct research that involves living human beings who are not considered human subjects by definition. Examples of research on living human beings that may involve no interaction, intervention, or identifiable private information include: analyses of aggregate human data (e. g. census data, labor statistics), studies of public statements or declarations, analyses of individual-level data (even on private topics) if the respondents are not identifiable (e. g. , survey data distributed for public use). If you are unsure whether a research project involves human subjects or is exempt from regulation, you should call the CHS office at (808) 956-5007, or send an inquiry by email to dendle@hawaii.edu.

In order to determine whether your research involving human subjects is exempt and to fulfill your responsibility to report exempt research to the CHS, please complete Steps 2 through 4.

Do any of the targeted populations for this research project consist of persons who are: legally incompetent; significantly mentally ill or impaired; or vulnerable to extraordinary institutional coercion, such as prisoners, residents of 24-hour skilled nursing facilities, or anyone who is involuntarily confined?

YES NO

If 'YES', then the project is not exempt and you must submit a complete protocol for review by the CHS.

If 'NO', please continue.

Step 2. CATEGORIES OF EXEMPTION.

Please review the exemption criteria described in the CHS Guidelines before making a judgment that your project is exempt from full Committee review. These Guidelines, which are based on rules established by the federal government (see 45 CFR 46), specify that an investigation may be exempt from regulation if the only involvement of human subjects will be in one or more of the following categories:

1. Educational Practices
2. Educational Tests
3. Surveying or Interviewing
4. Public Observations
5. Public Officials
6. Existing Data

Please state (by number) the category(ies) of exemption(s) that characterize this research project: _____

NOTE: All procedures for all subjects in this research project must be exempt in order to qualify for exemption. Further explanation of these exempt categories follows. Please proceed to Step 3.

Step 3. JUSTIFICATION OF EXEMPTION.

Fill out only those portions in Step 3 pertaining to the categories of exemption claimed in Step 2.

1. Educational Practices (1)

- A. Will this research involve the examination of school records for identifiable students, or the interviewing of instructors or other persons about identifiable students?

YES NO

If 'YES', then the project is not exempt and you must submit a complete protocol for review by the CHS.

If 'NO', then proceed to part B.

- B. Will the research be conducted in established or commonly accepted educational settings and involve normal educational practices, such as:

(i) Research on regular and special educational strategies; or

(ii) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods?

YES NO

If 'YES', then the research is exempt and proceed to part C.

If 'NO', then the project is not exempt and you must submit a complete protocol for review by the CHS.

- C. Please provide adequate details, on an attached sheet, about the educational setting and practices involved in this research to justify your answer in part B above.

2. Educational Tests (2)

- A. Does the research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) possess at least one of the following two conditions?:

(i) In the researcher's private data (including field notes) as well as in any published material, information taken from these sources is recorded in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects; or

(ii) The information, if disclosed outside the research, could not reasonably place the subject at risk of criminal or

civil liability or be damaging to the subject's financial standing, employability, or reputation.

YES NO

If 'YES', then the research is exempt. Please indicate which condition(s) above apply _____ and proceed to part B.

If 'NO', then the project is not exempt and you must submit a complete protocol for review by the CHS.

- B. Please provide adequate details, on an attached sheet, about the educational testing involved in this research to justify answer in part A above.

3. **Surveying or Interviewing (2) (3)**

- A. Will any of the subjects involved in this research be minor children? If children will be excluded from this research through an initial screening mechanism, such as asking the age of respondents at the beginning of an interview, then the appropriate answer to this question is 'NO'. "Minor Children" are persons who have not attained the legal age for consent under the applicable jurisdiction in which the research will be conducted. In the United States, this age is 18 years.

YES NO

If 'YES', then the project is not exempt and you must submit a complete protocol for review by the CHS.

If 'NO', please proceed to part B.

- B. Does the research involving surveying and interviewing possess at least one of the following two conditions?
- (i) In the researcher's private data (including field notes) as well as in any published material, responses are recorded in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects; or
 - (ii) The responses, even if disclosed outside the research, could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

YES NO

Note: Except in unusual political circumstances, surveys or interviews concerning attitudes on public issues are within section B. (ii) of this exemption.

If 'YES', then the research is exempt. Please indicate which condition(s) above apply _____ and proceed to part C.

If 'NO', then the project is not exempt and you must submit a complete protocol for review by the CHS.

- C. Please provide adequate details, on an attached sheet, about the surveying and interviewing involved in this research to justify your answer in part B above.

4. **Public Observations (2)**

- A. Will you participate in activities involving minor children at any time during the course of this research? If children will be excluded from this research through an initial screening mechanism, such as asking the age of respondents at the beginning of an interview, then the appropriate answer to this question is 'NO'. "Minor Children" are persons who have not attained the legal age for consent under the applicable jurisdiction in which the research will be conducted. In the United States, this age is 18 years.

YES NO

If 'YES', then the project is not exempt and you must submit a complete protocol for review by the CHS.

NOTE: Research involving observation of minors may qualify for exemption (if one of the conditions in part B. below is met). Any research involving participation in activities involving minors, however, is ineligible for exemption, except as provided under CHS exemptions #1 or #2.

If 'NO', please proceed to part B.

- B. Does the research involving the observation of public behavior possess at least one of the following two conditions?

- (i) In the researcher's private data (including field notes) as well as in any published material, observations are recorded in such a manner that individual human subjects cannot be identified, either directly or through identifiers linked to the subjects; or
 - (ii) The observations, even if disclosed outside the research, could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- YES NO

If 'YES', then the research is exempt. Please indicate which condition(s) above apply _____ and proceed to part C.

If 'NO', then the project is not exempt and you must submit a complete protocol for review by the CHS.

- C. Please provide adequate details, on an attached sheet, about the public observations involved in this research to justify your answer in part B above.

5. Public Officials (3)

- A. Are all of subjects of the research either elected or appointed public officials or candidates for public office? Please note that the staff of public officials, public administrators, and most personnel in state or federal agencies are not considered by the CHS to fit the definition of a "public official". If such persons will be subjects of research (perhaps in addition to public officials), then their participation may qualify separately for exemption under categories #2, #3, or #4, provided that this component of the research meets the appropriate criteria. Please complete all applicable pages of this form for the various human subjects involved in this project.

YES NO

Does the research involve educational tests, survey or interview procedures, or public observations?

YES NO

If all answers above are 'YES', then the research is exempt and proceed to part B.

If all answers above are 'NO', the project does not qualify for this exemption and you must submit a complete protocol for review by the CHS, or seek another exemption category that may apply to this research.

- B. Please provide adequate details, on an attached sheet, about the research involving public officials in this research to justify your answers in part A above.

6. Existing Data (4)

- A. Does the research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens possess at least one of the following two conditions?

- (i) These sources (data, records, specimens, etc.) are publicly available; or
- (ii) Both in the researcher's private data (including field notes) and in any published material, the information is recorded by the researcher in such a manner that subjects cannot be identified, either directly or through identifiers linked to the subjects.

YES NO

If 'YES', which condition(s) above apply? _____ Please proceed to part B.

If 'NO', then the project is not exempt and you must submit a complete protocol for review by the CHS.

- B. Please provide adequate details, on an attached sheet, about the use of existing data involved in this research to justify your answer in part A above.

Please attach a brief description or abstract of your proposed research. It must provide sufficient detail of the intent of the research and the involvement of human subjects to allow reviewers to make a thorough evaluation. If applicable, attach a copy of the survey instrument, consent and assent forms.

Send or deliver a signed original and 1 copy. Faxed/E-mail applications are not accepted.

I affirm that the above, to the best of my knowledge, is a true and accurate description of my proposed research.

Signature of PI: _____

Date: _____

Have you completed:

UH Researcher training (4 hour) YES NO

NIH On-line training YES NO