

GUIDELINES FOR SUBMITTING REQUESTS FOR EXEMPTION FROM IRB REVIEW OF RESEARCH USING HUMAN SUBJECTS

I. Necessity for Review

It must first be determined whether or not the activity to be undertaken involves research and involves human subjects. In a college setting there is frequently a pedagogical as well as research function to activities, especially in group student projects, which may make it difficult to determine whether actual research is involved as opposed to teaching the methodology of research.

Research is defined by federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." [Federal Policy 45CFR45.102(d).] Resulting *generalizable knowledge* is the key element in the definition. If results of a study are to be published, presented in a paper or otherwise implied to have implications beyond the test population, this is considered evidence of the intent to obtain generalizable knowledge.

Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [Federal Regulation 45CFR45.102(f).] Additionally, there are guidelines that distinguish therapeutic activities from research in the health fields. If the Responsible Project Investigator is unsure as to whether an activity should be classified as research, the Chair of the Institutional Review Board (IRB) should be consulted.

II. Determining Exempt Status

Research involving human subjects or data derived from human subjects falls into one of three review categories: Exempt, Expedited and Full IRB Review. To be exempt the research must meet the following conditions.

Exempt Research

- A. Categories of exempt research are established by federal regulations and cannot be amended. In general, research that does not disrupt or manipulate subjects' normal life experiences, or incorporate any form of intrusive procedures, may be exempt as long as it does not include one of 12 exceptions to the provisions for exemption (see Exemption Decision Aid attached to the Application for Review Exemption). These exceptions focus on more than minimal risk, lack of anonymity, and protection of vulnerable subjects. It should be noted that adults as well as children are subject to the above provisions, with additional protections in place for children.
- B. In the Application for Exemption, the criteria for exemption established by federal regulation 45CFR46.101(b)(1-6) are listed in the Decision Aid. If the proposed research conforms to one of these categories and does not include one of the 12 exceptions to the exemptions, then the investigator may apply for an exemption. When there is no more than minimal risk, some research involving vulnerable populations, particularly children, may be exempt in some instances. All six grounds for exemption may be applied to children except in some cases of exemption #2. The legislation regarding the differences in exemptions for children is as follows:

"The exemption at 45CFR46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at 45CFR46.101(b)(2) for research involving survey or interview procedures or observations of public behavior [of children] does not apply to research covered by this subpart, except for research involving observation of public behavior when the

Guidelines for Submitting Requests for Exemption from IRB Review of Research Using Human Subjects

investigator(s) do not participate in the activities being observed." [45CFR 46.401(b).]

- C. Based on applicable federal regulations and/or provisions of CCS administrative procedure 7.40.01A Research Involving Human Subjects, investigators whose research involves human subjects will not make final determination of exemption. Exemption requires the approval of the Principal Investigator's Department Supervisor.

III. Guidelines for Completing the Application for Exemption from Review

Principal Investigator. Please include all individuals, but not the faculty sponsor in case of student research unless the faculty member is actively involved as a researcher in the project. The mailing address listed here is the one to which all correspondence will be sent including requests for clarification and notification of approval/non-approval. Please list a telephone number where the PI can be reached, and email and/or fax if desired.

Responsible Faculty Sponsor. All student projects must have a faculty/staff sponsor who is officially liable for their work being conducted in accordance with the requirements of CCS and federal policy. Please include the faculty sponsor's campus phone number and mail stop.

Student's Course Requirements. All students must indicate, as applicable, what course the research is being conducted for, whether it is required to meet credit requirements, or, if it is not being conducted to meet an academic requirement, the reason for which it is being undertaken.

Anticipated starting date. This date must be subsequent to the date of submission of the application for exemption and allow sufficient time for review of the application. Applicants are reminded that they may not begin the research (e.g., collect data, recruit subjects), until they have received approval of their application.

Although every effort will be made to act upon applications as expeditiously as possible, it may take several weeks or more to review. It is therefore necessary that submission of requests for exemption be made sufficiently in advance of the need to begin the research. If there are unexpected time constraints beyond the applicant's control, e.g., a subject leaving the country, an unforeseen opportunity to gather data, etc., then you should explain this when you submit your application. If your proposal includes a pretest given at the beginning of a quarter you should submit your application for exemption the previous quarter.

Approval must be given before subject recruitment or initiation of any procedures that involve human subjects. Retroactive approval will not be given to use research data that were collected solely for the purpose of this research project prior to the date of approval. This does not mean that records and other data already collected for other purposes may not now be used for the specific project in the current application.

Rationale for exemption. Please state exactly why you feel the research meets the specific grounds listed in the exemption checked. If the applicant checks "yes" under any of the twelve conditions in the decision aid list that exclude an exemption then they should explain why an exemption should still be considered.

Purpose and methodology of the research. Please state concisely what the purpose of the research is and, as appropriate, the hypothesis to be tested, the dependent and independent variables, research methodology, etc. Be specific and provide sufficient information so that an informed decision can be made based on what the research will entail. Failure to provide sufficient information in this and the following question is the basic cause of slowing the approval process.

Procedure for the subjects. Please state explicitly what the subjects will be required to do for the research. To be exempt the subjects will usually be anonymous, not vulnerable, and will be involved in procedures that involve no more than minimal risk. If there is to be a survey or questionnaire administered please attach a copy of the questionnaire to the application as well as any written cover material or the script for an oral explanation

Guidelines for Submitting Requests for Exemption from IRB Review of Research Using Human Subjects

to the subjects as to what they will have to do. In cover material you should include IRB contact information using the following sentence: "If you have any concerns about your rights as a participant in this research or any complaints you wish to make, you may contact the Institutional Review Board Chairperson, Grants and Contracts Manager, at (509)-434-5185."

You should also indicate the method by which surveys, etc., will be distributed and collected in order to ensure anonymity. The normal procedure is for the Principal Investigator, rather than the subjects' teacher, supervisor, coach, etc., to pass the survey out to everyone in a class or at a meeting, telling them that they don't have to participate if they don't want to, and then have them return it anonymously to your mailbox or a manila envelope on the desk, in the office, etc. (as long as they don't hand them to the investigator). Alternately, the survey can be mailed, with an explanation of the project and instructions on how to return the survey anonymously; if a self-addressed, stamped envelope is provided there must be no identifying marks on it or the survey, for tracking or other purposes.

It should be noted that anonymous means that the investigator cannot associate the data with a specific subject. Confidential means that the investigator can associate a subject with his/her data but protects that association from being known by others.

If the researcher also has the role of teacher in relation to the subject, the pedagogical procedures should not be included, state only the procedures used in the research. Admittedly it will sometimes be difficult to distinguish between these two roles, but in the case of children, as a teacher the investigator can interact with the child, but when the same teacher is acting as a researcher they may not interact with the child or manipulate their environment solely for the purpose of the research (see above) and still be considered exempt. The latter case would entail a Full Board Review.

Vulnerable subjects. Depending on the specifics of the research, some vulnerable populations of subjects may not be granted exemptions that would apply to normal or non-vulnerable subjects.

Signatures. Applications without the requisite signatures will not be considered and will be returned to the applicant. All Principal Investigators for a project must sign the application.

Consent forms. Although a protocol that needs a consent form normally requires Expedited or Full Board review, there are some exceptions when a consent form is used for a protocol that would otherwise be considered exempt.

IV. Submission Instructions

The principal investigator should complete the Application for Review Exemption and submit it the investigator's department supervisor. This should be done in a timely manner prior to the start of research.

Approval of exempt protocols is valid for one year from the date of approval for students, and from one to five years for faculty and staff. Exempted research is not required to submit an IRB application. If research is to continue, with no substantial changes beyond that date, a renewal of approval must be obtained prior to continuation of the project. If, subsequent to initial approval, a research protocol requires minor changes, the department supervisor should be notified of those changes. Any major departures from the original proposal must be approved by the appropriate review process before the protocol may be altered.

The department supervisor should forward one copy of the approved application to the Grants and Contracts Office, MS 1006, for file.

V. Related Information

CCS administrative procedure [7.40.01A – Research Involving Human Subjects](#)