GRAND VALLEY STATE UNIVERSITY
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Human Research Review Committee

Human Subjects Research: Reference for Exempt Determination Applications

This document is designed to provide guidance to human subjects researchers completing the Application for Exempt Determination.

The federal regulations (**45 CFR 46**) governing human subjects research lists some categories of research as being exempt from the policy relating to Institutional Review Board (IRB) review. However, the policy also states that any "Exempt Status" determination must be made by a person with knowledge of human subject (HS) protections and regulations and not have a conflict of interest that might be perceived to affect the decision process (**e.g. researchers may not self-exempt their research**).

If the reviewer decides there is insufficient information or the nature of the research may not meet the exempt criteria, the researcher will be notified that a complete application for HRRC review will be required.

The Exempt Status Certification application associated with this guidance is designed to aid researchers in providing the Research Compliance Office with sufficient information to make a determination. It consists of contact information, a series of check-box type statements relating to the research, and three brief descriptions of the research. If the reviewer decides your application must undergo HRRC review, the text included in the exempt application can be copied to the IRB application.

Issuance of a determination of exempt status should not be construed or represented as HRRC approval. Once an exempt determination is made, an electronic document with project specific information (PI, title, and internal identification number) will be issued and can be used for inquiries by publishers, funding agencies, and others seeking to determine if regulatory requirements regarding this research were met.

The determination process is likely to be shorter than the HRRC review process. Exempt Status also means research does not require continuing annual review. If the basic methods remain the same, no further review is required under the regulations (however, GVSU policy may require a periodic status update for record-keeping purposes). Exempt Status does not mean exempt from human subjects protections; it just means your research is exempt from HRRC review.

The challenge in exempting projects from HRRC review is collecting sufficient information to make a determination and then maintaining adequate documentation of due diligence.

APPLICATION GUIDANCE:
PROJECT PERSONNEL

The primary investigator (PI) is the person who will be the primary contact for the Research Protections Program and the primary person responsible for ensuring the research methods employed in the future are consistent with the methods listed on the application. The primary investigator is also the signatory and submitter of the application. Students must send all application materials to their research advisor who will submit the application on their behalf.

Other key personnel should include faculty, staff, or students who will collect data or have access to data that includes information that could identify any subjects (this includes names or other unique identifiers or demographic information that could identify individuals in a known sample population, e.g. a class). Initially this information will be used to determine the type of personnel involved as well as the adequacy of training. It is the responsibility of the PI to ensure all key personnel working on an exempted project are adequately trained. Any project may be audited through the Post-Approval Monitoring program to determine if training standards are being met.

Undergraduate and graduate students must list a faculty advisor. The faculty advisor must approve of and submit the application in IRBNet (applications are not accepted directly from students).

Responsible Conduct of Research (RCR) training is required for all GVSU graduate students and those GVSU undergraduate students who have internal funding (e.g. McNair Scholars, S3, MS3, and students paid on GVSU R&D grants). National Science Foundation (NSF), National Institution of Health (NIH), and GVSU Research and Development Committee (R&D) funded research requires RCR training. All other investigators and personnel that will be in contact with subjects or data that can be linked to subjects are encouraged to complete RCR training every 3 years. Check to be sure all training is up-to-date before submitting your application.

PROJECT INFORMATION

Enter the title and anticipated beginning and ending dates for your research. Please note that your research may not begin until a determination has been made and you have received your letter. If your research is being supported by external funds, please list the source.

SUBJECT OF RESEARCH

Is the data being collected primarily *about* a program or other entity and collecting minimal demographic or personal information about the respondents?

While the answer "Yes" to this question does not necessarily exempt this research from IRB review, it is useful information for the reviewer when determining risk associated with the research. If the research is collecting

information about a program, for example, although collected from subjects, the data may not necessarily be *about* the subjects. However, such information can be harmful to the subjects. Imagine a subject being critical about a program associated with her employer. That information could jeopardize the employee if the employer learned of the criticism. Thus the Research Compliance Office will want to be assured that measures will be taken to protect the identity of the subject. Informing the subjects of the protective measures is important for your research because if the subjects feel the information they share will be held in confidence or without their identity associated with it, then they may feel comfortable sharing information they otherwise would not.

If the information collected is overwhelmingly *about* a non-human entity (e.g. GVSU Recreation Center), then risk to the respondents is reduced. For example, the question on a survey, "Are there enough elliptical machines at the recreation center?" is a question about the recreation center, whereas, "How many minutes per day and days per week do you spend at the recreation center?" is a question that gathers information about the survey respondent. Also, the reviewer must consider that the extent of demographic information that is collected can lead to increased possibility of identifying the subjects and the more possible it is for data to be used to harm a subject. While questions about the recreation center are relatively low risk, questions about health services or employers could be much more sensitive.

The answer to this question greatly informs the reviewer regarding the possibility that the project in question is a program evaluation or quality improvement project rather than a research project.

EXEMPTION CATEGORIES

Category 1:

Research will be conducted in established or commonly accepted educational settings (e.g. schools, training centers) involving normal educational practices, such as research on instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This category of research is applicable in normal educational settings when normal educational practices are being studied. The activities being studied must be those that could occur in the absence of research using metrics that would occur in the absence of research. For example, a high school teacher could have a method of teaching a lesson that she has used for several years. She has heard of a method that is commonly used in another high school, but wonders if it really would make a difference in learning. A study could be conducted to compare the two methods using standardized tests that would occur anyway at the end of the unit. If you are in a traditional educational setting and want to conduct research where anything you do is something that does not

To qualify for an exemption from HRRC review, the research must be low in risk to the subjects. Risks include physical, psychological, economic, social, or legal etc. Consider the risks involved with your research before applying for exempt status.

normally occur as part of classroom activities, then this category does not apply. You also should be careful about what you call "normal class room procedure." For example, while you may normally video record your classroom as a means of reviewing classroom behavior later, it would not be normal to take that video tape and use the information for research or display images of the students in a public forum. In the section under research description, you should provide information supporting your suggestion that your research involves normal practices. This could involve citing a relevant source from the literature of your field. For example, "The basis for the methods used in this research is "rereading" and "rereading" has been shown to have a positive influence on student fluency (Dowhower, 1989)."

It is Grand Valley policy that all researchers have permission from the site/location where they conduct research. In most cases the researchers must obtain evidence of permission (e.g. an email message from a facility manager). A copy of that permission should be included with your application.

Category 2:

Research will involve the use of: educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures (which includes focus groups), OR observation of public behavior uninfluenced by the research. Research cannot involve a physical activity (beyond completing surveys, being interviewed etc.) that is prescribed by the research. Such research must be submitted to the HRRC for review.

This category of exempt research is the most common category that may be applied at GVSU. However, it can seldom be applied when the subjects are under 18 years of age (Subpart D of the regulations; see below).

Category 2 Exemption can be used for:

1) Surveys
2) Interviews
3) Educational tests (e.g. cognitive, diagnostic, aptitude, achievement)
4) Observation of public behavior
    a. information obtained will be recorded in such a manner that subjects could not be identified (directly or through information that could identify the subjects) OR
    b. any disclosure of the subjects responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

If the research involves any small level of risk, then the information must be collected in a way that the subjects cannot be reasonably identified directly or through demographic information.

Neither the researcher nor the public should be able to identify the subject(s). This means that if there is risk to the subject(s) involved with the information that is being collected, then interviews, focus groups, or observations of public behavior would not qualify for the exemption since the physical appearance of the subject(s) would be known to the researcher even without recording a name. Likewise, if there is risk involved, a phone call based interview to a subject's home or office would not be acceptable as the phone number would

identify the subject. It is for these reasons the compliance office needs the descriptions of your research methods to make a determination.

If there is only minimal risk involved with the information being collected, then potential identification of subjects by the researchers is allowed.

When you have a sample population of a known composition, for example, a class or an email invitation to participate, you may collect identifying information as long as the information poses minimal risk to the subjects. Suppose you are conducting a study using students or any other subjects where you would like to offer compensation for the cost of participating, for example, offering a nominal amount of extra credit or a gift card for a small amount of money. If it were to be conducted using an online surveys, it is possible to both collect data with some risk and identity of the subjects to award the compensation through careful planning. A researcher could use a survey tool to collect the data on the survey (without identity). At the end of the survey, the survey could contain a link to a second survey or a web page where the identity information would be collected. If the survey software is configured to strip the IP addresses and time it is received from the saved data, it would be difficult to link the survey responses to the identities (assuming demographic data is not collected that would identify subjects).

Limitations on the application of Category 2: Exemption categories of the regulations (45 CFR 46) prohibits Category 2 from being applied when the subjects are under 18 years of age unless the research involves only observation of public behavior when the researcher does not interact with the subjects. For example, a researcher could go to a science museum (with permission) and observe children using interactive exhibits to gage the learning involved with these displays and make note of these observations. However, the researcher cannot in any way interact with the subjects (beyond asking for parental consent to observe). If interaction would be involved, the research may still be conducted, but the application must be submitted to the HRRC for expedited or full committee review.

Category 3:

This research will involve the use of educational tests (e.g. cognitive, diagnostic, aptitude, etc.), survey procedures, interviews, or observation of public behavior and is not exempt under Category 2 above, but

- *the subjects will be elected or appointed public officials or candidates for public office, OR*
- *federal statutes require without exception that confidentiality of collected information must be maintained beyond the end of the research (e.g. course grades).*

Category 3 can rarely be applied. Most of the limitations that apply to category 2, apply to category 3. The research must still entail minimal risk. However, where public officials are concerned, the requirement for anonymity and risk are relaxed. Also, if there are other federal requirements that identity be linked to the data, then category 3 can be applied. However, in practice, this is seldom required. For example, you may be doing research relating to educational assessments and those scores must be maintained for a period of years following.

And for the duration of your research, you must maintain linking information (before and after assessments), however, when both assessments have been completed, the identity information that links the two could be replaced by a code. Thus the assessment scores with identity are retained within the educational system, but the research data has been de-identified and can be used for research purposes. In most cases, exempt category 2 will apply anyway.

This category cannot be applied when the subjects are under 18 years of age.

Category 4:

This research involves the study of existing data or specimens. The data is publicly available OR GVSU researchers have never or will never access data with subject identifying information (original collected data may have identifiers but it must be edited before GVSU researchers have access and the data must arrive on campus without identifiers to qualify).

The data has to be either publicly available, downloadable from the internet or acquired by a simple data request to a government agency, or acquired by you without ever having had access to identifiers.

If you are a GVSU researcher and are acquiring data that already exists (you are not or were not involved with collecting the data), then this exemption category may apply to your research.

If you contact a government agency and because of concerns about potentially identifiable data, you enter into a confidentiality agreement to utilize the data, this is not publicly available data. If you enter into an agreement with an institution to conduct analysis for them on data that may contain identifiers, this is not publicly available data.

For assistance in establishing a confidentiality agreement contact the Research Protections Programs

In order to qualify otherwise, the data has to arrive at GVSU without identifiers. Identifiers include names or any other information that could be used to identify the subject. Identifiers can include: gender, ethnicity, age, income, number of children, and physical characteristics when the data is from a known and relatively small sample population.

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Category 5:

This research will be funded or conducted at the behest of and approved by the head of a federal agency for the purpose of studying: A public benefit or service program, or; Procedures for obtaining benefits or services under a program, or; Changes in payment or alternatives to a public benefit or service program.

The exemption is designed to be applied within federal agencies for assessing benefit programs. In some instances, the exemption can be applied outside of the federal government if the research is funded by the federal government and the research is requested by agencies or just requested by the federal agency.

A researcher who independently seeks to assess a public benefit program would not qualify for this exemption. Public benefit programs include programs that distribute funds (e.g. unemployment program, Temporary Assistance for Needy Families (TANF) program, etc.) or services (e.g. nutrition services). "Public Benefit Programs" does not include everything that is available to the public, including most state and local government sponsored programs.

RESEARCH DESCRIPTION

This is the section of the application where you explain to the reviewer how your research qualifies for the exemption category that you have indicated.

You need to provide enough detail about your research for the reviewer to understand your research and assess it relative to the regulatory requirements, as well as understand the degree of risk that might be involved.

A. The nature of the research:

This question begins by addressing one of the issues fundamental to human subjects protection: Beneficence. The reviewer must be able to understand the intended purpose and value of the study.

- *Describe the nature, purpose, and significance of the study. While a literature review is not required, in some cases, a well selected citation demonstrating the need for the research may help the reviewer. What do you expect to learn from this research that is not already known in your field?*

- *Briefly describe the research methods you will use (e.g. survey on paper, online survey, interview, observation). Remember, you need to provide sufficient information for the reviewer to understand what you are planning to do.*

- *Clearly delineate between the normal activities subjects are engaging in (would occur in the absence of the research) and the research activities.*

- *Describe the target subject population and the approximate number of subjects (age, gender, and ethnicity) and the measures that will be taken to avoid including unapproved subjects (e.g., during random interviews on a street corner, persons under 18 years of age will not be included). Describe how participants will be fairly recruited.*

- *You should also briefly discuss the intended fate of the results, that is, where, how, and in what form will you present or publish the results. For example, you could be planning on presenting aggregate results (unidentifiable "average" data) to your colleagues at a conference or you could be planning on publishing the results in a thesis, dissertation, or journal.*

The data that is collected in "exempt" research can still be published or presented like any other research.

B. Consent process:

The subjects must be informed and volunteer in all human subjects research. The applicant must describe the consent process included in their research.

- *Include provisions for gaining assent from subjects under age 18 years of age.*

- *Describe the process for ensuring subjects are voluntarily participating in the research activities throughout the study (address provisions for self-withdrawal)*

Informed consent refers to a person's freely made decision to participate in a research project based on full knowledge of relevant aspects of the project and its implications for the participant's welfare. It is an ongoing process in which participants are given an explanation of the research project in language that they can understand. The consent process can take many forms and is dictated by the nature of the research.

Examples include

- A consent form signed by the subject or legal representative. The consent form has to include all the required elements of consent and the subjects have to be given the opportunity to ask questions.

- If the situation warrants, an information sheet providing all of the required elements of consent can be supplied to the subject without requiring a signature. In some circumstances it is better not to have a signature if that is the only thing linking the subject to the research. In other situations the research is of such low risk the problems of gaining a signature may outweigh the cost of losing potentially important subject information.

- For surveys administered online, the opening page of the survey could contain the required elements of consent and the subject simply demonstrates consent by completing the survey (they must also have the option of not answering individual questions).

- The consent process description may need to include information about how subject assent will be obtained when subjects are less than 18 years of age and Exempt Category 1 may apply. For older minors (15-17 years of age), an information sheet might suffice along with verbal indication that they agree to participate. For younger subjects, the application should include a script of what the subjects will be told about the research so that the reviewer can assess the appropriateness of the vocabulary.

C. Research materials and additional information:

In this section, provide the reviewer with a listing and content of materials that will be used in the research. For example, if you are going to conduct interviews, list the interview questions noting that any follow up questions will relate to these questions you know you will be asking (i.e. you will not ask questions or include in your data collection of information that exceeds the risk level approved as exempt). If you are conducting an online survey(s), provide the reviewer with a listing of questions. It is GVSU policy that all researchers have permission from the site/location where they will conduct the research. Researchers must obtain evidence of permission and a copy of that permission should be included with your application.

INVESTIGATOR'S ASSURANCE STATEMENT

This is the final section of the exempt application. Submission of the application by email is your attestation that the research will be conducted in accordance with GVSU policies and that you accept responsibility for the ethical conduct of the research. If you are a student, you must submit the application to your faculty mentor who will then submit the application on your behalf.