

## **Human Subjects Research: Reference for Expedited or Full Committee Review Application Guidance**

This document is designed to provide guidance to human subjects researchers completing the Expedited or Full Committee Review Application.

### **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 PI 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 personnel initially 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 new 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**

Name your project and provide an anticipated starting and end date of your research. Please be aware that the start of the project cannot happen before an authorization by the HRRC. Also provide any sources of funding, if applicable. Next up, determine whether your research shall be reviewed by the full committee, or through expedited procedures. If you think that your project can be reviewed under expedited procedures, you have to specify under which of the following nine categories for expedited reviews your research falls.

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**Category 1: Clinical studies of drugs and medical devices** only when (a) research on drugs for which an investigational new drug application is not required. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. Or (b) research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Category 2: Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children<sup>1</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

**Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (I) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

**Category 4: Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indication.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging (MRI); (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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**Category 5: Research involving materials** (data, documents, records, or specimens) **that have been collected, or will be collected solely for non-research purposes** (such as medical treatment or diagnosis). (Also see Exempt from Full Board Review category 4)

**Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.**

**Category 7: Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Also see Exempt from Full Board Review category 2)

**Category 8: Continuing review of research previously approved by the convened IRB** as follows: (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis.

**Category 9: Continuing review of research**, not conducted under an investigational new drug application or investigational device exemption where categories 2-2 through 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Categories 1 through 9 cannot be used for classified research.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

For more information, refer to the Levels of Review page, on the HRRC website (<http://www.gvsu.edu/hrcc/levels-of-review-57.htm>)

### **1. Purpose of Research:**

This question begins to address one of the issues fundamental to human subjects protection: *Beneficence*. The HRRC conducts a Risk/Benefit analysis and to assess the benefit, the committee must understand the intended purpose and value of the study.

- Describe the nature, purpose, and significance of the study.
- Describe the specific objectives or aims of the research and what outcomes are expected, both general and specific.
- What do you expect to learn from this research?
- Describe how you will disseminate the gained knowledge/information
- Provide a brief literature review to demonstrate the need for conducting the research

## 2. **Subject Population Description:**

This section deals with the principles of **“Respect and Justice.”** For the reviewers to properly evaluate the risks, they must be informed about the probable level of the ability of the subjects to understand their rights as a subject and give consent. The reviewers must know the nature of the culture of the potential subject population or know that the researcher has adequate knowledge of the culture to determine if measures to protect the subjects are incorporated into the study design.

- Describe the anticipated number of subjects, age ranges, and where appropriate, gender, ethnic background, and health status.
- Identify the use of vulnerable populations such as children (under age 18 years), prisoners, mentally disabled persons, economically or educationally disadvantaged, or pregnant persons.
- Provide justification for why the number of subjects to be recruited is appropriate

### ***What is the optimal sample size?***

*It is important to find the balance between – not exposing more subjects to risk than will be needed to sufficiently answer the research question while at the same time including enough subjects to provide a valid result. The Statistical Consulting Center is a wonderful resource that can help you find this balance.*

## 3. **Research Procedures and Methods:**

### A. **Recruitment and Selection of Subjects**

One of the biggest concerns of the HRRC is that potential subjects freely volunteer to participate in research projects.

- Describe how participants will be fairly recruited.
- Describe the subject inclusion and exclusion criteria
- Describe the nature of the relationship between the researcher(s) and the subjects.

*Attach, describe,  
and refer to any  
advertisements  
and letters used  
for recruiting*

***Inclusion and  
Exclusion  
Criteria***

Examples of past abuses include prisoners who “volunteered” to participate in medical studies, or students whose perception was that they had to volunteer if they desired a passing grade in a course. These are readily recognized as problems with the “volunteer” requirement. However, researchers might not be sensitive enough to forms of implied pressure. For example, having a teacher distribute a survey for

her own research in her class and then having the students who do not want to volunteer hand back the survey in front of her and all the other students is an example of implicit compulsion that is not allowed. A procedure in which a researcher asks friends to do him a favor by volunteering is another example of pressure that is not allowed. Researchers may compensate subjects for participating, but payments must be described in the proposal to the HRRC. Payments should be appropriate to the risks associated with the research and not of an amount that would alone convince a person to volunteer or continue in the study when they may otherwise withdraw. Subjects must receive partial payment if they withdraw from the study.

In some projects, once potential subjects are attracted to the project, some type of screening or selection of appropriate subjects is performed. Potential subjects might need to be excluded from the study, for example, people with liver damage may be excluded from a nutrition study, or people who are depressed may be excluded from a memory study. The inclusion and exclusion criteria must be described.

## **B. Research Location**

It is GVSU policy that all GV researchers have permission to conduct research granted by the owner of the property or leadership of an organization.

- List all sites where the research will be conducted.
- When required, arrange for letters granting permission to recruit participants and conduct research at these locations to be submitted to the HRRC.

Having permission to conduct research is not only courteous, but it is a matter of maintaining research integrity and protecting human subjects. If the owner of a property or the leadership of an organization discovers an unapproved research project being conducted, they may stop the project midway through, thereby placing the research at risk and rendering the subjects already contacted to have been put at risk for limited benefit. Researchers are expected to obtain permission to conduct research and maintain documentation from the appropriate authority.

## **C. Consent Process.**

Informed consent refers to a person's freely made decision to participate in a research project based on 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.

- *Describe the process of informing the subjects/legal representatives about the study, obtaining consent, and documenting consent.*
- *Include provisions for gaining assent from subjects under age 18 years and those with cognitive impairment*
- *Describe the process for ensuring subjects are voluntarily participating in the research activities throughout the study (describe provisions for self-withdrawal)*

In most cases, subjects are informed about proposed research and the risks associated with the project via a written consent form; in fact Federal regulations require written consent or a case-specific waiver of written consent. The consent form describes the project and its risks; it also provides sources of additional information if the subject has questions about the project or his or her rights. The investigator must give the subject or the representative

adequate opportunity to read the consent form, or it may be read to them, and to have any questions about the study answered before it is signed. A copy of the form needs to be given to the person signing the form. It is important that investigators include a copy of this form with their HRRC application so that the HRRC can determine if the form is adequate given the risk level and subject population.

### **I. Basic Elements of Consent.**

In accordance with federal regulations and GVSU policy the written consent document shall include information on the following basic elements written in language readily understandable by the subjects. This requirement addresses the ability of the potential subjects to comprehend the text or presentation and is not limited to the actual language (English, Spanish, Vietnamese, etc.) of the text.

A short-form written consent document, stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative may be used. When this method is used, there must be a witness to the oral presentation. The HRRC must review a written summary of what is to be said to the subject or representative. A copy of the written statement about the research study and the short-form consent document must be given to the subject or representative.

### **II. Consent/Assent of Special Populations:**

- a. **Subjects under 18 years of age.** When the subjects are younger than 18 years of age, including college students, a parent or legal guardian must sign a written consent form, if appropriate. In addition, the child should be asked to "assent" to participate. For older children, (e.g. older than 14 years of age), this assent should be written. For younger children, this assent should be verbal. Researchers need to provide a script of what will be said to children to seek their agreement to participate.
- b. **Vulnerable Adults.** When subjects include individuals who are not legally or physically capable of giving documented informed consent because of mental incapacity, or inability to communicate, consent must be sought from a legal guardian as well as assent from the subjects themselves. The subjects should also be given an explanation of the procedures at a level appropriate to their condition and asked for their assent to participate in the research project. A written form to document assent may also be appropriate for mildly impaired adults. For persons with questionable consent capacity, please see HRRC policy 813.
- c. **Prisoners.** Incarceration places prisoners under constraints that may affect their ability to make truly voluntary and un-coerced decisions about whether or not to participate as subjects in research. Prisoners, therefore, constitute a vulnerable population for which additional protections are warranted.

### **III. Waiver of Some Elements of the Consent Process**

Although the use of a written informed consent form is encouraged by the HRRC, it is understood that there are situations in which the use of such a form creates problems and therefore the investigator may request a waiver to the requirement to document informed consent in writing. In these cases, the researcher should state in section 3C "I request a waiver to the requirement to document informed consent in writing" and provide the information the HRRC needs to justify waiving the requirement. Examples of situations that the HRRC will normally waive the requirement for signed written consent include:

- a. **Protecting the identity of participants.** The requirement for a signed consent form may be waived when the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- b. **Cross cultural research.** If the project involves people in a culture where signed consent forms are not appropriate, the researcher should propose alternative ways to assure that participants fully understand and

willingly participate in the research. Usually, verbal consent is required by the HRRC. A script describing the procedure should be included in the application.

*Basic Elements of Consent*

- a. **Description of the Research:** *The nature, purpose, and significance of the research.*
- b. **Research Procedures:** *The procedures to be followed.*
- c. **Time Required for Participation:** *The expected frequency and duration of each procedure and total amount of time required for participation.*
- d. **Risks:** *Any reasonably foreseeable risks or discomforts to the subjects.*
- e. **Benefits:** *Any benefits to the subject or others which may reasonably be expected from the research.*
- f. **Confidentiality:** *The extent to which confidentiality of records identifying the subject will be maintained. Note: Data should not be described as anonymous if there are any identifying names, or numbers, or information about the individual through which individual subjects could be linked by the researcher or anyone else to his or her responses.*
- g. **Voluntary Participation:** *A statement that:*
  - i. *participation is voluntary,*
  - ii. *refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled,*
  - iii. *the subject may discontinue participation at any time or decline to answer specific questions without penalty or loss of benefits to which the subject is otherwise entitled.*
- h. **Alternatives:** *If the potential subject or legal representative declines to participate, how might this effect the opportunities of the subject.*
- i. **Compensation for Injury:** *an explanation as to whether any compensation or medical treatment is available if injury occurs, and, if so, what they consist of, or where additional information may be obtained.*
- j. **Contact information:** *An offer to answer any questions about the procedures and an explanation of who to contact (the name, phone number and email address of the investigator and, in the case of student investigators, the faculty advisor) for answers to pertinent questions about the research. A statement that subjects may contact the Research Protections Program (616-331-3197) or <[rpp@gvsu.edu](mailto:rpp@gvsu.edu)> for questions or concerns about their rights as subjects.*

**D. Research Activities.**

Part of the “beneficence” consideration of the review process is the efficacy of the project being proposed. That is, if a project is logistically problematic or the researchers are not qualified to complete the project, the “good” of the project is diminished.

***What is the  
Research Activity?***

Quite often, research at GVSU involves a mixture of normal practices and research activities. For example, an evaluation of ongoing activities might include activities that need to be reviewed and activities that are outside of the purview of the HRRC. Some activities, e.g. family therapy at a clinic involving standard practices, may not be the research activity. The research activity might be an interview or survey regarding what brought the subjects to therapy and presentation of this data. If one therapy were being compared to a second experimental therapy, the therapy would then be part of the research. In Section 3D you should first describe the normal activity in general terms and then describe the activities that will be used for the research aspects of the project.

Include, as necessary, the following when relating your step-by-step research procedures.

- Address the frequency and length of time involved in activities for the purpose of the research and the overall length of research participation.
- Describe the data you are collecting. This includes the specific variables and, if tests/surveys are to be used, what these are. Has validity and/or reliability been demonstrated? How will the data be analyzed?
- Describe the training and experience of persons administering the treatment, collecting data, or accessing the data and relevance of this to human subjects protections.
- Describe the compensation, if any, to subjects for their participation. Payment should be reasonable and prorated with partial payment to those who withdraw before the completion of the research.

***Clearly distinguish between the activities that subjects would engage in regardless of the research and the activities that will occur only because the research is being conducted.***

***Attach and refer to data gathering instruments, copies of questionnaires or interview questions.***

### **E. Confidentiality of the Information**

Anonymity refers to the situation in which the dataset and/or research materials contain no personal identifiers through which anyone, including the investigator, could connect individual responses with a specific subject. Data collected through face-to-face interviews, video, and audio or photographic records are not anonymous.

There is a difference between confidentiality and anonymity. Treatment of data as confidential is required when a dataset and/or research materials include personal identifiers, such as a name, photograph, sound recording, or personal references. Examples of personal references include an address, phone number or identification number or any information that may be used to connect a particular subject with his or her data.

Consider how the following factors relate to human subjects protection when completing this section:

***Even without collecting explicitly identifying information along with responses, e.g. names, demographic information (such as male/female, age, occupation, income, education level, etc.) can be used to identify individuals within a group where the membership of the group is known.***

- Will the data will be treated as confidential or anonymous?
- How will participants' privacy be protected and confidentiality of data maintained?
- How long will confidential documents and information be retained after the end of the study?
- Where and how will data be stored?
- Who will have access to data for which subject identity is known or could be inferred?
- How will the data be disseminated?

Although the researcher is allowed access to confidential information, it is the responsibility of the researcher to develop procedures that assure that no unauthorized/unapproved person has access. At a minimum, the information should be kept in an inaccessible place, e.g. a locked file cabinet.

If the data is maintained in a computer system, then the system should be protected from outsiders. Researchers should be aware that there are legal means (e.g. subpoena) by which confidential information can be made public and that there are means (e.g. Certificate of Confidentiality) by which particularly sensitive data can be afforded some additional protection

*For as long as personal identifiers are present in a dataset, the researcher is responsible for maintaining the confidentiality of the dataset.*

If identifiers are linked to subject data, risk of harm exists, therefore, the research project will receive periodic review (at least annually) to insure that the procedures used to guarantee confidentiality are adequate.

The HRRC recognizes that in some research projects, the identity of the subjects is integral to the study and therefore the research material will contain the identity of the person; research oral histories and qualitative clinical studies are examples of this type of research. These projects should include explicit documentation in the informed consent document that the subject consents to maintaining identity in the dataset.

## **F. Deception and Debriefing**

A special problem of consent arises where informing subjects some aspects of the research is likely to impair the validity of the research. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects and truthful answers should always be given to direct questions about the research.

### *Deceiving your Subjects*

*Deception in research is justified only if it is of clear that:*

1. *incomplete disclosure is necessary to accomplish the goals of the research;*
2. *there are no undisclosed risks to subjects that are more than minimal, and*
3. *there is an adequate plan for debriefing the subjects.*

In preparing material for HRRC review, researchers must clearly identify any deception in the research.

- Provide a rationale and justification for deceiving subjects regarding the research activities
- Describe debriefing procedures.

Debriefing: The subjects always need to be told at the end of the activity what the real objective of the study was and why they needed to be told the study was about something else.

**G. Potential Modifications:**

*Are you planning research activities for the future, but you are not sure what they will be because intervening activities (research and otherwise) are likely to effect the design of that future activity?*

Often in research it is difficult or impossible to design all aspects of the research at the outset. For example, a project may start with a pre-activity survey, the research activity, perhaps using a variety of assignments in a class that would provide research data, and interaction with subjects ends with a post-activity survey. The nature and questions on the post-activity survey may depend greatly on the response of the subjects to the previous research activities. Another example would be when a study takes

place over many years and the researchers will need to respond to changes over time. When these types of circumstances exist, rather than attempt to anticipate or limit activities, in Section 3G justify the deferment in planning and likely timing of the submission of a protocol modification form.

**4. Potential Risks and Discomforts:**

*You should review your research procedures sections (Q 3), make note of, and address potential risks and discomforts associated with the procedures.*

Potential risks include physical, psychological, social, legal, economic, or other risk. The HRRC needs to determine whether or not the investigator has: properly assessed probability and potential magnitude of harm in his or her project; minimized risks to the extent possible; and communicated the nature of the risks and anticipated benefits to the subject prior to seeking agreement to participate in the project.

**Evaluate the likelihood of occurrence and the degree of seriousness of adverse events.**

Participation in any research project carries with it a level of risk of distress or harm that ranges from low to high. Low or minimal risk means that the probability and magnitude of harm or discomfort is no more than engaging in everyday activities or during the performance of routine physical or psychological examinations or tests (e.g., drawing a small amount of blood from a healthy person, or sitting through an hour of tests).

Some studies may involve a middle level of risk in which there is expectation of some temporary distress on the part of the subject (e.g. being asked to justify immoral decisions). High or significant risk means that the subjects may experience serious or lasting harm, (e.g. suffer a heart attack while participating in an exercise training program or be exposed

***After identifying risks, your emphasis should be:***

- *Describing procedures for minimizing risks.*
- *Describing provisions for insuring necessary the medical or professional intervention in the event of adverse effects on the subjects*

to legal, financial or personal repercussions if their responses become known outside the research). A high level of risk is not a sufficient reason to disapprove a proposal; if the anticipated benefits of performing research are high, and subjects are fully informed of the risks, then a proposal with a high level of risk can be approved. See HRRC Guidance G-5 to help determine the level of risk in your project.

## **5. Potential Benefits:**

Risks to human subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society. The central charge of the HRRC is to assess the anticipated benefits to be gained from the research in relation to the risks.

- Describe the potential benefits to subjects as a result of their participation in this research.
- Describe any potential benefits to society that may be expected from this research.

Benefits of research fall into two major categories: benefits to the subjects and benefits to society. Subjects who are experiencing a new teaching method or examination may benefit directly from research involving evaluation of a procedure or understanding of a learning disorder. Frequently, however, research projects have no immediate therapeutic intent for the subject. However, there may be benefits to society as a whole from the increased knowledge, improved safety, better technology, or improved practice in a field. Direct payments to subjects as an incentive or reward for participation should not be considered a “benefit” to be gained from research. It is important that you describe how you will minimize the chances of risks to subjects, and what you will do if a risk event occurs.

*Be realistic in your description of potential benefits for the subjects.*

## **INVESTIGATOR’S ASSURANCE STATEMENT**

This is the final section of the 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.

### **Appendices:**

Any materials that come into contact with subjects or their legal representatives need to be attached/inserted into the research description for review. It is important that the HRRC review the language used in the research. These materials include:

- consent forms
- consent scripts
- assent scripts and forms

- recruitment fliers
- recruitment email messages
- interview questions
- survey questions
- debriefing documents