Researcher's Guide to the IRB at GSU

(1st Edition)

August 2012

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1. Purpose of the Researcher Guide and Contact Information

1.1 Purpose of the researcher guide (45CFR46.103[4])

The first edition of this researcher guide was written by Dr. David Rhea, Ph.D., Communication Studies faculty, who served as Co-Chair of the IRB at the time it was written (2012). Special thanks go out to Dr. Dale Schuit, Ph.D. who served as Co-Chair of IRB alongside Dr. Rhea, the IRB members serving at that time Drs. Mary Bruce, Susan Gaffney, Pam Guimond, Caron Jacobson, Maribeth Kasik, Margaret Nugent, Lu Ning, and Renee Theiss, and all other faculty members who reviewed the document to help ensure this document was as useful as possible. Thanks also go to the IRB at the University of Minnesota. This guide was inspired by their *Protecting Human Subjects Guide* (2004) and modified for the needs and policies of Governors State University.

GSU Policy 53 is the university policy that dictates in writing the policies IRB follows in carrying out its work. Policy 53 helps the university be compliant with federal policy 45CFR46.103[4]. This manual was written to better clarify and educate the university community on federal and university policies that the IRB is responsible for maintaining. We also wanted the community to be aware of the IRBs expectations with regards to the IRB application and consent process, which is where researchers are most prone to difficulties with receiving IRB approval. We also wanted to make the community aware of faculty responsibilities with student researchers and policies, that may be unbeknownst to researchers (e.g. various waivers, policies with special populations, etc.) but relevant to your research.

We hope this document will help you as you work through the IRB application process as well as when you carry out your research work.

1.2 Contact information (45CFR46.103[3])

If you have any questions as you peruse this document, do not hesitate to contact the IRB. The IRB is here to do all it can to help researchers effectively, efficiently, and most importantly ethically, navigate through the IRB application process. You can contact us at irb@govst.edu or contact one of the IRB Members.

IRB Members		**Email**
Dr. David Rhea	CAS & Co-Chair	drhea@govst.edu
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Library/Student Affairs (Vacant)		
Community Member (Vacant)		

2. Minimal Risk & Personally Identifiable Information

2.1 Minimal risk (45CFR46.102i)

Is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encounter in daily life or during the performance of routine physical or psychological examinations or tests."

This is the only definition of risk in the federal guidelines that does not involve prisoner research (see 45CFR46.303). All studies are evaluated as to whether they have no more than minimal risk or greater than minimal risk. **According to the federal regulation definitions, there is no such thing as a study having "no risk."**

The federal government's definition is open to some interpretation. When applying the definition, IRB reviewers are primarily concerned with risks (bio-medical, social-behavioral, or legal, etc.) that (1) are directly related to the research protocol and (2) are immediate or foreseeable risks to participants or participating entities.

When the IRB decides if a study has "greater than minimal risk," there are two factors IRB members look for (1) the likelihood that harm may occur and (2) the magnitude of the harm. Magnitude of harm can include such issues as its severity, duration, or ability for harm to be reversed.

When the IRB considers the Risk/Benefit ratio of a study, the potential benefits of a study justify doing a study with greater than minimal risk, it does not change classification of the risks. The IRB can decide to disapprove research with greater than minimal risk if benefits to the participants or society are lacking.

2.2 Personally identifiable information (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 categorized 18 pieces of information as personally identifiable information. This is important because once you collect one of these pieces of data, regardless if your study is health oriented or not, your data is no longer anonymously collected. If you are collecting this information in your research study, you'll want to consider (1) how the data will be kept confidential and (2) if public disclosure of the data will potentially harm participants as collecting this data can potentially increase this participant risk in your study. Here are the identifiers:

1. Names
2. Address information (except state of address)
3. All dates related to an individual (e.g., birth date, date of marriage)
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Any vehicle identifiers, serial numbers, or license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet protocol (IP) address numbers

16. Biometric identifiers (finger and voice prints)
17. Full face photographic images or comparable images
18. Any other unique identifying number, characteristic, or code (excludes study ID code)

3. Aims & Scope of the IRB at Governors State University

3.1 Purpose of the IRB

The purpose of the Institutional Review Board (IRB) is to ensure the protection of human research subjects, that harms in research protocols are minimized, and to ensure participants make an informed decision to voluntarily participate in research.

The foundation for the IRB's policies (GSU Policy 53) is found in federal regulation *Title 45, Code of Federal Regulations, Part 46*. The Office of Human Research Protection (OHRP) and Food and Drug Administration (FDA) are primarily responsible for developing and maintaining federal policy on human subjects protection in research. Other policies that guide actions of the IRB include Title 21, CFR Parts 16, 20, 50, 312, 809 and 812 from the FDA and Title 34 CFR Part 97 from the Department of Education (DOE).

The purpose behind the IRB's actions is found in the *Belmont Report* and its three guiding principles of (a) Respect for Persons, (b) Beneficence, and (c) Justice. (www.hhs.gov/orhp/humansubjects/guidance/belmont.html)

A Federalwide assurance (FWA) is used by the OHRP to regulate GSU's compliance of federal policy. This assurance is approved every five years. Policy 53 is used by the IRB and identifies the actions the IRB at GSU will take to comply with federal policy on human subject research.

3.2 Authority of the IRB

To accomplish its purpose, the IRB at GSU has the following responsibilities:

1. The IRB at GSU will review all GSU-connected research involving human and animal subjects, and will approve only those research protocols that comply with its requirements for approval.
2. The IRB at GSU will conduct continuing review at least once per year for all research protocols for which continuing review is required.
3. The IRB at GSU will comply with federal regulations as well as state and local laws and authorities.
4. The IRB at GSU will investigate reports of harm to human or animal subjects and reports of non-compliance with approved research protocols. Such investigations can result in suspension or revocation of IRB protocol approval and reporting to the appropriate agencies

3.3 Membership of the IRB (45CFR46.107)

The IRB at GSU consists of a minimum of seven members who represent GSU faculty and local community members. The university requires at least one faculty member from each college and library/student affairs to be represented on the IRB.

IRB members are appointed via nominations from the Faculty Senate or from the Office of the Provost. These appointments are for two years. The IRB Chair is elected by the IRB members and serves a two-year term as Chair. Consecutive terms for IRB Members are allowed through re-appointment through the appropriate nominating body. New IRB Members must complete IRB Board Member Certification in the first semester of their appointment. All IRB Members must keep their IRB Certification active during their service.

The IRB strives for membership with diversity in race, gender, expertise, and experience, which allows the IRB to competently evaluate a large array of research protocols, respect professional standards of conduct and practices, and address any special requirements for vulnerable populations.

4. What does the IRB at GSU review?

4.1 Scope of review

All of the following research activities involving human subjects are subject to the review and approval of the IRB at GSU. This includes…

1. Research sponsored by GSU.
2. Research conducted by or under the direction of any employee or agent, including students or adjunct faculty, of the University in connection with his or her University responsibilities.
3. Research conducted by or under the direction of any individual or agent using the property of facilities of GSU. Projects being conducted on GSU property but not directed by a GSU employee must be approved by the IRB at GSU.

4.2 Research conducted by students – The GSU faculty/staff responsibilities

Independent student research projects such as an undergraduate independent research project, master's project, master's thesis, dissertation, or similar work involving human subjects research must have a research protocol submitted to IRB. In these cases, **a faculty or staff member is ultimately responsible** for the protection of human subjects and must be listed as project director on IRB paperwork even if the student is primarily responsible for directing the project.

The faculty director (for independent research) or course instructor (for class projects) is responsible for (1) educating students on proper ethical conduct of their research protocol and (2) help students prepare the proper paperwork for IRB approval. This may include educating students on (not an exhaustive list),

1. Vulnerable Populations
2. Informed Consent Forms
3. Recruitment Strategies
4. Protection of Data
5. The IRB Process and Paperwork

The faculty member should also be proactive in ensuring that students conduct their research according to the protocol approved by the IRB.

4.3 Research conducted in university courses

Class assignments that involve research with human subjects (e.g., survey research, clinical rotation case, physical training projects) with the goal of learning about research design and researcher conduct require IRB approval even if the exercise does not qualify as "true research" meaning research that is not intended for public presentation or publication. The IRB reviews the assignment rubric to assess risk and any potential needs for informed consent. This information may be submitted as a "Classroom Exemption."

See Section 5.2.4 for more information on Classroom Exemption Review Status.

4.4 Research conducted in another institution or external site

Unless an Institutional Authorization Agreement (IAA) is agreed to by the institutions involved, The IRB at GSU as well as the other institution(s) IRB or similar committee must review and approve the research protocol. When the other institution has no IRB-like board, an IAA or external site approval (e.g. signature from an external site administrator) can suffice. Please contact the IRB Chair with any questions about this.

If the other institution's IRB has already approved the project, reciprocal review arrangements can be set up to expedite the approval process from the IRB at GSU. Researchers should include copies of the application sent

to the IRB at GSU and approval letter when submitting a project to another IRB. Any changes in the research protocol required by the other institution's IRB must be brought to the attention of the IRB at GSU.

4.5 Pilot studies and feasibility studies

Pilot studies and feasibility studies involving human subjects must be reviewed by IRB. Researchers must identify both on the IRB application and during the consent process for participants, that the study is a pilot study or feasibility study.

5. What is involved in the review process for the IRB at GSU?

5.1 The process – At a glance (45CFR46.111)

Research protocols must first get the appropriate Division and Dean's approval before being received by the Provost office. This portion of the process typically takes 5 to 10 business days. Once the IRB receives the paperwork, the IRB reviews research protocols with the following concerns in mind…

1. The IRB's first task is to assess the protocol and determine that the research risks are minimized and research benefits outweigh the research risks. Any supporting materials (pre-developed recruitment scripts, survey and interview questionnaires, informed consent forms, child assent forms and the like) to help make this assessment are strongly encouraged to be included with the IRB application.
2. When appropriate, the IRB also reviews the protocol to ensure the protection of collected data, the privacy of the participants, and the confidentiality of data. The IRB will also check to see that the researchers have taken into account the rights and welfare of any vulnerable populations or any participants vulnerable to undue influences.
3. Next, the IRB closely reviews the consent form (if included) to see that participants are aware of project risks and benefits, that they voluntary participate in the project, and are aware of any other critical elements related to their participation (e.g., compensation, alternative procedures, audio/video consent, etc.).
4. Last, the IRB confirms that all faculty, staff, and students listed on the research protocol have completed the relevant IRB training program for their type of study (Biomed, Social/Behavioral, Student Researcher).

Typically the IRB completes its initial assessment of exempt and expedited research protocol within two weeks after receiving the protocol from the Provost office. Protocols requiring full board review are assessed at convened IRB meetings; see the IRB website for submission deadlines.

One the initial assessment is complete; researchers are entitled to a formal response to the protocol in writing via email, PDF, or physical letter from IRB staff or board members (45CFR46.109d). The IRB may require further clarification of the protocol and documents, revisions to the protocol and documents, or both. The IRB will review the project again when the revisions or updates are submitted. This revise-and-resubmit process continues until the IRB is satisfied with the protocol and documents and issues the appropriate approval letter.

The IRB at GSU must approve the research protocol before GSU's involvement on the project can begin.

5.2 Types of IRB review for research proposals

Once the IRB has reviewed the research protocol and made a determination on the potential risk to participants and federally defined categories, the protocol is reviewed at the appropriate level of scrutiny:

1. Exempt from IRB Review
2. Expedited IRB Review
3. Full Board IRB Review

Classroom exemption is a level of review that only applies for classroom assignments involving human subjects. Please see Section 5.2.4 for more information.

5.2.1 Exempt from IRB review status (45CFR.101b&c)

If researchers believe their research qualifies for exempt status, they may use the Project Exemption application to request exemption from review status. An IRB member or staff member will determine whether the protocol will be exempt from review or will receive an elevated review status. If the project is given a non-exempt status, the IRB may ask you to complete the non-exempt IRB application form.

Typically, studies with human subjects are exempt from review IF (1) they involve **no more than minimal risk** AND (2) meets at least one of the following six exemption criteria. If your protocol does not meet BOTH of these standards, your protocol is not eligible for exempt from IRB review status. NOTE: Research with participants that are prisoners is not eligible for exempt from IRB review status under any circumstances, regardless of the level of risk involved in the study.

Here are the six criteria for exemption (45CFR46.101b&c). For exact language: please go to www.govst.edu/irb.

1. The research is done in educational settings AND involves normal education practices. (**Example:** You are doing a study at a high school comparing the effectiveness of one-on-one vs. traditional instructional practices with special education studies.)
2. Research involving educational tests, survey procedures, interview procedures or observing public actions UNLESS (a) personally identifiable data was collected AND (b) there would be potential harm (e.g., criminal or civil liability, damage to financial, martial, job, psychological status, damage to reputation) to participants if the personally identifiable information collected was publically disclosed. NOTE: This exemption criterion is not allowed for participants who are minors UNLESS the researcher does not participate in the activities they are observing. (**Example:** You are doing a study on young adults to understand their uses of Facebook on mobile devices. At the end of the survey, you offer people the option to provide their email address if they are willing to be contacted for a follow-up interview. Because the participants have willingly provided their email address, we would interpret that there would be little risk to the participants if that address was publically disclosed.)
3. Research involving educational tests, survey procedures, interview procedures or observing public actions IF (a) human subjects are appointed or elected public officials or candidates for public office AND (b) confidentiality of any personally identifiable data is maintained. (**Example:** You are interviewing village leaders in the south suburbs of Chicagoland to understand how village leaders manage village affairs during times of financial crisis).
4. Research involving the study of previously collected data or specimens IF (a) the sources are publicly available OR (b) the participants are not personally identifiable from the data recorded or obtained. (**Example:** You are doing data analysis comparing happiness of Millennials to past generations. The dataset includes participants' date of marriage, but it is publicly available from the Pew Research Center).
5. Research conducted or approved by federal agency heads designed to examine (a) public benefit or service programs, (b) procedures to obtain benefits or services in those programs, (c) possible changes or alternatives to those programs or procedures, or (d) potential changes in methods of payment for benefits or services in those programs. No GSU study would qualify for this exemption category.
6. Studies that explore taste, food quality or consumer acceptance IF (a) foods are wholesome and without additives OR (b) the food has additives or chemicals at levels deemed safe by the FDA, approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture. (**Example:** The University is considering contracts for different food service providers and wants to do research comparing taste quality of food for the different providers.

5.2.2 Expedited review status (45CFR46.110)

Expedited reviews must be conducted by the IRB Chairperson OR at least one member of the IRB designated by the IRB Chairperson. All consent forms, assent forms, and supporting documents should be included with your paperwork. Expedited review is permitted for the following two reasons; at least one reason must apply to your protocol:

1. You have a minor change to make to an already approved research protocol.
2. You have a study protocol that (1) involves **no more than minimal risk** AND (2) meets at least one of the approved expedited research activities.

Here are the nine activities approved for expedited review (63FR60364-60367). For exact language: please go to www.govst.edu/irb. In your research protocol, you must explain how your research meets at least one of the categories below.

Typically BioMedical Research Related Activities

1. Clinical studies of drugs or medical devices.
2. Collection of blood samples via finger stick, heel stick, ear stick, or venipuncture.
3. Prospective of biological specimens for research purposes through noninvasive means.
4. Data Collection through noninvasive methods.

Typically Social/Behavioral/Education Related Activities

1. Research involving materials collected specifically for non-research purposes.
2. Collection of data from voice, video, digital or image recordings made for research purposes.
3. Research on individual or group characteristics or behavior.

Typically Continuing Review Related Activities

1. Continuing review of research previously approved with full board review status.
2. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the expedited review categories do not apply BUT the IRB has determined and documented at a convened meeting that the research involves no more than minimal risk and no new risks have been found.

The IRB reviewer will either: (a) approve your protocol, (b) approve with modifications, or (c) elevate the protocol to full board review status.

Continuing review will be required annually for studies with expedited review status. In studies where there is a significant risk to participants or unanticipated risks are identified and documented, the IRB may require continuing review more frequently.

5.2.3 Full board review status (45CFR46.108-109)

Protocols receiving full board status may only be reviewed at a convened meeting of the IRB. A majority of IRB members must be present including at least one member with expertise in nonscientific areas. The research protocol must be approved by a majority of the members present at the meeting (45CFR46.108)

Full Board Reviews are required for the following reasons:

1. You have a study protocol that involves **greater than minimal risk** to participants or GSU. This typically includes (but is not limited to) research with experimental drugs or devices, invasive procedures, non-routine medical procedures, intentionally deceiving participants, and data collection which may include information about illicit or illegal behaviors or cause undue stress to participants.
2. You have a study protocol that was denied expedited review status by the IRB.
3. You have a study protocol that meets standards for expedited review but the IRB's option to use expedited review has been suspended or restricted by the Office of the Provost or University President (45CFR46.110d).

The IRB will only conduct full board reviews on research protocols if the application is complete and all relevant supporting documents are included. If items are missing (e.g. external site approval, informed consent forms, etc.) the paperwork will be returned to you to be completed before the IRB reviews the protocol.

After the full board reviews the proposal, the IRB will make one of the following decisions on the protocol: (a) approved as-is, (b) approval with revisions that must be completed prior to approval (most common), or (c) not approved.

Continuing review will be required annually for studies with full board review status. In studies where there is a significant risk to participants or unanticipated risks are identified and documented, the IRB may require continuing review more frequently.

5.2.4 Classroom exemption review status

Classroom exemption review status is a special status to be utilized by course instructors if they assign a class project to students that involves human subjects data WITH THE INTENT to teach students about the concepts of research design, researcher conduct, data collection and data analysis. Findings from these projects may be presented in their respective classrooms or the Governors State University Student Researcher Conference, but may **NOT** be published, presented, or disseminated publicly in any way beyond the confines of GSU.

Course instructors should request a classroom exemption review status and submit a description of the assignment including the assignment goals and objectives. In the course description, the instructor must stipulate the following.

1. The instructor will direct students to complete IRB training for student researchers
2. The final project must be reviewed and graded by the faculty member(s); grading of such projects by graduate assistants is not permitted.
3. The assignment parameters must meet the research standards for exempt from IRB review status or expedited review status.

Classroom exemptions must be renewed every two years to ensure they meet any new federal guidelines. If the same assignment is used in multiple classes, one exemption protocol can be used for all classes.

Though a project may qualify for classroom exemption status, students (with course instructor serving as project director), may submit IRB paperwork for their individual project if they have intent to present findings from their assignment publicly or publish findings.

Classroom projects that do not adhere to the above classroom exemption guidelines are not eligible for classroom exemption review status. In these cases, each student must submit an individual IRB application for their assignment with course instructor acting as project director for all protocols.

5.3 Preparing the IRB application

When you are ready to submit your application, please select fill out the appropriate IRB form (Exempt or Non-Exempt). Feel free to contact IRB staff if you have questions on the appropriate form to complete. As you prepare your application, make sure to…

1. Address all relevant items on the application form.
2. Include CITI training completion date for the project director and all participants claiming authorship on the project.
3. Include an abstract of the study purpose.
4. Describe the study population and recruitment strategies.

5. Describe what participants will do in the study protocol.
6. Describe the perceived study benefits and perceived study risks.
7. Outline how you will minimize risk in your study.
8. Describe how provisions for care for participants that experience an injury or accident while participating in the study.
9. Describe how you will keep personally identifiable data confidential and who will have access to the data.
10. Describe the process by which consent will be obtained from relevant participants.
11. Include all supporting documents (pre-developed recruitment scripts, survey and interview questionnaires, informed consent forms, child assent forms and the like).

5.4 Application issues involving research with unique and vulnerable populations

Research risks and benefits should be distributed fairly. You must make a good-faith effort to recruit participants of all demographics that the study is intended to benefit. To purposely single out a particular demographic to bear the study burdens without receiving the study benefits or vice versa, without just cause does not reflect the principle of Justice as described in the *Belmont Report*. You must justify any purposeful exclusion of a potential study population that could benefit from your research. The IRB will consider your justification in its assessment of the research proposal.

5.4.1 Research involving GSU students and employees

Using university students and employees as participants in research studies is a common practice, however researchers must carefully consider their involvement in a study to avoid the potential for coercive behavior. Therefore researchers are encouraged not to use their own currently enrolled students or subordinates as participants in their study when possible. If there is just cause for researchers to use their own students or subordinates, then researchers should:

1. Make sure students and subordinates are aware that their participation, or lack of participation, will not influence any benefits (grades, job standing, etc.) that are under the influence of the researcher.
2. If extra credit is awarded for project participation, the amount of credit awarded should not have a major influence (e.g., more than 5%) on students' final grade. Researchers should consider including alternative methods for earning extra credit in their proposal, especially if you have students that would not qualify to participate in your study or you wish to recruit your own currently enrolled students.
3. Research participation should not occur during scheduled class time without just cause.
4. Research participation should not take a large portion of employee's time without just cause.

Convenience is not just cause to select your students or subordinates as participants. In the information submitted to the IRB, you must show what you will do to avoid coercive behavior in the research process.

5.4.2 Research involving children

Research involving children are subject to 45CFR46, Subpart D. Research proposals will be reviewed against the regulations mentioned in Subpart D (45CFR46.403).

Typically research involving children should involve no more than minimal risk (45CFR46.404). Research involving children that has greater than minimal risk must meet one of the following standards to be considered for approval:

1. The research conducted must have a direct benefit to the children (45CFR46.405).
2. The researchers must justify that their research proposal meet all standards in 45CFR46.406.
3. The researchers must justify that their research proposal meet all standards in 45CFR46.407.

The IRB can decide if parental consent is needed from one or both parents for proposals meeting approval standards in 45CFR46.404-405. Proposals meeting approval standards in 45CFR46.406-407 require the parental consent of BOTH parents. The only exceptions are for children with only one legal parent or guardian OR children with a parent that is deceased or incapable of signing a consent form (45CFR46.408b). The IRB may also require child assent for participation and has the right to dictate how the assent is documented (45CFR46.408e).

See Section 6.7 for more information about parental consent and child assent.

5.4.3 Research involving prisoners

Research involving prisoners are subject to 45CFR46, Subpart C. Research proposals will be reviewed against the regulations mentioned in Subpart C. Research involving prisoners is never eligible for exemption from IRB review status. Prior to beginning an IRB review on a proposal involving prisoners, the IRB must act to ensure proper composition of the IRB for the review of the study involving prisoners (45CFR46.304).

The IRB must ensure that the research proposal meets the stipulations listed in 45CFR46.305-306). Once the IRB approves the research protocol, the protocol must be evaluated by an employee with authority of the U.S. Department of Health and Human Services (DHHS) to confirm the protocol meets the approved reasons for prisoner research (45CFR46.306a2i-iv).

Researchers wanting to do research with prisoners as participants should submit their application several months in advance of when they want to start research to allow time for the IRB to assume the proper board composition and for a response from the DHHS.

5.4.4 Research involving pregnant women, human fetuses, and neonates

Special protections for pregnant women, human fetuses, and neonates are listed in 45CFR46, Subpart B. None of the special protections apply to research that is exempt from IRB review (45CFR46.201). The special protections are designed to prevent harm to a developing fetus, the health of a childbearing woman, or neonates. Please read Subpart B closely if you intend to do research that meets standards for expedited or full board review using:

1. Pregnant Women & Fetuses (45CFR46.204)
2. Neonates (45CFR46.205)
3. After Delivery, Dead Fetuses, Fetal Material, the Placenta (45CFR46.206)
4. Other research designed to understand, prevent, or alleviate serious problems that affect the health or welfare of pregnant women, fetuses, or neonates (45CFR46.207)

5.5 Unfolding research proposals

Research methods such as ethnography are unique. Often times research questions, surveys and interview questionnaires are developed and evolve while in researchers are in the midst of carrying out their research protocol. Thus it may not be practical for researchers to submit all such questionnaires for approval prior to using them.

Researchers engaging in an unfolding research proposal should note the following information in their project description.

1. That they are engaging in unfolding research.
2. They should provide information on the study's areas of interests, behaviors they intend to record and any interview or survey questions they will use to launch their research explorations (e.g., questions they know they will be asking participants as they begin the study).

3. Assure the IRB the research will be carried out in a manner ethical to the researcher's field of study.

5.6 Recruitment materials

As advertisements, recruitment letters and the like are part of the participant selection process and, in some cases, the consent process; they are subject to IRB review and should be included with your application OR when researchers decide to use the materials. This includes samples of items like flyers, bulletin board tear-offs, posters, recruitment scripts, and the like.

Recruitment information should include:

1. The name of involved researchers and university(ies) involved in the project
2. Contact info of the researchers
3. Criteria for involvement in the study
4. Truthful descriptions of any direct benefit or payment for participating in the study.

Researchers should avoid language or imagery that would pressure participants to participate in the study.

5.7 Monetary compensation for participation

If your project involves monetary compensation, this must be documented in your project description and will be closely reviewed by IRB; even if your protocol receives exempt from IRB review status. The informed consent form should thoroughly document the payment amount and method of payment.

Payments can be made for any reason (risk assumed, time participating, etc.) but cannot appear to be coercive or lead people to participate against their better judgment. Payment should correspond to burden of involvement for participation. Some examples would include paying some of or all of the parking fees for a study done at a location with a pay parking lot or a payment in line with the Illinois state minimum wage ($8.25/hr) for time participating in the study.

5.8 Research using investigational new drugs

If your project involves an item classified by the FDA as an investigational new drug (IND), you must assure the IRB you are complying with the IND regulations (21CFR312). The IND number must be included on your IRB application when submitted.

Approved drugs may also require an IND if their use in the study is…

1. Different from the FDA approved use
2. Administered in an unapproved way
3. Is in an altered dosage
4. Shipped by interstate commerce for clinical trial purposes.

Your study may be exempt from IND requirements if it lawfully marketed in the U.S. and meets ALL the following stipulations. All of these points must be discussed in your project description:

1. Results will not be reported to the FDA to submit a new usage for a drug or any major change in the labeling of the drug.
2. Results will not be used to support changes in how a drug is currently advertised.
3. The study does not involve a usage or dosage that significantly increases risks commonly associated with the use of the drug.
4. The study is done in compliance with Part 56 on institutional review and Part 50 on informed consent.
5. The study is done in compliance with 21CFR312.7.

5.9 Research using investigational new devices

If your project involves an item classified by the FDA as an investigational new device (IDE), you must assure the IRB you are complying with the IDE regulations (21CFR812 or 814). The IDE number must be included on your IRB application when submitted.

5.10 Externally funded research projects

Researchers should make note of whenever they have intent to submit their proposal for external grant funding. Ideally, research proposals should be approved by IRB prior to being submitted for external grant funding. If you are submitting your research proposal to IRB concurrently with a review for external grant funding, make sure to (1) include a copy of your external grant proposal with your IRB application and (2) let the IRB know the external grant funding application pending. Also please submit your IRB paperwork with sufficient time for IRB review and approval prior to the time when the external organization considers your grant proposal.

5.10.1 External grant consideration prior to IRB approval

If the external organization allows external grant review prior to receiving IRB approval, the researchers are responsible for notifying the organization when IRB approval has been received.

5.10.2 Funding awarded prior to IRB approval

If the external organization awards you funding prior to IRB approval, again you are responsible for notifying the organization when IRB approval is received. You are also responsible for submitting your IRB paperwork with sufficient time to meet any funding deadlines specified by the external organization.

5.10.3 External grant proposal denied

If the external organization denies you funding for your research project, please make the IRB aware of whether or not you will move forward with your research proposal without external funding.

5.10.4 Additional endorsements

If your external sponsor requires any additional endorsements other than IRB approval, please make those issues known to the university Office of Sponsored Research Programs (OSRP).

5.10.5 Change of project title ONLY

Should you wish to change ONLY the title of your research project to make it more competitive or relevant to a funding sponsor, this must be approved by IRB. Simply send an email to the IRB Chair with your IRB approval number, request for title change and why. Please also attach to the email any other documents that will change as result of the change in title (e.g. informed consent form). Please also notify to the IRB if you wish to "retire" any project titles that you do not wish you use on any further grant proposals.

While IRB extends this simplified process as a courtesy to researchers, the IRB does not wish to keep track of an excessive number of active project titles and reserves the right to deny your request to change your project title if it feels this procedure is being abused.

5.11 Doing human subjects research without IRB approval

If you are engaging in a human subjects research project without IRB approval, you are putting Governors State University out of compliance with federal regulations on human subjects research. It will also put GSU's certificate of federalwide assurance (FWA), assurance that we will comply with these federal regulations, at risk.

This may result in action taken by the federal government or GSU's Office of the Provost that will prevent you, your department, division, or even the university as a whole from doing human subjects research. The federal government also reserves the right to cut or suspend federal funding of various grant programs that are beneficial to GSU and its students if we are found in violation of federal regulations on human subjects research.

Human subjects research data collected without IRB approval cannot ethically be used in research, including theses and dissertations. If you are collecting data for a project for which you did not submit an IRB application and during the project you need to submit an IRB application (e.g., a project which was originally a class project, but you later wish to present your findings at a regional conference), please do so as soon as possible. Federal regulations do not allow for retroactive approval of projects once data collection is complete.

6. What is involved in the consent process?

6.1 Consent is an ongoing process

Consent forms are a very important part of the IRB application process. When they are used they are only one part of the larger informed consent process. Since participants voluntarily consent to participate and can withdraw at any time, consent is a process that begins when participants start learning about your study and ends when participation is complete.

If your study requires informed consent there are some general principles you should keep in mind. First, participants must understand what they are consenting to. This may involve writing the consent form in participant-appropriate language. Second, people should be given enough time to make a decision to consent; researchers should never rush participants into consenting. This may involve giving participants time to discuss the study with family or loved ones before making a final decision to consent, particularly if the study involves greater than minimal risk to participants.

6.2 Essentials to the consent process (45CFR46.116)

The IRB at GSU does not mandate any particular kind of specific template to be used for informed consent (though we have sample templates available if you want one). Federal regulations mandate the following information be included in the informed consent process unless the IRB approves otherwise (45CFR46.116a).

1. You must explain the purpose of your research.
2. You must report how long you expect the research will take.
3. You must identify the procedures of the study and any experimental products or procedures used.
4. You must describe why the participant is eligible to participate.
5. You must describe any perceived risks or discomforts. If there are no perceived risks beyond what is experienced in daily life, then you must include that on the consent form.
6. You must describe any perceived benefits either to the individual or society at large.
7. You must disclose any alternative procedures or treatments.
8. You must disclose the extent to which confidentiality of data will be maintained and who will have access to the data.
9. You must disclose contact information about who to contact (1) with questions about the study, (2) with questions about research subjects rights, and (3) in the event of a research-related injury.
10. For studies involving greater than minimal risk, you must disclose: (1) any information regarding compensation for participation, (2) any information on medical treatments available if an injury occurs and what the treatments consist of, (3) where any additional information can be obtained.
11. You must disclose that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that the participant may withdraw consent at any time without penalty or loss of benefits.

When it is relevant to your research protocol, you must also include the following information in the consent process (45CFR46.116b):

1. You must disclose that the potential for unforeseeable risks exist from a treatment or procedure (e.g., testing an experimental medicine where side effects are not well known).
2. You must disclose any circumstances in which a participant's involvement in your study may be terminated without regard to their consent.
3. You must disclose any costs the participant may incur by participating.

4. You must disclose any consequences a participant may experience from withdrawing from a study and the any procedures that may be required in order for a participant to withdraw from your study.
5. You must disclose to the participant that you will give the participant any information or findings from your research that may play a role in the participant's willingness to continue participation in your study.
6. You must disclose the approximate number of participants in your study.

The IRB may approve consent procedures that waive some or all of the elements required in the informed consent process (45CFR46.116c&d). If you wish to request an exception to the federally mandated requirements, you must make that request in your project description and provide justification for the request.

6.3 Assessing participants understanding of information

The **researcher is responsible** for making sure the participant understands the research procedures, risks, and benefits to participating in a study. As risk and complexity of the study increases, participants understanding of what's involved in study involvement become even more critical. In these cases, researchers should consider asking the participants open-ended questions (e.g., "Describe the purpose of this study as you understand it." Or "Can you convey to me the potential risks of your involvement in this study?") These kinds of questions will be answered in ways unique to the participant and will provide researchers with better information in assessing participants understanding of a study than closed-answered questions that can be simply answered "Yes or No".

6.4 Documenting consent

Once it is clear that the participant understands the study purpose, risks and benefits and wants to participate then consent must be documented. A signature certifies a participant's willingness to participate, a date certifies the when participants began participating after completing the informed consent process.

As there is often a wide range of research participants, one consent form may not be appropriate for all your participants. Studies involving minors may also require assent forms. Studies involving participants with limited understanding of the English language may require consent forms translated in the appropriate language(s).

Please see Section 6.7 for information about child assent and Section 6.8 on foreign language consent forms.

Here are some suggestions to keep in mind when creating your consent form:

1. Keep the font large enough to be readable for your participants.
2. Include the title of the study and contact information for the researchers claiming authorship. If the project is a student project, contact information for the faculty member serving as project director should also be included.
3. If your consent form has been revised since the start of data collection, please also include the version number of the consent form on the document.
4. Avoid language that suggests assumes participant understanding or limits the participant's ability to ask further questions (e.g. "The risks and benefits have been presented." or "You are aware of your of the study procedures.").
5. Use language appropriate for your participant pool.
6. Keep study descriptions brief. Use appendixes if more complex information or details need to be included.

6.5 When do I submit the consent form to IRB?

You should include all appropriate consent and assent forms with your IRB application. If the IRB has approved your consent form and you need to make substantive changes to it, the IRB must approve the modified consent form BEFORE you can begin to use it. If continuing review is required for your study, the IRB must also re-review your consent forms to make sure they are in-line with any new federal regulations.

See Section 7.3 for more information on the continuing review process.

6.6 When can informed consent be altered or waived? (45CFR46.116c&d)

The informed consent requirement described can be altered or waived altogether. There are three acceptable justifications for waiving or altering informed consent process; at least one justification must apply.

1. The study explores certain aspects of public benefit or service programs (45CFR46.116c)
2. The study meets ALL of the following stipulations (45CFR46.116d)
    a. There is no greater than minimal risk to participants.
    b. The waiver or alteration of informed consent will not unduly affect the rights and welfare of participants.
    c. The research could not be practically done without the waiver or alteration.
    d. If appropriate, pertinent information about the study will be given to participants after their participation in the study.
3. The exceptions to the informed consent process are justified to carry out emergency research meeting the guidelines in 21CFR50.23-24.

Keep in mind, only the IRB can authorize waiving or modifying the informed consent process. Researchers can request the waiver, but they are not allowed to make this decision on their own.

6.7 Parental consent and child assent (HHS 45CFR46.408; DOE 34CFR97.408)

6.7.1 Parental consent and waivers

Parental consent is typically required for studies involving children under age 18. A waiver of parental consent can be authorized by IRB for the same reasons stipulated in Section 6.6 of this manual. In addition, a parental consent waiver can be requested if there is a population for which seeking parental permission is not a reasonable requirement to protect the children (e.g. working with abused or neglected children). Waivers of parental consent are rarely given. If a waiver of parental consent is given, you must insure there are methods in place to protect the child and these methods must be approved by the IRB (45CFR46.408c).

6.7.2 Child assent

In many cases, once parental consent is obtained, researchers must also seek the assent of the child to participate in the study. Obtaining assent is important because it serves to show your respect for the rights of the children participating in your research activity. It also develops a sense of inclusion and understanding of the child in what you are asking them to do. The IRB determines if child assent is necessary (45CFR46408a) and if necessary, if and how child assent must be documented (45CFR46.408e).

When child assent procedures are required, they will be for children ages 8-17. Child assent procedures will not be expected for children under age 8, and parental consent will suffice. The IRB expects that you will develop study-focused assent forms which are appropriate for the child's age, physical, mental, and psychological capacities. In many cases, this will involve more simplified language than the parental consent form. In some cases, the IRB may also okay verbal child assent procedures for young children (under age 12).

Information on the assent form should be similar in content to the parental consent form and should include:

1. Why the study is being done.
2. What will happen and how long is the study duration.
3. That it is up to the child to participate or say no or quit participating when they feel like it
4. Explain if there will be any potential pain or discomfort.
5. Explain the good things that may happen to the children.
6. Explain any other options the children have.
7. Explain if there is any money or treats or any other compensation.
8. Let them know you are there to answer any questions they have.

Ideally child assent forms should be kept to one page.

6.7.3 Waiving child assent by IRB

Federal regulations state that the IRB, and not the researcher, makes the determination as to whether or not child assent procedures are necessary. Therefore, it is important that whenever you are doing a study with minor participants, to include their potential ages, physical, educational and psychological capabilities (whichever are relevant to your study). This information is invaluable in helping the IRB make a determination about requiring child assent. IRB reviewers may ask you for this information in the review process if you do not include it.

The IRB reserves the right to waive the child assent procedures for any of the following four reasons. Reasons 2-4 can apply even if the children are capable of understanding the study or providing assent:

1. If the capabilities of the children are so limited that they likely would not understand what assent is or what procedures they would be assenting to.
2. The study holds a direct benefit to the child's health or well-being that would only be realized in the context of the research done (e.g., therapeutic studies).
3. The study explores certain aspects of public benefit or service programs (45CFR46.116c)
4. The study meets ALL of the following stipulations (45CFR46.116d)
    a. There is no greater than minimal risk to participants.
    b. The waiver or alteration of informed consent will not unduly affect the rights and welfare of participants.
    c. The research could not be practically done without the waiver or alteration.
    d. If appropriate, pertinent information about the study will be given to participants after their participation in the study.

In addition to waiving child assent entirely for all participants, the IRB can choose to waive assent for particular study participants, groups of study participants, or can choose to waive the inclusion of particular details that would otherwise be included on the assent form (e.g., duration of the study). The IRB can also choose to waive documenting assent but require you to provide children with an information sheet about what will occur in the study.

If you believe your study meets one of stipulated reasons and a partial or complete waiver of child assent is important to your study, you are encouraged to make that known in your project description for the IRB to consider.

6.8 Language and cultural concerns regarding consent

When study participants will primarily be non-English speaking, researchers should prepare informed consent forms in all languages relevant to the participants. In addition, the researchers should also provide information explaining the language expertise of the translator and the consent form. The IRB reserves the right to consult

with foreign language experts regarding the consent form if deemed necessary. Alternative forms of informed consent can be considered. For example, IRB can authorize oral informed consent in English with a short document in the participant's language for documenting the consent, if the IRB is aware that participants can understand English but not read or write it.

The IRB should be made aware when cross cultural concerns (e.g., foreign cultures, Native American, religious, illicit) regarding study participants exist. There are cultures where signing a consent form can be threatening to the participant and pose more risk for participants than participating in the study. In these situations, you should make clear to the IRB, (a) the cultural constraints you will deal with and (b) how you intend to document consent given those cultural constraints. Waivers of written documentation of consent can be authorized by the IRB in such situations.

6.9 Waived consent in acute care situations (FDA 21CFR50.23a)

A waiver to informed consent can be given in situations when research on drugs or devices are used in emergency situations. The intent of this exception is to allow physicians and other healthcare personnel to use new treatments and procedures on patients unable to understand what they would be consenting to in the study. The exemption to consent may be considered by IRB if (1) the patients are in a life-threatening situation and (2) there is no other approved therapy with a better chance to save or improve the patient's life.

7. What is involved in the continuing review process?

7.1 What is continuing review?

Continuing review is done in compliance with federal regulations or when the IRB deems necessary to reassess a project. The IRB's goals in continuing review is to make sure (1) the approved IRB protocol is still followed, (2) the harms to benefits ratio is still appropriate, (3) measures to protect participants are in place, (4) that the current project is up-to-date with any changes in federal regulation to human subjects research.

The IRB may require changes or revisions to the research protocol based on whether study risks were over or underestimated OR if study benefits were over or underestimated.

7.2 When is continuing review required?

Federal regulations stipulate that continuing review is required for all projects with approved expedited or full board review status at least once per year (45CFR46.109e). The IRB treats continuing review with the same seriousness as an initial review process. The study expiration date is important. If a study expires, data CANNOT be collected for or further analyzed; NOR can funds be spent on the study.

Researchers should submit continuing review forms prior to their study expiration date. If a study expires, researchers will have 30 days to submit a continuing review form but MUST ALSO explain the reasons for allowing the study to expire. If researchers do not submit a continuing review form within 30 days after the study expiration date, the study will be considered "inactive" and the researchers will need to submit a new IRB application for initial review to reinstate the study.

Federally funded studies with "inactive" status due to lack of response for continuing review will be reported to Office of Human Research Protections (OHRP). Inactive studies using investigational drugs or devices will be reported to the FDA.

7.3 What information should be included with continuing review?

Continuing reviews are done the same level as the initial review or previous continuing review (expedited or full board review). The following information should be submitted with your continuing review application which is available on the GSU IRB website:

1. The total number of study participants since last review and overall.
2. The number of participants that have withdrawn from the study.
3. Participant breakdown by relevant population(s).
4. A summary of the results compiled thus far (if applicable).
5. Declaration of any unanticipated risks or adverse results.
6. Declaration of any unanticipated benefits.
7. Declaration and dates of any approved changes to study protocol.
8. Declare any difficulties recruiting or maintaining participants and reasons why.
9. If you have a study or funding sponsor, document any changes with that sponsor that may lead to a potential conflict of interest.
10. Include documentation for any investigational drugs or devices you are using that have received FDA approval since the last review.
11. Include a copy of the consent currently in use if you continue to recruit participants.

As with initial reviews, after assessment of a continuing review application, the IRB may request more information, revisions to documents, research protocol, or all of the above.

7.4 Changes in the research project

The **researcher is responsible** for carrying out their research according to the approved IRB protocol and with IRB approved documents. Substantive changes (i.e. changes in study population, procedures, sites, researcher personnel, consent forms, recruitment strategies) require IRB approval. Changes made without IRB approval violate the approved protocol. If you wish to make a change to your IRB approved project:

1. Submit a letter or email to irb@govst.edu to the IRB Chair.
2. Describe the change(s).
3. Explain why the change is needed.
4. Describe how the change will affect participants.
5. Provide any revised documents.

Most changes received expedited IRB review. Any changes that pose greater than minimal risk to participants will receive full board review.

7.4.1 Changing a project director

In the event a project director is either (1) on sabbatical or (2) permanently leaves GSU, a new or interim project director must be named for the project. The IRB should be made aware of this change and the qualifications of the new project director. Failure to do this will lead the IRB to place the study on "inactive" status effective from the date of the sabbatical or the date the director leaves the university.

7.5 Unanticipated Events

7.5.1 Adverse events

The IRB considers an adverse event to be an event itself or the nature, severity, or frequency of an event is unforeseen and not described in the research proposal. This is not solely limited to adverse events to participants and may also include errors in documenting consent or a breach of data confidentiality. Adverse events should be reported to the IRB within 10 working university business days. Please alert the IRB within 24 hours of any participant that dies while a participant in your study, whether or not the death is believed to be result of the study protocol. Depending on the severity or frequency of adverse events occurring, a study may IRB approval suspended or revoked to ensure participant safety.

When an adverse event occurs during the research process, please report the following to the IRB:

1. Document the Date, Description and Facts of the Event
2. If the event is related to the study procedures, drugs, or devices used in the study.
3. What has been done to address the event.
4. The perceived likelihood that a similar event could reoccur.
5. Whether the adverse event has uncovered new information about the study's risks which should be disclosed to participants.

7.5.2 New risks and benefits

As studies continue, new study risks and benefits may be uncovered which necessitate either a change in study protocol or an end to the study. An example of this is if a researcher finds significant evidence that a new physical therapy treatment being studied is effective at resolving whatever ailment it was being explored for. Once this is uncovered, it is not ethical to continue to have "control group" participants that do not receive the new benefits that have been uncovered.

Should this situation occur in your study, please alert the IRB, describe your findings, and mention the need to suspend the control group aspect of your study. If IRB approves, the researcher will need to contact all control group participants and invite them to participate in an "open label" study where participants will receive the beneficial treatment they did not receive as result of being in the control group.

7.6 Research project and researcher records

The **project director is responsible** for maintain a record (electronic or paper) for all items related to human subjects in their research and IRB approved documents. The project director's file should be similar to the IRB's documents. Whichever party holds the original documents, the other party should hold a copy of the document.

Documents that should be included in your records should include:

1. Copy of the IRB application and all supplemental documents that were included with the application.
2. The IRB's formal response to the application
3. Responses to/from the IRB regarding any requests for application changes or additional information.
4. The IRB's approval letter for the protocol.
5. Copies of all correspondence with IRB related to your proposal
6. Copies of continuing review forms and documents.
7. Notices of renewal approval