



## ***Guidelines for Learners***

# **Protection of Human Participants in Research**

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This information is taken directly from the college's *Guidelines for the Protection of Human Participants in Research*. Any materials referenced appear in the larger document. Faculty and Student *Quick Links* on the GSC portal provide access to all forms and materials.

### **Review Procedure**

Granite State College learners may conduct research or inquiries that involve human participants in various courses, independent learning contracts, or in other college sponsored activities. All research involving human participants must be reviewed and approved according to GSC Institutional Review Board (IRB) guidelines before learners begin collecting data.\* The following information regarding levels of review and guidelines for developing research are designed to inform learners about the steps that must be followed for review and approval, and the time frame necessary for planning and conducting research.

- Learners may begin research involving human participants only *after* the complete proposal has been reviewed and approved. GSC *does not* offer post hoc approval for research studies.
- Take into consideration the time necessary for review in order to complete a project within the term. All materials must be submitted to the IRB before proceeding. If research requiring an expedited or full review is planned, learners need to factor in additional time required for proposal review.
- Learners completing Independent Learning Contracts are encouraged to plan research that is exempt from review and should allow sufficient time for review of their proposal.
- Learners who have not completed a research methodology course are strongly encouraged to complete the National Institutes of Health online tutorial, *Protecting Human Research Participants*. Supervisors and contract mentors are also strongly encouraged to complete the NIH online tutorial.  
<http://phrp.nihtraining.com/users/login.php>

### **Types of IRB Review**

*All research involving human participants must be reviewed and approved regardless of the nature of the research proposal.* In order for this review to take place, learners proposing research projects that involve human participants must complete a research proposal (Appendix E) that will be first evaluated by the instructor or faculty mentor and then submitted to the IRB. The level of risk to participants in the research study will determine the type of IRB review conducted. GSC follows federal policy by defining three types of review that will be conducted by the IRB:

- *Exempt from further review*
- *Expedited review*
- *Full review*

**Exempt from Further Review:** Certain types of low-risk research involving human participants are exempt from federal regulations, and GSC learners are encouraged to develop proposals that fall within this category. Determining whether a proposal is exempt from further review is made by an individual not directly involved with the project. A designee of the GSC Institutional Review Board will make this determination. The Code of Federal Regulations: 45 CFR 46:101(b) identifies research that falls within this category, including:

1. Observational studies where the identity of participants remains anonymous
2. Record reviews with permission of the agency holding the records in which the results remain confidential.
3. Surveys or interviews with the following conditions:  
*Non-vulnerable (protected) adult populations.* Participants in the study are not categorized as a vulnerable population. These are individuals who have limited ability to protect their own interests. Vulnerable populations include (but are not limited to) children, individuals with questionable capacity to consent, prisoners, students/employees, health care facility residents/patients.  
*Informed consent* of participants has been obtained  
*Minimal risk:* The nature of the research involves no anticipated physical, emotional, or social risk to participants  
Procedures for maintaining *confidentiality* of data are in place

*To design a research proposal that will be exempt from further review:*

- *Use non-interactive methods of collecting data, e.g. observational methodology or record reviews.* Gather information by observing people in public places or reviewing available data, records, or documents while maintaining participants' anonymity.
- *Include only non-vulnerable populations as participants.* Collect survey or interview data from non-protected adults who can freely give their consent.
- *Avoid questions/content that could present physical, psychological, emotional, or social risk to the participants.* Sensitive topics may present these types of risk. Surveys and/or interviews with content that could be perceived to present any risk to participants will require further review by the IRB.

**Expedited Review:** If the research involves no more than minimal risk to participants, an expedited review of certain types of research will be conducted by the IRB designee or chair and another member of the Board. Projects that require at a minimum an expedited review include the following:

1. Research with a vulnerable (protected) population
2. Interviews/surveys that involve sensitive content or content that may provide physical, emotional, or social risk to the participants.
3. Any research involving intervention/treatment and/or deception.

**Full Review:** If research involves more than minimal risk to participants, full IRB review will be conducted. GSC students are discouraged from designing research proposals that may expose participants to more than minimal risk.

## **Summary of Steps in the Review Process**

### **Step 1 Application**

Learners complete a *Research Proposal* form (*Appendix E*), submit form and other required materials to faculty, contract mentor, or supervisor for review. Faculty/mentor/supervisor signs if he or she approves the conditions of the project. Refer to the *Research Proposal Checklist* (page 7) for a list of the information that is required with the *Research Proposal*.

### **Step 2 Review**

- Submit approved *Research Proposal* and *all required documents* via email to IRB designee (with cc to faculty) for first screening. IRB designee will determine whether proposal is exempt from review, conveys outcome of review to learner and faculty or contract mentor.
- IRB designee maintains log of all reviews and outcome, periodically reports to IRB chair; all information will be stored in the Office of the Dean of Academic Affairs.

### **Step 3 IRB review**

If the proposal is not exempt from further review, the IRB designee consults with IRB chair and additional review (expedited or full) is conducted.

### **Step 4 Notification**

*Complete* proposals will be reviewed and a decision rendered in no more than two weeks' time. Learner and faculty or contract mentor will receive written notification of the outcome of an Expedited or Full Review.

## RESEARCH PROPOSAL CHECKLIST

*For IRB review, develop a Research Proposal that contains the following information: (Appendix E)*

- 1. Research Objectives or Abstract:** Includes a brief description of your project that outlines the nature and purpose of your research. Clearly state the specific objectives of the research.
- 2. Description of Participants:** Identify the participants subjects of the study. If participants are members of a vulnerable (protected) population, explain how you will make necessary provisions in your research and provide your parent consent form and any letters that you will send to school/institution administrators, parents, etc. *(Appendix B, C)*
- 3. Recruiting Participants:** Explain the details of your plan for participants: source of your subjects, how they will be recruited, and whether they will be compensated.
- 4. Data Collection:** Describe the setting in which the study will be conducted. What will the subjects be asked to do? Outline procedures and instructions to be used with participants. Explain how data will be analyzed or studied. Describe how any interpretations will address the research questions. *Include sample copies of all surveys or interview questions.*
- 5. Confidentiality:** How will you maintain confidentiality? Describe how you will store the data that you collect and how you will maintain secure records. *(Appendix D)*
- 6. Informed Consent Procedures:** How will you obtain informed consent? Describe your procedures for obtaining consent from adults or assent from children. Provide a copy of the informed consent document you will use. *(Appendix A, C)*
- 7. Risk and Benefit Analysis:** Identify all foreseeable risks to participants subjects including physical, psychological, and economic. What are the risks associated with a breach of confidence? Summarize the benefits to participants. Include a statement of the value of your project. In studies involving risk, address the relationship between risks and benefits. *(Appendix D)*
- 8. Permission Letters:** Provide sample parent consent letters or letters of agreement from research site administrator, e.g. school principal, hospital or nursing home administrator, etc. If this is a workplace study, include a letter indicating the supervisor's consent to conduct the study.

*(Appendix A)*

## INFORMED CONSENT TEMPLATE

This template includes the information that you must provide subjects to obtain their consent to participate in your research. If you are mailing surveys to participants, include this information in a cover letter. In your Research Proposal explain how you intend to obtain informed consent and include a copy of the documents that you will use.

- **Purpose of the Study:** State the purpose of the research in as few words as necessary and in wording understandable to the subject population.
- **Description/Procedures:** *The use of human participants in this project has been approved in compliance with Granite State College's Guidelines for the Protection of Human Subjects in Research. If you volunteer to participate in this study, we would ask you to....* explain the procedures to be followed, expected duration of the subject's participation.
- **Potential Risks:** Describe any foreseeable risks, discomforts, inconveniences and how these will be managed. Include a description of the safeguards to be used to protect the subject.
- **Potential Benefits:** Describe benefits to subjects expected from the research. If the subject will not benefit from participation, clearly state this fact. State potential benefits, if any, to society that will be accrued from this research.
- **Participation and Withdrawal:** Tell subjects that participation is voluntary and they may refuse to participate. They may withdraw or be withdrawn at any time without penalty. *Participation in this study is voluntary. If you volunteer to be in this study, you may withdraw or be withdrawn at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. No coercion of any kind is used in seeking your participation.*
- **Payment for Participation:** State whether the subject will receive payment. If not, state so. If subject will receive payment, describe the nature and conditions of remuneration.
- **Confidentiality:** Explain how confidentiality will be maintained. If you feel that confidentiality cannot be maintained, describe why. If information will be audio or videotaped, describe the subject's right to review/edit the tapes, who will have access and where they will be stored, how they will be used, and whether they will be coded, cross-referenced, and when they will be erased. *Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as is required by law.*
- **Identification of Investigators:** Provide information of whom to contact if the subject experiences problems or for answers to questions about the research. Include name and phone number of the principal investigator and the supervising faculty.
- **Rights of Research Subjects:** *Information gained about you as a result of your participation will be provided at the conclusion of the research if you request. You may withdraw your consent or your data at any time and discontinue participation without penalty. If you have questions regarding your rights as a research subject, contact the Office of Academic Affairs at the GSC Administrative Center 603-228-3000.*
- **Consent and Signatures:** *I understand the procedures described above. My questions have been answered to my satisfaction. I have been given a copy of this consent form to keep. I consent to participate in this study.*

ADDITIONAL NOTES: Under age 7: parent/guardian signature—no signature from subject—date  
Ages 7-17: parent/guardian signature & subject signature—date  
Age 18 and over: subject's signature—date  
Signature of Investigator—date

## TEMPLATE FOR PARENT CONSENT LETTER

Parental permission is required if your research design involves interacting with minors, interviewing or administering questionnaires to minors, or asking classroom teachers to complete questionnaires about minor students. This template contains the necessary language for seeking permission to gather information from minors. You will need to tailor the consent letter to your particular research project. Include a copy of the consent letter that you will use when you submit your proposal for review.

Dear Parent or Guardian:

I am requesting your consent for your child to participate in a survey (*or other type of research*) of the (*group included in your survey*) at (*school name*). This survey is part of a research project that I am conducting as a student in *GSC course* at Granite State College. Your child's school principal and (*teacher name*) have agreed to participate in this study. *Identify who will administer the survey.*

*Describe the purpose of the survey and how the results will be used.*

Completing this paper and pencil survey posts no risk to your child. It will take approximately (*time*) to complete. Survey procedures have been designed to protect your child's privacy and allow for anonymous participation. No student will ever be mentioned by name in a report of the results. Participation is voluntary and there will be no action against your child if he or she does not participate.

If you have any questions or concerns about the project, please call me at *phone* or my instructor *name, phone*.

Please indicate below whether you give permission for your child's participation. I have enclosed two copies of this letter. I am asking that you sign and return one copy to your child's teacher by *date*. The second copy is for your records.

*Closing, your signature.*

\_\_\_\_\_ Yes, I consent for my child, \_\_\_\_\_, to participate in the survey described above.

\_\_\_\_\_ No, I do not give consent for my child, \_\_\_\_\_, to participate in the survey described above.

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Parent Signature

Date  
(Appendix C)

## GUIDELINES FOR OBTAINING ASSENT FROM CHILDREN

There are special considerations to take into account when the participants of a research study are minors. Federal guidelines (45 CFR 46) have defined the types of studies involving children that require review. In all cases, parental permission is required first, and in those studies that require full review, the researcher should also obtain assent from the child. For research purposes, “assent” is defined as a child’s *affirmative agreement to participate in research*. Mere failure to object should not be construed as assent. *Researchers working in education and/or clinical settings should be sure that the participants know that the research is separate from any instruction or treatment.*

The following are age-appropriate guidelines for obtaining assent from children of different ages. Because the ability of children to understand the elements of assent generally increases with age, researchers will likely provide less detailed explanations to younger children and more detail to older children. In addition, because there are individual differences in the development of children’s ability to understand the researcher’s requests, there is a necessary age overlap in the categories listed below.

**Ages 2-7:** For children between the ages of 2 and 7, the request for assent should be kept simple and direct. The researcher might ask the child if he or she would join the researcher in the next room to look at pictures. If the child were to say “yes”, that would imply assent for this age group. If the child were to say “no”, the researcher should respect the child’s wishes. It should be possible, however, to ask the child once again several minutes later. Sometimes children may not communicate verbally their refusal to participate. For example, a child may begin working on another task unrelated to the research activity. The researcher should be aware of such a cue and end the activity.

**Ages 6-14:** For children between the ages of 6 and 14, the request for assent should include:

- (1) a general description of the purpose of the child’s participation
- (2) a brief description of the experimental tasks
- (3) an assurance that the child’s participation is voluntary and that he or she may withdraw from the study at any point
- (4) an offer to answer questions

A researcher studying reading comprehension might say the following: “I am studying how fourth grade students read. I am going to ask you to read a few stories for me and answer questions about the stories when you are finished. You don’t have to read if you do not want to. If at any point you want to stop, that is fine; you may stop and go back to your class. If you want to read for me, do you have any questions before we begin?”

**Ages 12-17:** For children ages 12 through 17, the request for assent should include the elements of informed consent presented to adults, but this request should be presented in language appropriate to the child’s level of comprehension.

*Adapted from University of New Hampshire Office of Sponsored Research-Regulatory Compliance materials*

## **MAINTAINING CONFIDENTIALITY OF RESEARCH DATA**

1. Investigators must follow safeguards to ensure the confidentiality and security of all information obtained from human participants. Questionnaires, interviews, voice or video recordings, and other data-gathering procedures must be carefully designed to ensure that only information relevant to the project will be obtained.
2. Completed surveys, reference lists, voice or video recordings must be treated as confidential, and should be coded and kept in locked, secure files. Access to any data should be limited to authorized persons.
3. If the information is to be computer filed:
  - a. Distinct separation of the data from identifiable individuals must be maintained. In no case should the names of the participants or the identifying code be computerized. If identifiable numerical identifiers are necessary for file editing, they should be deleted as soon as the editing is complete.
  - b. Upon coding or computer filing, the original forms should be destroyed.
  - c. Access to computer sorted data should be on a limited basis by authorized persons only.
  - d. Responses from uniquely identifiable individuals, groups, or companies must never be filed in such a manner that the information can be identified by source.
4. If analysis is conducted on a sub-sample of the population, special care must be taken to be sure that the smaller group size does not lead to unintentional disclosures.
5. When reporting the results of any surveys or research, investigators must be aware that:
  - a. there is no statute of limitations on the confidentiality of subject information.
  - b. incidental identification of a subject or subjects may occur if the study involves a small sample size or if the general characteristics of the aggregate population are stated directly or indirectly.
6. For additional information, consult the safeguards specified in Public Law 91-513, Privacy Act.

*Adapted from University of New Hampshire Office of Sponsored Research-Regulatory Compliance materials*

**Granite State College Protection of Human Participants in Research  
RESEARCH PROPOSAL**

Student Name: \_\_\_\_\_ E-mail \_\_\_\_\_  
Instructor: \_\_\_\_\_ E-mail \_\_\_\_\_  
Course number, title: \_\_\_\_\_ Date: \_\_\_\_\_

**1. Project title:** \_\_\_\_\_  
**List your research objectives or provide an abstract of your proposal.**

**2. Does your research involve human participants in any way?**

- no     yes: *Who are the participants of your study?*
- minors
  - adults – age 18 or older
    - pregnant women
    - health care facility patients/residents
    - psychiatric facility patients/residents
    - other: \_\_\_\_\_
  - prisoners
  - human service agency clients

**3. How will you recruit the participants for your study?**  
Describe any incentives that you will offer for participation in the study.

**4. How will data be collected?**

- observation:  naturalistic  experimental
- record or archive review
- interview: *include a copy of interview questions*
- written or telephone survey: *include a copy of survey*
- psychological or educational test: *test name* : \_\_\_\_\_
- other: \_\_\_\_\_

**5. How will confidentiality and privacy of data be ensured as they are collected and retained?**

**6. How will informed consent be obtained?** *Attach the informed consent document.*

**7. Attach a risk assessment summary.** *Identify risks, risk level and protections in place.*

**8. Attach permission letters or letters of agreement.** *e.g. research site administrator, school principal, etc.*

➤ Learner signature: \_\_\_\_\_ Date: \_\_\_\_\_

I have reviewed and approved all student materials submitted.

➤ Instructor signature \_\_\_\_\_ Date: \_\_\_\_\_