Guidelines for Protection of Human Participants in Research

Student Version

NOTE FOR FALL 2018 STUDENTS: PLEASE ASK YOUR INSTRUCTOR FOR THE PASSWORD TO ACCESS THE "Granite State College Human Research Training" on Moodle. You will earn this certificate from the Moodle course.

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Review Procedure

Granite State College staff, faculty, and students may conduct research or inquiries that involve human participants. All research involving human participants must be reviewed and approved according to GSC Institutional Review Board (IRB) guidelines before researchers begin collecting data.

- In order for this review to take place, researchers proposing research projects that involve human participants must complete and submit a research proposal to the IRB.
- Researchers may begin recruiting human participants and collecting data only *after* the complete proposal has been reviewed and approved by the IRB. ***GSC does not offer post-hoc approval for research studies.***
- Student researchers must submit their research proposal to their course instructor or faculty mentor for approval and signature and then submit it to the IRB, with their instructor or faculty mentor included on **all** correspondence. Student researchers are urged to take into consideration the time necessary for review in order to complete a project within the term. If research requiring a full review is planned (e.g., studies involving minors or other protected populations), student researchers need to factor in additional time required for proposal review.
- Researchers must complete the Granite State College Human Research Training. Supervisors, contract mentors, and members of the IRB must also complete the online tutorial. **NOTE FOR FALL 2018 STUDENTS: PLEASE ASK YOUR INSTRUCTOR FOR THE PASSWORD TO ACCESS THE "Granite State College Human Research Training" on Moodle.**

The following includes definitions, information regarding the types of IRB review and guidelines for developing and submitting a research proposal. This includes a summary of the steps in the review process and a guide to completing a research proposal.

Definition of Research

Research is defined as an organized and systematic investigation to find answers to questions with the intent of broadly disseminating the results. A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains 1. data through intervention or interaction with the individual (such as, interviews, surveys, clinical testing, or any other physical intervention or personal intervention, or 2. identifiable private information- from the Code of Federal Regulations [46.102f].

The IRB is responsible for protecting the rights and welfare of human research participants for all research conducted by faculty, staff or students of Granite State College, whether conducted on-campus or off-campus. Protections are required for research using bodily materials, even if the researcher did not collect the materials or the materials are being discarded. Research that uses any GSC property or non-public information to identify or contact prospective subjects must be reviewed and approved prior to recruiting participants or collecting data. Approval by GSC is required in addition to approval from any other institution.

Research requiring IRB review prior to initiation, irrespective of funding:

- involves human subjects

- uses records on human subjects

Examples of projects/studies that do not need IRB review:

- Research projects that are limited to literature reviews or meta-analysis
- Archival studies retrieved from records available to the general public
- Anonymous surveys conducted for educational purposes

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Types of IRB Review

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 student researchers are encouraged to develop proposals that fall within this category. Whether a proposal is exempt from further review is determined 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. Archival studies using records 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 and the identity of participants remains fully anonymous, then 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 as long as responses remain anonymous:

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

1. Researchers must **complete** the following using the "Research Proposal Forms" template downloadable in the IRB webpage of my.granite.edu *(http://my.granite.edu/human-participants-and-institutional-review-board-irb)*:
    a. The Research Proposal form (Appendix F)
- The certificate for the Granite State College Human Research Training **NOTE FOR FALL 2018 STUDENTS: PLEASE ASK YOUR INSTRUCTOR FOR THE PASSWORD TO ACCESS THE "Granite State College Human Research Training" on Moodle. You will earn this certificate from the Moodle course.**
    b. The final certificate should be copied into the word document designated area as a .jpeg format image.
    c. The Checklist for IRB Proposal Review (Appendix G)
    d. Other required materials (including Appendices A - E if applicable)

These materials should be in one word document with the following file name convention: "IRBResearchProposalYYYYMMDD - LastName"

Researchers should refer to the section "Research Proposal Guide" for a comprehensive list of the information that is required with the Research Proposal.

Step 2 Submission

1. Researchers must have all materials **reviewed** by submitting it to their faculty, contract mentor, or supervisor prior to submitting to the IRB. The faculty/mentor/supervisor will sign the submission if he or she approves the conditions of the project.
2. Researchers must **submi**t the signed submission by email to **gsc.irb@granite.edu** (with cc to the faculty/contract mentor/supervisor) for the first screening.
3. The IRB reviewer will determine whether the proposal is exempt from review, as well as convey the outcome of the review to the student and faculty/contract mentor/supervisor.
4. IRB designee maintains a 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 Review

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

Step 4 Outcome

Complete proposals will be reviewed and a decision rendered in no more than two weeks. Researchers and, in the case of student researchers, their faculty, contract mentor, or supervisor will receive written notification of the outcome of an Expedited or Full Review.

Step 5 Final Report

Upon completion of your study, researchers must complete the IRB Final Report Form (Appendix H) and submit to the Institutional Review Board (IRB) along with a brief summary of findings for this study, for audit purposes. Copies of abstracts, articles, and/or publications specific to the project are acceptable. Send the report to the IRB, gsc.irb@granite.edu. Researchers must obtain the

electronic signature from their faculty, contract mentor, or supervisor prior to submitting to IRB.

Research Proposal Guide

For IRB review, develop a Research Proposal that contains the following information using the Research Proposal Form in Appendix F.

1. **Research Objectives or Abstract:** Includes a brief description of the research project by outlining the nature and purpose of the research. Clearly states the specific objectives of the research. Cites previous research to support the rationale for the research project. Approximately 120 words.

2. **Description of Participants:** Includes a statement describing the participants, which includes anticipated age and other demographic information; and inclusion and exclusion criteria. Includes a statement of whether or not minors (under age 18) will be involved as participants. If participants are members of a vulnerable (protected) population, explains necessary provisions.

3. **Recruiting Participants:** Explains the details of the recruitment strategy: place where participants will be recruited, how they will be recruited, and whether they will be compensated. Includes attachments of any advertisements, recruitment posts to be used on social media, letters, emails to people, etc., used to recruit participants.

4. **Data Collection:** Describes the setting in which the study will be conducted. Outlines procedures and instructions to be used with participants. Explains how data will be analyzed or studied. Includes sample copies of all surveys or interview questions. Indicates the source of all materials. References included in reference list.

5. **Confidentiality:** Includes how confidentiality will be maintained. Describes how data will be stored and secure records maintained. If research is not expected to lead to publication, then states that research records will be destroyed 6 months following the completion of the study. If research is expected to lead to publication, then states that aggregated results will be published or presented at conferences and that all records will be destroyed 3 years following publication.

   Appendix D provides **information on maintaining confidentiality of research data.**

6. **Informed Consent Procedures:** Describes procedures for obtaining consent from adults or assent from children. Provides a copy of the informed consent document in attachment. If participants are minors, provides parental consent forms and any letters that will be sent to school/institution administrators, parents, etc.

   Appendix A provides a template of an informed consent form.
   Appendix B provides a template for parental consent letter.
   Appendix C provides guidelines for obtaining assent from minors.

7. **Risk Analysis:** Identifies all foreseeable risks to participants including physical, psychological, and economic. What are the risks associated with a breach of confidence? In studies involving risk, addresses the relationship between risks and benefits. *(Appendix D).* Includes a statement that the researcher has no conflict of interest.

8. **Potential Benefits:** Summarizes the benefits to participants. Includes a statement of the value of the research project. Includes a statement indicating whether or not participant will receive payment for their participation.

9. **Permission Letters:** Provides 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, includes a letter indicating the workplace supervisor's consent to conduct the study. Please see Appendix E for sample permission letters.

10. **Signatures:** The researcher need not sign the form if submitting the documents using a Granite State College email. The email will serve as the signature. However, in the case of student researchers, the instructor must affix their electronic signature to the document to indicate their approval of the student research proposal.

Descriptions for the Checklist for IRB Proposal Review

Purpose

1. A statement of the purpose of the study and a brief description of the procedures to be followed. This includes your objectives of the study. What question(s) is your study trying to answer?
2. A brief statement of background and utility citing previous work.
   This is a brief summary of what your study is about. Make sure to use published research articles to support the need for your study. Why does past research say about this topic? Put that here. There needs to be a justification for why your research is important. Also make sure to have a "References" section where you will place the citations for all of the articles cited.

Participants

3. A statement describing the participants which includes anticipated age and other demographic information; and inclusion and exclusion criteria.
   This is important to make sure your sample will consist of people able to give consent, as well as allow the IRB committee to understand the nature of your study. Make sure to note the age range of participants anticipated, gender, and any specific inclusion/exclusion criteria. What does someone have to be to participate? For example, if you are studying blue collar workers' perceptions of job satisfaction, being in blue collar position would be an inclusion criterion.
4. A description of the specific methods to be used for participant recruitment.
   What are you actually going to do to collect the data? Will they be able to give consent? It is important to inform the IRB committee how you plan to collect your data to ensure the method is ethical.
5. A statement of whether or not minors (under age 18) will be involved as participants.
   No minors may participate in the research study, as they cannot give proper consent. Therefore, your proposal form must indicate that all participants will be 18 or older.

Materials

6. A description of the measurement procedures to be used. Include in-text citations.

   Will a survey be used? You must also include any advertisements that you will use to recruit people. Anything you plan to post on Facebook, email to people, etc. need to be included. It is important to inform the IRB committee how you plan to collect your data to ensure the method is ethical.

7. All instruments used to collect data from the participants are appended to the application including demographic forms and advertisements used to recruit participants.
   Make sure to include all questions you plan to ask your participants. Make sure to indicate where the survey came from. If it is a questionnaire from online or a published research study, you must cite the source. If the questionnaire was created for the study by you, you must indicate that.

Procedures

8. A description of the data collection methodology/procedure.
   Describe the process you plan to use to collect data. Include all steps you plan to take, from recruitment fliers to participant completion.
9. A statement of the risks to the participants.
   All foreseeable risks for participants must be noted in order to give a proper cost-benefit judgment on the proposed study. The benefits of the study should outweigh any risks.
10. A statement describing how risk will be managed or minimized.
    Here you discuss how you plan to minimize those risks. If resources are applicable, give resources or tools for support to your participants.
11. A statement describing any potential benefits to the participants. Will participants receive compensation?

Will the participants be paid for participating? Will they receive any sort of compensation? What are the benefits participants receive from participating?

12. A statement describing the specific methods to assure confidentiality.
    An important ethical question to consider is whether or not people's responses are confidential. You must describe how you plan to ensure their responses are confidential. No one outside of the study may have access to participants' responses/data.
13. A statement whether compensation will be provided to participants for participation.
    Explicitly state whether or not participants will be paid.
14. A description of where data will be kept and a date that all identifying data will be destroyed (e.g., 6 months).
    You must note where the data will be kept (e.g., in a locked file cabinet, password-protected computer) to ensure that the data is safe. You must also note when the data will be destroyed. Typically, this is within 6 months of the study's completion.

Other

15. Reference list (include only those references that are cited within the body of the IRB application).
    Make sure to cite ALL sources used throughout your application. These references are any that are from your background of previous research, your sources for questionnaires, etc. Proper credit must be given to the sources of the information you use.
16. A consent form with addenda as necessary.
    Make sure to include your consent form with everything required (described below). The consent form tells participants what to expect from participating, the risks/benefits involved, and their options for leaving a survey. This is a vital part of the study.
17. An assent form with addenda as necessary.
    This is only needed when studies use participants under 18 years old. If your study does not include this population, put "N/A."
18. Appendices including support for the project. This may include approval for use of equipment (e.g., video recorders), and approval with signed letter of support by appropriate person at site for collaboration.(e.g., signed letter from business administrators giving permission to recruit their employees to participate in study) .
    Any equipment that you may need must either be your own, or you must include a letter giving you approval from the owner. If you plan to recruit from a specific location (e.g., your place of work), approval letters are required. If your study requires no approval, put "N/A."
19. Conflict of interest disclosure statement has been completed and included with the application.
    You must include a statement that states whether or not there is a conflict of interest (i.e., if you have something to gain if certain results are found).
20. Principal investigator and faculty advisor signatures on the application.
    These signatures are required. Your faculty advisor's signature is your approval from them to perform the study. Your signature can however be your name typed in, with you emailing your IRB form acting as a proxy for your signature.

Language of Document

21. Is the language used in the consent form and research material appropriate for the reading level of participants? That is, research and participant rights, risks, and potential benefits are described in layman's terms.
    Make sure everything that the participants will read (survey, recruitment fliers, consent form) are written in a way that the average person can understand. If they cannot understand what they are reading, they cannot give their full consent.
22. A foreign language translation must be included if the study will include participants whose first language of choice is not English.
    If your study involves non-English speaking participants, you must include a foreign language translation for them. If your study does not involve this population, put "N/A."

Checklist for Informed Consent Form

23. A statement that the study involves the use of human participants and a general explanation of the purpose of the study and a brief description of the procedures to be followed.
    Include a general description of the study. The participant must be given the purpose of the study and description of the procedures to be able to decide if they wish to participate.
24. A statement of expected duration of the participant's participation (e. g., one hour).
    Indicate how long the study is expected to take for the participant. The participant needs to know what they're going to experience before agreeing to participate.
25. A description of all reasonable discomforts or foreseeable risks to the participants.
    The discomforts and risks from the proposal form must be included in the consent form so participants know what to expect when deciding to participate.
26. A description of any benefits (indirect or direct) the participant may gain from participating in the study. If compensation (e. g., monetary, course credit, treatment) is involved, a description of this compensation is included.
    The benefits from the proposal form must be included in the consent form so participants know what to expect when deciding to participate.
27. If there are no benefits to the participants, this should be clearly stated.
    You must explicitly state if there are no benefits to participation.
28. A statement related to confidentiality of records and identification of the participant.
    The confidentiality information in the proposal form is required here. Participants must know that their answers will remain confidential, as well as the steps you are taking to ensure that confidentiality.
29. A statement to the effect that (1) participation is voluntary, (2) refusal to participate will result in no penalty or loss of benefits to which the participant is otherwise entitled; and that (3) the participant may discontinue participation at any time without penalty.
    Participants must EXPLICITLY be told that that their participation is voluntary. Thus, they may be allowed any option to cease participation. Include the following: Participation is voluntary. You may refuse to participate at any time, without penalty or any loss of benefits. You may also discontinue at any time, and skip any questions you do not want to answer, without penalty.
30. The name of the contact person for information related to questions about the research (the Principal Investigator), the rights of human participants (the IRB chairperson), and whom to contact in the event of a research related injury.
    Include names of the investigator, the supervising faculty, as well as the IRB, as people to contact should there be any research-related injuries/harm. Participants must be told who to contact if they begin to experience undesirable results.
31. A statement that the investigator has answered and will answer all questions posed by the participant now and in the future to the best of his/her ability.
    The investigator must be willing and able to answer any questions posed by participants at the time of the survey, as well as following the survey. The participant must be allowed a full understanding of what their participation entails.
32. A statement indicating voluntary consent has been obtained, including signature lines for participant and investigator, and date.
    A statement that the participant has given their consent voluntarily must be included. No coercion is allowed to obtain consent. If the consent is paper/pencil, signature lines should be included.
33. For online surveys, a statement that clicking on a button indicates consent and that participants may print a copy of the consent form using their web browser.
    If an online survey, stating that clicking continue acts as consent is needed. Also note that they can print off a copy if they wish. If the study is not online, then put "N/A."
34. A statement indicating child assent, if applicable.
    If children are included in the study, you must include a statement allowing the participant to give assent for the child. If they study does not involve children, put "N/A."

35. A statement that the participant will receive a copy of the consent form (When an oral summary is read to the participants or a short consent form is used, the statement should read that a complete copy of the consent form will be provided to the participant).
    The participants must be given an opportunity to be given a copy of the consent form. If done in person, they should be given a copy of the form. If the study is online, they should be given instructions as to how they can print off a copy of the consent form.
36. A statement that the IRB has approved the solicitation of participants for the study; this appears after the signatures.
    While you are still in the process of receiving IRB approval, you must STILL include a statement indicating that the IRB approves the study. Make sure to "X" this item upon adding the statement.
37. A statement describing how the participant may obtain a summary of the final results should they desire a copy. In what format will the results be provided?
    Participants must be offered a summary of the results, should they want it. Indicate that participants may email the researcher if they wish to obtain a summary of results following the completion of the study.
38. Provide name and contact information of the researcher, supervising faculty advisor and GSC Academic Affairs.
    Please provide your name and GSC email address, as well as the name and GSC email address of your supervising faculty member. Also provide the contact information for GSC Academic Affairs. This information gives participants the contact information they need should they want additional information about the study.

Certificate of Completion

39. A copy of the completion certificate for the Granite State College Human Research Training.
    This certificate shows that you are qualified to conduct research using human subjects. Without the tutorial, you are not ethically allowed to conduct the research.

INFORMED CONSENT TEMPLATE

This template includes the information that you must provide participants to obtain their consent to participate in your research. The verbatim in italics should be included in your informed consent. If you are mailing surveys to participants, include this information in a cover letter. If you are creating an online survey, include this information in the first page of your survey. In your Research Proposal form, explain how you intend to obtain informed consent and include a copy of the documents that you will use.

1. **Purpose of the Study:** State the purpose of the research in as few words as necessary and in wording understandable to the participant population.
2. **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 participant's participation.
3. **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 participant.
4. **Potential Benefits:** Describe benefits to subjects expected from the research. If the participant will not benefit from participation, clearly state this fact. State potential benefits, if any, to society that will be accrued from this research.
5. **Participation and Withdrawal***:* Tell participants 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 wantto answer and still remain in the study. No coercion of any kind is used in seeking your participation.*
6. **Payment for Participation***:* State whether the participant will receive payment. If not, state so. If the participant will receive payment, describe the nature and conditions of remuneration.
7. **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 participant'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.*
8. **Identification of Investigators**: Provide information of whom to contact if the participant experiences problems or for answers to questions about the research. Include name and email of the principal investigator and the supervising faculty.
9. **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. Please contact the principal investigator, {name and email}, if you are interested in receiving a summary of the research results*
10. **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.*

For online surveys: *By clicking on the button below, you are consenting to participate in this research study. You may print out a copy of this informed consent to keep in your records. If you do not wish to participate, click the "x" in the top corner of your browser to exit.]*

ADDITIONAL NOTES: Under age 7: parent/guardian signature—no signature from participant—date
Ages 7-17: parent/guardian signature & participant signature—date
Age 18 and over: participant'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. Minors include all participants younger than 18 years of age at the time of recruitment. 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). (Student researchers can also include, "This survey is part of a research project that I am conducting as a student in a 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 (*verbiage describing the study)* poses no risk to your child. It will take approximately (*time)* to complete. 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 email me at (*email)* or my instructor (*name), (email).*

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.

Parent Signature Date

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. 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 3 years after publication or after completion of the study if the data is not published. In the case of student research projects, all material containing data should be destroyed 6 months after completion of the project.
    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 ensure 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 participant information.
    b. incidental identification of a participant or participants 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

SAMPLE PERMISSION LETTERS FOR ORGANIZATIONS

The following includes two sample letters:

- A sample researchers may use to request permission to recruit staff/employees from an organization such as a school, shelter, mental health clinic, food pantry, etc.
- A sample the organization's administrator(s) may use in order to give the researcher permission to recruit staff/employees at their organization. Note that the permission letter from the administrator should be printed on the organization's letterhead and should include the administrator's:
    - Printed name
    - Signature
    - Job title
    - Name of the organization
    - Organization's contact information (e.g., email, telephone number, and address)
    - Date.

Researchers can customize the documents by changing the information included in parentheses:

For Use by the Researcher to the Organization:

(To Request Permission to Recruit Participants for GSC Research Study)

[*Date of Letter*]

Dear [*Name of Administrator*],

My name is [*your name*] and I am presently finishing my degree in [*name of program of study, For example: Psychology*] at Granite State College. As part of my final integrative course, I'll be conducting a study on [*brief description of study*].

I am writing for your permission to recruit [*describe the employees/staff you seek to recruit for your study*]. This research is supervised by [*name of professor*] and will be submitted to the Institutional Review Board (IRB) at Granite State College. Your employees/staff would only be contacted once approval from the IRB was received.

Enclosed is a permission form to recruit your employees/staff for participation in my study. If you are willing to grant permission, I invite you to sign the form and [*describe how the permission form should be returned to you]*.

If you have questions regarding your employees' rights as research participants, please feel free to contact the Office of Academic Affairs at the GSC Administrative Center at (603) 228-3000 or my professor at [*provide your professor's go.granite.edu email*]. I would also be

very happy to answer any questions you may have with respect to my research project. Please do not hesitate to contact me at [*your go.granite.edu email or your telephone number*].

Sincerely,
[*your signature*]
[*your name*]

For Use by the Organization to the Researcher:

(To Request to Recruit Staff/Employees for Participation in GSC Research Study)

I, [*name of administrator*], [*job title*], give permission to [*name of student*) to recruit staff/employees from [*name of organization*] for a study on [*research topic*]. I understand that this research study is conducted in partial fulfillment of a course in [*include name of the course]* at Granite State College, supervised by professor [*name of professor*]. I also understand that my employees/staff will only be contacted once the student project receives approval from Institutional Review Board (IRB) at Granite State College.

Printed Name of Administrator:
Job Title:
Organization Name:

Administrator Signature:
Date:

Contact Information:

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

Please follow the section "Research Proposal Guide" when completing this form.

Researcher Name:
Click here to enter text.

Email:
Click here to enter text.

Instructor:
Click here to enter text.

Instructor Email:
Click here to enter text.

Course Number, Title:
Click here to enter text.

Project Title:
Click here to enter text.

1. Purpose:

Click here to enter text.

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

Click here to enter text.

3. How will you recruit the participants for your study?

Click here to enter text.

4. How will data be collected?

Click here to enter text.

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

Click here to enter text.

6. How will informed consent be obtained?

Click here to enter text.

7. Attach a risk assessment summary. ☐

8. Potential benefits to participants:

Click here to enter text.

9. Attach signed permission letters or letters of agreement. ☐

10. Signatures:

Researcher Signature: Date:

X _____ Click here to enter text. _____

I have reviewed and approved all student materials submitted.

Supervising Faculty Signature: Date:

X _____ Click here to enter text. _____

Reference List

Click here to enter text.

- Insert the certificate for the Granite State College Human Research Training.

  NOTE FOR FALL 2018 STUDENTS: PLEASE ASK YOUR INSTRUCTOR FOR THE PASSWORD TO ACCESS THE "Granite State College Human Research Training" on Moodle. You will earn this certificate from the Moodle course.

Granite State College Protection of Human Participants in Research
CHECKLIST FOR IRB PROPOSAL REVIEW

All items must be checked if completed or marked "N/A" if it is not applicable. No items should be left blank. Descriptions are available by hovering over the superscripts[1] of each sentence. To print the descriptions refer to the section "Descriptions for the Checklist for IRB Proposal Review".

Purpose

- ☐ A statement of the purpose of the study and a brief description of the procedures to be followed.[1] (☐ N/A)
- ☐ A brief statement of background and utility[1] citing previous work.[2] (☐ N/A)

Participants

- ☐ A statement describing the participants[1] which includes anticipated age and other demographic information;[2] and inclusion and exclusion criteria.[3] (☐ N/A)
- ☐ A description of the specific methods to be used for participant recruitment.[1] (☐ N/A)
- ☐ A statement of whether or not minors (under age 18) will be involved as participants.[1] (☐ N/A)

Materials

- ☐ A description of the measurement procedures to be used.[1] Include in-text citations.[2] (☐ N/A)
- ☐ All instruments used to collect data from the participants are appended to the application[1] including demographic forms and advertisements used to recruit participants.[2] (☐ N/A)

Procedures

- ☐ A description of the data collection methodology/procedure.[1] (☐ N/A)
- ☐ A statement of the risks to the participants.[1] (☐ N/A)
- ☐ A statement describing how risk will be managed or minimized.[1] (☐ N/A)
- ☐ A statement describing any potential benefits to the participants. Will participants receive compensation?[1] (☐ N/A)
- ☐ A statement describing the specific methods to assure confidentiality.[1] (☐ N/A)
- ☐ A statement whether compensation will be provided to participants for participation.[1] (☐ N/A)
- ☐ A description of where data will be kept and a date that all identifying data will be destroyed (e.g., 6 months).[1] (☐ N/A)

Other

- ☐ Reference list (include only those references that are cited within the body of the IRB application).[1] (☐ N/A)

- ☐ A consent form with addenda as necessary.[1] (☐ N/A)
- ☐ An assent form with addenda as necessary.[1] (☐ N/A)
- ☐ Appendices including support for the project. This may include approval for use of equipment (e.g., video recorders), and approval with signed letter of support by appropriate person at site for collaboration.[1] (e.g., signed letter from business administrators giving permission to recruit their employees to participate in study).[2] (☐ N/A)
- ☐ Conflict of interest disclosure statement has been completed and included with the application.[1] (☐ N/A)
- ☐ Principal investigator and faculty advisor signatures on the application.[1] (☐ N/A)

Language of Document

- ☐ Is the language used in the consent form and research material appropriate for the reading level of participants? That is, research and participant rights, risks, and potential benefits are described in layman's terms.[1] (☐ N/A)
- ☐ A foreign language translation must be included if the study will include participants whose first language of choice is not English.[1] (☐ N/A)

Checklist for Informed Consent Form

- ☐ A statement that the study involves the use of human participants and a general explanation of the purpose of the study and a brief description of the procedures to be followed.[1] (☐ N/A)
- ☐ A statement of expected duration of the participant's participation (e. g., one hour).[1] (☐ N/A)
- ☐ A description of all reasonable discomforts or foreseeable risks to the participants.[1] (☐ N/A)
- ☐ A description of any benefits (indirect or direct) the participant may gain from participating in the study. If compensation (e. g., monetary, course credit, treatment) is involved, a description of this compensation is included.[1] (☐ N/A)
- ☐ If there are no benefits to the participants, this should be clearly stated.[1] (☐ N/A)
- ☐ A statement related to confidentiality of records and identification of the participant.[1] (☐ N/A)
- ☐ A statement to the effect that[1] (1) participation is voluntary, (2) refusal to participate will result in no penalty or loss of benefits to which the participant is otherwise entitled; and that (3) the participant may discontinue participation at any time without penalty.[2] (☐ N/A)
- ☐ The name of the contact person for information related to questions about the research (the Principal Investigator), the rights of human participants (the IRB chairperson), and whom to contact in the event of a research related injury.[1] (☐ N/A)
- ☐ A statement that the investigator has answered and will answer all questions posed by the participant now and in the future to the best of his/her ability.[1] (☐ N/A)
- ☐ A statement indicating voluntary consent has been obtained, including signature lines for participant and investigator, and date.[1] (☐ N/A)
- ☐ For online surveys, a statement that clicking on a button indicates consent and that participants may print a copy of the consent form using their web browser.[1] (☐ N/A)
- ☐ A statement indicating child assent, if applicable.[1] (☐ N/A)

- ☐ A statement that the participant will receive a copy of the consent form (When an oral summary is read to the participants or a short consent form is used, the statement should read that a complete copy of the consent form will be provided to the participant).[1] (☐ N/A)
- ☐ A statement that the IRB has approved the solicitation of participants for the study; this appears after the signatures.[1] (☐ N/A)
- ☐ A statement describing how the participant may obtain a summary of the final results should they desire a copy. In what format will the results be provided?[1] (☐ N/A)
- ☐ Provide name and contact information[1] of the researcher, supervising faculty advisor and GSC Academic Affairs.[2] (☐ N/A)

Certificate of Completion

- ☐ A copy of the completion certificate for the Granite State College Human Research Training tutorial.[1] (☐ N/A)

Granite State College Protection of Human Participants in Research

IRB FINAL REPORT FORM

IRB Proposal No.: Click here to enter text.

Upon completion of your study, please provide the information requested below and submit to the Institutional Review Board (IRB) along with a brief summary of findings for this study, for audit purposes. Copies of abstracts, articles, and/or publications specific to the project are acceptable. Send the report to the IRB using the electronic address gsc.irb@granite.edu.

Complete all questions, or indicate by 'N/A' if the question is not applicable.

Project Title: Click here to enter text.

Date of Initial IRB Approval: Click here to enter text.

Date of Last Continuing Review Approval: Click here to enter text.

Research Completion Date: Click here to enter text.

1. How many participants have participated in this research project?

   Click here to enter text.

2. Describe the effects of your project on those participants who have participated. Note any unexpected or undesirable effects:

   Click here to enter text.

3. Have any participants complained or raised any questions about the desirability of the procedures, or seemed reluctant to participate? ☐ Yes ☐ No ☐ N/A

   If yes or N/A, explain:

   Click here to enter text.

4. Copies of signed Informed Consent Forms of all subjects participating in the research are on file and will be available to the IRB upon request. ☐ Yes ☐ No ☐ N/A

   If no or N/A, explain:

   Click here to enter text.

5. ☐ I will ensure that materials kept on file for this project that link subject identifiers with research-related information collected from subjects will be destroyed by Click here to enter text. to protect the confidentiality of the research participants.

OR

☐I need to maintain data with identifiers because Click here to enter text.. These links will be maintained until Click here to enter text. under secure conditions and any subsequent use of these data will not proceed until a new IRB approval has been obtained here or at any future institution where I may reside.

I certify the accuracy of the information provided and that I have abided by GSC policies and procedures governing research with human subjects.

Researcher Signature:	Date:
X	Click here to enter text.
Supervising Faculty Signature:	Date:
X	Click here to enter text.

Insert brief summary of findings here.