



HUMAN SUBJECTS RESEARCH POLICY



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SIT Graduate Institute | Study Abroad

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Human Subjects Research Policy

PREFACE

An Institutional Review Board (IRB) is a review committee established to ensure that the rights and welfare of human research subjects are protected.

SIT's IRB exists to uphold the ethical principles of *respect for persons, beneficence, and justice* for all human subjects of research, as stipulated in the Belmont Report, which informed the U.S. Department of Health and Human Services Code of Federal Regulations (45 CFR 46)¹ In developing the Human Subjects Research Policy, SIT has considered guidelines of various federal agencies, the ethical codes of principal scholarly associations (e.g., the American Association of University Professors), the Collaborative Institutional Training Initiative (CITI) Program, and other relevant sources of information. The intent of these policies and procedures is to ensure that the rights and safety of human subjects in research are protected. Faculty, Academic Directors (ADs), Program Directors (PDs), students, and staff at SIT and World Learning are expected to fulfill their obligation to protect the rights of people involved in their research.

This handbook describes SIT and World Learning's own institutional framework for research ethics. In addition, it is important to recognize that local research ethics regulations and norms must be considered and applied. In cases where these two codes of research ethics may differ, whichever is most restrictive should prevail.

The IRB has the authority to approve, disapprove, or require modifications of the submitted applications.

In the event of changes to approved research protocols, researchers are responsible for maintaining contact with the Institutional Review Board, and/or the SARB for SIT Study Abroad research to ensure researcher's personal safety and the safety of research participants during the research process. Student researchers and research assistants are also responsible for maintaining contact with research supervisors throughout the research process.

DEFINITIONS²

- *Research*: Systematic investigation, including research development (i.e., piloting instruments), testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- *Human Subject*: A living individual about whom an investigator (whether professional or student) conducting research:

¹ SIT's Institutional Review Board (IRB) is charged with overseeing the use of human subjects in research to partially fulfill the institution's ethical responsibilities within its stated mission and to, when indicated, satisfy requirements of the *Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects, Public Welfare, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks*.

² Definitions are retrieved from: <https://ori.hhs.gov>.

- Obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information, or
- Obtains, uses, studies, analyzes, or generates identifiable private information.
- *Researcher (also referred to as principal investigator)*: is someone who conducts research. For the purposes of SIT and World Learning, researchers may include Faculty, Academic and Program Directors, students, and World Learning staff.
- *Human Subjects Review (HSR) process*: The role of HSR process is to ensure that research participants are treated with respect and dignity, accorded participant rights, and, to the best of one's ability, protected from harm.
- *Institutional Review Board (IRB)*: SIT's institution-wide board charged with reviewing research proposals to ensure Human Subjects Review Policy compliance with guidelines established by federal law.
- *Study Abroad Review Board (SARB)*: The SIT Study Abroad program-level board charged with establishing appropriate standards and reviewing research proposals to ensure Human Subjects Review Policy compliance with particular attention to in-country ethical norms. The SARB operates under the auspices of the IRB committee and may refer HSR applications to the IRB for further review. Researchers are responsible for ensuring research is conducted in strict observance of ethical standards and the general norms of the scientific community in the United States. If research is conducted outside the United States, these standards still apply but there may be local norms and ethical standards that also must be followed.
- *Local Review Board (LRB)*: The role of local IRB is to protect the rights and welfare of participants in research carried out under the auspices of that institution. The office for Human Research Protections (OHRP) maintains the International Compilation³ of Human Research Standards that includes the laws, regulations, and guidelines of many countries. If the research study is designed in the United States but data collection takes places abroad, the researcher needs to comply with the local IRB process and with the host country's formal review process, as applicable.

SIT IRB and HSR Submission Process

The SIT IRB shall serve as a consultant and resource to all Faculty, Staff, Academic Directors and Program Directors in interpretation of the procedures and policies of the human subjects review process. IRB members will not participate in the approval of projects in which they have a conflicting interest. The following outlines the HSR application and review process for the Graduate Institute, Study Abroad, and World Learning researchers.

³ International Compilation of Human Research Standards: <https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/table1-description/index.html>

GRADUATE INSTITUTE APPLICATIONS

Application Steps

1. Before submitting an HSR Application, all researchers are required to complete CITI Program's Social-Behavioral-Educational Basic training course for Human Subjects Research and append their certificate of completion to the HSR form. The 4- to 8-hour course can be accessed here, under the Human Subjects Research (HSR) category: <https://libguides.sit.edu/irb/citi>. We recommend that the CITI training be included in graduate research methods courses at SIT.
2. All researchers should determine which institution(s) of site/country must approve local research, and how long that approval takes.
3. If applicable, apply to that local body to receive research approval (i.e., Ministry of Education, local research institution attached to the site where research will be conducted; a university research office).
4. Apply to SIT IRB, appending local approval or provide an explanation why the local approval is not required.

Please Note

- The researcher is ultimately responsible for conducting research in compliance with SIT IRB guidelines.
- The researcher is responsible for applying to the IRB for exempt, expedited, or full review status for proposed research and for completing all required documentation.
- All SIT Graduate Institute student research proposals must be approved by the IRB before research can begin.
- All HSR forms must be submitted to the IRB Administrator at irb@sit.edu for review and approval *before research can begin*. The IR reserves the right to disapprove an application.
- The IRB Committee meets on the first Tuesday of each month. For Exempt and Expedited review, HSR application is submitted on a rolling basis. HSR application requiring Full review must be submitted to IRB by the 25th day of the month.
- The IRB will notify the researcher of comments and recommendations via email within two - three business days of receiving Exempt proposals and two weeks of receiving Expedited HSR submissions. The IRB Committee's decision regarding a Full Review HSR submission will be provided via email within one week of the IRB Committee meeting at which a Full Review proposal is reviewed.
- For greater efficiency, the naming protocol for submissions to the IRB (irb@sit.edu) is as follows:
 - Last name_abbreviated title of the project_exempt_year.docx
 - Last name_abbreviated title of the project_expedited_year.docx

- Last name_ abbreviated title of the project_full_year.docx
- Questions pertaining to HSR forms submitted to the IRB Committee should be directed to irb@sit.edu.

STUDY ABROAD APPLICATIONS

Application Steps

1. Discuss your project with your academic director or program director to determine the topic.
2. Present the project to the academic director/program director and the HSR form.
3. The academic director will discuss the project and the HSR form with the local community members.
4. The SARB will sign an ethics form and inform the student if the project is approved or not. For Study Abroad, the Academic/Program Director scans and emails the SARB Action Form, Ethics Review form, and Statement of Ethics form to their program associate in Vermont and keeps a copy at the program site so that an institutional record is maintained every semester. Each student's Application for Human Subjects Review, together with the Action Form, must be kept on file at each SIT program office. In the event If the Study Abroad SARB would like to consult further with SIT IRB, it will contact SIT IRB for further review of the HSR application at irb@sit.edu.

Please Note

The Study Abroad student researcher is also responsible for checking with their home institution if a separate (sending school) Institutional Review Board application process is required.

All HSR forms must be submitted to the SARB for review and approval before research can begin. The timing of Study Abroad HSR forms being submitted to the SARB will vary by program, but a one-week HSR review period, at minimum, is recommended to allow thorough review of all proposals submitted to the SARB.

Sensitive topics or cases involving vulnerable populations whereby a decision cannot be reached at the level of the SARB may be submitted for full review by the SIT IRB. The SIT IRB approves or disapproves each project submitted to it by the Academic/Program Director, following initial review by the SARB. The IRB can also stipulate conditions for the conduct of any research involving human subjects and require certain changes in the research plan. Changes must be indicated (highlighted) when resubmitted to IRB.

- It is the responsibility of the AD/PD to review and share the SIT IRB policies and procedures for the protection of human subjects with students (e.g., in a course syllabus and/or in conversation with advisees) and to counsel the student on human subjects guidelines for research design.

It is the responsibility of the AD/PD to make an initial review of the proposal and determine if the proposal is: a) exempt from IRB review, b) deserves expedited IRB review, c) requires a full IRB review, or d) there is uncertainty about the proposal's status. However, all proposals must be

submitted to the SARB or SIT IRB, as applicable, for review. The AD/PD will sign the student's human subjects application with the assigned review recommendation. The student will then submit the application with the necessary supporting documentation to the SARB or SIT IRB, as applicable.

SIT Study Abroad SARBs

The SARB consists of the program Academic/Program Director and, additionally, at least two, and up to four, local faculty or professionals with expertise in the program theme and who do not work for SIT full-time. No other SIT staff should participate in the SARB. This measure provides for more objectivity and a wider range of input. SARB members will not participate in the approval of projects in which they have a conflicting interest.

- The SARB reviews proposals within the context of the IRB guidelines and within the ethical and value systems of the local community as well as those set forth by SIT/World Learning.
- The SARB must be satisfied that any research risks are mitigated through proper protocols and any research that exposes human subjects to the risk of unreasonable harm shall not be conducted.
- The SARB receives signed, human subjects research applications from the Academic/Program Director and convenes to review the applications.
- The SARB approves or disapproves each project. The SARB can stipulate conditions for the conduct of any research involving human subjects and require certain changes in the research plan.
- If any cases are referred for Full Review by IRB Committee in Vermont, the AD/PD will submit the proposal to the IRB Committee on behalf of the SARB via irb@sit.edu.

All ISP/FSP/Internship projects must be approved by the SARB before the projects may begin.

Interface between SIT IRB & SARB

Please note:

1. SIT upholds the principle that the SARB is the most qualified body to ensure observance of local norms of ethics and value systems for SIT Study Abroad field study proposals.
2. However, an AD/PD may elect to resubmit an HSR form denied by the SARB to SIT's IRB for appeal. The SIT IRB reserves the right to turn down an HSR form even if it was approved by the SARB if the IRB believes that that the HSR form contradicts any of the U.S. federal regulations and policies which regulate research on human subjects.

WORLD LEARNING APPLICATIONS

Application Steps

1. Before submitting an HSR Application, all researchers are required to complete CITI Program's Social-Behavioral-Educational Basic training course for Human Subjects Research and append their certificate of completion to the HSR form. The 4- to 8-hour course can be

accessed here, under the Human Subjects Research (HSR) category:
<https://libguides.sit.edu/irb/citi>.

2. All researchers should determine which institution(s) of site/country must approve local research, and how long that approval takes.
3. If applicable, apply to that local body to receive research approval (i.e., Ministry of Education, local research institution attached to the site where research will be conducted; a university research office).
4. Apply to SIT IRB, appending local approval or provide an explanation why the local approval is not required. All HSR forms must be submitted to the IRB Administrator at irb@sit.edu for review and approval before research can begin. The IR reserves the right to disapprove an application.

Please Note

- The researcher is ultimately responsible for conducting research in compliance with SIT IRB guidelines.
- The researcher is responsible for applying to the IRB for exempt, expedited, or full review status for proposed research and for completing all required documentation.
- All SIT Graduate Institute student research proposals must be approved by the IRB before research can begin.
- All HSR forms must be submitted to the IRB Administrator at irb@sit.edu for review and approval *before research can begin*. The IR reserves the right to disapprove an application.
- The IRB Committee meets on the first Tuesday of each month. For Exempt and Expedited review, HSR application is submitted on a rolling basis. HSR application requiring Full review must be submitted to IRB by the 25th day of the month.
- The IRB will notify the researcher of comments and recommendations via email within two - three business days of receiving Exempt proposals and two weeks of receiving Expedited HSR submissions. The IRB Committee's decision regarding a Full Review HSR submission will be provided via email within one week of the IRB Committee meeting at which a Full Review proposal is reviewed.
- For greater efficiency, the naming protocol for submissions to the IRB (irb@sit.edu) is as follows:
 - Last name_abbreviated title of the project_exempt_year.docx
 - Last name_abbreviated title of the project_expedited_year.docx
 - Last name_abbreviated title of the project_full_year.docx
- Questions pertaining to HSR forms submitted to the IRB Committee should be directed to irb@sit.edu.

Additional Responsibilities

World Learning staff conducting program evaluation/research projects involving human subjects have additional responsibilities and steps to follow before submitting their HSRs to the IRB.

- The project lead should complete a HSR submission form and submit it to the Monitoring, Evaluation, Research, and Learning (MERL) unit for review. After sign-off by the MERL unit, the World Learning project lead should then send the HSR application to the IRB.
- It is also the responsibility of the World Learning project lead to determine if the Monitoring and Evaluation (M&E) component of a project is considered as *research* involving human subjects and therefore needs to be submitted to the IRB.
 - M&E may be considered as research involving human subjects if it is likely to inform future projects or if it is used to write an article based on findings from the data.
 - The project lead should use the HHS Human Subject Regulations Decision Charts found at the end of this handbook to help make this determination for:
 - New World Learning projects and the related M&E plan.
 - Existing World Learning projects with an M&E plan that have not submitted to IRB.
 - An intention to do new or substantially modified M&E for an existing World Learning project in which an IRB was previously submitted.

Types of Human Subjects Research Review

The Department of Health and Human Services of the U.S. government and the School for International Training (SIT) recognize three review categories for research involving human subjects: full, expedited, and exempt.

Researchers may NOT engage in research that involves:

- Procedures that might physically harm them or their research participants.
- Activities that may be illegal.

All research with human subjects carries risk. For example, risks may be social, psychological, economic, physical, and legal in nature.

Risks of harm in social and behavioral research fall into three categories:

- invasion of privacy: instances when personal information is accessed or collected without the participant's knowledge and consent; or their participation in the study is disclosed without their knowledge and consent.

- breach of confidentiality: if information obtained by the researcher about the participant is disclosed outside of the research setting, and the resultant participant's confidentiality breach undermines the participant's psychological, social, or economic status.
- study procedures: when the study takes place in a data collection setting that might pose risk to disclosing the participant's identity; or other research participants might share the data shared by other participants outside of that setting.

It is advisable to review the literature in the researcher's respective field to determine what, if any, risks the study topic or design might pose to the participant, and what additional protections may need to be in place.

We should strive to ensure that risk is minimal so "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life" (45 C.F.R. § 46.102(i)).

FULL REVIEW (CONVENED)

Research with vulnerable populations will require full IRB committee review, or review by the SARB for SIT Study Abroad. Vulnerable subjects are defined as persons who "have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity ... or situational circumstances ... or because they are especially at risk for exploitation" (National Bioethics Advisory Committee, 2001). Examples include the following groups:

- All research involving children that does not fall into the exempt category (educational context).
- Research with vulnerable and/or at-risk populations (e.g. people who are: incarcerated or institutionalized, in nursing homes, or mental health facilities; pregnant (if the research may affect the pregnancy); refugees; racial, gender, or ethnic minorities; socio-economically disadvantaged; terminally ill or very sick; have physical disabilities; have mental disabilities or cognitive impairments; neonates; human fetuses).
- Research that deprives participants of necessary or accustomed resources.
- Research that may cause subjects mental stress.
- The use of participants not able to give free and informed consent.
- Research involving subjects who are available because of their need for the investigator's professional services, or other obligations (students or employees of the researcher).
- Explicit, or implicit, deception of participants about any aspect of the research significant to them (deception is permissible when it is required to obtain valid results; however, the researcher must disclose it to the subjects after the study is complete to describe the deception and the scientific rationale for its use).

Adequate safeguards for vulnerable subjects and explanations concerning the need for deception must be in place for approval. Informed consent and research with children are described in more detail in the sections titled *Vulnerable Subjects and Specific Research Consent Involving Children*.

Sensitive research topics include but are not limited to:

- Questions relating to sexual attitudes, preferences, or practices;
- Questions concerning the use of alcohol, drugs, or other addictive products;
- Research on activities that may be illegal, or likely to offend prevailing standards of ethical practice for a given country context;
- Information that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
- Information that would normally be recorded in a subject's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to an individual's psychological well-being or mental health;
- Information in other categories not listed may also be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation.

Given federal policy and the IRB's mandate to uphold the ethical principles of respect for persons, beneficence, and justice for all human subjects of research, research involving vulnerable subjects must be submitted for a full review. The IRB considers the risks and undue burden to subjects as well as whether the research offers sufficient benefit to research participants.

Research with vulnerable subjects is important for many reasons. In requesting that researchers submit their research for full review, the IRB does not aim to discourage such research, but seeks to make clear the additional burden of responsibility.

EXPEDITED

The expedited review procedure is a complete and thorough IRB review that does not require a convened IRB meeting but is conducted by an IRB member. Research in the expedited category presents no more than minimal risk to subjects and involves only procedures listed in one or more of the expedited categories.

Please note that research that involves children as participants will not be considered for Expedited review; please submit for Full review unless it meets the criteria for Exempt Research in Educational Settings.

- Research that involves "minimal risk." "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks or harm tend to be minimal only if not conducted with vulnerable populations, especially when gathering and reporting on aggregate data using surveys and interviews. Most common risks are psychological distress in involving sensitive research topics (e.g., studies of sexuality, mental health, interpersonal violence, illegal activities) and inadvertent disclosure of private information that can be identified.

- Collection of data from existing voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).
- The use of surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies in which subjects cannot be identified directly or indirectly in the collected data and the final report.

Minor changes in previously approved research design during the period (of one year or less) for which approval is authorized. Expedited review procedures may not be used where:

- Children are involved as research subjects, except in cases of educational research falling under exempt category
- Identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability.
- Identification could be damaging to the subject's financial standing, employability, insurability or reputation.
- Identification could be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- Identification of the subjects and/or their responses may cause any harm mentally and/or physically.

EXEMPT

Exempt research is any research that does not involve the participation of human subjects or presents no more than a minimal risk to human subjects. Researchers submitting an HSR application under the exempt category will receive IRB review to confirm it meets at least one of the following criteria:⁴

1. "Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
2. "Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public

⁴ The content on exempt categories was updated in January 2018 and is retrieved from the Revised Common Rule: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html>

behavior (including visual or auditory recording) if at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects."
3. "Research involving benign behavioral interventions:
 - i. In conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
 - ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
 - iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research."
4. "Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are publicly available;
 - ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq."
5. "Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
- i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects."
6. "Taste and food quality evaluation and consumer acceptance studies:
- i. If wholesome foods without additives are consumed, or
 - ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of

the U.S. Department of Agriculture.”

7. “Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by [§46.111\(a\)\(8\)](#).”
8. “Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained.
 - ii. Documentation of informed consent or waiver of documentation of consent was obtained.
 - iii. An IRB conducts a limited IRB review and makes the determination required and makes the determination that the research to be conducted is within the scope of the broad consent.
 - iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.”

Exempt proposals and supporting documentation for research conducted by faculty, SIT Graduate Institute students and World Learning staff must be submitted to the Institutional Review Board (IRB) (irb@sit.edu), where the application will be reviewed by the SIT IRB or SIT SARB Administrator, as applicable, for accuracy and completion. Exempt applications for research conducted by SIT Study Abroad students are reviewed by the SARB and retained at the program site; those submitted by the Graduate Institute will be kept at the SIT IRB Office.

PROTOCOL FOR COURSEWORK INVOLVING HUMAN SUBJECTS

All SIT courses, except for those courses listed below, receive blanket exempt approval status to engage human subjects for the purposes of completing a course assignment.

However, given the importance of protecting human subjects, we as an institution take seriously the need to take care in designing course assignments that engage human subjects.

All syllabi for courses involving human subjects should include the following text:

“This institution has pledged to uphold the ethical principles of respect for persons, beneficence, and justice in all human subjects research. It is the responsibility of the Institutional Review Board to protect human subjects by reviewing all research proposals. The IRB designates research using human subjects conducted in order to fulfill the requirements of a class as exempt. Exempt status in this instance is predicated on the assumption that research participants’ consent for participation in the course assignment is received before participation begins. If the protocol for engaging human subjects changes after the research plan is approved by the instructor of record, then the student(s) must not name subject participants in the assignment, subjects must not be vulnerable, and the

information gathered is not sensitive and/or is properly protected from public access (see definitions in the Full Review section of this document).”

It is the responsibility of the instructor of record to ensure that human subjects protection protocols are in place when students engage with people to gather information and complete assignments.

Human subjects protections are especially of concern should students engage people who are not enrolled in the course, such as members of the student body at large, staff, or community members.

The IRB Committee is available to answer questions about human subjects protocols for course assignments (and to visit classes to discuss human subjects policies, and the role of the IRB Committee, with students), but it is the responsibility of the instructor of record to ensure that human subjects protection protocols are in place when students engage with people to gather information and complete assignments.

Courses NOT covered by the blanket exemption include the SIT Graduate Institute’s capstone-related courses and MA TESOL Independent Professional Project. Additionally, SIT Study Abroad Independent Study course, as well as the Independent Study Project, Field Study Project, and Internship courses offered by SIT Study Abroad are NOT covered by the blanket exemption.

VULNERABLE SUBJECTS

Federal policy on the protection of human subjects stipulates that the following groups are considered vulnerable subjects: children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons. The Department of Health and Human Services states: “When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects” ([§46.111](#)). Human subjects policies were established after abuses perpetrated by medical science researchers. The category of vulnerable subject was necessary because the groups listed above do not or may not have the ability to consent freely to be subjects of research. Concern about experimentation that could affect a fetus who cannot consent is the reason why ‘pregnant women’ is a vulnerable group. Prisoners, for instance, are much more easily subjected to coercion and lack control over their lives.

Given federal policy and the IRB’s mandate to uphold the ethical principles of respect for persons, beneficence, and justice for all human subjects of research, research involving vulnerable subjects must be submitted for a full review. The IRB considers the risks and undue burden to subjects as well as whether the research offers sufficient benefit to research participants.

Vulnerable subjects in SIT Graduate Institute, Study Abroad, and World Learning research proposals might include:

1. *Members of economically disadvantaged groups.* If members of this group will be interviewed about the hardship they experience, the IRB would consider whether benefit of the research outweighs the trauma. Students might encounter members of this group as part of their practicum placement in an NGO whose clients are impoverished. This vulnerable population would then be in a position to experience coercion in the sense of being unable to refuse for fear of the withdrawal of services. Researchers must indicate how coercion will be avoided.

- 2. *Refugee and internally displaced populations.*** In addition to being economically disadvantaged whether in their home country, in a refugee camp or in resettlement, refugees may also have experienced different forms of violence. They may have been persecuted for reasons associated with class, caste, race, age, gender, religion, sexuality, nationality or citizenship status, ability, and/or political association, among other possibilities.
- 3. *Populations vulnerable in your research site.*** Researchers should know whether participants they might interview are vulnerable in the local context. Such vulnerability might be a consequence of class, caste, race, age, gender, religion, sexuality, nationality or citizenship status, ability, and/or political association, among other possibilities. For example, in the US and other countries, undocumented migrants would fall into this category.
- 4. *Children.*** Except for research concerning normal educational practices conducted in an educational setting, all research involving this vulnerable subject population must be submitted for full review.

SPECIFIC RESEARCH CONSENT INVOLVING CHILDREN

The U.S. standard specifies that subjects under the age of 18 may participate in research only with the signature of their parent or legal guardian, in addition to their own signature. This also applies to the completion of anonymous questionnaires since persons under 18 are not permitted legally to make the informed choice to participate.

Standards for Children

- 1.** When reasonable under the circumstances, researchers shall obtain assent from children in addition to obtaining permission from the child's parent or guardian. When obtaining permission from the legal guardian, signed documents and the written and/or verbal explanation shall both be in a language fully understood by the guardian. This may require document translation.
- 2.** Final responsibility rests with the IRB, or the SARB in the case of SIT Study Abroad student research, which shall determine that adequate provisions are made for soliciting the assent of the children or, if the IRB determines that the children are not capable of providing assent based on age, maturity, psychological state, or other factors, then the IRB will assure that the parents or other responsible party have done so in lieu of the children in a satisfactory manner.
- 3.** Children should have information about the research and have their participation in the research and what it means explained in a language and context familiar to them. A parent or guardian can sign the consent form or verbally agree to participate in the study on behalf of the child.
- 4.** Age in and of itself does not determine competency and even young children have the right to informed consent if they are capable of comprehending what is expected.
- 5.** In cases where members of a team, class, or organized group are being recruited for a study and participation could affect the performance of the whole team, class, or group, the informed consent of the coach, instructor, or group leader is required in addition to parental consent and child assent.

6. For more information on the U.S. standard, please see U.S. Department of Health and Human Services Office of Human Research Protections, <http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf>.

The following definitions hold:

- “*Children*” are persons who have not attained the legal age for consent to treatments or procedures involved in the research in the state/country where the study will be conducted. As the legal age for consent to participate in research in the US is, generally, 18, and though this age may differ in the many sites in which SIT is located, for the purposes of this Human Subjects Review policy and consent to participate in SIT research, children are defined as under 18 years of age. This age limit may be higher in local jurisdictions; local law should be followed in these cases.
- “*Assent*” means a child’s affirmative agreement to participate in the research following an age-appropriate explanation of the research project. Mere failure to object shall not be construed as assent.
- “*Permission*” means the agreement of the parent(s) or guardian to the participation of their child in the research following an appropriate explanation of the research project in a language fully understood by the parent.

THE RESEARCH PROCESS

Three foundational ethical principles govern the research process with human subjects: *respect for persons, beneficence, and justice*.

According to the [CITI Social-Behavioral-Educational \(SBE\) Science training program](#), the *respect for persons* principle is built on two convictions: “individuals should be treated as autonomous agents” who are fully informed about research and choose to participate in it or not; and “persons with diminished autonomy are entitled to protection.”

The *beneficence* principle implies that “persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.” The two rules for ensuring beneficence are “do no harm” and “maximize possible benefits and minimize possible risks.”

The *justice* principle is concerned with “fairness in distribution.” In other words, an injustice occurs when “some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.”

In applying these principles to the research process, researchers should consider all stages: recruitment, permission and informed consent, data collection, and data analysis and publication.

RECRUITMENT AND INFORMED CONSENT

The process of enrolling participants (and, in some cases, institutions, communities, and other social groupings) in research involves both recruitment and informed consent. Where minors are concerned, an additional step is required to obtain permission from the parent or guardian.

Recruitment

Recruitment is part of the consent process as it begins with providing the participant with information about the research study. Recruitment strategies—fliers, social media posts, email messages, phone calls, among others—must be reviewed and approved by the IRB before they are used.

In recruiting potential research participants, true and complete information should be provided about the research process and purposes. Recruitment must also be just in that selection of participants is clearly based on factors relevant to the research and is equitable in all other respects. No undue influence should be exercised in recruitment; for example, any compensation should be calibrated very carefully to not overbalance other factors a participant might consider in deciding whether to take part in the research. Those who are not selected for the research should not be unduly deprived of a beneficial intervention—for example, in a randomized controlled trial, they may be given access to an alternate beneficial intervention or may be scheduled to receive the research intervention at a later time.

Informed Consent

The informed consent process begins with the recruitment of the participant, before data collection begins, and continues throughout the participant's involvement in the study.

Informed consent consists of two parts: 1) the researcher provides adequate information about the study purpose, procedures, risks of harm and benefits, and what is expected of them, and answers any questions the participant might have; and 2) the researcher documents that the participant was adequately informed and records the participant's agreement to take part in the study. The researcher should provide the participant with sufficient time to consider their decision and voluntarily agree to take part in the study. This agreement is only to enter the study, as the participant may withdraw from the study at any time, decline to answer any of the questions, or complete the study.

If the participant agrees to participate in the study, the researcher should obtain the informed consent in a culturally appropriate manner of the participant, such as oral or written consent. Written informed consent is waived in favor of oral consent in the event written consent poses risks to the participant. Oral consent without documentation may be approved by the IRB. The federal regulations (at 45 CFR 46, Subpart A) account for flexibility in obtaining and documenting informed consent in social and behavioral research, particularly in challenging and complex circumstances, when research poses no more than minimal risk of harm.

Where minors are involved, parental permission is also required. *Please note that it is recommended that data and all consent forms be kept for five years.* Further details on informed consent requirements are provided below; example templates are also included at the end of the handbook.

Obtaining consent includes the following:

- The researcher shall explain to subjects (prior to their participation) the purpose of the study, the procedures to be followed (what the subject will be expected to do), and potential risks and benefits.
- The researcher shall not use individuals as subjects unless they, or those legally responsible for their well-being, consent to participation freely and with understanding of the consequences.
- Researchers shall respect the privacy of participants. They shall protect confidential information and advise participants as to how their confidentiality will be protected.
- Subjects shall not be induced to participate by means or in circumstances that might affect their ability to decide freely.
- It shall be made clear to participants that they are free to withdraw from active participation in the research at any time or may refuse to respond to any part of the research. Participants who desire to withdraw shall be allowed to do so promptly and without prejudice to their interests.
- The Participant Informed Consent Form must be written in a language and a style that the participant can read and understand (see [Participant Informed Consent Form template](#) at the end of this document). Researchers should create an informed consent form that is at an appropriate language level of the subject population (an 8th grade reading level or lower is advised).
- When conducting research in a language other than the researcher's native tongue, the researcher needs to ensure that translations represent accurate meaning of words and idiomatic expressions.
- Verbal consent in certain contexts may be more culturally appropriate than written consent. In such instances, the contents of the written Participant Informed Consent Form must be addressed in full with the research participant in order for the verbal consent to be considered informed consent.

The following elements are required:

1. Consent: "I have read the above and I understand its contents and I agree to participate in the study. I acknowledge that I am 18 years of age or older."
2. Consent to be recorded (if relevant): "I give my consent to be recorded."
3. Consent to have recordings played in public (if relevant): "I give my consent to be recorded and to allow that the recording be used in conference (classroom) presentation."
4. These statements must be following by a place for the subject to sign his/her name and to put the day's date.

Informed consent signature via email:

Informed consent generally indicated by signature is not always obtainable via email. Instead, an e-mail survey must include the following statements to which a subject must respond in an affirmative manner.

1. Please type a response after the statement below. A “YES” response indicates that you understand the statement and are at least 18 years of age and you agree to participate. If you respond “NO,” your response to this study will not be used.
2. I understand the potential risks associated with participation in this study. I also realize that while the researcher will keep responses confidential, e-mail surveys are not secure.
3. Furthermore, I am at least 18 years of age or older. YES/NO.

If the subject responds “NO” to any of these statements, any data received from the subject may not be included in the study.

In some cases, a participant may be unable to provide written consent:

In this case, the researcher shall still read the information in the Participant Informed Consent Form and explain the objectives of the study and its impact on the participant and shall wait for the participant’s oral consent to take part in the study articulated prior to involving them in research.

Two cases when an Informed Consent is not necessary:

- First, when the research solely involves observation of a person’s public behavior in locations where that person might reasonably expect that his/her behavior could be observed by another person.
- Second, when the subjects are only filling out an anonymous public questionnaire or survey, and they can choose not to participate by simply not returning the questionnaire (which is equivalent to refusal). However, the anonymous survey must still include an adequate explanation of the purposes of the study and other elements of informed consent prior to requiring subjects to respond to any questions.

Deception and Complete Non-Disclosure of Information

There are certain instances when deception and complete non-disclosure of information about the research study may be necessary and justified to obtain scientifically valid data and avoid participant response bias in the study. The IRB must review the HSR application to ensure there is adequate justification for deception or non-disclosure of information.

For example, deception may be justified when researching one’s behavior that may be altered if participants are informed about the phenomenon under study: e.g., participants are told that a study is about perception of visual phenomenon, when, in fact, it is about susceptibility to peer pressure (CITI, 2021). Complete non-disclosure is necessary during cover observations: e.g., if participants know they are being observed, they may alter their behavior in a way that obtaining meaningful and valid results is impossible (CITI, 2021).

In the event of justifiable deception, the researcher will be asked by the IRB to meet high ethical standards in every other way, including extra safeguards from harm, and debriefing participants with

full information after data collection has been performed and allowing retroactive withdrawal from the research.

DATA COLLECTION

For IRB purposes, data collection refers to the process of gathering information about or from human beings for purposes of new analysis. Data collection and analysis may be primary, in which the information is gathered directly from original subjects or social settings. Or it may be secondary, such as when performing new analysis on an existing dataset. In either case, the data is considered source data or raw data in that it has not already been summarized through analysis.

Guidance on primary data collection and analysis

Primary data collection includes all activities to collect information from original sources. Primary data collection activities include administration of tests, assessments, questionnaires, and surveys; interviews; focus group discussions; experiments; observation; analysis of written artifacts such as journals or social media postings; and other similar collection from first-hand sources.

Primary data collection that involves the opinions, characteristics, or behavior of identifiable human subjects in any way is subject to all of the human subjects ethical research protections discussed throughout this guide and is subject to IRB review, unless otherwise determined to be exempt (such as under the conditions discussed in the earlier section Exempt Research in Educational Settings). As a reminder, data collection should follow the core ethical principles of Respect for Persons (allowing people to make informed decisions without undue influence), Beneficence (minimizing risks of harm and maximizing possible benefits), and Justice (such that the burdens of research, and its possible benefits, are distributed with equity).

Guidance on secondary data collection and analysis

If the data are already created prior to beginning the study (i.e., tests, writing assignments, and evaluations done in a previous class, student records, or survey data collected previously), it may be exempt from research consent protocols. However, you will need to ensure that the data are anonymous before performing a novel analysis. Two types of educational data require special consideration when performing secondary collection and analysis: classroom data and student records.

Classroom Data

The following discussion refers to data that were collected in a previous semester or class as part of the normal classroom activity. For example, if a researcher wanted to compare scores on a math test given to second graders at the end of the second-grade year versus their scores on the same test taken at the beginning of the third-grade year, and the test was given as part of the school's routine schedule prior to beginning the study, the tests are archival data. These materials are not considered

public data, so to qualify for exemption, it is necessary that the data are collected in a way that does not identify the individual student.⁵

The IRB asks that a neutral third party link the data to a random code and then strip the identifying information from the data. The neutral third party should be someone who has access to the data outside of the research study. For example, a teacher (who is not the researcher), teacher's assistant, or school administrators are likely candidates. If the teacher and researcher are the same, the teacher has access to this information because of his professional position, but he or she does not have access to it as a researcher. If you are unable to create a de-identified data set, you will need to obtain consent from students and parents to use the data.⁶

Student Records

In the United States, FERPA and state regulations protect the privacy of student records. Any research conducted under SIT auspices in non-U.S. settings should comply with the most restrictive set of regulatory standards whether that be FERPA or regulations from the country in which research is being conducted.

Researchers who would not normally have reason or permission to access a student's educational record may not access that student's educational record without prior parental permission. Under certain circumstances, the researcher may request that the school provide de-identified data from student educational records if students cannot be identified or deduced from the data set. In this case, the data are linked and stripped of identifying information by a third party who has normal access to the data (such as a school administrator). Such data sets qualify for exemption. Please be advised that counties and school administrations also have authority to create policy for student record access, so you should check with a school administrator before submitting your protocol.⁷

Data sets may also be obtained from other sources for secondary analysis. It is the researcher's responsibility to ensure that identifying information has been removed from the data before it is shared by the originating researcher or institution.

DATA ANALYSIS AND PUBLICATION

Ethical obligations towards human subjects do not end with the data collection process—researchers must also conduct their data analysis and publication with respect for persons, justice, and beneficence in mind.

Data Fidelity

When analyzing and interpreting research data, it is important to avoid any falsification, fabrication, or manipulation of data that would violate the rights and respect due to your human subjects. In other words, data should be kept faithful to its original form and content. In some stages of data

⁵ http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_arch_records_student.html

⁶ <https://www.research.fsu.edu/research-offices/human-subjects/faq/>

⁷ http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_law_ferpa.html

cleaning, particularly in quantitative datasets, anomalies may be detected that require editing the information provided (such as when a person enters today's date instead of birth date, or a response is directly contradicted by other information the same person provided, suggesting a misreading or mis-response). When information can be reliably corrected using other sources, such corrections can be carefully made; another possibility is to omit the data point and treat it as missing information—in either case, there should be clear documentation of any changes.

In qualitative data, particularly in using extended quotations for publication, editing should be kept to the bare minimum and should never change the meaning or intent of the statement. It is a best practice to use brackets in place of a phrase or sentence to indicate when something has been omitted for brevity (using this format with ellipses: [...]) or to explain an unclear word (such as in the following example: “I don't usually like to talk with them [my parents]”).

Privacy and Confidentiality

If identifying information has been collected, and privacy and confidentiality have been promised to research participants during the consent process, it is important to maintain consideration for these issues at the forefront during data analysis and publication. Common methods for protecting privacy and confidentiality include: not collecting subject names or replacing names and other identifying information with a pseudonym or participant identification number as soon as possible; password protecting files and computers that hold identifying information; keeping printed information in a locked location; and storing the linking information/lists in a separate protected location.

Additionally, in publication, when individual cases must be referred to (whether particular individuals or particular institutions), pseudonyms must be used and it may be necessary to omit, conceal, or alter other information that could allow readers to deduce the source of the information—as long as these changes do not manipulate the core facts under analysis, as discussed in the previous paragraph.

The use of online data collection methods and cloud computing has raised privacy and confidentiality concerns that are not always well understood—for example even “anonymous” online surveys often collect IP address or location data. Data that poses an especially high risk to participants in terms of reputation or other negative consequences may require special efforts to ensure protection. See the Additional Information section for a link to further considerations on this issue.

Minimize Risk of Harm and Maximize Benefit in Research Publication

In publishing data and analyses, considerations of minimizing risk of harm and maximizing benefit must be kept in mind. These considerations apply whether the “publication” is nominally an internal degree program requirement, or for a more formal outlet such as a journal article—with the use of thesis and dissertation archives and platforms such as Academia.edu and Research Gate, many more analyses are now available publicly than they were previously, whether or not they have gone through peer review. In addition to protecting privacy and confidentiality, researchers should consider any other risks of harm that their publication may bring to either individuals or groups and seek all reasonable means to minimize those risks. Similarly, the principle of maximizing benefit should be considered in making the extra efforts needed to share research summaries with participants and incorporating their feedback whenever feasible, as well as making research results

available in spaces where they may be able to promote general knowledge and bring benefit to others.

INTERPRETERS AND TRANSLATORS

Human subjects research at SIT and World Learning frequently involves engaging interpreters and translators in the research process. As such, prior to engaging interpreters/translators in the research project, the researcher must train interpreters/translators in the fundamentals of research ethics and agree to abide by the approved research protocol. The role and expectations for interpreters and translators must also be a component of research training for researchers to ensure appropriate engagement of interpreters and translators throughout the research process. Furthermore, researchers are expected to maintain ethical engagement of interpreters/translators.

In some sensitive contexts, interpreters and translators themselves may be vulnerable—such as conflict regions where affiliation with a United States institution could be seen negatively. Researchers are responsible for taking such considerations into account and ensuring protection of these research collaborators as well as research participants.

Exempt Research in Educational Settings

Exempt research in educational settings involves normal educational practices. CFR 45 part 46.101.b(1) states that “research conducted in established or commonly accepted educational settings, involving normal educational practices...” is considered exempt. The federal regulations define normal educational practice as:

- i. “research on regular and special education instructional strategies, or
- ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”¹

The IRB is obligated to follow other regulations that may conflict with this definition (i.e. [Subpart D of 45 CFR 46](#), [FERPA](#) (Family Educational Rights and Privacy Act), and [PPRA](#) (Protection of Pupil Rights Amendment)). Subpart D specifically deals with children as a vulnerable population and most protocols that qualify for normal educational practice deal with children. If the IRB determines that a research study does not qualify for exempt status, then the extra protections for minors under Subpart D apply. Additionally, FERPA restricts researchers’ access to student records without written permission from parents. However, within FERPA [20 U.S.C. 1232g(b)(1)(F)], there are conditions under which student records can be disclosed without parental consent: “Organizations conducting certain studies for or on behalf of the school”. Investigators must contact each institution and follow that institution’s FERPA policy. Finally, PPRA outlines 8 categories of protected information for survey responses (for more information on FERPA and PPRA, see related links).¹

In order to qualify for exemption, the researcher must also demonstrate that participants will experience no more than minimal risk when they participate.

The IRB considers educational time very valuable and requests that you carefully develop your intervention to avoid wasting students’ learning time or unduly burdening teachers. If any of your research includes both elements: 1) that which qualifies as exempt (normal practices in accepted

educational settings) and 2) that which qualifies as expedited or full review, it cannot be reviewed as exempt.

What is an Educational Setting?

Federal regulations do not specify that normal educational practice takes place in schools only.³ The IRB defines a formal or non-formal educational setting as any setting where one would go in order to have an educational experience (a public or private school, an after-school club or program, a Boy or Girl Scout meeting, a professional development seminar for school district personnel, a garage for automotive training, a field for an exercise class, a conference or exchange held on an online audio and web conferencing platform, etc.). In this way, the IRB acknowledges that the educational setting covers activities in both formal and non-formal educational environments. Recognizing that SIT Graduate Institute and Study Abroad and World Learning research occurs in U.S. and non-U.S. settings, the IRB asks that researchers determine what the local context considers to be an established and commonly accepted educational setting. For the purposes of this document, and in seeking clarity, the IRB uses the terms “class” and “classroom” to refer to these environments.

Who are the Research Participants?

The participants should include those involved in the educational experience, which most likely will include the teacher(s)/facilitator(s)/instructor(s), student(s)/participant(s)/learner(s), and/or school/program administrators. Participants who are indirectly involved in the educational experience may be included in the study, but their inclusion may require additional consent procedures. For the purposes of this document, the term “teacher” also refers to an instructor or facilitator; “student” may refer to all learners.³

Participants can include populations with special educational needs (such as a developmental disability). In such cases, the IRB will expect you to demonstrate your ability to sensitively work with these populations, your credentials to work with these vulnerable populations, as well as a clear explanation of any additional procedures to minimize risks specific to working with this population. For example, if a child is significantly cognitively delayed, obtaining assent may not be appropriate, and the investigator must describe what steps will be taken to ensure that appropriate cues are taken from the child that may indicate an unwillingness to continue with study procedures.⁴

What Educational Practice is “Normal”?

The following are activities that would normally occur in the learning setting, often a classroom but not always. Additions to these will be considered. Research in these areas is typically considered exempt:

- Test development and development and pilot testing of new educational assessment tools.
- Experimentation with instructional methods.
- Assessments related to educational activities. The time commitment required to complete assessments should be described and should not exceed reasonable limits. The research design should clearly describe how results will be shared back with the school staff to assist in their instructional decisions as well as potential associated risks (e.g., Will students’ grades be affected by their scores on the assessments? Will results be shared at the individual

student/participant level or in aggregate? How will the data be used by the school/program?).⁵

- Evaluation of classroom or school/program activities that may include pre- and post testing, surveys, interviews or observations. For example, if you are studying a new writing technique and you want to ask the students what they think about the writing technique, this could qualify for exemption. However, if you want to ask the students questions that are beyond the technique, the IRB may approve these questions, but they may not qualify as normal educational practice that falls under the exempt designation. Observations, interviews, and surveys beyond the scope of normal educational practice do not qualify for exemption and require parental consent. Please justify the necessity for using these methods for collecting data and specify what will be collected (via testing or survey instruments, interview questions, and/or observation protocols).⁶
- Collecting affective data, specifically attitudes toward learning and teaching. The IRB recognizes that it is normal for a teacher to assess his or her students' attitudes regarding learning. Again, if you are using surveys and/or interviews, please see the bolded text above.⁷
- Data collection using videotape, audiotape, photography, and/or samples of student work may be eligible for exemption if FERPA regulations are met. Please justify the necessity for using these methods for collecting data and specify what will be collected. If the information collected can identify an individual student, it will be necessary to document consent using a consent form. Data collection methods must be outlined in the consent process. If the materials will be used in a presentation or publication, it may be necessary to obtain specific permission from parents and/or adult participants to do so.⁸
- Collecting data specific to teacher and/or student current knowledge, beliefs, or attitudes towards learning, or data about how these changes occur over time. These studies may be descriptive in nature and may even be longitudinal. Interviews, observations, and surveys must include questions and subject matter that fall within the scope of the educational activity being studied.⁹

Special Recruitment and Consent Consideration for Educational Contexts

The following paragraphs discuss recruitment and consent considerations for both “exempt” and “non-exempt” research in educational settings—for further information on whether a given educational research study should be considered exempt, see the dedicated section later in this guide.

The consent process for a study in an educational setting typically involves multiple groups. Ultimately it is important that you develop a process that adequately informs all parties involved (i.e., students, teachers, parents, administrators, or other participants and applicable guardians or institutional representatives) and obtains the appropriate documentation of consent where needed, in addition to creating an atmosphere where consent can be obtained voluntarily. If a student is in the instructional setting, he or she is generally obligated to participate in the instructional activity. In

⁸ http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_law_ferpa.html

⁹ http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_data_known.html

a normal educational practice study, the participant may be required to do instructional activities and assignments, but they should not feel obligated to release data to you. In your HSR form and proposal, please be clear about how you will handle situations where a participant wants to withdraw from the study and make sure that parents and students are aware of what is required by the instructor and what is requested by the researcher.⁸

When the researcher is the instructor or in another position of authority

For most confidential studies in which anonymity is promised, it is usually acceptable for the researcher to recruit her/his own students as long as she/he will have no knowledge of who decided to participate. For situations in which the researcher does have a position of authority, she/he should devise a method for recruiting participants and obtaining consent so that the participant is able to give consent voluntarily. For example, if you are the instructor of a class and have grading authority over students, or if you are an administrator and supervise the teachers you will study, you have authority over your participants. It may be advisable for a third party or another researcher to go through the consent process with the students and collect their consent forms.

As the instructor of the class, whether your students are minors or adults, you have a **position of authority over your students and over their parents** (if parents are a part of the study). As you will collect confidential materials about your students, the IRB may ask that this information be collected by a third party, such as another researcher who does not have the same influence over the students, or a research assistant. The optimal way to conduct this type of study would be that the students' teacher would receive a data set that is stripped of identifiers and the teacher will not be able to deduce the identities of the participants. The IRB understands that this may not always be possible; however, the IRB will want you to provide a thorough justification of your data collection methods and explain how the participants will be protected. In some cases, the IRB may not be able to approve studies where the conflict of interest proves to be too great of a risk to the students. However, the IRB will work with you to devise a methodology that is acceptable to both parties.⁹

Studies in which student identity is known: If your data include identifying information from your participants, it is important to demonstrate that the data are collected, studied, and stored in a manner so that students' identities are kept confidential. This storage process should be clearly spelled out in the HSR form.¹⁰

Letters of permission from research site authorities: When researchers propose research activities that occur in public or private schools or other educational institutions (other than colleges or universities), they should include a letter of permission (i.e., research site letter) from the appropriate school authority allowing the conduct of the research with their IRB application. The IRB strongly recommends contacting the administrative offices of the school / corporation / educational institution proposed to host the research activities in the beginning stages of the research project to identify the authorized school representative to grant such permissions. Additionally, should that representative have a conflict of interest with the research, a different representative should grant

¹⁰ http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_law_ferpa.html

the permission (e.g., if a school principal is the authorized individual, but s/he is an investigator on the research project, then the superintendent should grant the permission).

Some school districts have district-wide procedures for granting permission for research in schools, while others allow individual school principals to make decisions about research to take place in the schools they oversee. It is advisable that researchers check with each school district in which they intend to conduct research in order to determine at what level they must obtain permission.¹¹

Informed Consent and Minor Assent: Parent consent forms and student assent forms are appropriate when students are minors. Minors are unable to legally consent for themselves, thus it is important that you contact parents about your study. Please note that “consent” and “assent” are legal terms; all participants under the age of 18 are not legally able to consent for themselves and must have parental permission. The assent form, however, documents that the child or student understands and agrees to participate in the research study. If the parent consents but the child/student does not agree (dissents), the child’s refusal takes precedence—in other words, the child would not participate.

All studies with minors, whether they are exempt or not, will require that you send home a letter to parents to explain your presence in their child’s instructional setting, why you are conducting the study, how to contact you if they have questions, and what to do if they don’t want their child to participate. For some schools, the principal and/or teacher may want to send a letter home as well about the study. It is important that the principal/teacher’s letter does not promote the study to the parents but simply verifies that they gave permission for you to conduct the study at the school.¹²

If your research is exempt: In most cases, sending the Parent Notification Letter (see template) home to parents is the only contact you need to have with parents, though you will want to provide the same information from a consent form in your letter. In other words, you should introduce yourself and the research project, inform the parents about what you will do, what their child will do, and include information about the child’s confidentiality and any risks. Provide information about how to contact you if they have questions and what to do if they don’t want their child to participate (see template).¹³

As for a student assent, if the study is exempt, you will not need to document parental permission and minor assent. However, where appropriate, introduce yourself to the students and describe the purpose of your visit to their classroom. Take a moment to explain what it means to be a researcher and give them a chance to ask questions about your study.

If your research is NOT exempt: If your research does not fall into the exempt designation, you will need to provide permission forms to parents and assent forms to the students (see template). Often these forms can be sent home for parents to sign, but it may be appropriate to meet in person with parents and students to talk about the study. Generally, parents should be contacted first about the

¹¹ <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

¹² http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_consent_minor.html

¹³ Ibid.

study, so consider sending the consent form packet home in a sealed envelope or contacting parents directly about the study. Remember that the purpose of the permission and assent forms is to effectively communicate the ideas of the study to the participants and what their involvement will entail. Make sure that you are writing at a reading comprehension level that is appropriate for both the students and their parents. As needed, you should also translate documents into a language parents will understand. Be aware, too, of cultural considerations and take these into account in drafting your documents. If you have questions about the readability of your forms, consider asking the students' teacher or school administrator if they think their students and their parents will be able to understand your documents.¹⁴

Your research may be conducted in a context in which the parents are not literate and are minimally involved with the school. You may also encounter situations in which children may live with guardians or extended family members who are not their parents. In these cases, it will be necessary to find a suitable way to explain the research to the guardians or other caregivers. It is also possible that through thoughtful consultation with the principal you may determine that s/he may be able to provide consent instead of parents. It would be prudent to approach the principal to determine how best to proceed.

NON-EXEMPT RESEARCH IN EDUCATIONAL SETTINGS

Non-exempt research does not involve normal educational practices, and requires a full review.

What is NOT Normal Educational Practice?

The following types of research that takes place in an educational setting and involves children requires full review.

- Interviews, observations, and surveys where the questions and subject matter go beyond the scope of the educational activity being studied.
- Collecting information such as socio-economic status, sexual information, or information about abuse (or other details potentially related to traumatic experiences).
- Educational activities involving procedures that are rarely used and are not considered "best practice" in the field.
- Studies that may involve normal educational practice, but are greater than minimal risk to the students. This determination will be made by the IRB.¹¹
- The IRB must be able to determine that your research is exempt and ensures the protection of subjects. Therefore, when preparing your application for exempt status, be sure that your application materials and proposal address the following:
 - Will the research activities occur during instructional time or outside of instructional time?

¹⁴ http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_consent_minor.html

- If implementing a novel educational method, describe how it differs from the standard method.
- If conducting educational tests, describe when and how frequently.
- If reviewing and/or collecting student grades and/or standardized test scores, describe what grades or scores will be reviewed and/or collected, and if they will be individually identifiable.
- Identify if observing and recording data on teachers and/or students. If so, describe the activity.
- If reviewing student coursework, describe what coursework will be reviewed, if it will be identifiable, and how subjects' identities will be protected.
- State whether the educational activity is solely related to the research OR if the educational activity will occur regardless of whether the research is conducted.
- If extra credit (or equivalent for non-formal programs) will be offered for participation in the research activity, an alternative activity (involving a comparable amount of time and effort) must be provided to non-participating students for a comparable amount of credit. Such activities must be described.

If the researcher(s) is not directly involved in the implementation of the intervention, particular attention must be paid to the description of how the surrogate researchers will be trained in the conduct of human subjects research (e.g., obtaining consent, ensuring that those students whose parents do not want them to participate are excluded from the intervention).

- Describe who is responsible for distribution and collection of signed consent documents.
- Describe what plan is in place to monitor and manage data collection.
- Describe the plan for accommodating a participant who wants to withdraw from the study after permission/consent/assent has been obtained.
- Clearly describe the difference(s) between what would typically occur during instruction and what will occur related to the research (i.e., will all students be involved in the same activities or will there be individual learners/students singled out within a classroom?).

Coercion and undue influence is difficult to avoid in a classroom setting in which activities are determined and implemented by adults. Research designs should include strategies to reduce this risk. For instance, clear procedures should be in place for maintaining the educational activities of students who are not participating in the study in order to minimize interruption to the typical school day. Although students are generally obligated to participate in activities designed for the whole class, activities specifically implemented for the research need to be clearly explained and alternatives be provided for those choosing not to participate. Appropriate alternatives should be provided for those who opt out and must be described in the protocol as well as the consent documents. In general, researchers should not mandate that an entire class of students participate, unless implementation of the intervention is a part of the course curriculum and researchers are only seeking to collect de-identified data of previously outlined course activities.

Benefits or compensation for participation should extend to the entire class, regardless of how many children agreed to participate. This prevents scrutiny or peer pressure on the students who decline to participate.¹³

The risks and inconveniences should be assessed and clearly described in the proposal and consent process. For instance, in studies involving examination of classroom management techniques, will individual students be singled out for use of specific techniques? If so, what risks does that present to that child and to the other students (e.g., possibility of increase in disruptive behaviors)?¹⁴

Describe how privacy and confidentiality of all participants (e.g., students/learners, teachers/facilitators/instructors) will be maintained. For example, will study results be shared back with the school/program on an individual level or in aggregate? Will information about teacher performance be shared with school administration? What risks to participants are presented given how data will be both managed and shared?

When research activities involve the use of video and audio recording, it is incumbent on the researchers to ensure that only those participants who have consented to participate in the study and agreed to be video/audio recorded are included in the recording. If a parent/participant has not agreed to be video recorded, then the researchers must make sure that these participants are out of the video shot range and/or that these persons are deleted from any video recordings collected during the research process. Subsequent use of video recordings must exclude participants who did not agree to be video or audio recorded.¹⁴

Some school systems may require that researchers obtain criminal background checks prior to conducting research; researchers must follow the requirements of the school system.

EXAMPLES OF RESEARCH ELIGIBLE FOR EXEMPTION*

**Under normal educational practices in a commonly accepted educational setting*

Example 1

A researcher is interested in implementing an elementary school art education curriculum designed to help students develop visual vocabulary. The curriculum involves asking children to sort cards with reproductions of various Western artists as well as additional related activities. The basic curriculum has been widely used in school settings for over 15 years. The researcher is interested in adding some contemporary artists and those from other cultures to examine whether there are any differences in children's ability to make discriminations based on visual elements. These additions will not add significant time to the curriculum already being implemented and the assessments used in the study are typical of both length and content of current classroom assessments. Results of the study will be shared in aggregate form so that teachers can determine the benefit of including these curriculum modifications in the future.

Example 2

A middle school department of science teachers begins using graphic organizers to improve instruction of English language learners. The school has an existing relationship with the local university to partner on projects of collaborative interest. Thus, the school contacts researchers to ask for assistance in developing appropriate procedures for evaluating the hypothesized improved

instructional practices. Researchers plan to use the resulting data in aggregate form for purposes related to presentation and publication as well as providing individual data to teachers to inform their instructional practices.

EXAMPLES OF RESEARCH NOT ELIGIBLE FOR EXEMPTION*

**Under normal educational practices in a commonly accepted educational setting*

Example 3

A researcher wants to determine whether providing tangible reinforcement or verbal reinforcement will lead to greater increases in appropriate behavior and decreases in problem behavior for students identified with a serious behavior disorder. Individual students will be chosen for participation from classrooms of the same grade in consultation with the teachers. The students will be as closely matched for age and nature of the disorder, and then randomly assigned to an intervention condition. For example, one student will receive tangible reinforcement, one will receive verbal reinforcement, and the third will be the control.

Example 4

Researchers are interested in developing a new assessment for math skills that involve both scoring of written prompts as well as responses involving use of manipulatives. It is expected that a new standardized, norm-referenced product will result. According to the school, the planned assessment is aligned with current curriculum and will not require students to respond to questions that would be unfamiliar. However, the development process entails having students respond to more assessment items than would be expected. In addition, in order to validate the new assessment, additional tests not currently used in the school will be administered for comparison, thus extending total testing time and number of items beyond what would be considered normal educational practice.

Research with Animals and Environmental Research

Research involving animals is not covered by the HSR application but should follow the general lines of doing no harm to the animal or the student. Similar concerns will be raised in terms of protecting the environment. In other words, no matter what the subject matter, even if research does not involve direct analysis of human subjects, this does not make it exempt from ethical considerations.

Public Health Research

Research involving human beings is covered by the HSR application and follows the general lines of doing no harm to the student or the research participant. Similar concerns will be raised in terms of protecting the community where the research activity is being conducted. Public health research involves human beings and should seek IRB review and subsequent approval prior to start of the research project to ensure ethical considerations in the research project are met.

Templates for health-related Human Subject Research can be found here:

<https://grants.nih.gov/policy/clinical-trials/protocol-template.htm>

Annexes

ANNEX 1: ADDITIONAL INFORMATION

For more information about human subjects research from the U.S. Department of Health and Human Services please see:

- <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46>

Human Subjects Regulations and Policy, decision-making charts:

- <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts>

Informed Consent Checklist, developed by U.S. Department of Health and Human Services:

- <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html>

Research with Children:

- <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html>
- <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/fag/children-research/index.html>

Data and Privacy Concerns:

- <https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2019-workshop/session-2/index.html>
- <https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2019-workshop/session-3/index.html>

ANNEX 2: PARTICIPANT INFORMED CONSENT TEMPLATE

Please modify this consent form so that it is appropriate for your study. This includes making certain the letter is culturally appropriate, in a language comprehensible to participants, at a reading level they can understand, etc. In some cases, this text may serve as the basis for a verbal consent process. Please delete or modify any text in brackets/italics. Please note that you may reduce the length of the letter to make it more accessible for your participants so long as the core requirements listed in the template are met.



Participant Informed Consent

TITLE OF THE STUDY:

RESEARCHER NAME:

My name is ... I am a student with the SIT ... program.

I would like to invite you to participate in a study I am conducting (for partial fulfillment of my MA in ... or as part of the Study Abroad Program in ...). Your participation is voluntary.

Please read the information below, and ask questions about anything you do not understand, before deciding whether to participate. If you decide to participate, please sign this form and you will be given a printed or electronic copy of this form.

OR

Please listen to the information, and ask questions about anything you do not understand, before deciding whether to participate. If you decide to participate, please give consent orally either at the beginning of the recording or in another form of documentation (e.g., "You may say "yes" if you consent, and I will record it in my field notes").

PURPOSE OF THE STUDY

State what the study is designed to assess or establish. Technical or complicated language should be avoided. Participants should be able to easily understand the purpose of the study and that it is research.

The purpose of this study is to...

STUDY PROCEDURES

Describe what you will ask the respondent to do, how much time it will take, and where the study data collection (interview, focus group) will take place. If applicable, clearly state whether participants will be photographed and/or audio/video-recorded. Clarify if the participant can still participate in this research study if they do not wish to be audio/video-recorded or photographed.

Your participation will consist of ... and will require approximately ... of your time.

POTENTIAL RISKS AND DISCOMFORTS

Describe any reasonable, foreseeable risks – risks may be social, psychological, economic, and legal in nature – discomforts, and inconveniences, and how these will be minimized. If there are no anticipated risks, state so.

There are no foreseeable risks to participating in this study and no penalties should you choose not to participate; participation is voluntary. During the interview (focus group) you have the right not to answer any questions or to discontinue participation at any time.

POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY

State any anticipated benefits to the participant or others/society that may reasonably be expected from the study. If there are no direct benefits to the participant, the researcher may tell the participant what they hope to learn, how that knowledge will contribute to the field of study, or how the knowledge might benefit others if such a case can be made.

PAYMENT/COMPENSATION FOR PARTICIPATION

State whether the participant will receive payment/compensation or any other form of compensation and describe. If no compensation is involved, remove the section.

CONFIDENTIALITY

Describe the extent, if any, to which confidentiality of records identifying the participant will be maintained. The description must also a full disclosure of any state-mandated reporting requirements (e.g., suspicion of child abuse, neglect, or harm to others). State and international requirements vary, as such the researcher needs to be aware of that specific information.

Describe how you will maintain the confidentiality or anonymity of your respondents during data collection, after the study is finished, and in the presentation or publication of your research.

- Describe who will have access to these data.
- Describe how will personal information, research data, and related records will be stored to prevent access by unauthorized people (e.g., Will data be kept in a locked cabinet, or if in a computer, is data password protected?).

Explain when audio/video-recordings or notes will be erased or discarded. If data will be anonymized (e.g., by associating codes with names) explain how. Explain how you will protect the research participant's identity when the results are presented or published.

Any identifiable information obtained in connection with this study will remain confidential.... I will (explain in detail how you will protect these data).

When the results of the research are published or discussed in conferences, no identifiable information will be used.

FUTURE USE OF DATA

Include a statement on whether the data will be used for future research studies: if your research involves collection of private identifiable information, explain that identifiers might be removed and the information could be used for future research studies or shared with another researcher without additional consent from the participant, if the opportunity arises to use it in the future studies.

OR

Include a statement that the participant's information collected in this study, even if identifiers are removed, will not be used for future research studies or distribution.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study.

RESEARCHER'S CONTACT INFORMATION

If you have any questions or want to get more information about this study, please contact me at (email) or my advisor/supervisor at (email).

RIGHTS OF RESEARCH PARTICIPANT—IRB CONTACT INFORMATION

In an endeavor to uphold the ethical standards of all SIT proposals, this study has been reviewed and approved by the SARB or SIT IRB. If you have questions, concerns, or complaints about your rights as a research participant or the research in general and are unable to contact the researcher please contact the Institutional Review Board at: irb@sit.edu

School for International Training, Institutional Review Board, 1 Kipling Road, PO Box 676, Brattleboro, VT 05302-0676, USA irb@sit.edu, +001-802-258-3132

"I have read the above and I understand its contents and I agree to participate in the study. I acknowledge that I am 18 years of age or older."

Participant's signature: _____ *Date:* _____

Researcher's signature: _____ *Date:* _____

OPTIONAL STUDY ELEMENTS

This section should include other explicit consents for optional elements of the research procedures, such as audiotaping, videotaping, storing photographs for future use, or using the subjects' actual name in research publications.

Examples:

Consent to Quote from Interview

I may wish to quote from the interview with you either in the presentations or articles resulting from this work. If a pseudonym will be used, include this statement: A pseudonym (fake name) will be used in order to protect your identity.

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to quote from an interview

_____(initial) I do not agree to consent to quote from an interview

Consent to Audio-Record Interview

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to audio record an interview

_____(initial) I do not agree to consent to audio record an interview

Consent to Have Recordings Played in Public (if relevant)

I may wish record the interview with you and play that recording in public, either a conference or classroom presentation.

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to audio record an interview and that the recording be used in a conference (classroom) presentation.

_____(initial) I do not agree to consent to audio record an interview and that the recording be used in a conference (classroom) presentation.

ANNEX 3: PARENT NOTIFICATION LETTER TEMPLATE

This template is only for EXEMPT research in educational settings.

This letter is to be used after obtaining permission from the relevant authority in the educational setting. Note that authority to contact parents should be discussed with that authority; in some instances the researcher may not be allowed to contact parents directly.

Please modify this letter so that it is appropriate for your study. This includes making certain the letter is culturally appropriate, in a language comprehensible to parents, at a reading level they can understand, etc. In some cases, this text may serve as the basis for a verbal consent process. Please delete or modify any text in brackets/italics. For example, if you are addressing an adult student, write the letter directly to the student. Adapt the language to the educational contexts as appropriate, for instance, you may replace the word “class” for a non-formal education activity. Please note that you may reduce the length of the letter to make it more accessible for your participants so long the core requirements listed in the template are met.



Parent Notification Letter

Dear Parent,

My name is Researcher’s Name and I am conducting a research study in your child’s class. I am interested in studying please briefly explain the purpose of your study.

(In this next paragraph, explain when you will be in the class and what you will do in the class. Include an explanation about the child’s data and confidentiality issues. The following paragraph is a sample; please alter the paragraph so that it fits your study.)

I will be in your child’s class once each week for five weeks for about an hour per session. While I’m in the classroom, I will observe the teacher’s instruction methods and take notes (or video tape, etc). I will take great care in maintaining the confidentiality of your child. This means that I will not share your child’s name in any future uses of this information. If necessary, I will use a pseudonym/false name to protect your child’s identity. As part of this study, you/your child will not do anything outside of his/her/your normal classroom activities and there is no risk to you/your child. Your child’s participant will not affect his/her/your grade.

If you have any questions or concerns about the study, or if you would like to withdraw your child from the study, please contact me at:

Researcher’s Name & contact info

If you have questions about your rights as a research participant, please contact: the SIT Institutional Review Board:

School for International Training, Institutional Review Board, 1 Kipling Road, PO Box 676, Brattleboro, VT 05302-0676, USA irb@sit.edu, +001-802-258-3132

Sincerely,

Researcher's Name

ANNEX 4: PARENTAL PERMISSION FORM FOR CHILD'S RESEARCH PARTICIPATION TEMPLATE

This template is for use in research requiring a full review.

Please modify this consent form so that it is appropriate for your study. This includes making certain the letter is culturally appropriate, in a language comprehensible to participants/parents, at a reading level they can understand, etc. In some cases, this text may serve as the basis for a verbal consent process. Please delete or modify any text in brackets/italics, and where multiple options are given (such as two possible sentences marked as either/or) select one and delete the others. Please note that you may reduce the length of the letter to make it more accessible for your participants so long as the core requirements listed in the template are met.



Parental Permission Form for Child's Research Participation

STUDY TITLE:

RESEARCHER:

Your child is being asked to take part in a research study. This form has important information about the reason for doing this study, what we will ask your child to do, and the way we would like to use information about your child if you choose to allow your child to be in the study.

WHY ARE YOU DOING THIS STUDY?

Your child is being asked to participate in a research study about The purpose of the study is ...

WHAT WILL MY CHILD BE ASKED TO DO IF MY CHILD IS IN THIS STUDY?

Your child will be asked to explain what participants will be asked to do. Explain if you will be asking any personal or sensitive questions. Participation should take about insert expected amount of time.

If you will be tape recording subjects, include the following:

We would like to video record [or audio tape] your child as he/she performs study task(s) that will be recorded, to make sure that we remember accurately all the information. The researchers will keep these tapes in explain where you will keep them and they will only be used by explain who will have access to the tapes. We will only video record (or audio tape) your child if you and your child give us permission.

If subjects may participate without being taped, include I agree ... and I do not agree... options at the end of this form. If audio/video recording are not optional, then state Audio/Video recording is required for participation in this study. If you or your child do not wish to be recorded, it is not possible for your child to be in this study.

NOTE: if the parent is also a participant in the study, include a section describing what research tasks the parent will be asked to do OR create a separate consent form addressing the parent as a participant.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS TO MY CHILD?

Explain any foreseeable risks to subjects here.

Examples

To the best of our knowledge, the things your child would be doing in this study have no more risk of harm than the risks of everyday life.

OR

Your child's participation in this study does not involve any physical or emotional risk to your child beyond that of everyday life.

OR

Your child's participation in this study may involve the following risks... describe any reasonably foreseeable risks to psyche, reputation, employability, insurability, social status, criminal or civil liability that may occur as a result of participation.

Examples of Risk Explanations

- Your child may get tired during the tasks. We will explicitly explain to your child to tell the interviewer at any time if he/she wants to take a break or stop the interview.
- Your child may feel emotionally overwhelmed or may experience sensory integration issues when answering some of the questions. We will explicitly explain to your child to tell the interviewer at any time if he/she wants to take a break or stop the interview.
- Your child may be uncomfortable with some of the questions and topics we will ask about. If your child is uncomfortable, they are free to not answer or skip to the next question.

As with all research, there is a chance that confidentiality of the information we collect about your child could be breached; we will take steps to minimize this risk, as discussed in more detail below in this form.

WHAT ARE THE POSSIBLE BENEFITS FOR MY CHILD OR OTHERS?

Your child is not likely to have any direct benefit from being in this research study. This study is designed to learn more about insert purpose/topic of study. The study results may be used to help other people in the future.

OR

Taking part in this research study may not benefit your child personally, but we may learn new things that will help others.

OR

The possible benefits to your child from this study include...

Please describe the possible benefits to the child from this study. Do NOT include information on payment/reimbursement in the description of benefits – that information belongs in a separate Financial Information section.

HOW WILL YOU PROTECT THE INFORMATION YOU COLLECT ABOUT MY CHILD, AND HOW WILL THAT INFORMATION BE SHARED?

Results of this study may be used in publications and presentations. Explain measures to protect data confidentiality/personal privacy here. If disclosure of faces or voices is necessary to understanding the research and so identifying information may be used in reports/presentations, explain this and provide “I agree” “I do not agree” options at the end of the consent form.

CONFIDENTIALITY

[Describe how you will maintain the confidentiality or anonymity of your respondents during data collection, after the study is finished and in the presentation or publication of your research. Specifically, who will have access to these data? How will personal information, research data, and related records will be stored to prevent access by unauthorized people (e.g. will data be kept in a locked cabinet, or if in a computer, is data password protected?). Explain when audio/video-recordings or notes will be erased or discarded. If data will be anonymized (e.g. by associating codes with names) explain how. When the results are presented or published, how will you protect the research subject’s identity?]

Any identifiable information obtained in connection with this study will remain confidential.... I will (explain in detail how you will protect these data).

When the results of the research are published or discussed in conferences, no identifiable information will be used.

FINANCIAL INFORMATION

Participation in this study will involve no cost to you or your child. Your child will not be paid for participating in this study.

OR

If subjects will be paid, explain the amount and terms of payment/reimbursement. If payments will be prorated if a subject withdraws from the study, state the terms.

OPTIONAL STUDY ELEMENTS

This section should include other explicit consents for optional elements of the research procedures, such as audiotaping, videotaping, storing photographs for future use, or using the subjects' actual name in research publications.

Examples:

Consent to Quote from Interview

I may wish to quote from the interview with your child either in the presentations or articles resulting from this work. If a pseudonym will be used, include this statement: A pseudonym (fake name) will be used in order to protect your child's identity.

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to quote from an interview

_____(initial) I do not agree to consent to quote from an interview

Consent to Audio-Record Interview

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to audio record an interview

_____(initial) I do not agree to consent to audio record an interview

Consent to Have Recordings Played in Public (if relevant)

I may wish record the interview with you and play that recording in public, either a conference or classroom presentation.

Initial one of the following to indicate your choice:

_____(initial) I agree to consent to audio record an interview and that the recording be used in a conference (classroom) presentation.

_____(initial) I do not agree to consent to audio record an interview and that the recording be used in a conference (classroom) presentation.

WHAT ARE MY CHILD'S RIGHTS AS A RESEARCH PARTICIPANT?

Participation in this study is voluntary. Your child may withdraw from this study at any time -- you and your child will not be penalized in any way or lose any sort of benefits for deciding to stop participation.

Include this if research is being done in a school setting: If you and your child decide not to be in this study, this will not affect the relationship you and your child have with your child's school in any way. Your child's grades will not be affected if you choose not to let your child be in this study.

If your child decides to withdraw from this study, the researchers will ask if the information already collected from your child can be used or in the alternative, state that the information already collected will not be used.

WHO CAN I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH STUDY?

If you or your child have any questions, you may contact the researcher at add your contact information, including name, telephone number, and email address.

If you have any questions about your child’s rights as a participant in this research, you can contact the following office at the School for International Training:

School for International Training, Institutional Review Board, 1 Kipling Road, PO Box 676, Brattleboro, VT 05302-0676, USA irb@sit.edu, +001-802-258-3132

PARENTAL PERMISSION FOR CHILD’S PARTICIPATION IN RESEARCH

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I give permission for my child to participate in the research study described above and will receive a copy of this Parental Permission form after I sign it.

_____ *Date:* _____

Parent/Legal Guardian’s Name (printed) and Signature

_____ *Date:* _____

Name of Person Obtaining Parental Permission

For studies taking place in a school, this paragraph generally should be included (if you are unsure whether to include this paragraph for your study, please contact the SIT IRB for guidance)

Parents, please be aware that under the Protection of Pupils Rights Act (20 U.S.C. Section 1232(c)(1)(A)), you have the right to review a copy of the questions asked of or materials that will be used with students. If you would like to do so, you should contact [Researcher to obtain a copy of the questions or materials.

ANNEX 5: MINOR ASSENT TEMPLATE

Please modify this consent form so that it is appropriate for your study. This includes making certain the letter is culturally appropriate, in a language comprehensible to participants/parents, at a reading level they can understand, etc. In some cases, this text may serve as the basis for a verbal consent process. Please delete or modify any text in brackets/italics, and where multiple options are given (such as two possible sentences marked as either/or) select one and delete the others.

Please note that you may reduce the length of the letter to make it more accessible for your participants so long as the core requirements listed in the template are met. Assent processes and forms should be appropriate to the age of the minor; children under age 7 may require very simple oral explanations while children over age 7 may be able to read progressively more detailed text as they increase in age. For further considerations, please consult the HHS FAQs on research with children found here: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/fag/children-research/index.html>.



Minor Assent Form

TITLE OF THE STUDY:

RESEARCHER:

I am doing a study about ...

WHY HAVE YOU BEEN ASKED TO BE A PART OF THIS STUDY?

I would like you to participate in a research study about ...

The purpose of the study is ...

WHAT WILL YOU BE ASKED TO DO?

If you agree to be in this study, you will be asked to do the following things: [explain what participants will be asked to do].

Participation should take about [insert expected amount of time].

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS FOR YOU?

Participation in this study carries no reasonable foreseeable (or expected) risks. There may be unknown risks.

Your parents know about the study and have agreed that you can participate if you want to.

ARE THERE BENEFITS TO BEING IN THIS STUDY?

The study could benefit you in the following ways:

OR

The study will not benefit you directly etc.

CONFIDENTIALITY

This study is anonymous. We will not be collecting or retaining any information about your identity.

OR

The records of this study will be kept strictly confidential. Research records will be kept in a locked file, and all electronic information will be coded and secured using a password protected file. *[If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed and indicate how they will be destroyed or erased.]* We will not include any information in any report we may publish that would make it possible to identify you.

RIGHT TO REFUSE OR WITHDRAW

The decision to participate in this study is entirely up to you. You may refuse to take part in the study *at any time* without affecting your relationship with the investigator of this study or Smith College. Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

WHO WILL SEE THE INFORMATION COLLECTED ABOUT YOU?

When I am finished with this study, I will write a report about what I learned. This report will not include your name or that you were in the study. I will give you a fake name and I will not keep any of the materials you recorded.

Please feel free to contact me if you have any questions about the study.

ADVISOR:

I understand what I will be asked to do in this study. I understand that I can stop participating at any time. I want to take part in the study.

_____ Date: _____

Minor's Name (printed) and Signature

_____ Date: _____

Name of Principal Investigator and Signature