



# Human Subjects Research Policy

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SIT Graduate Institute  
SIT Study Abroad

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# HUMAN SUBJECTS RESEARCH POLICY

## PREFACE

SIT's Institutional Review Board (IRB) exists to uphold the ethical principles of respect for persons, beneficence and justice for all human subjects of research. The IRB specifically considers the aspects of informed consent, risks and benefits, and the selection of subjects.<sup>1</sup>

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) 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 are expected to fulfill their obligation to protect the rights of people involved in their research.

## DEFINITIONS

- *Research*: Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- *Researcher (also referred to as investigator)*: Human Subject Research policies apply to all research at the School for International Training conducted by faculty, academic and program directors, students, and World Learning staff.
- *Human Subjects Review (HSR)*: The process by which research proposals are reviewed so as to protect participants from harm.
- *Institutional Review Board (IRB)*: SIT's institution-wide board charged with reviewing research proposals and determining whether they comply with human subjects guidelines established by federal law.
- *Local Review Board (LRB)*: The SIT Study Abroad program-level board charged with establishing appropriate standards and reviewing research proposals to insure Human Subjects Review Policy compliance, with particular attention to in-country ethical norms. The LRB 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 other norms and ethical standards that also must be taken into consideration. All research carries risk, but

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<sup>1</sup> 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*.

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)).

Researchers are responsible for maintaining contact with the Institutional Review Board, and/or the Local Review Board for SIT Study Abroad research, in the event of changes to approved research protocols, and for ensuring 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.

## IRB/LRB PROPOSAL SUBMISSION PROCESS

All proposals must be submitted to the IRB Administrator at [irb@sit.edu](mailto:irb@sit.edu) for review and approval *before research can begin* or, in the case of SIT Study Abroad, to the LRB for review and approval before research can begin. The IRB/LRB reserves the right to disapprove an application.

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 proposals.

Proposals requiring Full Review must be submitted to the IRB Administrator at [irb@sit.edu](mailto:irb@sit.edu) at least ONE WEEK in advance of the next IRB Committee meeting. The IRB Committee’s decision with regard to a Full Review proposal will be provided via email within one week of the IRB Committee meeting at which a Full Review proposal is reviewed. The IRB Committee meeting schedule will be published at the start of each academic term, and can be found on the SIT websites:

<https://studyabroad.sit.edu/how-it-works/undergraduate-research/sit-institutional-review-board/> or <https://graduate.sit.edu/academics/sit-institutional-review-board/>.

The timing of SIT Study Abroad proposals submitted to the Local Review Board (LRB) will vary by program, but a one week proposal review period, at minimum, is recommended to allow thorough review of all proposals submitted to the LRB.

*Please see the Roles and Responsibilities section of this document for additional details regarding proposal submission protocols for researchers.*

Questions pertaining to a proposal submitted to the IRB Committee should be directed to [irb@sit.edu](mailto:irb@sit.edu).

## TYPES OF HUMAN SUBJECTS RESEARCH: EXEMPT, EXPEDITED, FULL REVIEW

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

Researchers may NOT engage in research that involves:

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

## Exempt

Exempt research is any research that does not involve the participation of human subjects or presents no more than minimal risk to human subjects and falls into one of the categories below:

- The collection or study of existing data, documents, or records if these sources are publicly available (historical texts, files downloadable online) or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects;
- Research that does not aim to contribute to generalizable knowledge;
- Regular and special education instructional strategies, on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods in an established or commonly accepted educational setting (e.g. Evaluating the use of accepted or revised standardized tests, comparing a lesson or curriculum);
- Cognitive, diagnostic, aptitude or achievement educational tests, if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research would NOT place the subjects at any risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
- Interviews, surveys or focus groups with elected or appointed public officials or candidates for public office;
- Surveys, interviews or observation of public behavior for which anonymity of the subjects is inherent. The information is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects (e.g. a person's voice). And, the subjects' responses would not, were they disclosed outside the research, place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. For instance, anonymous, identifier-disassociated surveys of teachers about a method or an outcome, interviews with nonprofit staff about a program, or a focus group about an experience;
- Research focusing on consumer consumption of food and the taste and quality of food if wholesome foods without additives are consumed.

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](mailto:irb@sit.edu)), where the application will be reviewed by the IRB Administrator for accuracy and completion. Exempt applications for research conducted by SIT Study Abroad students are reviewed by the Local Review Board and retained at the program site; those submitted by the Graduate Institute will be kept at the SIT IRB Office.

## Expedited

Research in the expedited category presents no more than minimal risk to participants and may include projects from the following categories:

- Research that involves “minimal risk,” unless it involves children as participants. “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;

- Collection of data from 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 are or can be identified directly or indirectly;
- 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:**

- 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.

## Full Review

The following research will require full IRB committee review, or review by the LRB for SIT Study Abroad, to assess potential benefits and risks:

- All research involving children that does not fall into the exempt category (educational context);
- Research with vulnerable and/or at risk populations (e.g. prisoners, refugees);
- 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, including, but not limited to children;
- Research involving subjects who are available because of their need for the investigator's professional services (students or employees of the researcher);
- Explicit, or implicit, deception of participants about any aspect of the research significant to them.

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 section titled *Children and Human Subjects Research*.

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.

## INTERFACE BETWEEN SIT IRB & SIT STUDY ABROAD LRB

Please note:

1. A proposal denied by the SIT Study Abroad LRB may be submitted by the Academic Director or Program Director to SIT's Institutional Review Board for review, but it is unlikely SIT's IRB would approve a proposal that was denied by the LRB. SIT upholds the principle that the LRB is the most qualified body to ensure observance of local norms of ethics and value systems for SIT Study Abroad field study proposals;
2. The SIT IRB reserves the right to turn down a research proposal even if the proposal was approved by the LRB if the IRB believes that that the proposal contradicts any of the U.S federal regulations and policies which regulate research on human subjects.

## CHILDREN AND HUMAN SUBJECTS RESEARCH

The US 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 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 LRB 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 the information about participation in the research explained to them in language they can understand (by their parent), and, if possible, they should also sign their consent form.
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 member of a team, class or organized group are being recruited for a study and participation could affect the performance of the team, class or group as a whole, the informed consent of the coach, instructor, or group leader is required.
6. For more information on the US 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.

## 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. 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.

Vulnerable subjects in SIT Graduate Institute and Study Abroad 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.* With the exception of research concerning normal educational practices conducted in an educational setting, all research involving this vulnerable subject population must be submitted for full review.

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

## THE IMPORTANCE OF INFORMED CONSENT

When conducting research with human subjects, the researcher should obtain, in a culturally appropriate manner, the informed consent of all human subjects who participate in the study. Obtaining consent includes the following:

- The researcher shall explain to subjects (prior to their participation) the objectives of the study, the procedures to be followed, 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).
- 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 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 or all 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.

**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.

## PROTOCOL FOR COURSEWORK INVOLVING HUMAN SUBJECTS

All approved SIT courses, but 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.

We propose syllabi for courses involving human subjects 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 as exempt research using human subjects conducted in order to fulfill the requirements of a class. Exempt status is predicated on the assumption that:

- The assignment topic is not sensitive (see definition in the Full Review section of this document);
- Human subject participants in the assignment are not vulnerable and the information gathered is not sensitive and/or is properly protected from public access;
- 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 notify the instructor and receive approval to proceed with the new protocol."

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, and 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 Reflective Practice Course and SIT Study Abroad's Independent Study course, as well as the Independent Study Project, Field Study Project, and Internship courses offered by SIT Study Abroad.

## ROLES AND RESPONSIBILITIES

### Faculty/Supervisor/Academic/Program Director (AD/PD):

- Faculty research projects involving human subjects must be submitted to the IRB.
- It is the responsibility of the Faculty/Supervisor/AD/PD to review the SIT IRB policies and procedures for the protection of human subjects, to share this information 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 Faculty/Supervisor/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 IRB for review.
- The Faculty/Supervisor/AD/PD will sign the student's human subjects application with the assigned recommendation and the student will submit the documentation:
  - SIT Graduate Institute students submit proposals directly to the IRB (irb@sit.edu).
  - Study Abroad students submit to the Local Review Board (LRB).
  - Any Study Abroad projects needing review by the SIT IRB in Vermont will be submitted by the AD/PD to irb@sit.edu.
  - For Study Abroad, the Academic/Program Director scans and emails the LRB/IRB 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 local SIT program office.

### Researcher:

- The researcher is ultimately responsible for conducting research in compliance with 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.

- The Study Abroad student researcher is also responsible for checking with their home institution if a separate Institutional Review Board application process is required.
- All Study Abroad Independent Study Project (ISP), Field Study Project (FSP) proposals, Internship & Seminar Proposals must be submitted to the Local Review Board for review and approved before research/participation may begin. When necessary, the proposal may be submitted by the AD/PD for full review by SIT's IRB in Vermont.
- All SIT Graduate Institute student research proposals must be approved by the IRB before research can begin.
- For greater efficiency, the naming protocol for submissions to the IRB (irb@sit.edu) is as follows:
  - Last name\_exempt\_year.docx or pdf
  - Last name\_expedited\_year.docx ○ Last name\_full\_year.docx

**Proposal submission process:**

- All proposals must be submitted to the IRB Administrator at [irb@sit.edu](mailto:irb@sit.edu) for review and approval *before research can begin* or, in the case of SIT Study Abroad, to the LRB for review and approval before research can begin. The IRB/LRB reserves the right to disapprove an application.
- 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 proposals.
- Proposals requiring Full Review must be submitted to the IRB Administrator at [irb@sit.edu](mailto:irb@sit.edu) at least ONE WEEK in advance of the next IRB Committee meeting. The IRB Committee's decision with regard to a Full Review proposal will be provided via email within one week of the IRB Committee meeting at which a Full Review proposal is reviewed.
- The IRB Committee meeting schedule will be published at the start of each academic term and can be found on the SIT websites: <https://studyabroad.sit.edu/how-it-works/undergraduate-research/sit-institutional-review-board/> or <https://graduate.sit.edu/academics/sit-institutional-review-board/>.
- The timing of SIT Study Abroad proposals submitted to the LRB will vary by program, but a one week proposal review period, at minimum, is recommended to allow thorough review of all proposals submitted to the LRB.
- Questions pertaining to a proposal submitted to the IRB Committee should be directed to [irb@sit.edu](mailto:irb@sit.edu).

## SIT Study Abroad Local Review Boards (LRBs)

The Local Review Board 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 LRB. This measure provides for more objectivity/for a wider range of input. LRB members will not participate in the approval of projects in which they have a conflicting interest.

- The LRB 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 LRB 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 LRB receives signed, human subjects research applications from the Academic/Program Director and convenes to review the applications.
- The LRB approves or disapproves each project. The LRB 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 LRB via [irb@sit.edu](mailto:irb@sit.edu).
- All ISP/FSP/Internship projects must be approved by the LRB before the projects may begin.

## SIT Institutional Review Board (IRB)

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.

- Extremely sensitive topics or cases whereby a decision cannot be reached at the level of the LRB may be submitted for full review by the SIT IRB.
- The SIT IRB approves or disapproves each project submitted to it by the Faculty Advisor or Academic/Program Director, following initial review by the LRB. 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.
- The SIT IRB will convene and review proposals requiring a Full Review once a month. Proposals for Full Review must be received by the IRB Administrator ([irb@sit.edu](mailto:irb@sit.edu)) at least ONE WEEK prior to the next IRB Committee meeting.

- The SIT IRB will review proposals requiring an expedited review within a timeframe of two weeks for receipt of referral.
- The IRB Committee will publish its meeting schedule at the start of each academic term.

## Interpreters and Translators

Human subjects research at SIT 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.

## Animals, The Environment, and Research

Research involving animals is not covered by the HSR but should follow the general lines of doing no harm to the student or the animal. 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.

# GUIDANCE ON RESEARCH CONDUCTED IN EDUCATIONAL SETTINGS

## Exempt Research in Educational Settings

Exempt research 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.”<sup>1</sup>

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

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<sup>1</sup> <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>



information for survey responses (for more information on FERPA and PPRA, see related links).<sup>2</sup>

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 that which would qualify as exempt (normal practices in accepted educational settings) and 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.<sup>3</sup> 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, 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 research occurs in US and non-US 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 that 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.<sup>4</sup>

Participants can include populations with special educational needs. 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.<sup>5</sup>

### **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.

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<sup>2</sup> [http://www.virginia.edu/vpr/irb/sbs/submissions\\_review\\_ex\\_exemption\\_nep.html](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_nep.html)

<sup>3</sup> <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

<sup>4</sup> <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

<sup>5</sup> <https://research.boisestate.edu/compliance/institutional-review-board-irb-home/guidelines-for-researchers/guidelines-on-normal-educational-practices>

- 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?).<sup>6</sup>
- 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).<sup>7</sup>
- 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.<sup>8</sup>
- 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.<sup>9</sup>
- Collecting data specific to teacher and/or student current knowledge, beliefs, or attitudes towards learning, or data about how these change 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.<sup>10</sup>

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<sup>6</sup> <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

<sup>7</sup> <http://research.uconn.edu/irb/researcher-guide/normal-educational-practices/>

<sup>8</sup> [http://www.virginia.edu/vpr/irb/sbs/submissions\\_review\\_ex\\_exemption\\_nep\\_normal.html](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_nep_normal.html)

<sup>9</sup> <http://research.uconn.edu/irb/researcher-guide/normal-educational-practices/>

<sup>10</sup> Ibid.

## 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;
- 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.<sup>11</sup>□

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?
- 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.<sup>12</sup>
- 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.<sup>13</sup>

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

<sup>12</sup> <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

<sup>13</sup> <http://irb.ufl.edu/irb02/informed-consent-instructions-procedures/students.html>

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 activity 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.<sup>14</sup>

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)?<sup>15</sup>

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

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<sup>14</sup> <https://www.umass.edu/research/guidance/research-k-12-settings>

<sup>15</sup> <http://research.uconn.edu/irb/researcher-guide/normal-educational-practices/>

during the research process. Subsequent use of video recordings must exclude participants who did not agree to be video or audio recorded.<sup>16</sup>

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

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<sup>16</sup> <https://www.umass.edu/research/guidance/research-k-12-settings>

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.<sup>17</sup>

## DATA COLLECTION

**Student data: classroom data and student records:** If the data are already created prior to beginning the study (i.e. tests, writing assignments, and evaluations done in a previous class) and/or if you need to access student records, you will need to ensure that the data are anonymous.

**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 take 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 in order to qualify for exemption, it is necessary that the data are collected in a way that does not identify the individual student.<sup>18</sup>

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.<sup>19</sup>

**Student Records:** In the US, FERPA and state regulations protect the privacy of student records. Any research conducted under SIT auspices in non-US settings should comply with the most restrictive set of regulatory standards.

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 as long as 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

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<sup>17</sup> Examples from: [https://officeofresearch.ucsc.edu/compliance/services/irb17.03\\_exempt\\_examples.html](https://officeofresearch.ucsc.edu/compliance/services/irb17.03_exempt_examples.html), [http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/exempt-determinations/category-1---educational-practices](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/exempt-determinations/category-1---educational-practices), <http://research.uconn.edu/irb/researcher-guide/normal-educational-practices/>, <http://www.umass.edu/research/topic/human-subjects/irb?page=6>, <http://research.uconn.edu/irb/researcher-guide/normal-educational-practices/>

<sup>18</sup> [http://www.virginia.edu/vpr/irb/sbs/submissions\\_review\\_ex\\_exemption\\_arch\\_records\\_student.html](http://www.virginia.edu/vpr/irb/sbs/submissions_review_ex_exemption_arch_records_student.html)

<sup>19</sup> <https://www.research.fsu.edu/research-offices/human-subjects/faq/>

protocol.<sup>20</sup>

## ADDITIONAL INFORMATION

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

- <http://www.hhs.gov/ohrp/humansubjects/index.html>
- <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Human Subjects Regulations and Policy, decision-making charts:

- <http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/index.html#c8>

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>
- <http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf>

## RECRUITMENT, PERMISSION AND INFORMED CONSENT

The consent process in 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) 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 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 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 investigator.<sup>21</sup>

Recruiting Students: 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

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<sup>20</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_law\\_ferpa.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_law_ferpa.html)

<sup>21</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_law\\_ferpa.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_law_ferpa.html)

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.

When the Instructor is the Researcher: As the instructor of the class, whether your students are minors or adults, you have a position of authority over your students and also 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 or will not attempt to deduce the identities of the participants. The IRB understands that this may not always be possible; however, the IRB will want to 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.<sup>22</sup>

Studies in which student identity is known: If you are unable to collect data from participants without collecting identifying information as well, it is important to demonstrate that the data are collected in a confidential manner and will be properly stored. It is important that the data are collected, studied, and stored so that students' identities are kept confidential. This storage process should be clearly spelled out in the proposal.<sup>23</sup>

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 must submit a letter of permission (i.e., research site letter) from the appropriate school authority allowing the conduct of the research. 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 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.<sup>24</sup>

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

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<sup>22</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_data\\_known.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_data_known.html)

<sup>23</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_data\\_known.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_data_known.html)

<sup>24</sup> <https://www.clemson.edu/research/compliance/irb/b1exemption.html>



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 consent. The assent form, however, documents that the student understands and agrees to participate in the research study.

All studies, 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.<sup>25</sup>

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).<sup>26</sup>

As for a student assent, if the study is exempt, you will not need to document consent. 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 consent 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 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 consent form 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 he or she thinks her or his students and their parents will be able to understand your documents.<sup>27</sup>

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 parents or guardians. It is also possible that through thoughtful consultation with the principal, you may determine that she may be able to provide consent instead of parents. It would be prudent to approach the principal to

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<sup>25</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_consent\\_minior.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_consent_minior.html)

<sup>26</sup> Ibid.

<sup>27</sup> [http://www.virginia.edu/vpr/irb/sbs/resources\\_guide\\_ed\\_consent\\_minior.html](http://www.virginia.edu/vpr/irb/sbs/resources_guide_ed_consent_minior.html)

determine how best to proceed. Notification and parental consent may need to be obtained by visiting parents/guardians.

# 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 red.**



## 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, you will be asked to sign this form and you will be given a copy of this form.*

**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 interview etc. 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, discomforts, inconveniences, including physiological risks/discomforts, 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 to society. If there are no anticipated benefits to the participant, state so.**

## **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 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.*

## **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.

**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 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 an SIT Study Abroad Local Review Board or SIT Institutional Review Board. 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:

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

**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.

“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:* \_\_\_\_\_

# PARENT NOTIFICATION LETTER TEMPLATE

This template is for EXEMPT research in educational settings

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 red.** 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.



## 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](mailto:irb@sit.edu), 802-258-3132*

Sincerely, **Researcher's Name**

# 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 red.**



## 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. Your child can rest/take a break at any time.
- Your child may feel emotional or upset when answering some of the questions. Your child can 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.

### **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, 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.

\_\_\_\_\_  
Parent/Legal Guardian's Name (printed) and Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Parental Permission

\_\_\_\_\_  
Date

**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.

# MINOR ASSENT AGE 14-17 TEMPLATE

[Delete text in red and insert other information where appropriate]



## Minor Assent Form (Ages 14 – 17)

### TITLE OF THE STUDY:

### RESEARCHER:

I am doing a study about ...

### WHY HAVE YOU BEEN ASKED TO BE 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.

\_\_\_\_\_  
Minor's Name (printed) and Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Principle Investigator and Signature

\_\_\_\_\_  
Date