

Behavioral & Social Sciences Research involving Human Participants: Guidance in Risk Assessment & Risk Reduction

The purpose of this guide is to assist student researchers, teachers/mentors and local School IRB's to assess and reduce risk as they design and review research projects so that the rights and welfare of human participants are protected. The complete Human participants rules and guidelines can be found in the [International Rules and Guidelines](https://www.societyforscience.org/isef/international-rules/) or on the Society for Science & the Public's website at <https://www.societyforscience.org/isef/international-rules/>.

This document contains information on the following topics:

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A. Introduction to Risk Assessment and Reduction and the Role of the IRB

Risk Assessment involves the consideration of **physical** and **psychological** risks along with the **protection of privacy**. The student researcher, adult sponsor and qualified scientist must develop procedures that reduce and minimize any risks to human participants.

It is the responsibility of the members of the IRB to thoroughly review the Research Plan and collectively decide whether to approve the project, request revisions to the methodology/require more oversight (e.g., QS) to reduce risk to participants, or to determine that the project is not appropriate for student research. Members of the IRB will collaboratively make the following determinations which are documented on Human Participants Form 4:

- whether the study contains no more than minimal risk or more than minimal risk (see definitions below) to potential participants. The IRB will consider characteristics (e.g., age, health status, vulnerability to coercion) of the study population, the specific risks (e.g., physical, psychological, social, privacy) associated with the research activity and local norms when making a risk level determination;
- whether documentation of informed consent can be waived
- whether a qualified scientist is required
- Finally, whether the study is a) approved as it is written, b) must be revised or c) is not appropriate for a student research project (due to level of risk to the student researcher and/or participants). **The IRB will sign Form 4 only if the project is approved.**

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Research projects considered no more than minimal risk typically involve anonymous data collection (i.e., the data/responses cannot be linked to a particular person). In summary, physical, psychological or possibility of sharing a person's private information must be very small to be considered no more than minimal risk.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life.

C. Types of Risk

1) Physical Risks:

a. **Exercise** other than ordinarily encountered in daily life *by that participant* would be considered more than minimal risk. One must consider characteristics of potential research participants as well as the type of exercise involved in the study.

Examples:

- Walking the length of standard hallway
 - For most healthy participants, this activity could be considered “minimal risk.”
 - For the elderly or someone recovering from knee surgery, this might be considered “more than minimal risk.”
 - Swimming 500 meters
 - For the general population, this activity would be considered “more than minimal risk.”
 - For members of the varsity high school swim team, some IRBs may consider this activity to be “no more than minimal risk.”
- b. **Ingestion, tasting, smelling, application of a substance** that pose any health risk are considered “more than minimal risk”. Ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB who will determine risk level based upon the nature of study and local norms around food typically encountered in the research setting. For Example:
- Some school IRBs may consider a tasting study minimal risk based on the fact that the food being studied is commonly available to all students in their school.
 - Conversely, an IRB at another school may deem the same study more than minimal risk if the food being studied is not commonly available to students or they believe that parents in their community would want to provide parental permission before their minor child could participate in the study.

2) Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress** would be considered **more than minimal risk**. For example, answering questions related to personal experiences such as sexual or physical abuse, experiences of trauma and/or psychological well-being (e.g. depression, anxiety, suicide) must be considered more than minimal risk and should have documented informed consent/minor assent/parental permission (as applicable). **A licensed mental health professional must be on the IRB reviewing these types of projects.**

Additionally, research activities that involve exposing participants to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk. Examples include violent or distressing video images, distressing questions, materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in participants.

Reducing Risk associated with Emotional Distress: Care must be taken to try to reduce potential emotional distress. For example, to reduce risk in a study involving a survey about depression and suicide, a mental health professional should be made available to talk with students while they are completing the survey.

3) Risks due to Invasion of Privacy & Breach of Confidentiality

The student researcher and the IRB must consider whether any activity could potentially result in negative consequences for the participant due to **invasion of privacy or breach of confidentiality**. For example, if the study involved collecting a student's GPA and the data were accidentally made available to unauthorized persons, the research participant could suffer embarrassment and feelings of distress related to the invasion of his privacy. Research projects that collect information of a personal nature (e.g., weight, private family information such as divorce, income, opinions about sensitive topics, sexual or gender, orientation, thoughts about suicide) put research participants at risk related to possible disclosure of personal information to others. Adults and student researchers must consider the ramifications of anyone (including the student researcher) becoming aware of a research participant's personal information. Breach of confidentiality can be especially complicated and problematic when a student researcher is collecting data from his/her peers at school. Adults and student researchers need to anticipate the possibility of inadvertent breach of confidentiality in the context of collecting data from known peers.

Reducing Risk:

Risk level can be reduced by appropriately protecting confidentiality or collecting data that is anonymous and uses data collection procedures that make it impossible to link any identifying information with his/her responses or data.

- a) **Anonymity** involves collecting research data in such a way that it is impossible to connect research data (e.g. responses, questionnaires) with the individual who provided the data. That is, personal identifiers (e.g. names, birthdates, student ID number, social security numbers) are not collected. **Whenever possible, student researchers should collect data anonymously.** While collecting data anonymously does reduce risk, not all anonymous studies are considered minimal risk.
- To collect data anonymously, student researchers must not require participants to give their name or any other identifiable information (birth date, email address, etc.)
 - Adults and student researchers need to anticipate challenges to anonymous data collection. For example, if a student researcher collects data from known peers that includes both personal, sensitive information and demographic, personal information (e.g., sports they are involved in, favorite band), it is possible that the student researcher could inadvertently deduce who a given participant is based on the demographic data, even if names are not collected. It is recommended that a professional researcher with experience in the field research be consulted and named as a qualified scientist when data collection involves sensitive and personal topics.
 - If documented informed consent, assent, and/or parental permission is/are required, the forms must always be kept in a secure location separate from the data.
- b) **Confidentiality** is necessary when personal identifiers such as name, birth date, telephone number, photograph, email address or mailing/street address are collected.
- Protecting confidentiality involves taking careful measures to ensure that the research data and/or responses are not disclosed to the public or unauthorized individuals with identifiable information.
 - Confidentiality must also be considered when research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints, emotional functioning, grades) or

health-related data (genetic material, blood, urine, tissue). The IRB reviewing a project involving sensitive mental or physical health issues, must consider the appropriateness of the study as a student research project with regards to the mental welfare of the human participants, especially if minors are involved.

- If the research involves data from the same participant on multiple occurrences, the data or survey would need to be labeled with an identifier to be linked with the data collected at a later date. In this case, confidentiality could be maintained by labeling the surveys or data with a participant number and keeping a list of names and participant numbers in a separate and secure (e.g., locked file cabinet, password protected computer) location. Once the second round of data is collected, the surveys/data may be matched using the participant number and any identifiers should be removed from the data/surveys. At this point, the list of names and participant numbers should be securely discarded (e.g., shred). If documented informed consent, assent, and/or parental permission is/are required, the forms must be kept in a secure location separate from the data.

Special Considerations:

Threats to Anonymity

- If the number of participants is relatively small and/or all participants are from an identifiable source (e.g., an English class, softball team), the anonymity of the data could be threatened. That is the student researcher or anyone with access to the data could potentially link the survey responses to an individual. In addition, presenting the results of the study (even in aggregate) could threaten the participants' privacy or result in negative consequences for the participants.
- If informed consent/assent/parental permission forms (which include names) are collected and the sample is relatively small, it could be possible for the student researcher or an unauthorized person to link the survey responses with participants.

Making Data Anonymous

- Sometimes data may not be collected anonymously, but can be made anonymous after data collection. For example, if the student researcher uses interviews or observations to collect the data, the data would not be anonymous at the time of collection. However, if names are not collected or are removed from the data soon after collection, the data set would then be anonymous.

Risks Related to Threats to Anonymity

- Be sure to consider any ramifications of the student researcher being able to link responses with participants. Most importantly, would there be any negative consequences for the research participants if the student researcher could link responses with the participants. This is especially important when the research participants are peers to the researcher. When the participants are peers of the student researcher, the researcher/QS/IRB should give extra consideration to any potential risks related to the student researcher having knowledge of his/her peers' data (e.g., grades, body weight, etc.). To eliminate such risks, it may be prudent to have an adult collect the data and hand it over to the student research after identifiers are removed and it is anonymous.
- Be sure to consider the possibility of and ramifications of an unauthorized person (e.g., another student, parent, teacher, administrator) getting access to the data and being able to link responses to individual participants or groups of participants (e.g., softball team).
- Consider the nature of the study/data collected. Issues of anonymity and confidentiality are most salient for studies involving sensitive and personal information. Examples of data that should receive special consideration include grades, health/mental health information, experiences of child abuse, illegal behavior, socially unaccepted behavior, anything that could cause the participant embarrassment or legal or disciplinary negative consequences.

4) Risk Groups:

As noted above, the physical, psychological and other risks of participation in a study may depend on the specific sample of participants involved. The physical risk of an activity such as jumping roping will be much higher for an elderly (or even middle-aged participant) than for a middle or high school participant. In contrast, the risks of a breach of confidentiality or anonymity would be greater for a group of high school students answering questions about alcohol use than for a group of older adults for whom it would be easier to collect the data in an anonymous fashion.

Some groups deserve special consideration. If the research study includes participants from any of the following groups described below, the student researcher and the IRB must consider whether the nature of the study requires consider special protections or accommodations for participants in these risk groups.

- 1) Any member of a group that is naturally at-risk (*e.g.*, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who suffer from a medical condition or disability such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, learning disorders, etc.). The nature of the study is an important consideration when determining if special protections are required. For example, special protections would not typically be necessary to include pregnant women in a study involving performance on a cognitive test or completion of a simple survey.
- 2) Special vulnerable groups that are covered by federal regulations (*e.g.* children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act). Specifically, the IRB and the student researcher should consider whether potential study participants who are receiving services under the Individual Disabilities Education Act need special accommodations and/or are appropriate for inclusion in the study as research participants. For example, an IRB may choose to require parental permission for minor participants receiving special education services even when parental permission has been waived for general education students. Confidentiality must be maintained so as not to identify/isolate students.

C. Informed Consent

Informed consent refers to the process of ensuring that potential human participants understand that they may choose whether or not to participate in a study. Individuals should never be forced or coerced to participate in a research study. A teacher, school administrator or anyone requiring students to participate in a research study as a human participant would be considered a serious violation of informed consent principles. That is, the research participant must freely decide to participate and not feel coerced or forced into doing so.

To make an informed decision about whether an individual wants to participate, the human participants must be informed about what they will be asked to do and if there are any risks or benefits involved. For example, if the participant will be asked to complete an interview or a survey, the nature of the survey should be described (*e.g.*, questions about emotional functioning, students' experiences around divorce, grades and SAT scores). The informed consent process should include a description of the purpose of the study. The IRB may require a QS to help develop appropriate informed consent procedures which respect the rights of human participants but do not threaten the validity of the study.

Participants 18 years and older **must** be provided with all of the information mentioned above and give their **Informed Consent** before participating in a research study. If participants are under the age of 18, a parent or legal guardian must be presented with all of the information described above before giving **Parental Permission** for their minor child to participate. **Minor Assent** refers to procedures giving developmentally appropriate information to children and to adolescents about the study and giving them a choice as to whether or not they will participate. **High school students should be supplied with ALL of the information mentioned above and give their verbal and/or written assent to participate.**

Obtaining Written Informed Consent, Parental Permission or Minor Assent

An informed consent form is typically used to provide written information to the human participant or parent/guardian and to document written informed consent/parental permission/minor assent. This form typically includes the purpose of the study, what the participant will be asked to do, the nature of any surveys, questionnaires or interviews, any risks and any benefits to the participant. The form should also contain information that explains to the potential research participant or parent/guardian that participation in the study is voluntary and that the participant is free to stop participating at any time. The Informed Consent Form in the International Rules provides an example of how this information can be presented.

If a study involves a survey or a questionnaire, the Informed Consent process should include attaching a copy of the survey or questionnaire to the form. This process allows the parent to review the material to which their child will be exposed and make an informed decision about whether they want their child to participate. If sharing the survey is a violation of a copyrighted test publisher's regulations or has other consequences that will invalidate the study, the IRB will need to determine if a description of the survey to the parents is enough or if this will not properly inform the parents and the study will need to be deemed inappropriate for student research.

Waiver of Written Informed Consent/Parental Permission/Minor Assent

Obtaining informed consent from an adult or minor assent is always required. However, the IRB may waive the requirement for documentation of written informed consent-if the research involves **only minimal risk and anonymous data collection and if it is one of the following:**

- a) Research involving normal educational practices
- b) Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.
- c) Surveys and questionnaires that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
- d) Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

As explained above, informed consent/minor assent or parental permission is always required. It is merely the process of obtaining a signature to document informed consent/minor assent or parental permission that can be waived in the circumstances mentioned above. **If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent or parental permission, it is strongly recommended that documentation of written informed consent/parental permission be obtained. In addition, it is recommended that parental permission not be waived for minor participants who are younger than high school age.**

D. Examples of Research Studies with suggested IRB decisions.

Note: School IRB's have the prerogative to make more conservative decisions.

- 1) Student researcher wants to compare career choices between 10th, 11th and 12th graders.
 - o *Minimal risk study:* Parental permission not required if data are collected anonymously and if participants are informed of voluntary nature and right to withdraw at any time.
- 2) Student wants to compare the amount of television and type of television shows viewed by boys and girls.

- *Minimal risk study*: Parental permission not required if data are collected anonymously and if participants informed of voluntary nature and right to withdraw at any time.
- 3) Student researcher wants to examine the relationship between favorite restaurant and weight in high school students.
- *More than minimal risk study*: Parental permission required because of emotional risks and impact on self-esteem associated with a student reporting on his/her weight. Even with parental permission, procedures for anonymous data collection should be used. Care should be taken to ensure that the student researcher is not able to link data with a particular participant.
- 4) Correlate television viewing with mood
- *Potentially more than minimal risk study*: Parental permission may be required depending on the nature of questions regarding mood. The IRB would want to consider how to handle participant reports of depressed or anxious mood. The IRB would also consider whether completing a questionnaire asking questions about mood is detrimental to participants who might be prone to depression? If so, parental permission would be required. The IRB might also require a school psychologist or counselor to be present to respond to any negative reactions by participants. Participants would then be told that a counselor is available to help participants deal with any negative reactions to the study.
- 5) A student wants to show his classmates an optical illusion graphic and compare the responses of boys and girls.
- *Minimal risk study*: The IRB would want to consider the nature of the optical illusion. Would anyone find it offensive? If not and the data are collected anonymously, parental permission could be waived.
 - The student researcher must provide information to the research participants about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.
- 6) Do students do better memorizing words while listening to Mozart or rock music?
- *Potentially more than minimal risk study*: The IRB would first want to know exactly what music was to be used. What if the rock music had profanity? Who determines the definition of profanity - the most conservative parent?
 - If the IRB determines that the music might be offensive (even slightly) to someone, parental permission should be required. The consent form should describe the music to be presented and give parents the opportunity to hear the music if he or she requests.
 - If the IRB determines that the music would not be offensive to anyone and the data are collected anonymously, they may waive the requirement of documentation of informed consent. However, the student researcher must provide information to the research participants about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.
- 7) Do students who have math class in the morning do better on a test of “simple” math problems than those who have math class in the afternoon?
- *Potentially more than minimal risk study*: The IRB must determine the stress level associated with a “simple” math test. The committee might consult with both math teachers regarding the level of stress associated with the test for all students. If math teachers and IRB are comfortable with the “simple” math test not resulting in stress, the data are collected anonymously and the potential participants are not at risk for negative feelings related to the findings, the IRB could waive need for documentation of parental permission. However, some IRBs may require documentation of parental permission in this situation.
 - The student researcher must develop recruiting procedures that highlight that participation in the

study is voluntary and that students can withdraw from the study at any time. Efforts must also be taken to ensure that students that do not want to participate must be able to decline participation inconspicuously.

- 8) Do children do better on a spelling test after listening to a certain type of music?
 - *Minimal risk*: The IRB should consider potential risks associated with whether some might find the music “offensive,” or whether there is stress associated with taking a spelling test. Are there privacy and confidentiality issues?
 - If the music was deemed to be innocuous, parental permission could be waived.
 - *More than minimal risk*: The IRB, school principal or teacher should require parental permission due to any reservations they have about the impact of the project on the participants or parents’ reaction to their child being part of a research project.
- 9) Student researcher wants to know how fast boys and girls can run upstairs.
 - *More than minimal risk*: Documented parental informed consent required due to risk of injury. IRB might require safety precautions (e.g., a school nurse must be present, limit the distance of stairs to one flight)
- 10) Student researcher goes to the swim practice and times the swimmers as they are engaged in their regular swim practice (supervised by an adult coach)
 - *Minimal risk*: Student researcher is only observing. IRB may waive the need for parental permission because the swimmers are not being asked to do anything by the student researcher.
- 11) Student researcher asks members of the swim team to participate in her study in which they have to swim 2 laps. This occurs after swim practice or on a day in which there is not practice
 - *Potentially more than minimal risk*: two possible options for IRB: 1) Require parental informed consent and require that a lifeguard present, 2) Instead of parental permission, the swim coach verifies that swim team members are capable and the coach and/or lifeguard are present. In either case, the research participant must be informed directly that participation is completely voluntary and that he/she is free to stop participating in the project at any time.
- 12) Student researcher wants to know if listening to rock music affects driving ability. He plans to test driving ability in the school parking lot with students driving their own cars around cones.
 - *More than minimal risk*: Requires documentation of parental permission for participants and multiple safety precautions, including direct supervision of the methodology by an adult. The IRB may also require documentation that the school principal is aware of and approved the study. While some school IRBs might approve this type of project, other IRBs (and school administrators) may not allow this project to be conducted because of safety and school liability issues.
- 13) Student researcher wants to know if listening to rock music affects driving ability. He plans to test driving ability with a video game.
 - *No more than minimal risk*: The IRB should listen to the proposed music and consider whether any parents would be take offense to the music. IRB would also want to consider the nature of the video game. IRB action may depend on the age of potential participants (e.g., 6th versus 12th graders)
 - Different IRBs may come to different conclusions or different courses of action. IRBs that decide to waive parental permission in such situations may wish to document that the study was reviewed and approved by a principal or administrator.

Additional Resources

<http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html>

Code of federal regulations for the protection of human participants

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

A guide produced by Office for Protection of Research Risk (OPRR) of the US Department of Health and Human Services (HHS). This resource can be used by IRBs to help them with their review. Includes an extensive appendix of additional resources.

<http://www.nihtraining.com/ohrsite/IRBCBT/intro.html>

A computer-based training course for new IRB members.

<http://www.fda.gov/oc/ohrt/irbs/informedconsent.html>

A guide to informed consent from the Food and Drug Administration