Risk Assessment Guide

The purpose of this guide is to assist student researchers, teachers/mentors and local IRB's as they evaluate risks and design research projects that respect the rights and welfare of human subjects. The complete Human Subjects rules and guidelines can be found on the Web at: www.societyforscience.org/isef/document/.

This document contains information on the following topics:

A. Risk Assessment and Risk Reduction

Risk Assessment involves 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 subject participants.

The IRB will review the Research Plan and make the following determinations:

- whether the study is approved or must be revised
- whether the study contains no more than minimal risk or more than minimal risk 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/subject assent and/or parental permission are required or can be waived
- whether a qualified scientist is required

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. Studies must involve **anonymous data** 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.

B. Types of Risk

1) Physical Risks:

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

Examples:

- Walking the length of standard hallway
    - For most healthy subjects, 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, this activity could be considered "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.

c. **Medical examples**

Blood glucose testing with a glucometer that is conducted by a diabetic on a daily basis could be considered minimal risk. However, it would be considered more than minimal risk when a glucometer is used by a subject who does not perform this test as a function of their daily life. Student researchers must receive training by a qualified scientist on the proper technique of capillary blood glucose sampling. Risks to the subject include pain, infection, and injury and risks to the researcher could include possible exposure to blood/body fluids, or needle stick.

A project involving the measurement of blood pressure in which a student researcher uses a commercially available automatic blood pressure device would be considered a minimal risk study. The study would be considered more than minimal risk if a manual sphygmomanometer is used. Risks include vascular spasm, nerve damage, and bruising due to improper technique. The IRB

must examine the context of the research plan to ascertain these risks. Training of the student researcher should be required by the IRB. The IRB may also require a qualified scientist. Most often, these measurements are obtained in conjunction with exercise. If that is the case, the IRB should refer to item 1a above to assess the overall risk to the subject. Each research plan that employs vital sign measurements should also include a plan of how to deal with vital signs measurements that are out of range. For example, when a reading is obtained that is outside of the normal range, the person should be referred to their healthcare provider or the nearest emergency facility.

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, divorce 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).

Additionally, research activities that involve exposing subjects 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 subjects.

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, consider having a school counselor available to talk with students if they are feeling distressed or having a statement at the end of the survey directing students to the school counselor or school psychologist.

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 subject 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 subject could suffer embarrassment and feelings of distress related to the invasion of his privacy.

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, 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 subjects to give their name or any other identifiable information (birth date, email address, etc.)

- 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. 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, tissue) the researcher must consider risks related to invasion of privacy and possible breach of confidentiality.

- If the research involves data from the same subject 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 subject number and keeping a list of names and subject numbers in a separate and secure (e.g., locked file cabinet, password protected computer) location. Once the 2nd round of data is collected, the surveys/data may be matched using the subject number and any identifiers should be removed from the data/surveys. At this point, the list of names and subject 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 subjects' privacy or result in negative consequences for the subjects.
- 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 subjects.

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 subjects. Most importantly, would there be any negative consequences for the research subjects if the student researcher could link responses with the subjects. This is especially important when the research subjects are peers to the researcher. When the subjects 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 subjects or groups of subjects (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 subject 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 subjects involved. The physical risk of an activity such as jumping roping will be much higher for an elderly (or even middle aged subject) than for a middle or high school subject. 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 a anonymous fashion.

Some groups deserve special consideration. If the research study includes subjects from any of the following groups described below, the student researcher and the IRB must consider whether the nature of the study requires special protections or accommodations for subjects 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 with diseases 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 a research subjects. For example, an IRB may choose to require parental permission for minor subjects 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 subjects 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 subject would be considered a serious violation of informed consent principles. That is, the research subject 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 subjects must be informed about what they will be asked to do and if there are any risks or benefits involved. For example, if the subject 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). In most cases, the informed consent process also includes a description of the purpose of the study. However, in rare circumstances detailed information about the purpose of the study will not be included if purpose of study requires innocuous deception that poses minimal risk to the human subject. A school's IRB may allow innocuous deception studies such as a study designed to determine if colored paper affects the time it takes a student to complete a given written task. The IRB may require a QS to help develop appropriate informed consent procedures which respect the rights of human subjects but do not threaten the validity of the study.

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

A copy of any survey or questionnaire must be attached to the form when parents/guardians are being asked to give their permission for their minor child to participate. 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. However, in some cases sending home a copyrighted survey may be a violation of the test publisher's regulations. In other cases, sending home a copy of the survey may threaten the validity of the study. The IRB must decide whether an appropriate description of the survey on the Sample Informed Consent Form provides enough details so that the parent or guardian can make an informed decision.

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/assent and/or parental permission 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 subjects' 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. Online Studies

Studies that collect data via use of the internet (e.g., email, web based surveys) require special consideration from the IRB. The use of the internet for data collection will pose challenges in

a) collecting anonymous data (e.g., IP addresses are recorded by many online survey tools),
b) obtaining informed consent and
c) ensuring that participants are of the appropriate age to give informed consent.

The research plan must explicitly address how these challenges were evaluated and addressed.

Guidelines to school IRBs:

1) It is recommended that studies deemed to be "more than minimal risk" (e.g., about personal/sensitive issues) only be conducted online if the student is working with a qualified scientist who has experience conducting IRB approved research at a Research Institution, University or College. Because IP addresses are gathered by many online survey tools, specialized procedures are needed to ensure that the data is collected anonymously. Ideally, this type of research should be done through a Research Institution, University or College with formal IRB approval by the institution.
2) Studies deemed to be "minimal risk" and targeted to adult subjects (18 years and older) can be conducted online and/or subjects can be recruited by email. The research plan must address how the researcher will ensure that only adult subjects are actually recruited. See below for more information about what is needed in the informed consent process for an online survey.
3) Studies deemed to be "minimal risk" that include minor subjects (under the age of 18 years) can be conducted online with the subjects' parental/guardian permission. In this case, the parent/legal guardian must give consent using a traditional, paper consent form before the minor participant completes the online survey. After formal parental permission is secured, the researcher can email or give the subject a link to the online study. As always, minor assent procedures must also be included. That is, the minor must be given the same information given to the parent/guardian and must be aware that participation is completely voluntary. See below regarding what information must be given to parents/guardians and minor subjects to secure parental permission and minor assent.
4) It is strongly recommended that members of the IRB test the link the student will provide to human subjects to complete the online study to ensure that the correct procedures for obtaining adult consent and/or minor assent are in place.
5) The student researcher, adult sponsor or QS, and at least one member of the IRB should be knowledgeable about the specific online survey tool (e.g., whether IP addresses or other identifiers are gathered, how secure the online survey is, who has access to responses, whether responses are able to be securely deleted, etc).

Procedures for Obtaining Adult Subjects' Consent and Minor Subjects Assent for Online Surveys

1) All information required for the Informed Consent/Assent Process must be presented to the potential research subject before the survey begins.
2) The following statement or something similar must also be included:

There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility

of hacking or other security breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question.

3) The survey should be set up in a way that the potential subject must click on a "button" or type in a response indicating that he/she has read the consent/assent information and agrees to participate to take the potential subject to the actual survey. That is, the survey questions are not viewed by subject until he/she clicks on or types in a response to indicate his/her voluntary participation.

Extra Information to be Included on the Parental Permission Form

1) Parental permission cannot be obtained online. When required, a traditional, paper form must be signed by the parent before a minor can participate.
2) In addition to all of the information required for parental permission, the following statement or a similar statement must also be included:

There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your child's responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security breaches that could threaten the confidentiality of your child's responses. Your child will be instructed that he/she is free to decide not to answer any question.

Procedures for Protecting Confidentiality Related to Downloading of Data

- If IP addresses are collected by the survey tool, the addresses should be deleted from the downloaded data file. All responses should then be deleted from the online survey. The resulting data file that is used for data analysis should be free of any identifier, including an IP addresses or other electronic identifiers.
- The data file should be stored on a password protected computer. Any back up data files should be stored in a secure location.

Examples of Research Studies with Acceptable Suggested IRB Decisions note that IRB's have the prerogative to be more conservative.

• Student researcher wants to compare career choices between 10^{th}, 11^{th}, and 12^{th} graders.

Minimal risk study: Parental permission not required if data are collected anonymously and if subjects are informed of voluntary nature and right to withdraw at any time.

• 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 subjects informed of voluntary nature and right to withdraw at any time.

• Student researcher wants to examine the relationship between favorite restaurant and weight in $9^{th} - 12^{th}$ graders.

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 subject.

• 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 subject reports of depressed or anxious mood. The IRB would also consider whether completing a questionnaire asking questions about mood is detrimental to subjects 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 subjects. Subjects would then be told that a counselor is available to help subjects deal with any negative reactions to the study.

• Student researcher wants to investigate the relationship between SAT scores and GPA through peer's self report.

Minimal risk study: Parental permission not required if data are collected anonymously and subjects are informed that their participation is voluntary and that they can withdraw at any time.

• 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 subjects about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.

• 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 subjects about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.

• 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 withdrawal 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.

A student wants to show elementary students an optical illusion graphic and compare the responses of boys and girls.

Minimal risk: As long as the optical illusion is not offensive to anyone, the study could be considered minimal risk and parental permission could be waived. However, some IRBs and school professionals may decide to require parental permission.

• 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 subjects or parents' reaction to their child being part of a research project.

• 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 amount of stairs to 1 flight)

• 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.

• 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 gives the OK that swim team members are capable and the coach and/or lifeguard are present. In either case, the research subject must be informed directly that participation is completely voluntary and that he/she is free to stop participating in the project at any time.

• 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 subjects and multiple safety precautions. The IRB may also require documentation that the school principal is aware of and approved the study. Many IRB's would not allow this project to be conducted because of school liability issues.

• 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 subjects (e.g., 6th graders vs. 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 subjects

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 additonal resources.

http://www.nihtraining.com/ohsrsite/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

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