Human Participant Project Rules

Student Researchers must follow **federal guidelines** to protect the human research participants and the Student Researcher. When students conduct research with humans, the rights and welfare of the participants must be protected.

Studies Exempt from IRB Review/Approval

The following are the ONLY human subject type projects that are exempt from IRB pre-approval and informed consent:

- When the testing of a student-designed invention, prototype or computer application is done **ONLY** by the Student Researcher **AND** where the testing does not pose a health or safety hazard.
- Data/record review studies where the data are taken from pre-existing data sets that are publicly available and/or published and do not involved any interaction with humans or the direct collection of any data from a human participant.
- Behavioral observations of unrestricted, **public settings** in which **all** of the following apply:
  - The Student Researcher has **no interaction** with the subjects being observed; **AND**
  - The Student Researcher **does not manipulate** the environment in any way; **AND**
  - The Student Researcher **does not record any personally identifiable** data about the subjects being observed.
- Projects in which the Student Researcher receives pre-existing data in a **de-identified/anonymous** format and complies with both of the following conditions:
  - The professional providing the data certifies **in writing** that the data have been appropriately de-identified before being given to the Student Researcher and are in compliance with all privacy and HIPPA laws, **AND**
  - The Regional Science Fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Studies Exempt from Full IRB Review (Expedited)

An expedited IRB review where only one qualified member of the IRB is needed to review and approve the project may be allowed as long as the human participants are testing a student designed invention, prototype or computer application in which the feedback obtained is **ONLY** related to the invention, prototype or computer application and **NOTHING** else. NOTE: *The expedited review process may NOT be used for medical testing of devices.*

Studies Needing Full IRB Review

All other human subject projects **REQUIRE** a full IRB review and pre-approval and **may require** written informed consent/minor assent/parental permission. Examples of such studies include, but are not limited to:

- Subjects participating in physical activities.
- Subjects ingesting any substance.
- Subjects participating in any medical procedure.
- Subjects participating in any psychological, educational and/or opinion studies (surveys & questionnaires).
- Studies where the Student Researcher is the subject of the research and the study might pose a health risk.
- Subjects test student-designed inventions or concepts where personal data may be collected or there is more than minimal risk.
- Data/record review projects that include data that are not de-identified/anonymous.
- Behavioral observations that:
  - Involve any interaction with the observed individual(s);
  - Where the Student Researcher has modified the environment;
  - Occur in non-public or restricted access settings; and/or
  - Involve the recording of personally identifiable information.

Other Human Subject Guidelines

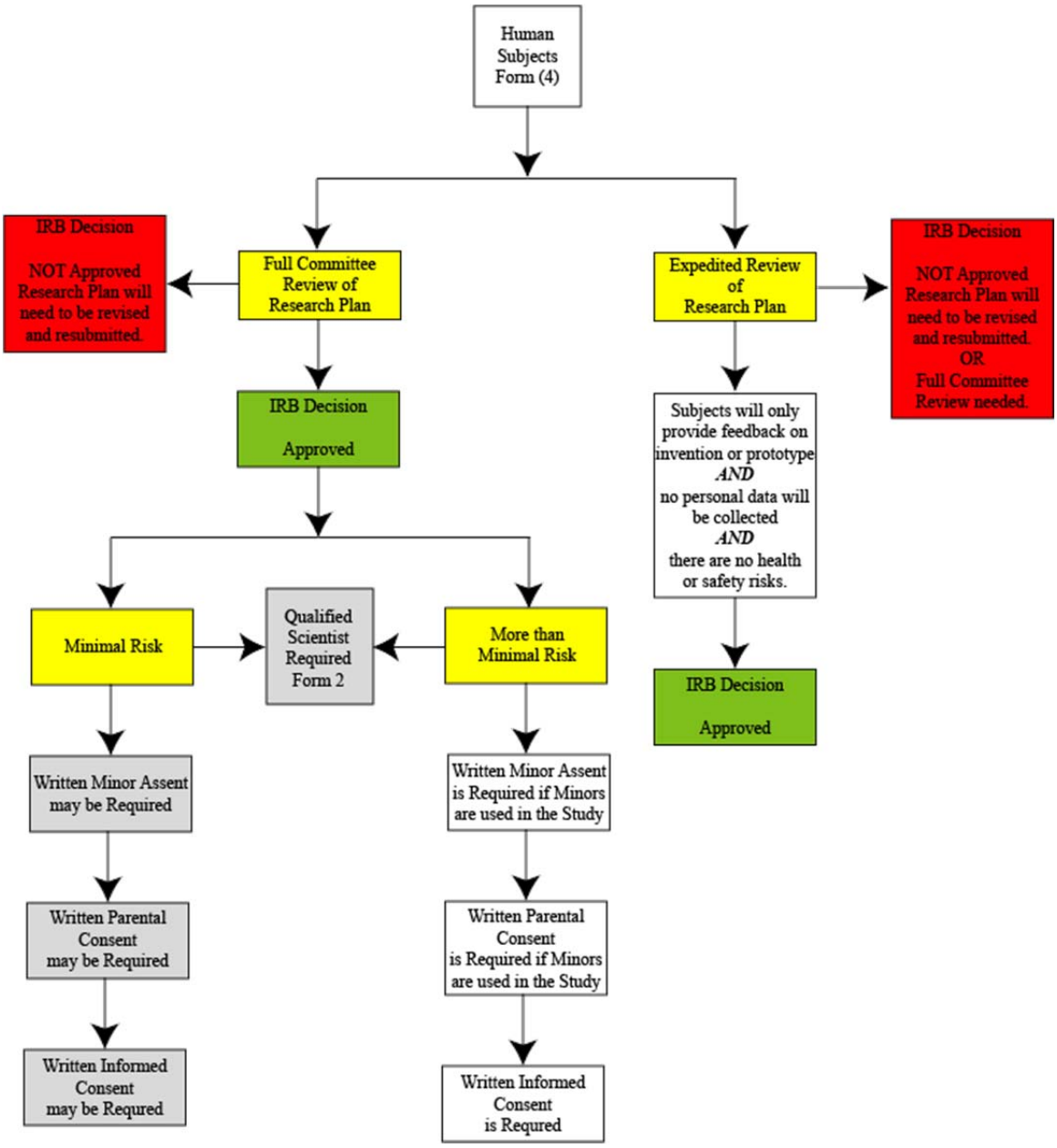
The following are various guidelines that may or may not apply to a student's project.

- The Student Researcher must include ALL parts (a-g) of the Human Subjects Research Plan requirements found on page 9.
- The study should be in compliance with all privacy laws (FERPA and HIPAA) when they apply to the project (i.e. the project involves medical information).
- Once a study has been approved, if the Student Researcher has any proposed changes to the methods and/or procedures, they must repeat the review process before continuing with data collection/experimentation.
- Research conducted at a Regulated Research Institute must be reviewed and approved by THAT INSTITUTION'S IRB – NOT the school or regional IRB. A copy of the IRB approval for the entire project and/or an official letter from the IRB attesting to approval is required. A letter from the Qualified Scientist/Mentor is NOT ACCEPTABLE.
- The Student Researcher may observe and collect data for analysis of medical procedures and medication administration only under the DIRECT SUPERVISION of a medical professional.
- The Student Researcher is prohibited from administering medication and/or performing invasive medical procedures on human subjects.
- The Student Researcher may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photos) without written consent from the participants.
- All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist/Mentor as required by the publisher of the instrument. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.
- Studies that involve the collection of data using the Internet are allowed, but the Student Researcher should be aware that they can pose challenges in:
  - Collecting anonymous data;
  - Obtaining informed consent; and
  - Ensuring that participants are of the appropriate age to give informed consent

Informed Consent Guidelines

If required by the IRB, research participants must voluntarily give informed consent/assent (and in some cases, parental permission) **BEFORE** participating in the study. The school/local IRB will determine whether this can be verbal or must be written, depending on the level of risk, the type of study and the demographics of the subjects.

- Informed consent requires that the subject be provided with ALL information about POTENTIAL risks and benefits of participating in the study.
- Participation MUST BE VOLUNTARY, with no adverse consequences of not participating and subjects may stop participating at any time.
- Informed consent MUST NOT involve coercion and is an on-going process – subjects may choose to stop participating AT ANY TIME.
- When written parental permission is required and the study includes a survey or questionnaire, these MUST BE ATTACHED to the consent form for the parent to review.



Human Subject Risk Assessment (for the local IRB)

All human participant projects are considered to have some level of risk.

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 everyday life or during performance of routine physical or psychological examinations or test **by the subject population** being studied.

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 **by the subject population** being studied.

Privacy Concerns

The Student Researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to an invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level can be reduces by protecting confidentiality or collecting data that is strictly anonymous – where it is impossible to connect research data with the individual who provided the data.

Please remember that the following examples are not all inclusive and it is the IRB's responsibility to assess the potential risk to the Student Researcher(s) as well as the human subjects participating in the study.

Examples of Greater than Minimal Physical Risk

Studies where more than minimal PHYSICAL risk exists and informed consent/assent and parental consent should be obtained, include, but are not limited to:

- Exercise other than that ordinarily encountered in everyday life (by that particular subject population).
- Ingestion, tasting, smelling, or application of any substance.
- Exposure to any potentially hazardous material.

Examples of Greater than Minimal Psychological Risk

Studies where more than minimal PSYCHOLOGICAL risk exists and informed consent/assent and parental consent should be obtained, include, but are not limited to:

- Answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety, etc.
- Answering questions that could result in feelings of depression, anxiety, or low self-esteem; etc.
- Viewing violent or distressing video images.
- Any research activity (survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress.

At-Risk Groups

If the research study purposely targets participants from any of the following groups, the IRB must consider whether the nature of the study requires special protections or accommodations.

- Pregnant women;
- Developmentally disabled persons;
- Economically or educationally disadvantaged persons;
- Individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.;
- Children/minors;
- Prisoners; and/or
- Students receiving services under the Individuals with Disabilities Education Act.

Waiver of Written Informed Consent

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the project involves only minimal risk AND anonymously collected data AND if involves one of the following:

- Normal educational practices (*the school administrator must make this determination*).
- Individual or group behavior or characteristics of individuals where the Student Researcher(s) does not manipulate the subjects' behavior AND does not involve more than minimal psychological risk (*a mental health professional should make this determination*).
- Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, game theory, etc. AND that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress (*a mental health professional should make this determination*).
- Physical activity where there is no more than minimal risk AND where the probability and magnitude of harm or discomfort are NOT greater than those ORDINARILY encountered in daily life or during the performance of ROUTINE physical activities (*a medical health professional should make this determination*).

Middle School - Human Subjects Form (4)

This form is required for ALL projects involving human subjects and MUST be completed and approved by the IRB PRIOR to experimentation.

To be completed by the Student Researcher/Team Leader in collaboration with the Adult Sponsor.

1. Student's Name(s):_____
2. Project Title:_____
3. Adult Sponsor:_____ Email:_____
4. ☐ Attached to this form is the Research Plan, which addresses ALL areas under the Human Subjects section of the Research Plan Instructions (page 9).
5. This project ☐ ***will*** / ☐ ***will not*** include giving my human participants any surveys, questionnaires, tests, photos, videos, or other items to view or complete. If yes, a copy of ALL such materials is attached.
6. This project ☐ ***will*** / ☐ ***will not*** include any published instrument(s) If yes, documentation of my permission to use such material is attached.
7. ☐ Attached is a copy of an Informed Consent Form that I/we would use, if required by the IRB.
8. I/We ☐ ***will*** / ☐ ***will not*** be working with a Qualified Scientist/Mentor. If yes, a copy of the Qualified Scientist/Mentor Form 2 is attached.

To be completed by the Institutional Review Board (IRB) after review of the research plan.

Mark only ONE designation (Full Committee Approval OR Expedited Review Approval). DO NOT sign if not approved; return paperwork to the student with instructions for modifications.)

☐ **Approved with Full Committee Review** (3 signatures required) and the following conditions (ALL 5 must be answered to be valid):

1. Risk Level (check one): ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist/Mentor Required: ☐ Yes ☐ No
3. Written Minor Assent Required (for participants under the age of 18):
   ☐ Yes ☐ No ☐ Not Applicable (no minors used in this study)
4. Written Parental Permission Required (for participants under the age of 18):
   ☐ Yes ☐ No ☐ Not Applicable (no minors used in this study)
5. Written Informed Consent Required (for participants 18 years and older):
   ☐ Yes ☐ No ☐ Not Applicable (no participants over 18 used in this study)

☐ **Approved with Expedited Review** (1 signature required) and the study meets the following condition:
Human participants will only provide feedback on the project design, student-designed invention, prototype, etc., no personal data will be collected AND there are no health or safety hazards.

I attest that I have reviewed the Student Researcher's project, that ALL of the above have been properly marked indicating the IRB determination and that I agree with the decision. *None of the individuals signing below may be the adult sponsor, designated supervisor, qualified scientist/mentor or a relative of the Student Researcher (conflict of interest).*

Medical or Mental Health Professional: (medical doctor, nurse practitioner, physician's assistant, doctor of pharmacy, registered nurse, psychologist, licensed social worker, licensed clinical professional counselor) with expertise related to this project.

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

Educator:

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

School Administrator: (school principal or assistant principal)

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

Middle School - Human Subjects Informed Consent Form

Instructions to the Student Researcher/Team Leader:

- An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor.
- This form is used to provide information to the research participant (or parent/guardian) about the study.
- This form documents written informed consent, minor assent, and/or parental permission when required.
- All signed informed consent forms are to be kept by the Student Researcher/Team Leader or Adult Sponsor in a safe, non-public place and NEVER sent to the regional, state or international competition SRCs.
- Student Researchers may use this sample form or copy ALL elements of it into a new document. Documents not incorporating ALL of the elements below will make the Informed Consent Form invalid.
- A separate photo release form should be developed and used if photographs of people other than the Student Researcher(s) are to be used in the display.

Student's Name(s):_____

Project Title:_____

I am asking for your VOLUNTARY participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

The purpose of the project is to:

If you participate, you will be asked to:

The time required for participation is:

The potential risks of participating in the study include, but may not be limited to:

The benefits to you personally include, but may not be limited to:

Confidentiality will be maintained by:

If you have any questions about this study, feel free to contact:

Adult Sponsor:_____ Email:_____

Participation Disclaimer: Participation in this study is completely voluntary. If you decide not to participate, there will not be any negative consequences. Please be aware that if you do decide to participate, you may stop participating AT ANY TIME and you may decide not to answer any specific question.

By signing this form, I am attesting that I have read and understood the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent/Minor Assent:

Participant's Printed Name	Signature	Date Reviewed (mm/dd/yy)

Parental/Guardian Permission (if applicable):

Parent/Guardian's Printed Name	Signature	Date Reviewed (mm/dd/yy)