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 must be the highest priority.

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 10.
- Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) BEFORE any interaction with subjects may begin. It is the responsibility of the IRB (not just the student) to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for both the student researcher and the participants.
  - Projects that are conducted at school, at home or in the community and not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the school or regional IRB before the student may begin recruiting and/or interacting with the human participants. Documentation of review and approval is done on Form 4 for these projects.
  - Projects that are 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 must comply with all determinations made by the IRB before beginning any interaction with human participants:
  - If the IRB requires that a Qualified Scientist/Mentor is a consulted about the project, then Form 2 must be completed and reviewed before the IRB approves the project.
  - If the IRB requires written informed consent, parental consent or minor assent, then a sample Informed Consent Form must be completed and reviewed before the IRB approves the project.
- The study must be in compliance with all privacy laws (FERPA and HIPAA) when they apply to the project (i.e. the project involves medical information).
- Student Researchers are prohibited from independently diagnosing disease, administering medication and/or performing medical procedures on human participants.
  - The Student Researchers may observe and collect data for analysis of medical procedures, medication/treatment efficacy and diagnosis of illness, only under the DIRECT SUPERVISION of a licensed health care provider/professional.
  - The healthcare provider/professional MUST BE NAMED in the research plan approved by the IRB. The IRB must also confirm that the student is not violating the appropriate medical practice (medical, nursing, pharmacy, etc.) act of Colorado.
  - The Student Researchers are prohibited from providing diagnostic or medical information to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approval.
- 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.

  a. Studies that involve the use of minors in conducting online surveys must have Informed Consent and the parent/guardian of the minor must provide written parental permission before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.
  b. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be explained in the Research Plan.

  Students should consult the ISEF Guidelines for Online Survey Consent Procedures prior to conducting an online survey.
- Student Researcher-designed invention, prototype, computer application, engineering/design and product testing projects that involve testing of the invention by any human participant requires an assessment of the potential risks to the individual(s) testing or trying out the invention/prototype.
  - If the invention/prototype is tested by human participants OTHER THAN the Student Researcher(s) or a single adult guardian (Adult Sponsor, Qualified Scientist/Mentor, Designated Supervisor, Parent – ONLY when the testing requires an adult tester), then **IRB review and PRIOR approval is required**. This includes surveys regarding potential use, review or the product and/or opinions regarding the project/product.
  - Projects in which the invention, prototype or project involves a medical diagnosis or intervention and is tested on human subjects must follow the above rules regarding the prohibition of medical procedures and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention or consumer product.
- 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.

Informed Consent Guidelines

If required by the IRB, participation in a research study may begin ONLY AFTER research participants have voluntarily given informed consent/assent (and in some cases, parental permission). The school/local IRB will determine whether this can be verbal or must be written, depending on the level of risk, type of study and demographics of the subjects.

- Adult research participants may give their own consent.
- Research participants under 18 give their assent with parent/guardian providing permission.
- 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.
- The student researcher may request that the IRB waive the requirement for written informed consent/parental permission if the project meets specific requirements (see page 21).

Studies Requiring IRB Review/Approval

These are examples of studies involving human participants that require IRB review and pre-approval and **may require** written informed consent/minor assent/parental permission. Remember, this is not an all inclusive list.

- 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 and questionnaires).
- Studies where the Student Researcher is the subject of the research.
- Subjects testing student-designed inventions, prototypes, applications, etc. This includes surveys conducted regarding potential use, review of the product and/or opinions regarding the project.
- 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.

Studies Exempt from IRB Review/Approval

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

- When the testing of a student-designed invention, prototype or computer application is done **ONLY** by the Student Researcher (or a single adult guardian when the testing requires an adult tester) **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).

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 reduced 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

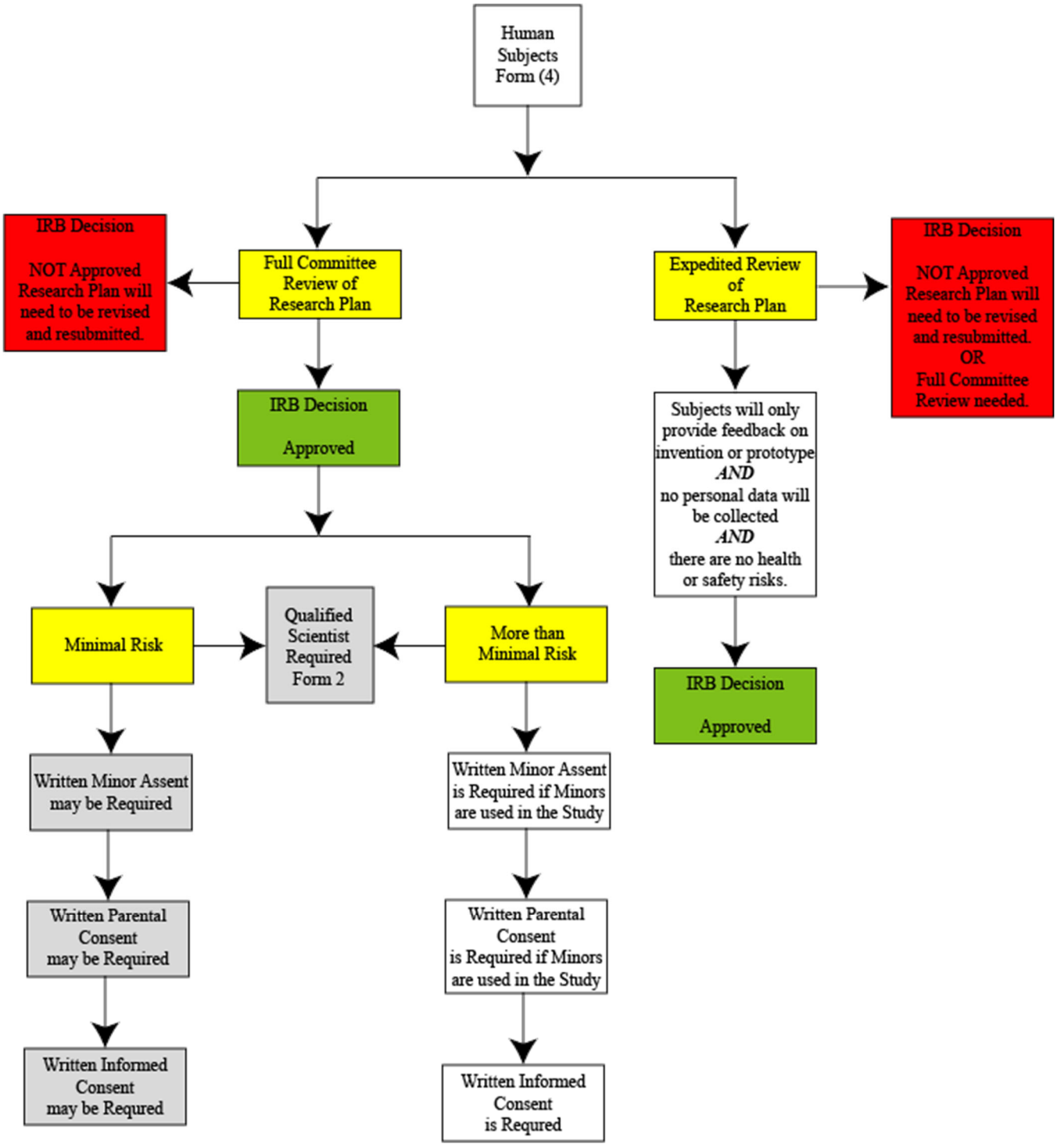
If the research study purposely targets participants from any of the following groups, the IRB must consider whether the nature of the study requires special protections or accommodations.

- 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*).


Human Subjects Form (4)
Full Committee Review of Research Plan
IRB Decision NOT Approved Research Plan will need to be revised and resubmitted.
IRB Decision Approved
Expedited Review of Research Plan
IRB Decision NOT Approved Research Plan will need to be revised and resubmitted. OR Full Committee Review needed.
Subjects will only provide feedback on invention or prototype AND no personal data will be collected AND there are no health or safety risks.
IRB Decision Approved
Minimal Risk
Qualified Scientist Required Form 2
More than Minimal Risk
Written Minor Assent may be Required
Written Parental Consent may be Required
Written Informed Consent may be Requred
Written Minor Assent is Required if Minors are used in the Study
Written Parental Consent is Required if Minors are used in the Study
Written Informed Consent is Requred