GUIDE TO CREATING SCHOOL-LEVEL INSTITUTIONAL REVIEW BOARDS

Students who are interested in pursing human participant research in a high school setting may share this guide with their science teacher or mentor. This document outlines the steps required to form an Institutional Review Board at the high school level, and how a high school can create their own IRB process to approve student projects.

Note: If research is conducted at a federally regulated research institution (e.g., university, medical center, NIH, correctional institution, etc.), the research plan must be reviewed and approved by that institution's IRB and proper documentation must be provided.

INSTITUTIONAL REVIEW BOARD

An Institutional Review Board (IRB) is an independent committee that, according to federal regulations (45-CFR46), evaluates the potential physical and/or psychological risk of research involving human participants. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes any surveys or questionnaires to be used. Projects completed at a federally registered research institution should use their IRB (university, etc). If a project is conducted at school or home, then a school-level IRB is acceptable.

HOW TO FORM A SCHOOL-LEVEL IRB

1. Projects conducted at home or school may gain approval through a school level IRB. Any high school can form their own IRB. For projects completed at the high school or home environment, school-level IRBs must consist of a minimum of three members. A school-level IRB must include:
    a. a science teacher not involved with project(s) being reviewed,
    b. a school administrator (preferably a principal or vice principal), and
    c. one of the following who is knowledgeable and capable of evaluating the physical and/or psychological risk involved in a given study: a physician, psychiatrist, physician's assistant, registered nurse, psychologist, or licensed social worker who is not involved with the project being reviewed.
2. No member of any IRB may be personally related to the student researcher. Teachers and advisors who oversee a specific project must not serve on the IRB reviewing that project. An improperly constituted IRB invalidates the approval of a project. IRBs must secure additional alternate members to ensure the eligibility of the projects being reviewed.

RESPONSIBILITIES OF THE SCHOOL-LEVEL IRB

1. The IRB should carefully review the Regeneron STS Rules for Human Participant Research to determine what is allowable. Note that the rules adjust annually.
2. The IRB should develop an approval form based on the sample IRB Approval Form and Sample Informed Consent Forms in this rules book. Schools may use these forms or adapt them to include additional rules.
3. The IRB should share the forms and process with high school teachers and students, set appropriate deadlines for submitting forms to the IRB, and make a plan to review approval forms on a schedule that fits the school's typical research plan.
4. High School Level-IRBs should require that students:
    a. Follow the Regeneron STS official rules.
    b. Draft a research plan that includes a description of research participants, recruitment procedures, research methodology, assessment of risks and benefits of the research, procedures for minimizing physical, psychological and privacy risks to participants and procedures for obtaining informed consent.

c. Complete an IRB Approval Form (available in Appendix 10) and submit to the IRB prior to starting research.

5. The research plan must be reviewed and approved by the IRB prior to the start of experimentation. After initial IRB approval, a student with any proposed changes to the research plan must repeat the approval process before experimentation/data collection resumes.
6. The IRB should maintain a record of approved student project proposals.
7. The IRB should complete the Human Participant Form submitted by the student with their assessment of risk, required consent process, supervision and approval with checkmarks in the appropriate places and via dated signatures. Without the form completed with checkboxes and signatures, the documentation is not valid. The IRB should provide the student with a copy of this signed documentation.

IRB REVIEW CHECKLIST FOR STUDENT PROJECTS

1. The proposed research study adheres to Regeneron STS human participant rules.
2. The research study must be in compliance with all privacy and HIPAA laws when they apply to the project. Students are prohibited from administering medications and performing invasive medical procedures on human participants. The IRB must confirm that the student is not violating the Medical Practice Act of the particular state or territory in which he/she is conducting the research.
3. Research participants must voluntarily give informed consent/assent, and in cases where the research participant is a minor, parental permission may be required. The IRB determines whether written documentation of consent/assent/permission is necessary.
4. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs), without written consent (Public Health Service Act, 42, USC 241 (d)).
5. If a student-designed invention, program, concept, etc. is product tested by human participants, other than the student researcher, the project must be reviewed and approved by an IRB as described above before the product testing takes place.

Note that some studies involving human data or human tissue samples are not considered human participant projects and are exempt from IRB review and approval. See official rules.

REGENERON STS INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL FORM

Required for all research involving human participants. (Institutional Form or Intel ISEF form may be substituted.)

Student's Name: _____ Title of Project: _____

Adult Sponsor: _____ Contact Phone/Email: _____

To be completed by Student Researcher in collaboration with the Adult Sponsor/Designated Supervisor/Qualified Scientist:

1. ☐ I have submitted my Research Plan which addresses research methodology, participant recruitment, confidentiality and privacy issues, informed consent procedures and a risk and benefit analysis for the human participants.
2. ☐ I have attached any surveys or questionnaires I will be using in my project.
3. ☐ I have attached an informed consent that I would use if required by the IRB.
4. ☐ Yes ☐ No Are you working with a Qualified Scientist?

Name: _____ Degree: _____

Email Address/Phone Number: _____

Experience/Training as it relates to this project: _____

ITEMS IN THIS BOX MUST BE COMPLETED TO BE VALID

To be completed by Institutional Review Board (IRB) after review of the research plan. The submitted Research Plan must address all areas indicated on the Human Participants section of the Research Plan Instructions.

Check one of the following:

☐ Research project requires revisions and is NOT approved at this time. IRB will attach document indicating concerns and/or requested revisions.

☐ Research project is Approved with the following conditions below: (All 5 must be answered)

1. Risk Level (check one) : ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Written Minor Assent required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
4. Written Parental Permission required for minor subjects:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Informed Consent required for subjects 18 years or older:
   ☐ Yes ☐ No ☐ Not applicable (No subjects 18 yrs or older in this study)

IRB SIGNATURES (All 3 signatures required) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project and agree with the above IRB determinations.

Medical or Mental Health Professional (a psychologist, psychiatrist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)

Printed Name _____ Degree/Professional License _____

Signature _____ Date of Approval _____

School Administrator

Printed Name _____ Degree _____

Signature _____ Date of Approval _____

Educator (not involved with the project)

Printed Name _____ Degree _____

Signature _____ Date of Approval _____

SAMPLE INFORMED CONSENT FORM

INSTRUCTIONS TO THE STUDENT RESEARCHER:

- An informed consent/assent/permission form like the version below should be developed in consultation with the student researcher's Project Mentor, Designated Supervisor or Qualified Scientist. This consent form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission. When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form below or may copy ALL elements of it into a new document.
- If the form is serving to document parental permission, a blank copy of any survey or questionnaire must be attached when shared with parents/guardians.
- Student researcher must upload a copy of the consent form shared with research participants, and a blank copy of any surveys used, in their Regeneron STS application.

STUDENT RESEARCHER:

TITLE OF PROJECT:

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.

PURPOSE OF THE PROJECT:

IF YOU PARTICIPATE, YOU WILL BE ASKED TO:

TIME REQUIRED FOR PARTICIPATION:

RISKS:

BENEFITS:

HOW CONFIDENTIALITY WILL BE MAINTAINED:

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

Adult Sponsor: _____ Phone/email: _____

VOLUNTARY PARTICIPATION:

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 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 understand the information above and I freely give my consent/ assent to participate or permission for my child to participate.

ADULT INFORMED CONSENT OR MINOR ASSENT Date Reviewed & Signed: _____

Printed Name of Research Subject: _____ Signature: _____

Parental/Guardian Permission (if applicable) _____ Date Reviewed & Signed: _____

Parent/Guardian Printed Name: _____ Signature: _____