GUIDE TO CREATING INSTITUTIONAL REVIEW BOARDS (IRBs)

Human research often requires pre-approval by an Institutional Review Board. Students who are interested in pursuing human participant research in a high school setting may share this guide with their science teacher or mentor. Prior to any recruitment or interaction with human participants, the research plan must be reviewed and approved by an IRB. This document outlines the steps required to form an Institutional Review Board at the high school level or district level to approve student projects.

Schools or districts should ONLY form new IRBs in instances where the process does not already exist. The first step of any person seeking to create a new IRB should be to check with the school about current processes in place.

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 OR DISTRICT-LEVEL IRB

1. Projects conducted at home or school may gain approval through a school-level or district-level IRB. Any district or high school can form their own IRB, but should seek any required permissions from the Superintendent's Office. Some Districts prefer to create one IRB for all middle and high schools to have broader oversight of projects; high schools in these districts should not create their own IRBs.
2. 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. an educator 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 not involved with the project being reviewed and is knowledgeable and capable of evaluating the physical risk in a given study: a physician, psychiatrist, physician's assistant, registered nurse, psychologist or licensed social worker.
3. 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 permissible. 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 and restrictions; a local IRB must adhere to all STS rules, but may be more strict.

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 academic research program calendar.
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 12) 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 IRB Approval Form (Appendix 12) 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. 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., Qualified Scientist) to reduce risk to participants, or to determine that the project is not appropriate for student research and that the research plan abides by all local, state and federal laws and the Regeneron STS Official Rules. Members of the IRB will collaboratively make the following determinations which are documented on the IRB Approval Form:
    - 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 of the study population, the specific risks associated with the research activity and local norms when making a risk level determination.
    - 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 the IRB Approval form only if the project is approved.
2. Resource to help determine risk: https://sspcdn.blob.core.windows.net/files/Documents/SEP/ISEF/Resources/Risk-Assessment-Guide.pdf
3. Research participants must voluntarily give informed consent/assent. In cases where the research participant is a minor, parental permission must 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.