Checklist for SRC Review

This document was developed to provide guidance for an SRC to review a project after experimentation.

ABSTRACT

Review the abstract text and check boxes keeping the following questions in mind, and then review the information provided on each form to see if it answers the questions, has any inconsistencies, etc. that will require follow up.

Did the area of study require PREAPPROVAL?

Human Participants: Does the study mention people, interviews, responses, answers, consent, etc? (requires Form 4). Exempt studies include prototype/invention testing if only done by student researcher, public data review, some observational studies. All others require IRB preapproval.

Animals: Look for indications of type of study and research site. Strictly observational studies with no interaction are exempt. Tissue studies in which the student is given the tissue and did not interact with the animal do not need animal forms but will still need preapproval as a PHBA tissue study.

A. Projects may be conducted at home, school, or field ONLY IF the study involved agricultural, behavioral, observational, or supplemental nutrition AND was non-invasive AND had no negative effects on health and wellbeing (requires Form 5A).

B. Projects must be conducted at research institution with IACUC preapproval in all other cases (requires Form 5B).

PHBA's Study included microorganisms, rDNA, or fresh/frozen tissue, blood, body fluids. Used terms like culturing, plating, tissue, source of tissue, etc. Exemptions include non-primate established cell lines, yeast, lactobacillus, meat from a grocery store, and other items listed in the rules (all non-exempt PHBA's require Form 6A and IRB pre-approval; tissue studies require Form 6A, 6B, and IRB pre-approval)

Was the study done at a Regulated Research Institute/Industrial Setting (RRI)? Is the terminology or equipment very sophisticated? Look for possible RRI. (Form 1C)

Does this appear to be a Continuation? Any mention of previous research? Uses terms like previously, earlier research, improved, redesigned, year 3, etc. (Form 7)

Any discussion of a Partner in a non-team study? Uses "we" consistently (math projects and international studies frequently use "we" for all studies). Form 1C answers this question for studies done at a university.

Any possibly hazardous chemicals, activities, or devices? Includes high voltage, hazardous equipment, radioactivity, firearms, explosives, prescription drugs, DEA-controlled substances, alcohol and tobacco. (Form 3)

Time Line: Project appears too long/too old: more than one year or started before January of last year. (Form 1A contains this information)

CHECKBOXES ON ABSTRACT

Checkbox 1. Project involved human participants, vertebrate animals, or PHBA's. Requires preapproval and additional forms. Exempt studies do not check this box.

Checkbox 2. Abstract may only reflect their work not the mentor's. May require abstract rewrite.

Checkbox 3. Worked at RRI. (Requires 1C)

Checkbox 4. Project is a continuation. (Requires Form 7, previous abstract & research plan)

CHECKLIST FOR ADULT SPONSOR (1)

This form asks more specifically about projects that required preapproval (humans, animals, PHBA's), continuations, RRI's, and lists the forms that are required. The answers to this checklist need to be consistent with the answers on other forms.

This page is signed when the project is reviewed which should be before the project starts.

STUDENT CHECKLIST (1A)

Grade: Student must have been in high school at time of research in order to compete.

Contact information: If questions cannot be resolved from the paperwork, it is sometimes necessary to contact the student or adult sponsor.

Continuation: If a continuation, must include Form 7, previous abstracts, and last year's research plan. This information should match the checkmarks on the abstract and on Form 1.

Start/End Dates: Project may only be one year in length and may not have started before January of the previous year. Student should have competed in the first fair which was held after the end date. Fair dates can be found in the Find-a-Fair search.

Information regarding Research Site: This will tell you if you need additional paperwork. For example, Form 1C for RRI, Form 5A if animals at school, field, home, Form 5B if animals at RRI, no culturing of microorganisms is allowed at home (FTQ), Form 6A for BSL-1 & BSL-2 studies which must be in the appropriate facilities.

RESEARCH PLAN/POST PROJECT SUMMARY

Review the research plan and post project summary to find information regarding each of the questions asked in previous section under Abstract. The Research Plan and Post Project Summary Instructions page lists the items that should be included. This needs to be very detailed and must be consistent with the documentation found on all other forms. If more information is needed about the study, the student or adult sponsor may need to be contacted (email, phone or interview).

Human Participants:

Look for information about subjects (any risk groups), recruitment, methods, risks & benefits, protection of privacy (HIPPA & FRPA), and informed consent (participant knows what they are being asked to do, that they may withdraw at any time, there is no coercion, etc.). Must have preapproval and often will require written consents. (Requires Form 4)

Is the level of risk appropriate? What risk assessment was done? Should the study have written Consent/Permission/Assent? Is the survey attached?

Animals:

Pay particular attention to the detailed procedures and care of the animals in the research and if they looked for alternatives to animal research.
(Requires 5A or 5B and SRC or IACUC pre-approval)

Look for any potential FTQ items such as a study conducted at home, school or field that should have been done at an RRI, no indication of preapproval, any animal deaths due to experimental procedures, weight loss ≥15% in any group or subgroup, toxicity studies, studies designed to kill, studies which cause more than momentary pain or suffering, predator/prey, inappropriate water or food restriction, euthanasia by student, etc. Ensure that an allowable embryonic study didn't hatch and become a vertebrate study that is not permitted.

PHBA's:

The source, quantity, and Biosafety Level (BSL) must be indicated for all microorganisms including established cell lines. All non-exempt microorganisms, cell lines, and tissues require SRC pre-approval, Form 6A and sometimes Form 6B.

Culturing of microorganisms may NOT be conducted at home. (FTQ) All BSL-1 studies must be conducted at a BSL-1 facility or higher. If a petri dish or culture container with unknown or BSL-2 microorganisms is opened, it becomes a BSL-2 study and may only be conducted at a BSL-2 facility. (FTQ if opened, subcultured, etc. in BSL-1 lab.) Most high school laboratories are BSL-1 facilities but it is possible that a high school could meet the more stringent requirements of a BSL-2 lab. BSL-3 or -4 studies, culturing CRE (Carbapenem Resistant Enterobacteriacae), and studies designed to engineer bacteria with multiple antibiotic resistance are not permitted.

Procedures to minimize risk must be clearly indicated. rDNA studies require close review to ensure proper oversight. Proper disposal methods must be listed (autoclaving, 10% bleach solution/sodium hypochlorite, biosafety pick up, etc.).

Hazardous Chemicals, Activities, or Devices:

Look for detailed descriptions of risks and safety precautions and procedures used including methods of disposal.

APPROVAL FORM (1B)

Dates**:** Signatures from student and parent should be before the start date shown on 1A.

Preapproval **#2a:** Must be signed by SRC or IRB before experimentation begins (Start date on 1A) for human, animal, and PHBA studies but possible FTQ if no preapproval is documented.

Postapproval #2b: SRC signs after experimentation ends (End date on 1A) if the study was conducted at a RRI. Institutional approval forms must also be submitted. (Possible FTQ)

Note: Some fairs will have the fair SRC pre-review a study before it is done at an institution, even if it is approved before experimentation by the institution, and then will also post-approve after the study is complete. They will therefore sign both boxes. Usually, however, it is either pre- or post-approval, not both.

Final SRC Approval: This is signed after the project is complete (End date Form 1A) and immediately before competition.

REGULATED RESEARCH INSTITUTION FORM (1C)

The information provided by the scientist on this form must be consistent with what the student answered on other forms. It must not be filled out by the student. This form is posted so the judges can easily see exactly what the student did rather than what the mentor or others in the research group did. All information must be on the form not "see attached." This form may only be from a university, college, or industrial site and may not be from their high school.

Checkboxes a) and b) help determine who did what and where.

Questions:

1. "Have you reviewed the rules" helps determine the amount of oversight and if an error was made in following the rules, if this an adult problem or a student problem or both.

2. "Is this a subset of your work" helps differentiate student research from mentor research.

3. "How did student get idea" helps determine originality by student.

4. "Was student part of a research group" indicates whether student worked with another high school student, which is only allowed for team projects not individual, or was part of a larger team of adult researchers, undergraduate or graduate students, which is allowed. Students are judged only on their own work, so it needs to be clear what part of the study was done by the entire group or the mentor and what was the student's work.

5-6. "What procedures" and "how independent" again help indicate what was actually done by the student.

Continuation: Frequently, the mentor will say "the student worked with me last year" or "in his previous research" or list dates of research which will indicate that the study must be treated as a continuation with Form 7, etc. It also could indicate that the study is too old, too long, or that the student is presenting multiple years of research.

This form is signed by the mentor AFTER the study is completed (End date on 1A).

QUALIFIED SCIENTIST FORM (2)

Look for answers that are consistent with the information on other forms. For example, if the scientist marks yes to 'used humans' but other human subject forms aren't present, will need to clarify. Any yes responses on #2 will require documentation on additional forms.

This form documents the amount of oversight that the student had and the safety precautions needed. The QS and DS review the study before the experiment begins. All approval signatures must be before research begins (Start date on 1A).

Even when not required, this form may be submitted to show the oversight of the study.

RISK ASSESSMENT FORM (3)

Documents that both the student and the supervisor have assessed the risks involved in the research and describes what safety precautions and procedures are needed including the disposal procedures. This form is completed before experimentation (Start date on 1A).

This risk assessment is required for hazardous chemicals, activities, or devices, and for some PHBA's including protists, composting, coliform water test kits, decomposition of vertebrate organisms, etc.

Even when not required, this form may be submitted to show the oversight of the study.

HUMAN SUBJECTS FORM (4)

Make sure Form 4 is complete including decision checkmarks in the box and all 3 signatures. (If project is approved with expedited review, only one signature is required.) Missing checkmarks or signatures indicates no documentation of prior review and therefore could Fail to Qualify. All approval dates must be before research begins. (Start date on 1A.) The IRB should not include the adult sponsor, designated supervisor, qualified scientist or a relative (e.g. parent) of the student because of conflict of interest.

Research Plan: Refer to the research plan for subject information: any risk groups, recruitment, methods, risks and benefits, protection of privacy (HIPPA & FRPA), and informed consent (participant knows what they are being asked to do, that they may withdraw, no coercion, etc).

Risk Level: Is the level of risk marked appropriate? Was a risk assessment done? Should the study have written Consent/Permission/Assent? Is the survey attached?

HUMAN INFORMED CONSENT FORM

Does the form clearly explain what the participant is being asked to do, how long it will take, the potential risks and steps that will be taken to mitigate risk, the benefits to the participant or to society, how confidentiality will be maintained, that it is completely voluntary and that they may withdraw at any time.

Adult participants sign giving their consent, minors give their assent, and parents of participants give permission. All approval signatures must be before research begins (Start date on 1A).

VERTEBRATE ANIMAL FORM (5A)

Since these animals are not in a research institution, which would provide a high level of oversight, special attention must be paid to the housing and husbandry that will be provided by the student. The final disposition of the animals must

also be appropriate. Any death, illness, or unexpected weight loss must have been investigated and documented by an attached letter from the QS, DS, or a veterinarian. If there were any deaths due to the experimental procedure, the project will Fail to Qualify.

All approval signatures must be before research begins (Start date on 1A). Capture & Release approvals must be attached when applicable.

VERTEBRATE ANIMAL FORM (5B)

Research which causes more than momentary pain or suffering is prohibited. Appropriate use of anesthetics, analgesics and/or tranquilizers must be documented. Any death, illness, or unexpected weight loss must have been investigated and documented by an attached letter from the QS, DS, or a veterinarian.

Euthanasia by student researchers is prohibited so the final disposition of the animals should also be indicated. If there were any deaths due to the experimental procedure, the project will Fail to Qualify.

If tissues were collected, how were they obtained and how will they be used.

The IACUC approval forms must be attached. They must clearly cover this study and must indicate that the study was approved before the start of the student research. Not all IACUC approval documentation will list the student individually, but the student research training must be indicated on the Form 5B. A letter from the QS or Principal Investigator indicating that the study had IACUC approval is not sufficient.

PHBA FORM (6A)

Identification, Including Biosafety Level (BSL): The source, quantity, and BSL must be indicated. A plant or non-primate established cell line will not require Form 6A but the student may fill out this form in order to document that it is from ATCC, etc. However, human and other primate established cell lines and tissue cultures require Form 6A.

Prohibited Studies: BSL-3 or -4 studies, culturing CRE (Carbapenem Resistant Enterobacteriacae), and studies which are designed to engineer bacteria with multiple antibiotic resistance are not permitted. (FTQ)

Site: Microorganisms may NOT be cultured at home. (FTQ) All BSL-1 studies must be conducted at a BSL-1 facility or higher. If a culturing plate with unknown microorganisms is opened, except for disinfection or disposal, it becomes a BSL-2 study and may only be conducted at a BSL-2 facility. FTQ if opened, subcultured, etc. in BSL-1 lab. Most high schools are BSL-1 facilities but it is possible that a high school could meet the more stringent requirements of a BSL-2 lab.

Risk Reduction: Procedures to minimize risk must be clearly indicated. rDNA studies require close review to ensure proper oversight.

Disposal: Proper disposal methods must be listed: autoclaving, bleach solution, biosafety pick up, etc.

Approval Dates: All approval signatures must be before research begins (start date on 1A.)

HUMAN AND VERTEBRATE ANIMAL TISSUE FORM (6B)

Students may conduct tissue studies with tissue they are given from an IACUC approved study within a research institution but the animal may not be euthanized solely for the student's tissue study. The first checkbox in the signature box indicates this.

The second checkbox in the signature box is marked to indicate that the substances were handled in accordance with the safety standards for Blood Borne Pathogens.

All approval signatures must be before research begins (start date on 1A).

CONTINUATION FORM (7) Previous Year's Abstract & Research Plan

This form is posted with the project so that the judges can tell at a glance exactly what was new and different about this year's study. All information must be on the form, not "see attached." Because research projects may only be 1 year's work, they will be judged on the current work only not on previous work, and this form is used to document current versus previous research. Previous Regeneron ISEF projects can be found here.

Frequently, students don't wish to call their project a continuation, but it's good research to continue a line of investigation even when the focus is now totally different. If the study is in the same field, if anything they learned in a previous

year helped with the current study, or if the current study refers to any earlier research, then it is a continuation and Form 7 and previous abstract and research plan are required.

Repetition of a previous study that reflects no changes but simply retests or increases sample size is not permitted.

A longitudinal study, in which time is a critical variable, is permitted but the original data from previous years cannot be presented only the comparison between years.