

Overview of ISEF Forms

The Intel ISEF forms constitute written documentation of what will occur, or in some cases, has already occurred, in a research project. They are designed to provide the information that is needed to review the project to ensure compliance with the Intel ISEF rules and with laws and regulations that apply to the project. The forms **MUST** be filled out and signed before any research takes place. Simply stated, **all** students participating in Upper Miami Valley Science Days at the County, District 1 and State levels **MUST** complete ISEF Forms 1, 1A and 1B. These forms **MUST** be completed in full prior to experimentation. (Only Forms 1C, 5B, 7, and the abstract are done after the research.) The dates of the signatures reflect when the approval or consent is given. Use MM/DD/YY format for all dates.

SUMMARY ISEF FORMS TO READ ABOUT IN THIS OVERVIEW

ALL PROJECTS

Forms 1, 1A, 1B

WORKING ON YOUR PROJECT AT A UNIVERSITY OR COMPANY

Form 1C

WORKING ON A PROJECT FROM A PREVIOUS YEAR

Form 7

USING OTHER PEOPLE IN YOUR EXPERIMENTS

Forms 2, 3, 4

USING VERTEBRATE ANIMALS IN YOUR EXPERIMENTS

Forms 2, 3, 5A, 5B

USING HAZARDOUS CHEMICALS, ACTIVITIES, OR DEVICES IN YOUR EXPERIMENTS

Forms 2, 3

USING BACTERIA, MOLD, YEAST, OR VIRUSES IN YOUR EXPERIMENTS

Forms 2, 3, 6A

USING RECOMBINANT DNA, HUMAN OR ANIMAL TISSUE, CELLS, BLOOD, BLOOD PRODUCTS, OR BODY FLUIDS IN YOUR EXPERIMENTS

Forms 2, 3, 6A, 6B

DESCRIPTIONS OF ISEF FORMS

FORM 1: CHECKLIST FOR ADULT SPONSOR (ONE COMPLETED FORM PER PROJECT)

The checklist is provided so that the adult sponsor can review what information (and, therefore, which forms) must be provided. The date signed is the date that the sponsor first reviews the project plan before the experiment begins. This must be submitted at the time of District Science Day registration.

FORM 1A: STUDENT CHECKLIST (ONE COMPLETED FORM PER PROJECT)

On this page, the student outlines what the project is about. This must be submitted at the time of District Science Day registration. Items that especially need to be clear are the following:

#5 Most projects that involve human subjects, vertebrate animals, or potentially hazardous biological agents require pre-approval. Refer to the Intel ISEF Rules for complete details.

#6 Any project conducted in a similar area of research as previous projects should be considered a continuation. If the project is a continuation, explain on Form 7 as completely as possible how the project will differ from previous experimentation because ONLY a new and different research project is allowed. The current year project must demonstrate significant progress.

#7 Explain when the actual experimental procedure (not the background literature review) will begin and end because ONLY a 12-month project that occurred within the last 18 months before this Intel ISEF is allowed.

#8 Explain where the experimental research will be done: research institution, school, field, home. Universities, research facilities, and industrial settings will require additional documentation on Form 1C to explain what was done at each facility. (Note: Pathogens may NOT be cultured at home.)

#10 Attach a Research Plan and Project Summary, as outlined in the Research Plan and Summary Instructions, which describes the project in detail and answers all applicable questions.

FORM 1B: APPROVAL FORM (ONE COMPLETED FORM FOR EACH STUDENT)

These statements attest that each of these people (or committees) approves or consents to this project. The dates should be signed as described below and are before experimentation unless otherwise indicated:

1a) Student Date they attest that they understand the possible risks, that they have read and will follow the rules, and that they will abide by the ethics statement. This must be completed for District Science Day registration.

1b) Parent/Guardian Date they consent to their child doing this project. This must be completed for District Science Day registration.

2a) SRC Approval
BEFORE Date that the local research committee reviews this project **BEFORE** the experimentation. Projects that must be preapproved are most research in these

areas: human participants, vertebrate animals, and PHBA's (potentially hazardous biological agents) including microorganisms, recombinant DNA, and human or animal tissue. This must be completed for District Science Day registration ONLY if SRC preapproval is required for the project.

2b) SRC Approval
AFTER

This applies only to projects that needed preapproval by the SRC but were done at a research institution and were preapproved by that institution instead of the affiliated fair SRC. The date signed indicates when the SRC approved this project after it was completed. All documentation from the research institution showing approval of the project must be attached. This must be completed for District Science Day registration ONLY if SRC preapproval is required for the project but project was completed at a research institution.

3) Intel ISEF Affiliated
Fair SRC Approval

This section should not be completed for District Science Day registration.

FORM 1C: REGULATED RESEARCH INSTITUTION

This form is completed by the supervising adult, explains what the student researcher actually did and is signed after the project is completed. This must be submitted at the time of District Science Day registration only if the research was done at a research institution (university lab, for example) or in an industrial setting, but is not completed or submitted for work done at home or at a middle or high school.

FORM 2: QUALIFIED SCIENTIST

On this page, the scientist explains what will be done to oversee this project. The qualified scientist (QS) and, if needed, the designated supervisor (DS), will sign with the date that they approve this project (before experimentation takes place). This must be completed for District Science Day registration ONLY if a Qualified Scientist is required for the project.

A Qualified Scientist is required for all projects involving potentially pathogenic biological agents (BSL-2 organisms), DEA-controlled substances and for many projects involving hazardous materials or procedures, human participants and vertebrate animals. Refer to the Intel ISEF Rules for complete details.

FORM 3: RISK ASSESSMENT FORM

This must be completed for District Science Day registration ONLY if the project involves hazardous chemicals, activities or devices, and some potentially hazardous biological agents, including protists, composting, coliform test kits, decomposition of vertebrate organisms and microbial fuel cells, and must be completed and signed by the Designated Supervisor or Qualified Scientist prior to student experimentation.

FORM 4: HUMAN PARTICIPANT FORM

This must be completed for District Science Day registration ONLY if the project involves human participants in the research. This form is filled out by the student researcher when the experiment is conducted in a Non-Regulated Research Site such as home or school and, along with the research plan, is submitted by the student researcher to explain to the SRC/IRB how the safety and well-being of the test subjects and the confidentiality of results will be ensured. The SRC/IRB reviews the project, checks the risk level and determines if written documentation of assent/consent/permission is required. All questions must be answered and boxes checked. Each SRC/IRB member signs with the date they approve this project. This review and the date signed must be **BEFORE** any experimentation takes place.

When required by the SRC/IRB, a written informed assent/consent/parental permission form is used to explain to the research participant and their parent/guardian the risks and benefits associated with participation. (See Human Informed Consent Form) Questionnaires, sample tests, etc., MUST be given to the IRB and to the parent/guardian. If the participant wishes to participate and when required, the parent/guardian also agrees, they each sign the Human Informed Consent Form with the date that they approve (**BEFORE** experimentation begins). The Human Informed Consent Form may be waived by the SRC/IRB under certain circumstances that are outlined in the Intel ISEF Rules.

Some human-based studies are exempt from SRC/IRB preapproval and Human Participants Paperwork. These studies typically involve the use of preexisting data or records, behavioral observations in unrestricted public settings, and testing of student-designed inventions in which the student is the only person testing the invention. Refer to the Intel ISEF Rules for complete details.

FORM 5A: VERTEBRATE ANIMAL FORM

This must be completed for District Science Day registration ONLY if the project involves the use of vertebrate animals. This form is filled out by the student researcher when the experiment is conducted in a Non-Regulated Research Site such as home or school and describes the housing and care for the animals. The SRC reviews this document and determines the level of supervision required for the study and signs and dates BEFORE experimentation begins. The bottom of the form is filled out by a veterinarian and Designated Supervisor or Qualified Scientist and is signed and dated when they approve this project with these housing conditions. (**Before** experimentation begins.)

If there was any illness, unexpected weight loss, or death of an animal during the experimentation, the cause must be investigated and a letter from the Qualified Scientist, Designated Supervisor, or a veterinarian which documents the situation and the results of the investigation must be attached.

FORM 5B: VERTEBRATE ANIMAL FORM

This must be completed for District Science Day registration ONLY if the project involves the use of vertebrate animals. This form is filled out by the Qualified Scientist when the research is conducted at a Regulated Research Institution (university lab, for example) and describes the study. A copy of the IACUC approval (not a letter from the Qualified Scientist or Principal Investigator) must be attached.

If there was any weight loss or death of an animal during the experimentation, the cause must be investigated and a letter from the Qualified Scientist, Designated Supervisor, or a veterinarian which documents the situation and the results of the investigation must be attached.

FORM 6A: POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

This must be completed for District Science Day registration ONLY if the project involves the use of biological agents. This form is filled out by the student researcher and is required for all research involving microorganisms, rDNA and fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products, and body fluids. SRC/IACUC/IBC/RAC approval required **BEFORE** experimentation. The qualified scientist will sign and date. The SRC will choose one or more statements that describe the approval process for the study and will add the date that approval occurred. Refer to the Intel ISEF Rules for complete details.

FORM 6B: HUMAN & VERTEBRATE ANIMAL TISSUE

This must be completed for District Science Day registration ONLY if the project involves human and/or vertebrate animal tissue. This form is filled out by the student researcher and explains the source of the tissue. The Qualified Scientist or Designated Supervisor signs and dates to document the source and handling of this tissue (**BEFORE** experimentation).

FORM 7: CONTINUATION PROJECTS FORM

This must be completed for District Science Day registration ONLY if the current project is in a similar area of research as any previous project of the student or any team member. Explain as completely as possible how the project is different from previous experimentation because ONLY a new and different research project is allowed. The date signed is the date the student researcher is certifying that this information is correct.