



High School Research Projects:

What exactly needs Pre-Approval?

Complete rules, regulations, and details can be found in the [MSEF HS Manual](#).

All projects must fill out the **three basic forms** (1, 1A and 1B) and complete a **research plan**.

★ Some topics or materials will require the student(s) to fill out additional forms.

- The intent of the form is for the student to show that they know and understand the risks (or potential risks) - but are following best practices, being cautious, have proper permissions, and will be supervised if they need it.
- These forms (as highlighted below) are in addition to the research plan and must be submitted and approved BEFORE experimentation can begin. This is called “pre-approval”.
- All research plans and forms must be completed and submitted to the SRC for your school’s [Region](#) using the zFairs online system.

★ Any other projects (that do not include the items below) can be **reviewed and approved by the teacher/mentor** in order to begin experimentation.

- Items marked EXEMPTIONS still must follow all the rules of that category, however they do not need pre-approval by the Regional SRC and can complete a Form 3 instead.

A. Regulated Research Institutional/Industrial Setting (Form 1C, Form 2)

*****This rule is specific to MSEF.*****

- a. Even if a project does not involve any of the items listed below, if a student is performing the work in/at a lab setting outside of their high school, pre-approval is required.

B. Potentially Hazardous Biological Agents (Form 2, Forms 6A and 6B)

- a. Suggested language to be used for completing forms can be found [here](#).
- b. [Defined as:](#)

- bacteria
 - viruses, virions, prions, rDNA, parasites
 - fungi (Baker's/Brewer's yeast and edible mushrooms are exempt)
 - human or animal tissue /blood/body fluids (ie: spit, blood sample)
- c. **EXEMPTIONS** (no pre-approval required - use Form 3 instead):
- **non-culturing experiments** with: microbial fuel cells, color-change coliform test kits, decomposing vertebrates, manure for composting/fuel production
 - **some** bacteria: *E. coli* k-12, Lactobacillus, *Bacillus thuringiensis* (Bt), nitrogen-fixing bacteria, oil-eating bacteria, algae-eating bacteria, water/soil microbes
 - protists, archaea, slime molds, edible mushrooms, baker's or brewer's yeast
 - meat, meat byproducts, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses (*there should be little chance of contamination with unknown microorganisms*)
 - mold growing on food IF you terminate experiment once mold appears
 - plant tissue and plant cell lines
 - hair, hooves, nails, feathers, teeth (if sterilized), fossilized tissue, pre-prepared fixed tissue slides

C. Human Participants/Subjects (Form 2, Form 4)

- a. An IRB [determines risk level](#) and approves based on a review of: research plan, survey/test, and a sample of the informed consent form participants will complete
- Consider anonymity/confidentiality, physical or health risks, psychological stress/anxiety/discomfort, and at-risk groups
 - **Minimal risk** means the test/survey does not exceed risks encountered in DAILY LIFE by that group of humans
 - Informed Consent is **always** required, but can verbal or written (as determined by the IRB)
- b. [Defined as](#):
- participants engage in physical activity
 - participants complete educational, opinion, and/or psychological studies (e.g., surveys, questionnaires, tests - whether in person or online)
 - the researcher is the subject of the research
 - testing of student designed invention, prototype or computer application by human participants **other than** student researcher (exempt if only the student researcher is testing it)
 - Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables)
 - Behavioral observations that
 - involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
 - occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
 - involve the recording of personally identifiable information.
- c. **EXEMPTIONS** (no pre-approval required - use Form 3 instead):

- student-designed Invention, Prototype, Computer Applications or Engineering/Design Project in which the student is the only person testing the invention, prototype or computer application and the testing does not pose a health or safety hazard
- data/record review studies IF data is from a pre-existing, publicly available data set
- behavioral observations of unrestricted, public settings and the researcher does not interact with subjects, does not manipulate the environment, and does not record any identifiable information of participants

D. **Potentially Hazardous Chemicals, Activities, and Devices** (Form 2, Form 3)

a. Defined as:

- **Hazardous Chemicals** (attach SDS)
 - the form should address: toxicity, reactivity, flammability, corrosiveness, and disposal
- **Hazardous Devices**
 - Equipment in or outside of the school/lab that require moderate to high level of expertise:
 - a. high vacuum equipment
 - b. heated oil baths
 - c. NMR equipment
 - d. high-temperature ovens
 - e. high-voltage equipment (able to cause harm: >1000V AC or >1500V DC)
 - f. welding equipment
 - g. lasers (Class II-IV which includes even a laser pointer)
 - Consider whether any student designed inventions should be included on the form
- **Radiation** (ionizing radiation)
 - include anything beyond that normally encountered in daily life (UV, visible light, infrared (IR), microwave (NW), radiofrequency (RF))

b. Specific rules apply to the following Regulated Areas (*review guidelines carefully*)

- DEA-controlled Substances
- Prescription Drugs
- Alcohol & Tobacco
- Firearms and Explosives
- Regulated Drones
- Radiation

E. **Vertebrate Animals** (Form 2, Forms 5A and 5B)

**** any death, illness or unexpected weight loss requires experimentation to STOP and MUST be investigated and documented by a letter from the qualified scientist, designated supervisor or a veterinarian.**

- a. **Use Form 5A:** research that is conducted in a school/home/field research site

Use Form 5B: research that is conducted in at a Regulated Research Institution

b. Defined as:

- live, nonhuman vertebrate mammalian embryos or fetuses
- tadpoles
- bird and reptile eggs within three days (72 hours) of hatching
- all other nonhuman vertebrates (including fish) at hatching or birth
- **Exception:** Because of their delayed cognitive neural development, zebrafish embryos are not considered vertebrate animals until 7 days (168 hours) post-fertilization

c. The following types of studies are **prohibited**:

- Induced toxicity studies with known toxic substances that could cause pain, distress, or death, including but not limited to, alcohol, acid rain, pesticides, or heavy metals or studies with the intent to study toxic effects of a substance on a vertebrate animal.
- Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
- Studies of pain.
- Predator/vertebrate prey experiments.

d. **Exempt Studies** (do not require SRC pre-approval)

- Studies involving **behavioral observations** of animals are exempt from prior SRC review if ALL of the following apply:
 - There is no interaction with the animals being observed,
 - There is no manipulation of the animal environment in any way, and
 - The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.