Connecticut Science Fair Research Pathways

Middle School and (possibly) High School students have a choice of the EZ Path or the Unrestricted Research Path.
Prior to the start of research, the Student and Teacher choose the desired path route and informs the teacher prior to start of research

All Non-EZ PATH Projects must register by Dec. 1

EZ PATH

*Projects **MUST NOT** involve the following items:*

Biological

- Blood products, fresh tissue, teeth & bodily fluids
- Human Subjects[§]
- Nonhuman vertebrate animals or their parts
- Potentially pathogenic agents, including all bacteria
- Recombinant DNA

Chemical

- Controlled substances
- Carcinogenic, mutagenic & toxic chemicals
- Explosive chemicals
- Radioactive materials
- Compressed gases

Energy

- Hazardous substances or devices
- High voltage equipment
- Class 3 and 4 Lasers
- Ionization radiation (X-rays/nuclear energy)

FORMS REQUIRED

- Checklist for adult sponsor (1)
- Registration Form (on line)
- Research Plan (on line)
- Release Form (1D)(signed by parent)

Note: CSF may determine your project does not qualify for EZ Path. See exclusions above and contact us if there are questions.

UNRESTRICTED RESEARCH PATH

*Projects **MUST** conform with all ISEF and CSF rules and regulations.*

FORMS REQUIRED

- Checklist for Adult Sponsor (Form 1)
- Registration Form (on line)
- Research Plan (on line)
- Release Form (1D)(signed by parent)

AND THE FOLLOWING, AS APPROPRIATE:

	Form Title	Purpose
1C	Research Institution	For student research conducted in a regulated research institution or industrial setting
2	Qualified Scientist	For projects involving human subjects, vertebrate animals, potentially hazardous biological agents. Submit prior to work
3	Risk Assessment	For projects using hazardous chemicals & biological substances, and hazardous activities or devices
4	Human Subject Form	For projects involving humans). Submit prior to work
5A/ 5B	Vertebrate Animals	For animal projects. Submit prior to work
6A/ 6B	Potentially Hazardous Biological Agents, Animal Tissue	Submit prior to work
7	Continuation Projects	

[§]Very few human subject projects may qualify for EZ Path. See 'Exempt Studies' on page 8 of the ISEF Rules at: http://www.societyforscience.org/isef/document Other human projects can be approved by your school IRB but do not qualify for EZ Path and a form 4 (at least) will be required by the IRB.

Human Participants Rules

Rules involving human participants

Student researchers must follow federal guidelines (Code of Federal Regulations 45 CFR 46) to protect the human research participant and the student researcher. When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB)/Human Subjects Participant Program (HSPP) and informed consent/assent from the research participant.

Exempt Studies (Do Not Require IRB Preapproval or Human Participants Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for the Intel ISEF and affiliated fairs are:

1. Testing of a student-designed invention or prototype is done only by the student researcher and where the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed. (The use of other human participants for this testing is not exempt from IRB review and approval.)

2. Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.

3. Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
   a. the researcher has no interaction with the individuals being observed
   b. the researcher does not manipulate the environment in any way and
   c. the researcher does not record any personally identifiable data.

4. Projects in which the student receives pre-existing/retrospective data in a **de-identified/anonymous** format which complies with both of the following conditions:
   a. the professional providing the data certifies in writing that the data have been appropriately de-identified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
   b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Rules

1. The use of human participants in science projects is allowable under the conditions and rules in the following sections. Based upon the Code of Federal Regulations (45 CFR 46), the definition of a **human participant** is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information. **These projects require IRB review and preapproval** and may also require documentation of written informed consent/assent/parental permission. Examples of studies that are considered "human participant research" requiring IRB preapproval include:
   a. Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
   b. Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
   c. Studies in which the researcher is the subject of the research
   d. Testing of student designed invention or concept by human participants other than student researcher
   e. 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).
   f. Behavioral observations that
      1) involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
      2) occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
      3) involve the recording of personally identifiable information

2. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment below and the Risk Assessment Guide for additional guidance.

3. The research study should be in compliance with all privacy laws (e.g., Family Educational Rights and Privacy Act (FERPA) and Health Insurance Portability and Accountability Act (HIPAA)) laws when they apply to the project (e.g. the project involves medical information).

4. All research projects involving human participants, including any revisions, must be reviewed and approved by an Institutional Review Board (IRB) before the student may begin recruiting and/or interacting with human participants. The IRB must assess the risk and document its determination of risk on Form 4. After initial IRB approval, a student with any proposed changes in the Research Plan must repeat the approval process and regain approval before laboratory experimentation/data collection resumes.

5. Research conducted by a pre-college student at a Regulated Research Institution (e.g., university, college, medical center, government lab, correctional institution) must be reviewed and approved by that institution's IRB. A copy of the IRB approval for the entire project (which must include the research procedures/measures the student is using) and/or an official letter from the IRB attesting to approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.

6. Research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants may give their own consent. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing permission. The IRB will determine whether the consent/assent/parental permission