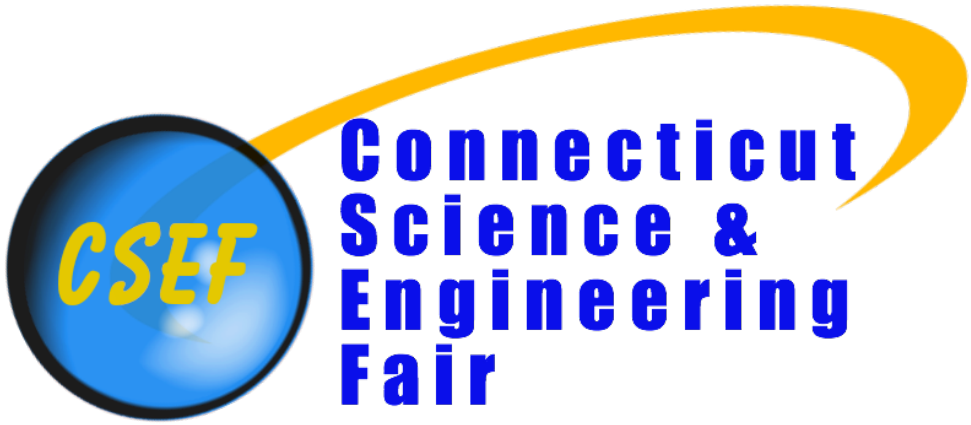

CSEF Forms

Connecticut Science Fair Association, Inc.
Form 1D - Release Required with Registration

Name _____ School _____ Town_____

(Submit a release for each team member.)

Liability for Exhibits & Risks of Research Plan

Since the exhibition of projects at the Connecticut Science & Engineering Fair is open to the public, The Connecticut Science Fair Association, Inc., and its committees cannot and will not accept any liability or responsibility of any nature for any theft of, or loss or damage to, any Exhibit or any other property of any Exhibitor. There is no need for any equipment of value to be part of the exhibit. During final judging when equipment may be displayed each Exhibitor should secure and guard his/her Exhibit and/or other property at all times.

I have read the Research Plan prepared by my child and understand the risks and possible dangers involved in the research anticipated.

I understand and accept that the Connecticut Science & Engineering Fair cannot and will not accept any liability or responsibility for theft, damage, or risk and possible danger involved in my or my child's participation in this activity.

Research Ethics

I have read and will abide by the Connecticut Science & Engineering Fair ethics statement. I recognize that my failure to abide by the ethics statement may result in my disqualification in the Fair and possible exclusion from future Fairs.

Publicity

The Connecticut Science & Engineering Fair is a statewide event, and your participation is newsworthy. The organizations or businesses sponsoring awards at the fair may want to publicize their involvement in such an important science competition by using photographs or information about you. Your cooperation may make it possible for other promising young students to get involved in science and engineering.

You have my permission to use appropriate information about me for publicity purposes. This includes photography submitted by me as well as any photographs, videos or likenesses that may be used by the Connecticut Science & Engineering Fair, its grant sponsors or the sponsors of awards for the purposes of illustration, advertising or publication in any manner. I also consent to the use of my name in connection therewith.

_____ _____

Finalist Signature / Date Parent/Legal Guardian Signature / Date

_____

Printed Name / Relationship

Revised Nov. 2012

Connecticut Science Fair Association, Inc.
Student Research Ethics Statement

The Connecticut Science & Engineering Fair (CSEF) expects all participants to operate at the highest code of conduct and ethics. More specifically, the CSEF will take all actions necessary to ensure:

1. All students who register projects with the CSEF, regardless of the institution where the research takes place, certify that the research proposed, hypothesis developed, experiments designed and executed, data collected, analysis performed, and conclusions reached represents the novel, unique, and independent contribution of the student.

2. The CSEF aims to promote and encourage scientific collaboration, mentorship, and advisement opportunities between students and practicing scientists and engineers. However, advisors should be careful to limit their assistance and involvement to instruction of required background theory or experimental techniques, and providing critical feedback to student generated ideas, hypotheses, data, analysis, and conclusions. Furthermore, all advisors are expected to operate at the highest level of scientific ethics and monitor the activities of the student to ensure their simultaneous compliance.

3. Plagiarism, of any type and format, is strictly prohibited. For clarity, plagiarism is defined as, "when an author attempts to pass off someone else's work as his or her own." (Nature Journal Editorial Policy, 2009). Examples of plagiarism include, but are not limited to:

    - Copying another person's work from any resource (i.e., periodical, book, Internet) and submit it as one's own.
    - Paraphrasing or using parts of another person's work (i.e., ideas, written work, diagrams, graphs, charts, images) without properly citing it as a resource.
    - Duplicate publication, by reusing substantial parts of his or her own published work without providing appropriate references.

Should any member of the CSEF staff detect ethics misconduct, it will immediately be brought to the attention of the CSEF Director. Should misconduct be confirmed, the student's project will immediately be disqualified from further participation, the student's school and any advisers will be notified. At the discretion of the CSEF Director, the student may be prohibited from future participation at the CSEF.

Participants are required to abide by the Ethics statement and recognize that their failure to abide by the ethics statement may result in my disqualification in the Fair and possible exclusion from future Fairs.

Definitions (Oxford English Dictionary):

Ethics: moral principles that govern a person's behaviour or the conducting of an activity.

Plagiarism: when an author attempts to pass off someone else's work as his or her own.

Revised Nov. 2012

Research Plan/Project Summary Instructions

A complete Research Plan/Project Summary is required for ALL projects and must accompany Student Checklist (1A).

The Research Plan/Project Summary is a succinct detailing of the rationale, research question(s), methodology, and risk assessment of your research project and should be completed before the start of your experimentation. Any changes you make to your study should to be added to the final document.

The research plan for ALL projects should include the following:

a. What is the **RATIONALE** for your project? Include a brief synopsis of the background that supports your research problem and explain why this research is important scientifically and if applicable, explain any societal impact of your research.
b. State your **HYPOTHESIS(ES), RESEARCH QUESTION(S), ENGINEERING GOAL(S), EXPECTED OUTCOMES**. How is this based on the rationale described above?
c. Describe in detail your **RESEARCH METHODS AND CONCLUSIONS**.
   - **Procedures:** Detail all procedures and experimental design including methods for data collection. Describe only your project. Do not include work done by mentor or others.
   - **Risk and Safety:** Identify any potential risks and safety precautions needed.
   - **Data Analysis:** Describe the procedures you will use to analyze the data/results that answer research questions or hypotheses.

d. Bibliography: List at least five (5) major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.

Items 1–4 below are subject-specific guidelines for additional items to be included in your research plan/project summary as applicable.

1. **Human participants research:**
   - **Participants.** Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
   - Recruitment. Where will you find your participants? How will they be invited to participate?
   - Methods. What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
   - Risk Assessment
     - ◊ Risks. What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize the risks?
     - ◊ Benefits. List any benefits to society or each participant.
   - **Protection of Privacy.** Will any identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?
   - **Informed Consent Process.** Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

2. **Vertebrate animal research:**
   - Briefly discuss potential **ALTERNATIVES** to vertebrate animal use and present a detailed justification for use of vertebrate animals
   - Explain potential impact or contribution this research may have
   - Detail all procedures to be used
     - ◊ Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experimentation
     - ◊ Detailed chemical concentrations and drug dosages
   - Detail animal numbers, species, strain, sex, age, source, etc.
     - ◊ Include justification of the numbers planned for the research
   - Describe housing and oversight of daily care
   - Discuss disposition of the animals at the termination of the study

3. **Potentially hazardous biological agents research:**
   - Describe Biosafety Level Assessment process and resultant BSL determination
   - Give source of agent, source of specific cell line, etc.
   - Detail safety precautions
   - Discuss methods of disposal

4. **Hazardous chemicals, activities & devices:**
   - Describe Risk Assessment process and results
   - Detail chemical concentrations and drug dosages
   - Describe safety precautions and procedures to minimize risk
   - Discuss methods of disposal

Regulated Research Institutional or Industrial Setting Form (1C)

This form must be completed AFTER experimentation by the adult supervising the student research conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

This form MUST be displayed with your project; responses must be on the form.

Student's Name(s) _____

Title of Project _____

To be completed by the Supervising Adult in the Setting (NOT the Student(s)) after experimentation:
(Responses must remain on the form as it is required to be displayed at student's project booth.)

The student(s) conducted research at my work site:

a. ☐ to use the equipment b. ☐ to perform experiment(s)/conduct research

1. Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐ No

2. Is this research a subset of your work? ☐ Yes ☐ No

3. How did the student get the idea for her/his project?
(e.g. Was the project assigned, picked from a list, an original student idea, etc.)

4. Did the student(s) work on the project as a part of a research group? ☐ Yes ☐ No
If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)

5. What specific procedures or equipment did the student(s) actually use for the project?
Please list and describe. (Do not list procedures student only observed.)

6. How independent or creative was the student's/students' work?

Student research projects dealing with human participants, vertebrate animals or potentially hazardous biological agents require review and approval by an institutional regulatory board (IRB/IACUC/IBC). **Copy of approval(s) must be attached, if applicable.**

Supervising Adult's Printed Name _____ Signature _____ Title _____

Institution _____ Date Signed (must be after experimentation) _____

Address _____ Email/Phone _____

Qualified Scientist Form (2)

May be required for research involving human participants, vertebrate animals, potentially hazardous biological agents, and DEA-controlled substances. Must be completed and signed before the start of student experimentation.

Student's Name(s) _____

Title of Project _____

To be completed by the Qualified Scientist:

Scientist Name: _____

Educational Background: _____ Degree(s): _____

Experience/Training as relates to the student's area of research:

Position: _____ Institution: _____

Address: _____ Email/Phone: _____

1) Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐ No

2. Will any of the following be used?
   a. Human participants ☐ Yes ☐ No
   b. Vertebrate animals ☐ Yes ☐ No
   c. Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products) ☐ Yes ☐ No
   d. DEA-controlled substances ☐ Yes ☐ No

3. Was this study a sub-set of a larger study? ☐ Yes ☐ No

4. Will you directly supervise the student? ☐ Yes ☐ No
   a. If no, who will directly supervise and serve as the Designated Supervisor? _____

To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the Research Plan prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the Research Plan. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my direct supervision.

_____
Qualified Scientist's Printed Name

_____ _____
Signature Date of Approval

To be completed by the Designated Supervisor when the Qualified Scientist cannot directly supervise.

I certify that I have reviewed the Research Plan and have been trained in the techniques to be used by this student, and I will provide direct supervision.

_____
Designated Supervisor's Printed Name

_____ _____
Signature Date of Approval

_____ _____
Phone Email

Risk Assessment Form (3)

Required for projects using hazardous chemicals, activities or devices and microorganisms exempt from pre-approval. Must be completed before experimentation.

Student's Name(s)_____

Title of Project _____

To be completed by the Student Researcher(s) in collaboration with Designated Supervisor/Qualified Scientist: (All questions must be answered; additional page(s) may be attached.)

1. List/identify microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules), and all hazardous chemicals, activities, or devices that will be used.

2. Identify and assess the risks involved in this project.

3. Describe the safety precautions and procedures that will be used to reduce the risks.

4. Describe the disposal procedures that will be used (when applicable).

5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):
I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan and will provide direct supervision.

_____ _____ _____

Designated Supervisor's Printed Name | Signature | Date of Review (mm/dd/yy)

_____ _____

Position & Institution | Phone or email contact information

_____

Experience/Training as relates to the student's area of research

Human Participant Studies - Risk Assessment Guide
(updated June 2014)

The purpose of this guide is to assist student researchers, teachers/mentors and local IRB's as they evaluate risks and design research projects that respect the rights and welfare of human participants. The complete Human participants rules and guidelines can be found in the International Rules and Guidelines or on the Student Science website at https://student.societyforscience.org/human-participants.

This document contains information on the following topics:

A. Risk Assessment and Risk Reduction

Risk Assessment involves consideration of **physical** and **psychological** risks along with the **protection of privacy**. The student researcher, adult sponsor and qualified scientist must develop procedures that reduce and minimize any risks to human participants.

The IRB will review the Research Plan and make the following determinations:

- whether the study is approved or must be revised
- whether the study contains no more than minimal risk or more than minimal risk to potential participants. The IRB will consider characteristics (e.g., age, health status, vulnerability to coercion) of the study population, the specific risks (e.g., physical, psychological, social, privacy) associated with the research activity and local norms when making a risk level determination;
- whether documentation of informed consent/participant assent and/or parental permission are required or can be waived
- whether a qualified scientist is required

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Studies must involve **anonymous data** to be considered no more than minimal risk.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life.

B. Types of Risk

1) Physical Risks:

a. **Exercise** other than ordinarily encountered in daily life *by that participant* would be considered more than minimal risk. One must consider characteristics of potential research participants as well as the type of exercise involved in the study.

Examples:

- Walking the length of standard hallway
    - For most healthy participants, this activity could be considered "minimal risk."
    - For the elderly or someone recovering from knee surgery, this might be considered "more than minimal risk."
- Swimming 500 meters
    - For the general population, this activity would be considered "more than minimal risk."
    - For members of the varsity high school swim team, this activity could be considered "minimal risk."

b. **Ingestion, tasting, smelling, application of a substance** that pose any health risk are considered "more than minimal risk"**.** Ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB who will determine risk level based upon the nature of study and local norms around food typically encountered in the research setting. For Example:

- Some school IRBs may consider a tasting study minimal risk based on the fact that the food being studied is commonly available to all students in their school.
- Conversely, an IRB at another school may deem the same study more than minimal risk if the food being studied is not commonly available to students or they believe that parents in their community would want to provide parental permission before their minor child could participate in the study.

c. **Medical examples**

Blood glucose testing with a glucometer that is conducted by a diabetic on a daily basis could be considered minimal risk. However, it would be considered more than minimal risk when a glucometer is used by a participant who does not perform this test as a function of their daily life. Student researchers must receive training by a qualified scientist on the proper technique of capillary blood glucose sampling. Risks to the participant include pain, infection, and injury and risks to the researcher could include possible exposure to blood/body fluids, or needle stick.

A project involving the measurement of blood pressure in which a student researcher uses a commercially available automatic blood pressure device would be considered a minimal risk study. The study would be considered more than minimal risk if a manual sphygmomanometer is used. Risks include vascular spasm, nerve damage, and bruising due to improper technique. The IRB must examine the context of the research plan to ascertain these risks. Training of the student researcher should be required by the IRB. The IRB may also require a qualified scientist. Most often, these measurements are obtained in conjunction with exercise. If that is the case, the IRB should refer to item 1a above to assess the overall risk to the participant. Each research plan that employs vital sign measurements should also include a plan of how to deal with vital signs measurements that are out of range. For example, when a reading is obtained that is outside of the normal range, the person should be referred to their healthcare provider or the nearest emergency facility.

2) Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress** would be considered **more than minimal risk**. For example, answering questions related to personal experiences such as sexual or physical abuse, divorce and/or psychological well-being (e.g. depression, anxiety, suicide) must be considered more than minimal risk and should have documented informed consent/minor assent/parental permission (as applicable).

Additionally, research activities that involve exposing participants to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk. Examples

include violent or distressing video images, distressing questions, materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in participants.

Reducing Risk associated with Emotional Distress: Care must be taken to try to reduce potential emotional distress. For example, to reduce risk in a study involving a survey about depression and suicide, consider having a school counselor available to talk with students if they are feeling distressed or having a statement at the end of the survey directing students to the school counselor or school psychologist.

3) Risks due to Invasion of Privacy & Breach of Confidentiality

The student researcher and the IRB must consider whether any activity could potentially result in negative consequences for the participant due to **invasion of privacy or breach of confidentiality**. For example, if the study involved collecting a student's GPA and the data were accidentally made available to unauthorized persons, the research participant could suffer embarrassment and feelings of distress related to the invasion of his privacy.

Reducing Risk:

Risk level can be reduced by appropriately protecting confidentiality or collecting data that is anonymous and uses data collection procedures that make it impossible to link any identifying information with his/her responses or data.

a) **Anonymity** involves collecting research data in such a way that it is impossible to connect research data (e.g. responses, questionnaires) with the individual who provided the data. That is, personal identifiers (e.g. names, birthdates, social security numbers) are not collected. **Whenever possible, student researchers should collect data anonymously. (**While collecting data anonymously does reduce risk, not all anonymous studies are considered minimal risk**.)**

   - To collect data anonymously, student researchers must not require participants to give their name or any other identifiable information (birth date, email address, etc.)

   - If documented informed consent, assent, and/or parental permission is/are required, the forms must always be kept in a secure location separate from the data.

b) **Confidentiality** is necessary when personal identifiers such as name, birth date, telephone number, photograph, email address or mailing/street address are collected.

   - Protecting confidentiality involves taking careful measures to ensure that the research data and/or responses are not disclosed to the public or unauthorized individuals with identifiable information. When research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints, emotional functioning, grades) or health-related data (genetic material, blood, tissue) the researcher must consider risks related to invasion of privacy and possible breach of confidentiality.

   - If the research involves data from the same participant on multiple occurrences, the data or survey would need to be labeled with an identifier to be linked with the data collected at a later date. In this case, confidentiality could be maintained by labeling the surveys or data with a participant number and keeping a list of names and participant numbers in a separate and secure (e.g., locked file cabinet, password protected computer) location. Once the 2nd round of data is collected, the surveys/data may be matched using the participant number and any identifiers should be removed from the data/surveys. At this point, the list of names and participant numbers should be securely discarded (e.g., shred). If documented informed consent, assent, and/or parental permission is/are required, the forms must be kept in a secure location separate from the data.

Special Considerations:

Threats to Anonymity

- If the number of participants is relatively small and/or all participants are from an identifiable source (e.g., an English class, softball team), the anonymity of the data could be threatened. That is the student researcher or anyone with access to the data could potentially link the survey responses to an individual. In addition, presenting the results of the study (even in aggregate) could threaten the participants' privacy or result in negative consequences for the participants.
- If informed consent/assent/parental permission forms (which include names) are collected and the sample is relatively small, it could be possible for the student researcher or an unauthorized person to link the survey responses with participants.

Making Data Anonymous

- Sometimes data may not be collected anonymously, but can be made anonymous after data collection. For example, if the student researcher uses interviews or observations to collect the data, the data would not be anonymous at the time of collection. However, if names are not collected or are removed from the data soon after collection, the data set would then be anonymous.

Risks Related to Threats to Anonymity

- Be sure to consider any ramifications of the student researcher being able to link responses with participants. Most importantly, would there be any negative consequences for the research participants if the student researcher could link responses with the participants. This is especially important when the research participants are peers to the researcher. When the participants are peers of the student researcher, the researcher/QS/IRB should give extra consideration to any potential risks related to the student researcher having knowledge of his/her peers' data (e.g., grades, body weight, etc). To eliminate such risks, it may be prudent to have an adult collect the data and hand it over to the student research after identifiers are removed and it is anonymous.
- Be sure to consider the possibility of and ramifications of an unauthorized person (e.g., another student, parent, teacher, administrator) getting access to the data and being able to link responses to individual participants or groups of participants (e.g., softball team).
- Consider the nature of the study/data collected. Issues of anonymity and confidentiality are most salient for studies involving sensitive and personal information. Examples of data that should receive special consideration include grades, health/mental health information, experiences of child abuse, illegal behavior, socially unaccepted behavior, anything that could cause the participant embarrassment or legal or disciplinary negative consequences.

4) Risk Groups:

As noted above, the physical, psychological and other risks of participation in a study may depend on the specific sample of participants involved. The physical risk of an activity such as jumping roping will be much higher for an elderly (or even middle aged participant) than for a middle or high school participant. In contrast, the risks of a breach of confidentiality or anonymity would be greater for a group of high school students answering questions about alcohol use than for a group of older adults for whom it would be easier to collect the data in a anonymous fashion.

Some groups deserve special consideration. If the research study includes participants from any of the following groups described below, the student researcher and the IRB must consider whether the nature of the study requires consider special protections or accommodations for participants in these risk groups.

1) Any member of a group that is naturally at-risk (*e.g.*, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, learning disorders, etc.). The nature of the study is an

important consideration when determining if special protections are required. For example, special protections would not typically be necessary to include pregnant women in a study involving performance on a cognitive test or completion of a simple survey.

2) Special vulnerable groups that are covered by federal regulations (*e.g.* children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act). Specifically, the IRB and the student researcher should consider whether potential study participants who are receiving services under the Individual Disabilities Education Act need special accommodations and/or are appropriate for inclusion in the study as research participants. For example, an IRB may choose to require parental permission for minor participants receiving special education services even when parental permission has been waived for general education students. Confidentiality must be maintained so as not to identify/isolate students.

C. Informed Consent

Informed consent refers to the process of ensuring that potential human participants understand that they may choose whether or not to participate in a study. Individuals should never be forced or coerced to participate in a research study. A teacher, school administrator or anyone requiring students to participate in a research study as a human participant would be considered a serious violation of informed consent principles. That is, the research participant must freely decide to participate and not feel coerced or forced into doing so.

To make an informed decision about whether an individual wants to participate, the human participants must be informed about what they will be asked to do and if there are any risks or benefits involved. For example, if the participant will be asked to complete an interview or a survey, the nature of the survey should be described (e.g., questions about emotional functioning, students experiences around divorce, grades and SAT scores). In most cases, the informed consent process also includes a description of the purpose of the study. However, in rare circumstances detailed information about the purpose of the study will not be included if purpose of study requires innocuous deception that poses minimal risk to the human participant. A school's IRB may allow innocuous deception studies such as a study designed to determine if colored paper affects the time it takes a student to complete a given written task. The IRB may require a QS to help develop appropriate informed consent procedures which respect the rights of human participants but do not threaten the validity of the study.

Participants 18 years and older **must** be provided with all of the information mentioned above and give their **Informed Consent** before participating in a research study. In most cases, if participants are under the age of 18, a parent or legal guardian must be presented with all of the information described above before giving **Parental Permission** for their minor child to participate**. Minor Assent** refers to procedures giving developmentally appropriate information to children and to adolescents about the study and giving them a choice as to whether or not they will participate. **High school students should be supplied with ALL of the information mentioned above and give their verbal and/or written assent to participate.**

Obtaining Written Informed Consent, Parental Permission or Minor Assent
An informed consent form is typically used to provide written information to the human participant or parent/guardian and to document written informed consent/parental permission/minor assent. This form typically includes the purpose of the study, what the participant will be asked to do, the nature of any surveys, questionnaires or interviews, any risks and any benefits to the participant. The form should also contain information that explains to the potential research participant or parent/guardian that participation in the study is voluntary and that the participant is free to stop participating at any time. The Informed Consent Form in the International Rules provides an example of how this information can be presented.

IRBs may require that a copy of any survey or questionnaire be attached to the form when parents/guardians are being asked to give their permission for their minor child to participate. This process allows the parent to review the material to which their child will be exposed and make an informed decision about whether they want their child to participate. While this is an ideal way to ensure that parents are informed about the nature of the study, in some cases sending home a copyrighted survey may be a violation of the test publisher's regulations. In other cases, sending home a copy of the survey may threaten the validity of the study. Ultimately, the IRB must decide whether the risks of the study require parent/guardian's to be aware of the exact survey questions or whether an appropriate description of the survey on the Informed Consent/Parental Permission Form will suffice. If the IRB has concerns about the nature of the study and believes parents/guardians should see the survey questions to make an informed decision about their minor child participating, but publisher regulations or concerns about threats to study validity prohibit the survey from being sent home, the topic or particular survey may be deemed inappropriate for student research.

Waiver of Written Informed Consent/Parental Permission/Minor Assent

Obtaining informed consent from an adult or minor assent is always required. However, the IRB may waive the requirement for documentation of written informed consent/assent and/or parental permission if the research involves **only minimal risk and anonymous data collection and if it is one of the following**:

a) Research involving normal educational practices

b) Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.

c) Surveys and questionnaires that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

d) Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

As explained above, informed consent/minor assent or parental permission is always required. It is merely the process of obtaining a signature to document informed consent/minor assent or parental permission that can be waived in the circumstances mentioned above. **If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent or parental permission, it is strongly recommended that documentation of written informed consent/parental permission be obtained. In addition, it is recommended that parental permission not be waived for minor participants who are younger than high school age.**

D. Online Survey Consent Procedures

Online surveys require **Informed Consent** (from human research participants age 18 and older) and **Minor Assent** (from participants under age 18). The IRB will determine whether **documentation of Parental Permission** is required.

1. All information regarding the research and the voluntary nature of their participation must be given to the research participants before they begin the survey.
2. The following statement or something similar should be included:

   There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question.

3. The survey should be set up in a way that the potential participant must click on a 'button' or type in a response indicating that he/she has read the consent/assent information and agrees to participate. Once the 'button' is selected, the potential participant will be redirected to the research survey questionnaire. That is, the survey questions are not viewed by participant until he/she clicks on or types in a response to indicate his/her voluntary participation.
4. The following procedures should be used to protect confidentiality of downloaded data:
    - If IP addresses are collected by the survey tool, the addresses should be deleted from the downloaded data file. All responses should then be deleted from the online survey. The resulting data file that is used for data analysis should be free of any identifiers, including IP addresses or other electronic identifiers.
    - The data file should be stored on a password protected computer. Any back up data files should be also be stored in a secure location.

Documented Parental Permission when required by the IRB

The following are several ways to obtain documented/written parental permission (when required by the IRB) prior to a minor participant completing the survey:

1. Parental consent may be obtained using valid electronic signatures and emailed to the researcher.
2. A copy of a signed permission document may be scanned and e-mailed (or faxed) back to the researcher.
3. The minor participant could complete an online form that collects parental contact information such as an email address, phone number, fax number, and physical address. This form would then be emailed to the researcher who would then contact the parent/guardian directly.
4. Programs exist that will assist the researcher in collecting documented Parental Permission. Some commercial survey packages contain this functionality.
5. Another option is to setup two surveys: one to collect information for Parental Permission and one to conduct the actual survey. For example:
    - A participant recruitment survey could be constructed that describes information related to the survey document and the aims of the research. When minor participants are interested in participating in the survey, they complete this survey document that collects the parental contact information as described above. A parental information packet with proper consenting documents and information is then provided to the participant's parent/guardian. Once completed by the parent/guardian, the form is returned to the researcher via the method specified in the study information packet (email, postal mail, or fax).
    - When this form is obtained from the participant's parent/guardian, an email link is then sent to the minor participant, containing a link to the actual survey and a password. The participant would follow the link, type in the password, give their electronic assent to participating, and then complete the survey.

E. <u>Examples of Research Studies</u> with suggested IRB decisions.

Note: IRB's have the prerogative to make more conservative decisions.

Student researcher wants to compare career choices between 10th, 11th, and 12th graders.

- *Minimal risk study*: Parental permission not required if data are collected anonymously and if participants are informed of voluntary nature and right to withdraw at any time.

Student wants to compare the amount of television and type of television shows viewed by boys and girls.

- *Minimal risk study*: Parental permission not required if data are collected anonymously and if participants informed of voluntary nature and right to withdraw at any time.

Student researcher wants to examine the relationship between favorite restaurant and weight in $9^{th} - 12^{th}$ graders.

- *More than minimal risk study*: Parental permission required because of emotional risks and impact on self esteem associated with a student reporting on his/her weight. Even with parental permission, procedures for anonymous data collection should be used. Care should be taken to ensure that the student researcher is not able to link data with a particular participant.

Correlate television viewing with mood

- *Potentially more than minimal risk study*: Parental permission may be required depending on the nature of questions regarding mood. The IRB would want to consider how to handle participant reports of depressed or anxious mood. The IRB would also consider whether completing a questionnaire asking questions about mood is detrimental to participants who might be prone to depression? If so, parental permission would be required. The IRB might also require a school psychologist or counselor to be present to respond to any negative reactions by participants. Participants would then be told that a counselor is available to help participants deal with any negative reactions to the study.

Student researcher wants to investigate the relationship between SAT scores and GPA through peer's self report.

- *Minimal risk study*: Parental permission not required if data are collected anonymously and participants are informed that their participation is voluntary and that they can withdraw at any time.

A student wants to show his classmates an optical illusion graphic and compare the responses of boys and girls.

- *Minimal risk study*: The IRB would want to consider the nature of the optical illusion. Would anyone find it offensive? If not and the data are collected anonymously, parental permission could be waived.

  The student researcher must provide information to the research participants about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.

Do students do better memorizing words while listening to Mozart or rock music?

- *Potentially more than minimal risk study*: The IRB would first want to know exactly what music was to be used. What if the rock music had profanity? Who determines the definition of profanity - the most conservative parent?

  If the IRB determines that the music might be offensive (even slightly) to someone, parental permission should be required. The consent form should describe the music to be presented and give parents the opportunity to hear the music if he or she requests.
  If the IRB determines that the music would not be offensive to anyone and the data are collected anonymously, they may waive the requirement of documentation of informed consent. However, the student researcher must provide information to the research participants about what they will be asked to do, the voluntary nature of participation and their right to withdraw at any time.

Do students who have math class in the morning do better on a test of "simple" math problems than those who have math class in the afternoon?

- *Potentially more than minimal risk study*: The IRB must determine the stress level associated with a "simple" math test. The committee might consult with both math teachers regarding the level of stress associated with the test for all students. If math teachers and IRB are comfortable with the "simple" math test not resulting in stress, the data are collected anonymously and the potential participants are not at risk for negative feelings related to the findings, the IRB could waive need for documentation of parental permission. However, some IRBs may require documentation of parental permission in this situation.
  The student researcher must develop recruiting procedures that highlight that participation in the study is voluntary and that students can withdrawal from the study at any time. Efforts must also be taken to ensure that students that do not want to participate must be able to decline participation inconspicuously.

Do children do better on a spelling test after listening to a certain type of music?

- *Minimal risk*: The IRB should consider potential risks associated with whether some might find the music "offensive," or whether there is stress associated with taking a spelling test. Are there privacy and confidentiality issues?

  If the music was deemed to be innocuous, parental permission could be waived.

- *More than minimal risk*: The IRB, school principal or teacher should require parental permission due to any reservations they have about the impact of the project on the participants or parents' reaction to their child being part of a research project.

Student researcher wants to know how fast boys and girls can run upstairs.

- *More than minimal risk*: Documented parental informed consent required due to risk of injury. IRB might require safety precautions (e.g., a school nurse must be present, limit amount of stairs to 1 flight)

Student researcher goes to the swim practice and times the swimmers as they are engaged in their regular swim practice (supervised by an adult coach)

- *Minimal risk*: Student researcher is only observing. IRB may waive the need for parental permission because the swimmers are not being asked to do anything by the student researcher.

Student researcher asks members of the swim team to participate in her study in which they have to swim 2 laps. This occurs after swim practice or on a day in which there is not practice

- *Potentially more than minimal risk*: two possible options for IRB: 1) Require parental informed consent and require that a lifeguard present , 2) Instead of parental permission the swim coach gives the OK that swim team members are capable and the coach and/or lifeguard are present. In either case, the research participant must be informed directly that participation is completely voluntary and that he/she is free to stop participating in the project at any time.

Student researcher wants to know if listening to rock music affects driving ability. He plans to test driving ability in the school parking lot with students driving their own cars around cones.

- *More than minimal risk*: Requires documentation of parental permission for participants and multiple safety precautions. The IRB may also require documentation that the school principal is aware of and approved the study. Many IRB's would not allow this project to be conducted because of school liability issues.

Student researcher wants to know if listening to rock music affects driving ability. He plans to test driving ability with a video game.

- *No more than minimal risk*: The IRB should listen to the proposed music and consider whether any parents would be take offense to the music. IRB would also want to consider the nature of the video

game. IRB action may depend on the age of potential participants (e.g., 6th graders vs. 12th graders). Different IRBs may come to different conclusions or different courses of action. IRBs that decide to waive parental permission in such situations may wish to document that the study was reviewed and approved by a principal or administrator.

Additional Resources

http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html
Code of federal regulations for the protection of human participants

http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
A guide produced by Office for Protection of Research Risk (OPRR) of the US Department of Health and Human Services (HHS). This resource can be used by IRBs to help them with their review. Includes an extensive appendix of additional resources.

http://www.nihtraining.com/ohsrsite/IRBCBT/intro.html
A computer based training course for new IRB members.

http://www.fda.gov/oc/ohrt/irbs/informedconsent.html
A guide to informed consent from the Food and Drug Administration

Human Participants Form (4)

Required for all research involving human participants not at a Regulated Research Institution. If at a Regulated Research Institution, use institutional approval forms for documentation of prior review and approval.
(IRB approval required before experimentation.)

Student's Name(s) | Title of Project

Adult Sponsor Contact | Phone/Email

Must be completed by Student Researcher(s) in collaboration with the Adult Sponsor/Designated Supervisor/Qualified Scientist:

1. ☐ I have submitted my Research Plan which addresses ALL areas indicated in the Human Participants Section of the Research Plan Instructions.
2. ☐ I have attached any surveys or questionnaires I will be using in my project or other documents provided to human participants.
   ☐ Any published instrument(s) used was /were legally obtained.
3. ☐ I have attached an informed consent that I would use if required by the IRB.
4. ☐ Yes ☐ No Are you working with a Qualified Scientist? If yes, attach the Qualified Scientist Form 2.

Must be completed by Institutional Review Board (IRB) after review of the research plan. All questions must be answered for the approval to be valid. (If not approved, return paperwork to the student with instructions for modifications.)

☐ Approved with Full Committee Review (3 signatures required) and the following conditions:
(All 5 must be answered)

1. Risk Level (check one) : ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Written Minor Assent required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
4. Written Parental Permission required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Informed Consent required for participants 18 years or older:
   ☐ Yes ☐ No ☐ Not applicable (No participants 18 yrs or older in this study)

☐ Approved with Expedited Review (1 signature required). Study involves either of the following:

- ☐ Human participants will only provide feedback on project design/invention/etc., no personal data will be collected and there are no health or safety hazards.
- ☐ Student is the only subject of the research and no more than minimal risk is involved.

IRB SIGNATURES (All 3 signatures required unless expedited review checked above) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project, that the checkboxes above have been completed to indicate the IRB determination and that I agree with the decisions above.

Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)

Printed Name | Degree/Professional License

Signature | Date of Approval (Must be prior to experimentation.)

Educator

Printed Name | Degree

Signature | Date of Approval (Must be prior to experimentation.)

School Administrator

Printed Name | Degree

Signature | Date of Approval (Must be prior to experimentation.)

Human Informed Consent Form

Instructions to the Student Researcher(s): An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist. This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form or may copy ALL elements of it into a new document.

If the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.

Student Researcher(s): _____

Title of Project: _____

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

Purpose of the project:

If you participate, you will be asked to:

Time required for participation:

Potential Risks of Study:

Benefits:

How confidentiality will be maintained:

If you have any questions about this study, feel free to contact:

Adult Sponsor/QS/DS: _____ Phone/email: _____

Voluntary Participation:
Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent or Minor Assent Date Reviewed & Signed: _____

_____ _____

Printed Name of Research Participant: Signature:

Parental/Guardian Permission (if applicable) Date Reviewed & Signed: _____

_____ _____

Parent/Guardian Printed Name: Signature:

Vertebrate Animal Form (5A)

Required for all research involving vertebrate animals that is conducted in a school/home/field research site. (SRC approval required before experimentation.)

Student's Name(s)_____

Title of Project _____

To be completed by Student Researcher:

1. Common name (or Genus, species) and number of animals used.

2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc.

3. What will happen to the animals after experimentation?

4. Attach a copy of wildlife licenses or approval forms, as applicable

5. The Intel ISEF Vertebrate Animal Rules require that any death, illness or unexpected weight loss be investigated and documented by a letter from the qualified scientist, designated supervisor or a veterinarian. If applicable, attach this letter with this form when submitting your paperwork to the SRC prior to competition.

To be completed by Local or Affiliate Fair Scientific Review Committee (SRC) BEFORE experimentation

Level of Supervision Required for agricultural, behavioral or nutritional studies:

☐ Designated Supervisor REQUIRED. Please have applicable person sign below.

☐ Veterinarian and Designated Supervisor REQUIRED. Please have applicable persons sign below.

☐ Veterinarian, Designated Supervisor and Qualified Scientist REQUIRED. Please have applicable persons sign below and have the Qualified Scientist complete Form (2).

The SRC has carefully reviewed this study and finds it is an appropriate study that may be conducted in a non-regulated research site.
Local or Affiliate Fair SRC Pre-Approval Signature:

SRC Chair Printed Name	Signature	Date of Approval (must be prior to experimentation) (mm/dd/yy)

To be completed by Veterinarian:

☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation.

☐ I certify that I have approved the use and dosages of prescription drugs and/or nutritional supplements.

☐ I certify that I will provide veterinary medical and nursing care in case of illness or emergency.

Printed Name	Email/Phone
Signature	Date of Approval

To be completed by Designated Supervisor or Qualified Scientist when applicable:

☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation and I accept primary responsibility for the care and handling of the animals in this project.

☐ I certify that I will directly supervise the experiment.

Printed Name	Email/Phone
Signature	Date of Approval

Vertebrate Animal Form (5B)

Required for all research involving vertebrate animals that is conducted in at a Regulated Research Institution. (IACUC approval required before experimentation.)

Student's Name(s) _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

1. Species of animals used: _____ Number of animals used: _____

2. Describe, in detail, the role of the student in this project: animal procedures and related equipment that were involved, oversight provided and safety precautions employed. (Attach extra pages if necessary.)

3. Was there any weight loss or death of any animal? If yes, attach a letter obtained from the qualified scientist, designated supervisor or a veterinarian documenting the situation and the results of the investigation.

4. Does the student's project also involve the use of tissues?
   - ☐ No
   - ☐ Yes (Forms 6A and 6B also required)

5. What laboratory training, including dates, was provided to the student?

6. Attach a copy of the Regulated Research Institution IACUC Approval. A letter from the Qualified Scientist or Principal Investigator is not sufficient**.**

Qualified Scientist/Principal Investigator	
Printed Name	
Signature	Date

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, 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 approval required before experimentation.

Student's Name(s)_____

Title of Project _____

To be completed by Student Researcher(s) in collaboration with Qualified Scientist/Designated Supervisor:

(All questions are applicable and must be answered; additional page(s) may be attached.)

1. Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism.

2. Describe the site of experimentation including the level of biological containment.

3. Describe the procedures that will be used to minimize risk. (personal protective equip., hood type, etc.)

4. What final biosafety level do you recommend for this project given the risk assessment you conducted?

5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

To be completed by Qualified Scientist or Designated Supervisor

1. What training will the student receive for this project?
2. Do you concur with the biosafety information and recommendation provided by the student researcher above?

   ☐ Yes ☐ No If no, please explain.
3. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable)

QS/DS Printed Name	Signature	Date of Signature (mm/dd/yy)

To be completed by Local or Affiliate Fair SRC: (Check all that apply.)

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-1 study, which must be conducted at a BSL-1 or above laboratory.
Date of SRC approval (prior to experimentation) _____

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-2 study, which must be conducted at a BSL-2 or above laboratory.
Date of SRC approval (prior to experimentation) _____

☐ This project was conducted at a Research Institution and was reviewed and approved by the appropriate institutional board (e.g. IACUC, IBC) before experimentation at a BSL-1 or BSL-2 laboratory and complies with the Intel ISEF rules. The required institutional forms are attached.
Date of SRC approval (after experimentation) _____

☐ The Research Institution where this study was conducted does not require approval for this type of study. The student has received proper training and the project complies with Intel ISEF rules. Attached is institutional documentation certifying the above.

Date of SRC approval

SRC Chair's Printed Name	Signature

Human and Vertebrate Animal Tissue Form (6B)

Required for research involving fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids. If the research involves living organisms please ensure that the proper human or animal forms are completed. All projects using any tissue listed above must also complete Form 6A.

Student's Name(s)_____

Title of Project _____

To be completed by Student Researcher(s):

1. What vertebrate animal tissue will be used in this study? Check all that apply.
   - ☐ Fresh or frozen tissue sample
   - ☐ Fresh organ or other body part
   - ☐ Blood
   - ☐ Body fluids
   - ☐ Primary cell/tissue cultures
   - ☐ Human or other primate established cell lines

2. Where will the above tissue(s) be obtained. If using an established cell line include source and catalog number.

3. If the tissue will be obtained from a vertebrate animal study conducted at a research institution attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.

To be completed by the Qualified Scientist or Designated Supervisor:

☐ I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.

AND/OR

☐ I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

Printed Name	Signature	Date of Approval (Must be prior to experimentation.)

Title	Phone/Email

Institution

Continuation/Research Progression Projects Form (7)

Required for projects that are a continuation/progression in the same field of study as a previous project.
This form must be accompanied by the previous year's abstract and Research Plan.

Student's Name(s)_____

To be completed by Student Researcher:

List all components of the current project that make it new and different from previous research. The information must be on the form; use an additional form for 2011–2012 and earlier projects.

Components	Current Research Project	Previous Research Project
1. Title		2013–2014 2012–2013
2. Change in goal/purpose/ objective		2013–2014 2012–2013
3. Changes in methodology		2013–2014 2012–2013
4. Variables studied		2013–2014 2012–2013
5. Additional changes		2013–2014 2012–2013

Attached are:

☐ 2013–2014 Abstract and Research Plan ☐ 2012–2013 Abstract

I hereby certify that the above information is correct and that the current year Abstract & Certification and project display board properly reflect work done only in the current year.

Student's Printed Name(s) Signature Date of Signature