# Intel International Science and Engineering Fair



# International Rules and Guidelines 2016

### International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs 2015–2016

# **Table of Contents For ALL Projects**

lr	ntel ISEF Ethics Statement	3
	ntel ISEF Eligibility/Limitations	
Ir	ntel ISEF Requirements	3
C	Continuation/Research Progression of Projects	4
Т	Team Projects	4
	es and Responsibilities of Students and Adults	
	. The Student Researcher(s)	
	2. The Adult Sponsor	
	3. The Qualified Scientist	
	I. The Designated Supervisor	
	5. The Institutional Review Board (IRB)	
	5. Affiliated Fair Scientific Review Committees (SRC)	
	7. Other Review Committees	
8	3. The Intel ISEF Scientific Review Committee	/
Hum	nan Participants Rules	•
	L. Exempt Studies	
	2. Rules	
3	3. Human Participant Risk Assessment	10
Vort	tebrate Animals Rules	
_	l. Rules for ALL Vertebrate Animal Studies	11
	2. Additional Rules for Projects Conducted at School/Home/Field	
	B. Additional Rules for Projects Conducted in a Regulated Research Institution	
J.	7. Additional Nates for Frojects conducted in a Regulated Research institution	13
Pote	entially Hazardous Biological Agents Rules	
R	Rules for ALL Projects Involving Potentially Hazardous Biological Agents	14
	Additional Rules for Projects Involving Unknown Microorganisms	
	Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies	
	Additional Rules for Projects Involving Tissues and Body Fluids Including Blood and Blood Products	
Haza	ardous Chemicals, Activities or Devices Rules	18
C		20
Soui	rces of Information	20
וטsp	olay and Safety Regulations	23
Info	rmation on Required Abstract	26
Cate	egories & Sub-Categories	27
Forn	ns	28
		20

student.societyforscience.org/international-rules-pre-college-science-research

The International Rules and Guidelines for Science Fairs is available at <u>student.societyforscience.org/intel-isef</u> in multiple formats. Familiarity with the rules is critical for students, parents, teachers, mentors, fair directors and local and affiliated fair scientific review committees (SRC) and institutional review boards (IRB).

- International Rules and Guidelines The full text of the International Rules and forms in html and as a downloadable pdf.
- The Intel ISEF Rules Wizard —An interactive tool which asks questions about your intended project and provides a list of forms required.
- Common SRC Problems Frequent problems that emerge during Scientific Review Committee review for qualification at the Intel ISEF. Read these to learn what NOT to do.

These Rules are applicable for:

### The Intel International Science and Engineering Fair 2016 Phoenix, Arizona, USA, May 9–14, 2016

The purpose of these rules is to:

- protect the rights and welfare of the student researcher
- protect the rights and welfare of human participants
- protect the health and welfare of vertebrate animal subjects
- ensure adherence to federal regulations
- · ensure use of safe laboratory practices
- protect the environment
- · determine eligibility for competition in the Intel ISEF

For pre-review and approval of your project, find your fair at http://apps2.societyforscience.org/ssp-affiliate-fair/

For Intel ISEF questions, contact:
Society for Science & the Public
Science Education Programs
1719 N Street, NW, Washington, DC 20036
office: 202-785-2255, fax: 202-785-1243
email: sciedu@societyforscience.org

For rules questions, contact the Intel ISEF Scientific Review Committee: SRC@societyforscience.org

#### ALL PROJECTS

#### **Ethics Statement**

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes plagiarism, forgery, use or presentation of other researcher's work as one's own and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and the Intel ISEF. Society for Science & the Public reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

#### Eligibility/Limitations

- Each Intel ISEF-affiliated fair may send the number of projects provided by their affiliation agreement.
- 2. A student must be selected by an Intel ISEF-affiliated fair, and:
  - a. be in grades 9-12 or equivalent;
  - not have reached age 20 on or before May 1 preceding the Intel ISEF.
- 3. Each student is only allowed to enter one project. That project may include no more than 12 months of continuous research and may not include research performed before January 2015.
- Team projects must have no more than three members. Teams competing at Intel ISEF must be composed of members who all meet Intel ISEF eligibility.
- 5. Students may compete in only one Intel ISEF affiliated fair, except when proceeding to a state/national fair affiliated with the Intel ISEF from an affiliated regional fair.
- 6. Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.
- 7. All sciences (physical, life, social) are represented at the Intel ISEF. Review a complete list of categories and sub-categories with definitions.
- 8. A research project may be a part of a larger study performed by professional scientists, but the project presented by the student must be only their own portion of the complete study.

#### Requirements

#### General

- All domestic and international students competing in an Intel ISEF-affiliated fair must adhere to all rules as set forth in this document.
- 2. All projects must adhere to the Ethics Statement above.
- 3. It is the responsibility of the student and the Adult Sponsor to evaluate the study to determine if the research will require forms and/or review and approval prior to experimentation, especially projects that include human participants, vertebrate animals, or potentially hazardous biological agents.
- 4. Projects must adhere to local, state and U.S. Federal laws, regulations and permitting conditions. In addition, projects conducted outside the U.S. must also adhere to the laws of the country and jurisdiction in which the project was performed.

- The use of non-animal research methods and alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project.
- 6. Introduction or disposal of non-native and/or invasive species (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. It is recommended that students reference their local, state or national regulations and quarantine lists.
- 7. Intel ISEF exhibits must adhere to Intel ISEF <u>display and safety</u> requirements.
- 8. All projects must adhere to the requirements of the affiliated fair(s) in which it competes to qualify for participation in the Intel ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.

#### **Approval and Documentation**

- 9. Before experimentation begins, a local or regional Institutional Review Board (IRB) or Scientific Review Committee (SRC) associated with the Intel ISEF-affiliated fair must review and approve most projects involving human participants, vertebrate animals, and potentially hazardous biological agents. Note: If a project involves the testing of a student designed invention, prototype or concept by a human, an IRB review and approval may be required prior to experimentation. See Human Participants Rules for details.
- 10. Every student must complete the <u>Student Checklist (1A)</u>, a <u>Research Plan</u> and <u>Approval Form (1B)</u> and review the project with the Adult Sponsor in coordination with completion by the Adult Sponsor of the <u>Checklist for Adult Sponsor (1)</u>.
- A Qualified Scientist is required for all studies involving Biosafety Lab-2 (BSL-2) potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.
- After initial IRB/SRC approval (if required), any proposed changes in the <u>Student Checklist (1A)</u> and Research Plan must be re-approved before laboratory experimentation/data collection resumes.
- 13. Projects which are continuations of a previous year's work and which require IRB/SRC approval must undergo the review process with the current year proposal prior to experimentation/data collection for the current year.
- 14. Any continuing project must document that the additional research is new and different. (Continuation Projects Form (7)).
- 15. If work was conducted in a regulated research institution, industrial setting or any work site other than home, school or field at any time during the current Intel ISEF project year, the Regulated Research Institutional/Industrial Setting Form (1C) must be completed and displayed at the project booth.

- 16. After experimentation, each student or team must submit a (maximum) 250-word, one-page abstract which summarizes the current year's work. The abstract must describe research conducted by the student, not by the supervising adult(s).
- 17. A project data book and research paper are not required, but are strongly recommended for judging purposes. Regional or local fairs may require a project data book and/or a research paper.
- 18. All signed forms, certifications, and permits must be available for review by all regional, state, national and international affiliated fair SRCs in which the student(s) participate. This review must occur after experimentation and before competition.

#### **Continuation/Research Progression of Projects**

- As in the professional world, research projects may build on work performed previously. A valid continuation project is a sound scientific endeavor. Students will be judged only on laboratory experiment/data collection performed over 12 continuous months beginning no earlier than January 2015 and ending May 2016.
- 2. Any project based on the student's prior research could be considered a continuation/research progression project. These projects must document that the additional research is a substantive expansion from prior work (e.g. testing a new variable or new line of investigation). Repetition of previous experimentation with the same methodology and research question, even with an increased sample size, is an example of an unacceptable continuation.
- The display board and abstract must reflect the current year's work only. The project title displayed in the finalist's booth may mention years (for example, "Year Two of an Ongoing Study"). Supporting data books (not research papers) from previous related research may be exhibited if properly labeled as such.
- 4. Longitudinal studies are permitted as an acceptable continuation under the following conditions:
  - a. The study is a multi-year study testing or documenting the same variables in which time is a critical variable. (Examples: Effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time.)
  - b. Each consecutive year must demonstrate time-based change.
  - c. The display board must be based on collective past conclusionary data and its comparison to the current year data set. No raw data from previous years may be displayed.
- 5. All projects must be reviewed and approved each year and forms must be completed for the new year.
- 6. NOTE: For competition in the Intel ISEF, the <u>Continuation/Research Progression Project Form (7)</u> is required for projects in the same field of study as a previous project. This form must be displayed at the project booth. Retention of all prior years' paperwork is required and must be presented to the Intel ISEF SRC upon request.

#### **Team Projects**

- 1. Team projects compete and are judged in the scientific category of their research at the Intel ISEF. All team members must meet the eligibility requirements for Intel ISEF.
- 2. Teams must have no more than three members. A team with members from different geographic regions may compete at an affiliated fair of one of its members, but not at multiple fairs. However, each affiliated fair holds the authority to determine whether teams with members outside of a fair's geographic territory are eligible to compete, understanding that if the team wins the right to attend Intel ISEF, all team members' expenses must be supported by the fair.
  - a. Team membership cannot be changed during a given research year unless there are extenuating circumstances and the local SRC reviews and approves the change, including converting a team project to an individual project or vice versa. Such conversions must address rationale for the change and include a clear delineation between research preceding the change and that which will follow. A memorandum documenting this review and approval should be attached to Form 1A.
  - Once a project has competed in a science fair at any level, team membership cannot change and the project cannot be converted from an individual project to a team project or vice versa.
  - c. In a future year, any project may be converted from an individual to a team project, from a team to an individual project and/or have a change in team membership.
- 3. Each team is encouraged to appoint a team leader to coordinate the work and act as spokesperson. However, each member of the team should be able to serve as spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members and will be evaluated using similar rules and judging criteria as individual projects.
- Each team member must submit an Approval Form (1B). Team members must jointly submit the Checklist for Adult Sponsor (1), one abstract, a Student Checklist (1A), a Research Plan and other required forms.
- 5. Full names of all team members must appear on the abstract and forms.
  - Contact the <u>Science Education Programs</u> or the <u>Scientific</u> <u>Review Committee</u> with questions.

# Roles and Responsibilities of Students and Adults

#### The Student Researcher(s)

The student researcher is responsible for all aspects of the research project including enlisting the aid of any required supervisory adults (Adult Sponsor, Qualified Scientist, etc.), obtaining necessary approvals (SRC, IRB, etc.), following the Rules & Guidelines of the Intel ISEF, and performing the experimentation, engineering, data analysis, etc.

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and the Intel ISEF. Society for Science & the Public reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

#### The Adult Sponsor

An Adult Sponsor may be a teacher, parent, professor, and/or other professional scientist in whose lab the student is working. This individual must have a solid background in science and should have close contact with the student during the course of the project.

The Adult Sponsor is responsible for working with the student to evaluate any possible risks involved in order to ensure the health and safety of the student conducting the research and the humans and/or animals involved in the study. The Adult Sponsor must review the student's <u>Student Checklist (1A) and Research Plan</u> to certify that: a) experimentation is within local, state, and Federal laws and Intel ISEF rules; b) forms are completed by other required adults; and c) criteria for the Qualified Scientist adhere to those set forth below.

The Adult Sponsor must be familiar with the regulations that govern potentially dangerous research as they apply to a specific student project. These may include chemical and equipment usage, experimental techniques, research involving human and/or vertebrate animals, and cell cultures, microorganisms, or animal tissues. Some experiments involve procedures or materials that are regulated by state, federal or non-U.S. national laws. If not thoroughly familiar with the regulations, the Adult Sponsor should help the student enlist the aid of a Qualified Scientist.

The Adult Sponsor is responsible for ensuring the student's research is eligible for entry in the Intel ISEF.

#### The Qualified Scientist

A Qualified Scientist should have earned a doctoral/professional degree in a scientific discipline that relates to the student's area of research. Alternatively, the SRC may consider an individual with extensive experience and expertise in the student's area of research as a Qualified Scientist. The Qualified Scientist must be thoroughly familiar with local, state, and federal regulations that govern the student's area of research.

The Qualified Scientist and the Adult Sponsor may be the same person, if that person is qualified as described above. A student may work with a Qualified Scientist in a city, state or country that is not where the student resides. In this case, the student must work locally with a Designated Supervisor (see below) who has been trained in the techniques to be applied by the student.

#### The Designated Supervisor

The Designated Supervisor is an adult who is directly responsible for overseeing student experimentation. The Designated Supervisor need not have an advanced degree, but must be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Adult Sponsor may act as the Designated Supervisor.

If a student is experimenting with live vertebrates and the animals are in a situation where their behavior or habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

#### **Review Committees**

#### The Institutional Review Board (IRB)

An Institutional Review Board (IRB), is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement. Therefore, it is advisable that an IRB be established at the school level to evaluate human research projects. If necessary, the local or Intel ISEF-affiliated SRC can serve as an IRB as long as it has the required membership. An IRB must:

- 1. consist of a minimum of three members
- 2. include an educator
- include a school administrator (preferably principal or vice principal),
- 4. include an individual who is knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study. This may be a medical doctor, nurse practitioner, physician's assistant, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor.

**Additional Expertise:** If an expert is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of that expert.

No Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Designated Supervisor who oversees the project may serve on the IRB reviewing that project. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

Most projects require review by the full three member IRB.

IRBs exist at federally Regulated Research Institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research participants are incarcerated. The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor and the local IRB are responsible for ensuring that the project is appropriate for a pre-college student and adheres to the Intel ISEF rules.

An IRB is responsible for assessing risk and documenting the determination of risk level on <u>Human Participant Form 4</u>. However, in reviewing projects just prior to a fair, if the SRC serving at that level of competition judges an IRB's decision as inappropriate, thereby placing human participants in jeopardy, they may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with the Intel ISEF SRC in questionable cases.

#### **IRB Waiver of Written Informed Consent**

- The IRB may waive the requirement for documentation of written informed consent/assent/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
  - 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, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that 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.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

#### **Expedited Review**

An expedited review by one member of the IRB may be conducted for the following types of projects. This person must have the expertise necessary to make such a decision and/or receive advisement from the appropriate expert.

- Projects that involve the testing by anyone other than the student researcher of a student-designed invention or prototype where the feedback received is a direct reference to the design, where personal data is not collected, and where the testing does not pose a health or safety hazard.
- 2. Projects in which the student is the subject of their research and the research does not involve more than minimal risk.

#### The Affiliated Fair Scientific Review Committee

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, certifications, research plans and exhibits for compliance with the rules, applicable laws and regulations at each level of science fair competition. Affiliated Fairs may authorize local SRCs to serve in this prior review capacity. The operation and composition of the local and Affiliated Fair SRCs must fully comply with the International Rules. Directions for obtaining preapproval are available from the affiliated fair. A list of fairs is at: <a href="https://apps2.societyforscience.org/ssp-affiliate-fair/">https://apps2.societyforscience.org/ssp-affiliate-fair/</a>.

Most proposed research projects involving vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved BEFORE experimentation. Local or regional SRC prior review is not required for human studies previously reviewed and approved by a properly constituted IRB.

ALL projects, including those previously reviewed and approved by an IRB must be reviewed and approved by the SRC after experimentation and before competition in an Intel ISEF Affiliated Fair. Projects which were conducted at a Regulated Research Institution (not home, high school or field) and which were reviewed and approved by the proper institutional board before experimentation, must also be approved by the Intel ISEF Affiliated Fair SRC.

An Affiliated Fair SRC must:

- 1. include a minimum of three persons
- 2. include a biomedical scientist with an earned doctoral degree
- 3. include an educator
- 4. include at least one additional member

Additional expertise: many project evaluations require additional expertise (e.g., on biosafety and/or of human risk groups.) If the SRC needs an expert as one of its members and one is not in the immediate area, all documented contact with an external expert must be submitted. If animal research is involved, at least one member must be familiar with proper animal care procedures. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied.

No Adult Sponsor, parent or other relative of the student(s), the Qualified Scientist, or the Designated Supervisor who oversees the project may serve on the SRC reviewing that project. Additional members are recommended to diversify and to increase the expertise of the committee.

A Scientific Review Committee (SRC) examines projects for the following:

- 1. evidence of literature search and appropriate attribution
- 2. evidence of proper supervision
- 3. use of accepted and appropriate research techniques
- completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (where required)
- 5. evidence of search for alternatives to animal use
- 6. humane treatment of animals
- compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents
- 8. documentation of substantial expansion for continuation projects
- 9. compliance with the ISEF ethics statement

Sources of Information are available as a separate section at the end of the document.

#### **Combined SRC/IRB Committee**

A combined committee is allowed as long as the membership meets both the SRC and IRB requirements listed above.

#### Regulated Research Institutions/Industrial Settings Review Committees

Regulated Research Institution: A Regulated Research Institution within the U.S. is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For project conducted outside of the United States, a Regulated Research Institution would be a comparable research institution that adheres to country laws governing the care and use of vertebrate animals.

Certain areas of research conducted in a regulated research institution or an industrial setting require review and approval by federally mandated committees that have been established at that institution. These committees include:

- Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
- 2. Institutional Review Board (IRB); Human Subjects Participant Program (HSPP)
- 3. Institutional Biosafety Committee (IBC)
- 4. Embryonic Stem Cell Research Oversight Committee (ESCRO)
- 5. Safety Review Committee

#### The ISEF Scientific Review Committee (Intel ISEF SRC)

All projects are reviewed by the Intel ISEF Scientific Review Committee prior to competition. The Intel ISEF SRC is the final arbiter of the qualification of students to participate in the Intel ISEF. Before the fair, committee members review research plans and all required forms to confirm that applicable Intel ISEF rules have been followed. The Intel ISEF SRC may request additional information from students prior to the Intel ISEF or may interview potential Intel ISEF participants at the fair to ensure that they qualify to compete.

The Intel ISEF SRC, like an Affiliated Fair SRC, is made up of adults knowledgeable about research regulations. In addition to the review of all projects at the Intel ISEF, committee members answer questions about the rules throughout the year from students and teachers. The ISEF SRC can be contacted at SRC@societyforscience.org.

Mrs. Christine Miller, Chair

Ms. Susan Appel

Mr. Henry Disston

Dr. Jennifer Green

Dr. Paula Johnson

Mrs. Evelyn Montalvo

Dr. Jason Shuffitt

### **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 preapproval or additional human participant forms. Exempt projects for the Intel ISEF and affiliated fairs are:

- 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.)
- 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.
- 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
  - 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
  - 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:

- 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)
- Studies in which the researcher is the subject of the research
- Testing of student designed invention or concept by human participants other than student researcher
- 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
  - 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)
  - involve the recording of personally identifiable information
- 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

may be verbal or must be written depending on the level of risk and the type of study, and will determine if a Qualified Scientist is required to oversee the project. See Risk Assessment below and the Risk Assessment Guide for further explanation of informed consent.

- a. Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
- Participants must be informed that their participation is voluntary (i.e., they may participate or decline to participate, with no adverse consequences of nonparticipation or aborted participation) and that they are free to stop participating at any time.
- Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature.
- d. When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
- 7. A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a medical professional. This medical professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medication and/or performing invasive medical procedures on human participants. The IRB must also confirm that the student is not violating the medical practice act of the state or country in which he/she is conducting the research.
- 8. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).
- 9. All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.
- 10. Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in a) collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the Online Studies Section of the Risk Assessment Guide.
- 11. After experimentation and before Intel ISEF competition, the Intel ISEF SRC reviews and approves previously-approved projects to ensure that students followed the approved Research Plan and all of the Intel ISEF rules.

- 12. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - b. Human Participants Form (4) with applicable consents and survey(s)
  - Regulated Research Institution Form (1C), when applicable
  - d. Qualified Scientist Form (2), when applicable

### **Human Participant Risk Assessment**

Use this information to help determine the level of risk involved in a study involving human participants.

Projects involving no more than minimal risk and those with more than minimal risk are allowed under the following guidelines.

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.

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. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

#### 1. Examples of Greater than Minimal Physical Risk

- a. Exercise other than ordinarily encountered in everyday life
- b. Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
- c. Exposure to any potentially hazardous material.

#### 2. Examples of Greater than Minimal Psychological Risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing video images.

#### 3. Privacy Concerns

- a. The student researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.
- b. Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

#### 4. Risk Groups

If the research study includes participants from any of the following groups, the IRB and student research must consider whether the nature of the study requires special protections or accommodations:

- a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
- b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA).

See the online Risk Assessment Guide and Online Survey Consent Procedures for more detailed information on risk assessment.

#### **Vertebrate Animals Rules**

#### Rules involving vertebrate animals

The following rules were developed to help pre-college student researchers adhere to the federal regulations governing professional scientists and to protect the welfare of both animal subjects and the student researcher. When students conduct research with animal subjects, health and well-being is of high priority.

SSP strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals.

All projects involving vertebrate animals must adhere to the rules below AND to either Section A or Section B rules, depending on the nature of the study and the research site.

A project is considered a tissue study and not a vertebrate animal study if tissue is obtained from an animal that was euthanized for a purpose other than the student's project. (Documentation is required of the IACUC approval for the original animal study from which tissues are obtained.) In tissue studies, a student may observe the vertebrate study, but may not manipulate or have any direct involvement in the vertebrate animal experimental procedures.

#### **Rules for ALL Vertebrate Animal Studies**

- The use of vertebrate animals in science projects is allowable under the conditions and rules in the following sections.
   Vertebrate animals, as covered by these rules, are defined as:
  - a. Live, nonhuman vertebrate mammalian embryos or fetuses
  - b. Tadpoles
  - Bird and reptile eggs within three days (72 hours) of hatching
  - d. 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.

- Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. The guiding principles for the use of animals in research include the following "Four Rs":
  - **a. Replace** vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible.
  - Reduce the number of animals without compromising statistical validity.
  - **c. Refine** the experimental protocol to minimize pain or distress to the animals.
  - **d. Respect** animals and their contribution to research.
- 3. All vertebrate animal studies must be reviewed and approved before experimentation begins. An Institutional Animal Care and Use Committee, known as an IACUC, is the institutional animal oversight review and approval body for all animal studies at a Regulated Research Institution. The affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any affiliated fair SRC

serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.

- 4. All vertebrate animal studies must have a research plan that includes:
  - a. Justification why animals must be used, including the reasons for the choice of species, the source of animals and the number of animals to be used; description, explanation, or identification of alternatives to animal use that were considered, and the reasons these alternatives were unacceptable; explanation of the potential impact or contribution this research may have on the broad fields of biology or medicine.
  - b. Description of how the animals will be used. Include methods and procedures, such as experimental design and data analysis; description of the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation; identification of the species, strain, sex, age, weight, source and number of animals proposed for use.
- 5. Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:
  - a. There is no interaction with the animals being observed,
  - b. There is no manipulation of the animal environment in any way, and
  - c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.
- Students performing vertebrate animal research must satisfy US federal law as well as local, state, and country laws and regulations of the jurisdiction in which research is performed.
- 7. Research projects which cause more than momentary or slight pain or distress are prohibited. Any illness or unexpected weight loss must be investigated and a veterinarian consulted to receive required medical care. This investigation must be documented by the Qualified Scientist, Designated Supervisor who is qualified to determine the illness or a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.
- 8. No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup.
  - a. Studies that are designed or anticipated to cause vertebrate animal death are prohibited.
  - b. Any death that occurs must be investigated by a veterinarian, the Qualified Scientist or the Designated Supervisor who is qualified to determine if the cause of death was incidental or due to the experimental procedures. The project must be suspended until the cause is determined and then the results must be documented in writing.
  - c. If death was the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.

- 10. Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:
  - a. 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.
  - Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
  - c. Studies of pain.
  - d. Predator/vertebrate prey experiments.
- 11. Justification is required for an experimental design that involves food or fluid restriction and must be appropriate to the species. If the restriction exceeds 18 hours, the project must be reviewed and approved by an IACUC and conducted at a Regulated Research Institution.
- 12. Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. All appropriate methods and precautions must be used to decrease stress. Fish may be obtained from the wild only if the researcher releases the fish unharmed, has the proper license, and adheres to state, local and national fishing laws and regulations. The use of electrofishing is permissible only if conducted by a trained supervisor; students are prohibited from performing electrofishing.
- A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.
- 14. After initial SRC approval, a student with any proposed changes in the Research Plan of the project must repeat the approval process before laboratory experimentation/data collection resumes.

#### A. Additional Rules for Projects Conducted at School/ Home/Field

Vertebrate animal studies may be conducted at a home, school, farm, ranch, in the field, etc. This includes:

- a. Studies of animals in their natural environment.
- b. Studies of animals in zoological parks.
- Studies of livestock that use standard agricultural practices.
- d. Studies of fish that use standard aquaculture practices

These projects must be reviewed and approved by an SRC in which one member is either a veterinarian and/or an animal care provider/expert with training and/or experience in the species being studied.

- These projects must adhere to BOTH of the following guidelines:
  - a. The research involves only agricultural, behavioral, observational or supplemental nutritional studies on animals.

#### AND

b. The research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

- All vertebrate animal studies that do not meet the above guidelines must be conducted in a Regulated Research Institutions. See Section B.
- 2. Animals must be treated kindly and cared for properly. Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species. They must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned frequently. Proper care must be provided at all times, including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and well-being. A Designated Supervisor is required to oversee the daily husbandry of the animals. Any of the following U.S. documents provide further guidance for animal husbandry:
  - Federal Animal Welfare Regulation
  - Guide for the Care and Use of Laboratory Animals
  - Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag-Guide)
  - Quality Assurance Manuals (for the appropriate species)
- 3. The affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research plan and animal husbandry plans is required. This certification is required before experimentation and SRC approval and is documented on Vertebrate Animal Form 5A. A veterinarian must certify experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.
- 4. If an illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian. A student researcher must stop experimentation if there is unexpected weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors. If death is the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- Studies in which livestock or fish are being raised for food using standard agricultural /aquacultural production practices are allowed. The livestock or fish raised may be euthanized by a qualified adult for carcass evaluation.
- The final disposition of the animals must be described on Vertebrate Animal Form 5A. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site.
- 7. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - b. Vertebrate Animal Form (5A)
  - c. Qualified Scientist Form (2), when applicable

### B. Additional Rules for Projects Conducted in a Regulated Research Institution

All studies not meeting the criteria in Section A. but are otherwise permissible under Intel ISEF rules must be conducted in a Regulated Research Institution (RRI). A Regulated Research Institution within the U.S. is defined as a professional research/ teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For project conducted outside of the United States, a Regulated Research Institution would be a comparable research institution that adheres to country laws governing the care and use of vertebrate animals.

Some protocols permitted in a Registered Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

- The Institutional Animal Care and Use Committee (IACUC) or the comparable animal oversight committee must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local and regional SRC must also review the project to certify that the research project complies with Intel ISEF Rules. This local and regional SRC review should occur before experimentation begins, if possible.
- 2. Student researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
- Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.
- 4. Research in nutritional deficiency or research involving substances or drugs of unknown effect is permitted to the point that any clinical sign of distress is noted. In the case that distress is observed, the project must be suspended and measures must be taken to correct the deficiency or drug effect. A project can only be resumed if appropriate steps are taken to correct the causal factors.

- 5. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - b. Regulated Research Institution Form (1C)
  - c. Qualified Scientist Form (2)
  - d. Vertebrate Animal Form (5B)
  - e. PHBA Risk Assessment Form (6A) for all studies involving tissues and body fluids.
  - Human and Vertebrate Animal Tissue Form (6B) for all studies involving tissues and body fluids.

Sources of Information are available as a separate section at the end of the document.

### Potentially Hazardous Biological Agents (PHBA) Rules

Potentially Hazardous Biological Agents Rules for use of microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids.

Research using microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids may involve potentially hazardous biological agents. Students are permitted to do some research projects with potentially hazardous biological agents meeting the conditions and rules described below which were designed to protect students and to ensure adherence to federal and international biosafety regulations and guidelines.

When dealing with potentially hazardous biological agents, it is the responsibility of the student and all of the adults involved in a research project to conduct and document a risk assessment on Form (6A) to define the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The risk assessment determines a biosafety level which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training, and supervision required.

All projects involving microorganisms, recombinant DNA technologies and human or animal fresh/frozen tissues, blood or body fluids must adhere to the rules below AND, depending on the study, to the additional rules in Section A, B or C.

### Rules for ALL Studies with Potentially Hazardous Biological Agents (PHBA)

- The following types of studies are exempt from prior SRC review and require no additional forms:
  - Studies involving baker's yeast and brewer's yeast, except in rDNA studies.
  - b. Studies involving Lactobacillus, Bacillus *thurgensis*, nitrogen-fixing, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment.)
  - c. Studies involving water or soil not concentrated in media conducive to their growth (please review all rules below to ensure that there are not more specific rules that may apply).
  - d. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold.
  - e. Studies of mushrooms and slime molds.
  - f. Studies involving E. coli k–12 which are done at school and are not recombinant DNA studies.
- The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
  - Studies involving protists, archaea and similar microorganisms.
  - b. Research using manure for composting, fuel production, or other non-culturing experiments.
  - Commercially-available color change coliform water test kits. These kits must remain sealed and must be properly disposed.
  - d. Studies involving decomposition of vertebrate organisms (such as in forensic projects).
  - e. Studies with microbial fuel cells.
- Prior review and approval is required for the use of potentially hazardous microorganisms (including bacteria, viruses, viroids,

prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids:

- a. An affiliated fair SRC, an IBC or an IACUC must approve all research before experimentation begins. The initial risk assessment determined by the student researcher and adults supervising the project must be confirmed by the SRC, IBC or IACUC.
- b. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the affiliated fair SRC.
- c. Research determined to be at Biosafety Level 1 (BSL-1) must be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Designated Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.
- d. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above (commonly limited to a Regulated Research Institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter or document from the Regulated Research Institution that the research does not require review. The research must be supervised by a Qualified Scientist. For a high school BSL-2 laboratory, the SRC must review and approve.
- Students are prohibited from designing or participating in an experiment associated with the following types of PHBA studies:
  - BSL-3 or BSL-4 Research
  - Culturing CRE (Carbapenem Resistant Enterobacteriacae)
- f. Students are prohibited from genetically engineering bacteria with multiple antibiotic resistance
- g. Laboratory studies culturing known MRSA (Methicillinresistant Staphylococcus aureus), VRE (Vancomycinresistant enterococci) and KPC (Klebsiella pneumonia) must be conducted at a Regulated Research Institution with a minimum BSL-2 laboratory with documented IBC Committee review and approval.
- h. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms require at least BSL-2 containment.
- Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
- The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
- k. All potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or BSL 2 organisms: Autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable.
- l. Any proposed changes in the Research Plan by the student after initial local or affiliated fair SRC approval

must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.

- 4. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - b. Regulated Research Institution Form (1C) when applicable
  - c. Qualified Scientist (2), when applicable
  - d. Risk Assessment (3), when applicable
  - e. PHBA Risk Assessment Form (6A), when applicable
  - f. Human and Vertebrate Animal Tissue Form (6B) for all studies involving tissues and body fluids.

### A. Additional Rules for Projects Involving Unknown Microorganisms

Studies involving unknown microorganisms present a challenge because the presence, concentration and pathogenicity of possible agents are unknown. In science fair projects, these studies typically involve the collection and culturing of microorganisms from the environment (e.g. soil, household surfaces, skin.)

- Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
  - a. Organism is cultured in a plastic petri dish (or other standard non-breakable container) and sealed. Other acceptable containment includes two heavy-duty (2-ply) sealed bags.
  - b. Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
  - The sealed Petri dish is disposed of via autoclaving or disinfection under the supervision of the Designated Supervisor.
- If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.

# B. Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies

Studies involving rDNA technologies in which microorganisms have been genetically modified require close review to assess the risk level assignment. Some rDNA studies can be safely conducted in a BSL-1 high school laboratory with prior review by a knowledgeable SRC:

- All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems must be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or Designated Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in E. coli K-12, S. cerevesiae, and B. subtilis host-vector systems.
- 2. Commercially available rDNA kits using BSL-1 organisms may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation.
- An rDNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.

- 4. All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the IBC prior to experimentation.
- 5. Propagation of recombinants containing DNA coding for oncogenes or other human, plant or animal toxins (including viruses) is prohibited.

# C. Additional Rules for Projects with Tissues and Body Fluids, including Blood and Blood Products

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

- 1. The following types of tissue do not need to be treated as potentially hazardous biological agents:
  - a. Plant tissue
  - b. Plant and non-primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures must be identified in the Research Plan.
  - Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses
  - d. Hair, hooves, nails and feathers
  - e. Teeth that have been sterilized to kill any blood- borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended
  - f. Fossilized tissue or archeological specimens.
  - g. Prepared fixed tissue
- Research involving human and/or non-human primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection) must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/ or catalog number of the cultures must be identified in the Research Plan.
- If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.
- 4. If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and is subject to the vertebrate animal rules for studies conducted at a Regulated Research Institution. (See vertebrate animal rules.)
- 5. Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 7) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.
- 6. Biosafety level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or -2. These studies must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist.

- 7. All studies involving human or wild animal blood or blood products should be considered a Biosafety level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Studies involving domestic animal blood may be considered a BSL-1 level study. All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z. Any tissue or instruments with the potential of containing blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation.
- 8. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered BSL-2.
- 9. Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or -4 is prohibited.
- 10. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.
- 11. A project involving a student researcher using their own body fluids (if not cultured)
  - a. can be considered a BSL-1 study
  - b. may be conducted in a home setting
  - c. must have IRB review if the body fluid is serving as a measure of an effect of an experimental procedure on the student researcher (e.g. Student manipulates diet and takes a blood or urine sample). An example of a project not needing IRB review would be collecting urine to serve as a deer repellent.
  - d. must receive prior SRC review and approval prior to experimentation.
- 12. Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

Sources of Information are available as a separate section at the end of the document.

### Potentially Hazardous Biological Agents Risk Assessment

Use this information to complete PHBA Risk Assessment Form (6A)

Risk assessment defines the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The end result of a risk assessment is the assignment of a biosafety level which then determines the laboratory facilities, equipment, training, and supervision required. Risk assessment involves:

- 1. Assignment of the biological agent to a risk group
- 2. Studies involving a known microorganism must begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
- 3. The study of unknown microorganisms and the use of fresh tissues relies on the expertise of the supervising adult(s).
- 4. Determination of the level of biological containment available to the student researcher to conduct the experimentation. (See "Levels of Biological Containment" for details.)
- Assessment of the experience and expertise of the adult(s) supervising the student.

- Assignment of a biosafety level for the study based on risk group of biological agent, level of biological containment available and the expertise of the Qualified Scientist or Designated Supervisor who will be supervising the project
- 7. Documentation of review and approval of study prior to experimentation:
  - a. If a study is conducted at a non-regulated site (e.g. school), the SRC reviews the Research Plan.
  - If the study was conducted at a Regulated Research Institution, and was approved by the appropriate institutional board (e.g. IBC, IACUC), the SRC reviews the institutional forms provided and documents SRC approval (Form(6A)).
  - c. If a PHBA study was conducted at a Regulated Research Institution but the institution does not require review for this type of study, a letter from an institutional representative stating that review was not required must be obtained. The SRC must review the study and document approval on Form 6A that the student received appropriate training and the project complies with Intel ISEF rules.

#### Classification of Biological Agents Risk Groups

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes.

**BSL-1** risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: Agrobacterium tumifaciens, Micrococcus leuteus, Neurospora crassa, Bacillus subtilis.

**BSL-2** risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. Examples of BSL-2 organisms are: Mycobacterium, Streptococcus pneumonia, *Salmonella choleraesuis*.

**BSL-3** risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. Projects in the BSL-3 group are prohibited.

**BSL-4** risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are prohibited.

#### **Levels of Biological Containment**

There are four levels of biological containment (Biosafety Level 1–4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques.

**BSL-1** containment is normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in a fume hood. Standard microbiological practices are used when working in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats and gloves are required. The laboratory work is supervised by an individual with general training in microbiology or a related science.

**BSL-2** containment is designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats and gloves are required; eye protection and face shields must also be worn as needed. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

**BSL-3** containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Projects in the BSL-3 group are prohibited.

**BSL-4** containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Projects in the BSL-4 group are prohibited.

### Hazardous Chemicals, Activities or Devices Rules

Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms and explosives, radiation, lasers, etc.

The following rules apply to research using hazardous chemicals, devices and activities. These include substances and devices that are regulated by local, state, country, or international law, most often with restrictions of their use by minors such as DEA-controlled substances, prescription drugs, alcohol, tobacco, firearms and explosives. Hazardous activities are those that involve a level of risk above and beyond that encountered in the student's everyday life.

These rules are intended to protect the student researcher by ensuring proper supervision and the consideration of all potential risks so that the appropriate safety precautions are taken. Students are required to meet all standards imposed by Intel ISEF, school, local, and/or regional fair(s).

### Rules for ALL Projects Involving Hazardous Chemicals, Activities and Devices

- The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Designated Supervisor, except those involving DEA-controlled substances, which require supervision by a Qualified Scientist.
- The student researcher must conduct a risk assessment in collaboration with a Designated Supervisor or Qualified Scientist prior to experimentation. This risk assessment is documented on the Risk Assessment Form 3.
- Student researchers must acquire and use regulated substances in accordance with all local, state, U.S. federal and country laws. For further information or classification for these laws and regulations, contact the appropriate regulatory agencies.
- 4. For all chemicals, devices or activities requiring a Federal and/ or State Permit, the student/supervisor must obtain the permit prior to the onset of experimentation. A copy of the permit must be available for review by adults supervising the project and the local affiliated and the ISEF SRCs in their review prior to competition.
- 5. The student researcher must minimize the impact of an experiment on the environment. Examples include using minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner and in accordance with good laboratory practices.
- 6. The following forms are required:
  - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan and Approval Form (1B)
  - b. Regulated Research Institution Form (1C), when applicable
  - c. Qualified Scientist Form (2), when applicable
  - d. Risk Assessment Form (3)

#### **Additional Rules for Specific Regulated Substances**

There are additional rules for the following regulated substances:

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

#### 1. DEA-Controlled Substances

The U.S. Drug Enforcement Administration (DEA) regulates chemicals that can be diverted from their intended use to make illegal drugs. Other countries may have similar regulatory bodies; students outside of the U.S. must adhere to their own country's drug regulatory agency requirements in addition to U.S. DEA regulations. DEA-controlled substances and their schedule number are at the DEA website under Sources of Information. It is the responsibility of the student to consult this list if there is a possibility that substances used in experimentation could be regulated.

- a. All studies using DEA-controlled substances must be supervised by a Qualified Scientist who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.
- b. All studies using DEA Schedule 1 substances must have the research protocol approved by DEA before research begins. Schedule 2, 3 and 4 substances do not require protocol approval by DEA.

#### 2. Prescription Drugs

Prescription drugs are drugs regulated by federal or country laws to protect against inappropriate or unsafe use. Special precautions must be taken in their use for a science project as follows:

- a. Students are prohibited from administering prescription drugs to human participants.
- b. A veterinarian must supervise student administration of any prescription drugs to vertebrate animals.

#### 3. Alcohol and Tobacco

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the production of alcohol and distribution of alcohol and tobacco products. Many such products are restricted by age for purchase, possession and consumption. Students outside of the U.S. must adhere to U.S. regulations and to their local and country laws and regulations.

- a. The Designated Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
- Production of wine or beer by adults is allowable in the home and must meet TTB home production regulations.
   Students are allowed to design and conduct a research project, under direct parental supervision, involving the legal production of the wine or beer.
- Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
- d. Students are prohibited from conducting experiments where consumable ethyl alcohol is produced by distillation. However, students are allowed to distill alcohol for fuel or other non-consumable products. To do so, the work must be conducted at school and a TTB permit must be obtained by school authorities. Details regarding this process are available from the Alcohol and Tobacco Tax and Trade Bureau (TTB) website.

#### 4. Firearms and Explosives

The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), along with state agencies, regulates the purchase and use of firearms and explosives. A firearm is defined as a small arms weapon from which a projectile is fired by gunpowder. An explosive is any chemical compound, mixture or device,

the primary purpose of which is to function by explosion. Explosives include, but are not limited to, dynamite, black powder, pellet powder, detonators, and igniters.

The purchase of a firearm by a minor is generally unlawful. The use of a firearm, without proper state certification, is illegal. Students should check the training and certification requirements of individual states and countries.

- Projects involving firearms and explosives are allowable when conducted with the direct supervision of a Designated Supervisor and when in compliance with all federal, state and local laws.
- 2. A fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.
- 3. Potato guns and paintball guns are not considered firearms unless they are intended to be used as weapons. However, they must be treated as hazardous devices.

#### **Guidance for Risk Assessment**

Please find below guidance on conducting risk assessment when using the following:

- Hazardous Chemicals
- Hazardous Devices
- Radiation

#### 1. Hazardous Chemicals

A proper risk assessment of chemicals must include review of the following factors:

- Toxicity the tendency of a chemical to be hazardous to health when inhaled, swallowed, injected or in contact with the skin.
- Reactivity the tendency of a chemical to undergo chemical change.
- Flammability the tendency of a chemical to give off vapors which readily ignite when used under normal working conditions.
- d. Corrosiveness the tendency of a chemical, upon physical contact, to harm or destroy living tissues or physical equipment.

When assessing risk, the type and amount of exposure to a chemical must be considered. For example, an individual's allergic and genetic disposition may have an influence on the overall effect of the chemical. The student researcher must refer to Material Safety Data Sheets provided by the vendor (MSDS) to ensure that proper safety precautions are taken. Some MSDS sheets (e.g., Flinn) rank the degree of hazard associated with a chemical. This rating may assist students and adult sponsors in determining risk associated with the use of a chemical.

A risk assessment must include proper disposal methods for the chemicals used in an experiment. The Flinn Catalog (referenced in the Sources of Information section) provides information for the proper disposal of chemicals. If applicable, the student researcher must incorporate in the research plan disposal procedure required by federal and state guidelines.

#### **Environmentally Responsible Chemistry**

The mission of environmentally responsible (green) chemistry is to avoid the use or production of hazardous substances during chemical process. The principles of green chemistry are described on the EPA website in the Sources of Information section. Whenever possible the following principles should be incorporated into the research plan.

- Waste prevention
- Use of the safest possible chemicals and products
- Design of the least possible hazardous chemical syntheses
- Use renewable materials
- · Use catalysts in order to minimize chemical usage
- Use of solvents and reaction conditions that are safe as possible
- Maximization of energy efficiency
- Minimization of accident potential

#### 2. Hazardous Devices

The documentation of risk assessment (Form 3) is required when a student researcher works with potentially hazardous/dangerous equipment and/or other devices, in or outside a laboratory setting that require a moderate to high level of expertise to ensure their safe usage. Some commonly used devices (Bunsen burners, hot plates, saws, drills, etc.) may not require a documented risk assessment, assuming that the student researcher has experience working with the device. Use of other potentially dangerous devices such as high vacuum equipment, heated oil baths, NMR equipment, and high temperature ovens must have documentation of a risk assessment. It is recommended that all student designed inventions also have documentation of a risk assessment.

#### 3. Radiation

A risk assessment must be conducted when a student uses non-ionizing radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (NW), radiofrequency (RF) and extremely low frequency (ELF). Lasers usually emit visible, ultraviolet or infrared radiation. Lasers are classified into four classes based upon their safety.

Manufacturers are required to label Classes II – IV lasers. Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study and appropriate safety precautions must be taken. Depending upon the level of exposure, radiation released from these sources can be a health hazard.

A risk assessment must take into account the time of exposure, distance and shielding involved in the study.

- A study of natural radiation that is no more than encountered in everyday life is exempt from the following requirements.
- b. All studies may not exceed the dose limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
- c. If the voltage needed in the study is <10 kvolts, a risk assessment must be conducted. The study may be done at home or school, and SRC preapproval is not required.
- d. A study using 10-25 kvolts must have a risk assessment conducted and must be preapproved by the SRC to assess safety. Such a study must be conducted in a metal chamber using a camera only, not direct view through

- glass. A dosimeter or radiation survey meter is required to measure radiation exposure.
- e. All studies using > 25 kvolts must be conducted at an institution with a Licensed Radiation Program and must be preapproved by the Institutions' Radiation Safety Officer or the Committee which oversees the use of ionizing radiation to ensure compliance with state and federal regulations.

#### Sources of Information for All Projects

United States Patent and Trade Office
 Customer Service: 1-800-786-9199 (toll-free);
 571-272-1000 (local); 571-272-9950 (TTY)
 www.uspto.gov/
 www.uspto.gov/patents/process/index.isp

2. European Patent Office

www.epo.org/ www.epo.org/applying/basics.html

3. The Mad Scientist Network at Washington University School of Medicine:

www.madsci.org

4. ANS Task Force www.anstaskforce.gov

> Aquatic Nuisance Species (ANS) Task Force www.anstaskforce.gov www.anstaskforce.gov/Documents/ISEF.pdf

5. APHIS

www.aphis.usda.gov/ Animal and Plant Health Inspection Service Invasive Species List

6. Invasive Species Specialist Group

www.issg.org

The Global Invasive Species database contains invasive species information supplied by experts from around the world.

7. Invasive Species Information

www.invasivespeciesinfo.gov/resources/lists.shtml
Provides information for species declared invasive, noxious, prohibited, or harmful or potentially harmful.

8. Success with Science: The Winner's Guide to High School Research

Gaglani, S. and DeObaldia, G. (2011). Research Corporation for Science Advancement. ISBN 0-9633504-8-X

#### **Human Participants**

- Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46) <a href="http://ohsr.od.nih.gov/guidelines/45cfr46.html">http://ohsr.od.nih.gov/guidelines/45cfr46.html</a>
- Dunn, C. M. and Chadwick, G. L., Protecting Study Volunteers in Research, 3rd Edition (2004). Boston, MA: Thomson Centerwatch. ISBN 1-930624-44-1. Can be purchased from: www.amazon.com

- 3. NIH tutorial, "Protecting Human Research Participants" http://phrp.nihtraining.com/users/PHRP.pdf
- 4. Belmont Report, April 18, 1979 www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
- Standards for Educational and Psychological Testing. (1999).
   Washington, DC: AERA, APA, NCME.
   www.apa.org/science/programs/testing/standards.aspx
- American Psychological Association 750 First Street, NE Washington, DC 20002-4242 phone: 202-336-5500; 800-374-2721 www.apa.org

Information for students:

www.apa.org/science/leadership/students/information.aspx Information regarding publications: www.apa.org/pubs/index.aspx

Educational and Psychological Testing
 Testing Office for the APA Science Directorate
 phone: 202-336-6000
 email: <a href="mailto:testing@apa.org">testing@apa.org</a>
 www.apa.org/science/programs/testing/index.aspx

 The Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. §§ 6501–6506)
 www.ftc.gov/privacy/coppafags.shtm

#### Vertebrate Animals Animal Care and Use

- Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research <a href="http://dels.nas.edu/ilar">http://dels.nas.edu/ilar</a>
- Guide for the Care and Use of Laboratory Animals, 8<sup>th</sup> Edition (2011) http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf www.nap.edu/catalog.php?record\_id=12910
- 3. Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003), Institute for Laboratory Animal Research (ILAR).

dels.nas.edu/report/guidelines-carey/10732

To order these ILAR publications contact: National Academies Press 500 Fifth Street, NW Washington, DC 20055

phone: 888-624-8373 or 202-334-3313; fax: 202-334-2451

www.nap.edu

Federal Animal Welfare Act (AWA)
 U.S.C. 2131-2157
 Subchapter A - Animal Welfare (Parts I, II, III)
 www.nal.usda.gov/awic/legislat/awicregs.htm

Above document is available from: USDA/APHIS/AC 4700 River Road, Unit 84 Riverdale, MD 20737-1234 email: <a href="mailto:ace@aphis.usda.gov">ace@aphis.usda.gov</a>

phone: 301-734-7833; fax: 301-734-4978

http://awic.nal.usda.gov

 Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide) Federation of Animal Science Societies (FASS) 1800 S. Oak Street, Suite 100 Champaign, IL 61820-6974

phone: 217-356-3182 email: <u>fass@assochq.org</u>

www.fass.org

 Guidelines for the Use of Fish in Research (2014), American Fisheries Society. www.fisheries.org

www.fisheries.org/afs/docs/policy\_16.pdf

7. Euthanasia Guidelines

AVMA Guidelines on Euthanasia (2013)
American Veterinary Medical Association
www.avma.org/KB/Policies/Documents/euthanasia.pdf

#### Alternative Research and Animal Welfare

The National Library of Medicine provides computer searches through MEDLINE:
 Reference & Customer Services
 National Library of Medicine
 8600 Rockville Pike
 Bethesda, MD 20894
 888-FIND-NLM or 888-346-3656; 301-594-5983;

email: info@ncbi.nlm.nig.gov www.nlm.nih.gov www.ncbi.nlm.nih.gov/sites/entrez

 National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.

Animal Welfare Information Center National Agriculture Library 10301 Baltimore Avenue, Room 410 Beltsville, MD 20705-2351

phone: 301-504-6212, fax: 301-504-7125

email: awic@ars.usda.gov www.nal.usda.gov/awic

3. Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in ILAR Journal. ILAR — The Keck Center of the National Academies 500 Fifth Street, NW, Keck 687 Washington, DC 20001

phone: 202-334-2590, fax: 202-334-1687

email: <u>ILAR@nas.edu</u> http://dels.nas.edu/ilar

 Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing may be obtained from:

Specialized Information Services NLM/NIH

2 Democracy Plaza, Suite 510 6707 Democracy Blvd., MSC 5467 Bethesda, MD 20892-5467

phone: 301-496-1131; Fax: 301-480-3537

email: tehip@teh.nlm.nih.gov

www.sis.nlm.nih.gov;

http://toxnet.nlm.nih.gov/altbib.html

Johns Hopkins Center for Alternatives to Animal Testing (CAAT)
has worked with scientists since 1981 to find new methods to
replace the use of laboratory animals in experiments, reduce
the number of animals tested, and refine necessary tests to
eliminate pain and distress.

email: caat@jhsph.edu http://caat.jhsph.edu/

6. Quality Assurance Manuals (for appropriate species)

Poultry: http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3002393 Beef: http://www.bqa.org/manuals.aspx

Pork: http://old.pork.org/filelibrary/youthpqaplus/ypqamanual.pdf

#### **Potentially Hazardous Biological Agents**

- American Biological Safety Association: ABSA Risk Group Classification – list of organisms www.absa.org
- American Type Culture Collection (ATCC) www.atcc.org
- Bergey's Manual of Systematic Bacteriology website follow the links for resources and microbial databases for a collection of international websites of microorganisms and cell cultures. www.bergeys.org/resources.html
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
   4th Edition. Published by CDC-NIH,
   www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf
- World Health Organization Laboratory Safety Manual www.who.int/diagnostics\_laboratory/guidance/en/
- 6. Canada Agency of Public Health list of non-pathogenic organisms

  www.phac-aspc.gc.ca/lab-bio/index\_eng.php

  www.phac-aspc.gc.ca/lab-bio/res/index-eng.php
- 7. Microorganisms for Education Website list of organisms www.science-projects.com/safemicrobes.htm
- 8. NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health. http://oba.od.nih.gov/oba/index.html
- OSHA Occupational Health and Safety Administration www.osha.gov

#### Hazardous Chemicals, Activities or Devices

**General Lab/Chemical Safety** 

 Safety in Academic Chemistry Laboratories, Volumes 1 and 2, 2003. Washington, DC: American Chemical Society.

Order from (first copy free of charge): American Chemical Society

Publications Support Services 1155 16th Street, NW Washington, DC 20036

phone: 202-872-4000 or 800-227-5558

email: <a href="mailto:help@acs.org">help@acs.org</a>, <a href="mailto:www.acs.org/education">www.acs.org/education</a>

2. General

Howard Hughes Medical Institute has resources for working with cell cultures, radioactive materials and other laboratory materials.

www.hhmi.org/resources/

3. Environmental Protection Agency (EPA) website for green chemistry

www.epa.gov/greenchemistry

4. Material Safety and Data Sheets (MSDS)

www.flinnsci.com/msds-search.aspx

A directory of MSDS sheets from Flinn Scientific Inc. that includes a ranking of hazard level and disposal methods.

www.ilpi.com/msds/index.html - A listing of numerous sites that have free downloads of MSDS sheets.

5. Pesticides

National Pesticide Information Center <a href="http://npic.orst.edu/ingred/products.html">http://npic.orst.edu/ingred/products.html</a>

Describes the various types of pesticides and the legal requirements for labelling. Provides links and phone numbers to get additional information.

**Environmental Protection Agency** 

http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1

A database of product labels. Enter the product name or company name to view the approved label information of pesticides which are registered with the agency.

6. DEA Controlled Substances

Drug Enforcement Agency website:

www.justice.gov/dea/index.htm

Controlled Substance Schedules— a list of controlled substances:

www.deadiversion.usdoj.gov/schedules/

7. Alcohol, Tobacco, Firearms, and Explosives Alcohol and Tobacco Tax and Trade Bureau www.ttb.gov/

Bureau of Alcohol, Tobacco, Firearms and Explosives <a href="https://www.atf.gov">www.atf.gov</a>

8. Radiation

Radiation Studies Information (CDC) www.cdc.gov/nceh/radiation/default.htm

 CDC Laboratory Safety Manuals www.cdc.gov/biosafety/publications/index.htm

10. Occupational Safety and Health Administration

<u>www.osha.gov</u>

Safety and Health Topics:

www.osha.gov/SLTC/

www.osha.gov/SLTC/reactivechemicals/index.html

www.osha.gov/SLTC/laserhazards/index.html

www.osha.gov/SLTC/radiationionizing/index.html

11. U.S. Nuclear Regulatory Commission

Material Safety and Inspection Branch One White Flint North 11555 Rockville Pike Rockville, MD 20852

phone: 301-415-8200; 800-368-5642

www.nrc.gov

### **Intel ISEF Display and Safety Regulations**

Please address any questions regarding Intel ISEF Display and Safety Regulations to Diane Hecht, Display and Safety Committee Chair at displayandsafety@societyforscience.org

#### **Display and Safety Authority**

The Intel ISEF Display and Safety Committee is the final authority on display and safety issues for projects approved by the SRC to compete in the Intel ISEF. Occasionally, the Intel ISEF Display and Safety Committee may require students to make revisions to conform to display and safety regulations. The Regulations that follow have been divided into two main categories to separate those that deal specifically with display regulations and those that pertain to safety regulations.

### **Display Regulations**

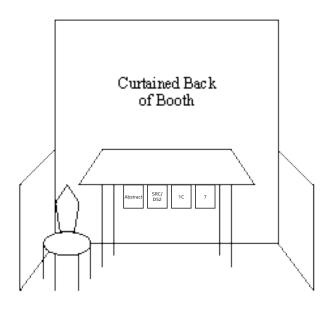
The following regulations must be adhered to when a finalist exhibits a project at Intel ISEF.

#### **Maximum Size of Project**

**Depth** (front to back): 30 inches or 76 centimeters **Width** (side to side): 48 inches or 122 centimeters **Height** (floor to top): 108 inches or 274 centimeters

Please be aware when ordering posters that the mechanism that supports the poster should conform to the maximum size limitations stated above.

- All project materials and support mechanisms must fit within the project dimensions.
- Fair provided tables will not exceed a height of 36 inches (91 centimeters).
- If a table is used it becomes part of the project and must not exceed the allowed dimensions.
- Nothing can be attached to the rear curtain for display.
- All demonstrations must be done within the confines of the finalist booth. When not being demonstrated, the component must be returned to project and must fit within allowable dimensions.



#### **Position of Project**

Position of project must be parallel to, and positioned at, the back curtain of the booth. Projects may NOT lean against the back curtain.

# Display Content for Research Institution and/or Continuation Projects

- Research Institution Projects
  - The display must reflect on the work conducted by the finalist.
    - Minimal reference to mentor's or other researcher's work must only reflect background information or be used to clarify differences between finalist's and others' work.
    - If Box 3 is checked YES on the official Intel ISEF Abstract and Certification, Regulated Research Institution/Industrial Setting Form 1C must be vertically displayed.
- · Continuation Projects
  - The display board should summarize ONLY the CURRENT year's work.
    - The Title may include the duration of the project (for example, "Year Two of an Ongoing Study").
    - Minimum reference to conclusions of previous years' work may be shown without any specific data being displayed.
    - If Box 4 is checked YES on the official Intel ISEF Abstract and Certification, Continuation Form 7 must be vertically displayed, summarizing clear differences between current and previous years' work.

#### Forms Required to be Visible and Vertically Displayed

The suggested placement of the required forms is on the front edge of the table, on the display board, or in a free-standing frame placed on the table top.

#### Forms required at all projects:

- Original of official Abstract and Certification as approved and stamped/embossed by the Intel ISEF Scientific Review Committee.
- Completed Intel ISEF Project Set-up Approval Form SRC/ DS2 (Received on-site at the Fair)

# Forms required when applicable (indicated on Form SRC/DS2)

- 1. Regulated Research Institutional/Industrial Setting Form (1C)
- 2. Continuation Projects Form (7)

#### Informed Consent Forms Not to be Displayed

Informed consent forms are not allowed to be present at the project display.

Forms Required at Project but not Displayed

Forms including, but not limited to, Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan and Approval Form (1B) which are required for the project or for Scientific Review Committee approval do not have to be displayed as part of the project but must be available in the booth in case asked for by a judge or other Intel ISEF official. A photograph/video release form signed by the subject is required for visual images of humans (other than the finalist) displayed as part of the project. All other forms not specifically called for in the above sections are NOT required to be Displayed at the booth.

#### Photograph/Image Display Requirements

Display of photographs other than that of the finalist must have a photo release signed by the subject, and if under 18 years of age, also by the guardian of the subject. Sample consent text: "I consent to the use of visual images (photos, videos, etc.) involving my participation/my child's participation in this research." (These forms must be available upon request by a Display & Safety Inspector, but shall not be displayed.)

Finalists using audio-visual or multi-media presentations (for example, 35mm slides, videotapes, images, graphics, animations, etc., displayed on computer monitors; or other non-print presentation methods) must be prepared to show the entire presentation to the Display and Safety Inspectors before the project is approved.

Any photograph/visual image/chart/table and/or graph is allowed if:

- It is not deemed offensive or inappropriate (which includes images/photographs showing invertebrate or vertebrate animals/humans in surgical, necrotizing or dissection situations) by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. The decision made by any one of the groups mentioned above is final.
- It has a credit line of origin ("Photograph taken by..." or
   "Image taken from..." or "Graph/Chart/Table taken from...").
   (If all images, etc. being displayed were taken or created
   by the finalist or are from the same source, one credit line
   prominently and vertically displayed on the backboard/
   poster or tabletop is sufficient.)
- 3. It is from the Internet, magazine, newspaper, journal, etc., and a credit line is attached. (If all photographs, etc. are from the same source, one credit prominently and vertically displayed is sufficient.)
- 4. It is a photograph or visual depiction of the finalist.
- 5. It is a photograph or visual depiction for which a signed consent form is at the project or in the booth.

### Handouts Allowed at Project Official Abstract

Handouts to judges and to the public must be limited to UNALTERED photocopies of the official abstract and certification.

The Intel ISEF Scientific Review Committee defines the "official abstract and certification" as an UNALTERED original abstract and certification as stamped/embossed by the Intel ISEF Scientific Review Committee. If the Scientific Review Committee requires a finalist to make changes to the abstract and certification submitted with registration papers, the revised version will be stamped/embossed, will replace the earlier version, and will become the finalist's official abstract and certification.

- The finalist will be provided with 25 copies of the Official Abstract and Certification.
- The term abstract may NOT be used as a title or reference for any information on a finalist's display or materials at the project except as part of displaying the official abstract.
- An original stamp/embossed official abstract and certification must be vertically displayed at the project.

#### Items/Materials Not Allowed at Project

The following is a list of what cannot be displayed at the project:

- Any items that are acknowledgments (including patent pending statements) and/or are intended for distribution including:
  - a. Any disks, CDs, business cards, printed materials, etc.
     (including unofficial abstracts) designed to be distributed to judges or the public
  - Flash drives, brochures, booklets, endorsements, and additional give-away items including, but not limited to, pins, key chains, food etc.
  - c. Any awards or medals, except for past or present Intel ISEF medals that may be worn by the finalist.
- Postal addresses, World Wide Web, email and/or social media addresses, QR codes, telephone and/or fax numbers of a project or finalist.
- Active Internet or email connections as part of displaying or operating the project at the INTEL ISEF.
- 4. Prior year's written material or visual depictions on the vertical display board. (Exception: The project title displayed in the finalist's booth may mention duration of the project.) For example, Year 2 of an Ongoing Study. Please note continuation projects must vertically display the Continuation Project Form 7.
- \* Any attempt to replenish or return removed items from the above list is a violation of the Ethics Agreement and will result in items being confiscated by the Display and Safety Committee and may result in the project failing to qualify for competition.

#### Other Display Regulations

- No changes, modifications, or additions to projects may be made after approval by the Display and Safety Committee and the Scientific Review Committee. Finalists who do not adhere to the signed agreement on the SRC/DS2 Form regarding this regulation will fail to qualify for competition.
- If a project fails to qualify and is not removed by the finalist, Society for Science & the Public will remove the project in the safest manner possible but is not responsible for damage to the project.
- It is highly recommended that your project number be placed on all notebooks or materials that will be left at your booth. A project data book and research paper are not required but are highly recommended.
- 4. Judges will preview projects without finalist's present beginning at noon on Tuesday.

### **Safety Regulations**

The following regulations must be adhered to when a finalist exhibits a project at Intel ISEF.

#### Not Allowed at Project or Booth

- 1. Living organisms, including plants
- 2. Soil, sand, rock, cement and/or waste samples, even if permanently encased in a slab of acrylic
- 3. Taxidermy specimens or parts
- 4. Preserved vertebrate or invertebrate animals
- 5. Human or animal food as part of the exhibitor demonstration of the project.
- 6. Human/animal parts or body fluids (for example, blood, urine)
- Plant materials (living, dead, or preserved) that are in their raw, unprocessed, or non-manufactured state (Exception: manufactured construction materials used in building the project or display)
- 8. All chemicals including water (projects may not use water in any form in a demonstration)
- All hazardous substances or devices (Example: poisons, drugs, firearms, weapons, ammunition, reloading devices, and lasers)
- Items that may have contained or been in contact with hazardous chemicals (Exception: Item may be permitted if professionally cleaned and document for such cleaning is available)
- 11. 3-D Printers
- 12. Dry ice or other sublimating solids
- 13. Sharp items (for example, syringes, needles, pipettes, knives)
- 14. Flames or highly flammable materials
- 15. Batteries with open-top cells or wet cells
- 16. Glass or glass objects unless deemed by the Display and Safety Committee to be an integral and necessary part of the project (for example, glass that is an integral part of a commercial product such as a computer screen)
- 17. Any apparatus deemed unsafe by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public (Example: large vacuum tubes or dangerous ray-generating devices, empty tanks that previously contained combustible liquids or gases, pressurized tanks, 3D printers etc.)

#### **Electrical Regulations at Intel ISEF**

- Electrical power supplied to the project is 120 or 220 Volt, AC, single phase, 60 cycle. No multi-phase will be available or shall be used. Maximum circuit amperage/wattage available is determined by the electrical circuit capacities of the exhibit hall and may be adjusted on-site by the Display and Safety Committee. For all electrical regulations, "120 Volt AC" or "220 Volt AC" is intended to encompass the corresponding range of voltage as supplied by the facility in which the Intel ISEF is being held.
- 2. Electrical devices must be protectively enclosed. Any enclosure must be non-combustible. All external non-current carrying metal parts must be grounded.
- 3. Energized wiring, switches, and metal parts must have adequate insulation and over-current safety devices (such as fuses) and must be inaccessible to anyone other than the finalist. Exposed electrical equipment or metal that possibly may be energized must be shielded with a non-conducting material or with a grounded metal box to prevent accidental contact.

- For lighting used for decoration or illumination, lamp wattage must not exceed fixture ratings. Lighting must not pose risk of injury if touched. As low a voltage as possible must be used.
- 5. When student is not at exhibit, all electrical power must be disconnected, or power bars must be switched off. (Exception: during pre-judging audio visual displays may be available.)
- 6. An insulating grommet is required at the point where any wire or cable enters any enclosure.
- 7. No exposed live circuits over 36 volts are allowed.
- There must be an accessible, clearly visible on/off switch or other means of quickly disconnecting from the 120 or 220 Volt power source.

#### **Laser Requirements**

Class 1 and Class 2 lasers are allowed to be used provided a finalist avoids indiscriminate exposure to other finalists, judges, or visitors (except if passed through magnifying optics such as microscopes and telescopes, in which case they may not be used). No other lasers may be used or displayed. Display and Safety Inspectors may revoke the privilege and require lasers to be removed if careless or indiscriminate use is observed. Serious offenses may result in failure to qualify.

#### **Other Safety Regulations**

- Any inadequately insulated apparatus producing extreme temperatures that may cause physical burns is not allowed.
- Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points must be for display only.
- 3. Society for Science & the Public, the Scientific Review Committee, and/or the Display and Safety Committee reserve the right to remove any project for safety reasons or to protect the integrity of the Intel ISEF and its rules and regulations.
- Project sounds, lights, odors, or any other display items must not be distracting. Exceptions to this rule may be permitted for judging demonstrations. Approval must be given prior to judging.
- 5. No personal items or packaging materials may be stored underneath the booth.

### Information on Required Abstract & Certification for ALL Projects at the Intel ISEF

\* This form may not be relevant for your regional or state fair; please refer to instructions from your affiliated fair.\*

In ADDITION to the basic form requirements for ALL Projects and any other requirements due to specific areas of research, an Abstract & Certification is required at the conclusion of research. Details on this requirement follow.

School Name, City and State, Country

Title

Finalist's Name

#### **Completing the Abstract**

After finishing research and experimentation, you are required to write a (maximum) 250 word, one-page abstract. This is written on the Official Abstract and Certification Form as provided by Society for Science & the Public. It is recommended that it **include the following:** 

- a. purpose of the experiment
- b. procedure
- c. data
- d. conclusions

It may also include any possible research applications. Only minimal reference to previous work may be included. An abstract must not include the following:

 a. acknowledgments (including naming the research institution and/or mentor with which you were working), or selfpromotions and external endorsements
 b. work or procedures done by the mentor

#### **Completing the Certification**

At the bottom of the Abstract & Certification form there are six questions. Please read each carefully and answer appropriately. The Intel ISEF Scientific Research Committee will review and approve the abstract and answers to the questions.

Revisions or questions will be resolved via a SRC appointment on site at the Intel ISEF. Please bring an electronic copy of your Abstract & Certification to the Fair. Only after final Intel ISEF SRC approval has been obtained via a stamped/embossed copy of this Abstract & Certification may a Finalist make copies to hand out to the judges and the public. (SSP provides the first 20 copies.)

#### Intel ISEF Sample Abstract & Certification

Category

Pick one only-mark an "X" in

box at right

Start Typing the Body of Your Abstract Here Beginning at the Left Margin	Animal Sciences Behavioral & Social Sciences Biochemistry Biomedical & Health Sciences Cellular & Molecular Biology Chemistry Computational Biology & Bioinformatics Earth & Environmental Sciences Embedded Systems Energy: Chemical Energy: Physical Engineering Mechanics Environmental Engineering Materials Science Mathematics Microbiology Physics & Astronomy Plant Sciences Robotics & Intelligent Machines Systems Software	00 00 0 00 0 000000000000
As a part of this research project, the student directly handled, manipulated all that apply):	l, or interacted with (chec	ck
<ul> <li>□ human participants potentially hazardous biological agents:</li> <li>□ vertebrate animals □ microorganisms □ rDNA □</li> </ul>	□ tissue	
2. This abstract describes only procedures performed by me/us, reflects my/o search, and represents one year's work only.	ur own independent re- □ no	
3. I/We worked or used equipment in a regulated research institution or indus $\Box$ yes $\Box$ no	trial setting.	
4. This project is a continuation of previous research.	□ no	
<ul> <li>5. My display board includes non-published photographs/visual depictions of humans (other than myself):  yes  no</li> <li>6. I/We hereby certify that the abstract and responses to the above statements are correct and properly reflect my/our own work.</li> </ul>	FOR INTEL ISEF OFFICIAL USE ONLY	\
□ yes □ no		_

**NOTE:** Your abstract must be on the Intel International Science and Engineering Fair Abstract & Certification form and embossed/stamped by the Intel ISEF Scientific Review Committee before it is displayed or handed out. No pasted or taped text will be permitted. No other format or version of your approved Abstract & Certification will be allowed for any purpose at the Intel ISEF.

### **Intel ISEF Categories and Subcategories**

The categories have been established with the goal of better aligning judges and student projects for the judging at the Intel ISEF. Local, regional, state and country fairs may or may not choose to use these categories, dependent on the needs of their area. Please check with your affiliated fair(s) for the appropriate category listings at that level of competition.

Please visit our website at <u>student.societyforscience.org/intel-isef-categories-and-subcategories</u> for a full description and definition of the Intel ISEF categories:

#### **ANIMAL SCIENCES**

Animal Behavior
Cellular Studies
Development
Ecology
Genetics
Nutrition & Growth
Physiology
Systematics & Evolution
Other

### BEHAVIORAL & SOCIAL SCIENCES

Clinical & Developmental Psychology Cognitive Psychology Physiological Psychology Sociology & Social Psychology Other

#### **BIOCHEMISTRY**

Analytical Biochemistry General Biochemistry Medicinal Biochemistry Structural Biochemistry Other

### BIOMEDICAL & HEALTH SCIENCES

Disease Diagnosis
Disease Treatment
Drug Development & Testing
Epidemiology
Nutrition
Physiology & Pathology
Other

### CELLULAR & MOLECULAR BIOLOGY

Cell Physiology Genetics Immunology Molecular Biology Neurobiology Other

#### **CHEMISTRY**

Analytical Chemistry Computational Chemistry Environmental Chemistry Inorganic Chemistry Materials Chemistry Organic Chemistry Physical Chemistry Other

### COMPUTATIONAL BIOLOGY & BIOINFORMATICS

Biomedical Engineering Computational Pharmacology Computational Biomodeling Computational Evolutionary Biology Computational Neuroscience Genomics Other

### EARTH & ENVIRONMENTAL SCIENCES

Atmospheric Science Climate Science Environmental Effects on Ecosystems Geosciences Water Science Other

#### **EMBEDDED SYSTEMS**

Circuits
Internet of Things
Microcontrollers
Networking & Data
Communications
Optics
Sensors
Signal Processing
Other

#### **ENERGY: CHEMICAL**

Alternative Fuels
Computational Energy Science
Fossil Fuel Energy
Fuel Cells & Battery
Development
Microbial Fuel Cells
Solar Materials
Other

#### **ENERGY: PHYSICAL**

Hydro Power Nuclear Power Solar Sustainable Design Thermal Power Wind Other

#### **ENGINEERING MECHANICS**

Aerospace & Aeronautical Engineering Civil Engineering Computational Mechanics Control Theory Ground Vehicle Systems Industrial Engineering-Processing Mechanical Engineering Naval Systems Other

### ENVIRONMENTAL ENGINEERING

Bioremediation Land Reclamation Pollution Control Recycling & Waste Management Water Resources Management Other

#### **MATERIALS SCIENCE**

Biomaterials
Ceramic & Glasses
Composite Materials
Computation & Theory
Electronic, Optical & Magnetic
Materials
Nanomaterials
Polymers
Other

#### **MATHEMATICS**

Algebra
Analysis
Combinatorics, Graph Theory, &
Game Theory
Geometry & Topology
Number Theory
Probability & Statistics
Other

#### **MICROBIOLOGY**

Antimicrobials & Antibiotics Applied Microbiology Bacteriology Environmental Microbiology Microbial Genetics Virology Other

#### **PHYSICS & ASTRONOMY**

Astronomy & Cosmology Atomic, Molecular, & Optical **Physics Biological Physics** Computational Physics & **Astrophysics** Condensed Matter & Materials Instrumentation Magnetics, Electromagnetics & Plasmas Mechanics **Nuclear & Particle Physics** Optics, Lasers, Masers **Quantum Computation** Theoretical Physics Other

#### **PLANT SCIENCES**

Agronomy
Ecology
Genetics/Breeding
Growth & Development
Pathology
Physiology
Systematics & Evolution
Other

### ROBOTICS & INTELLIGENT MACHINES

Biomechanics Cognitive Systems Control Theory Machine Learning Robot Kinematics Other

#### **SYSTEMS SOFTWARE**

Algorithms Cybersecurity Databases Operating Systems Programming Languages Other

### **Checklist for Adult Sponsor (1)**

This completed form is required for ALL projects.

To be completed by the Adult Sponsor in collaboration with the student researcher(s): Student's Name(s): Project Title: \_ 1. 

I have reviewed the Intel ISEF Rules and Guidelines. 2. 

I have reviewed the student's completed Student Checklist (1A) and Research Plan. 3. \( \Box \) I have worked with the student and we have discussed the possible risks involved in the project. 4. The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC: ☐ Humans Potentially Hazardous Biological Agents ☐ Vertebrate Animals ☐ Microorganisms ☐ rDNA ☐ Tissues 5. Items to be completed for **ALL PROJECTS** ☐ Adult Sponsor Checklist (1) ☐ Research Plan ☐ Student Checklist (1A) ☐ Approval Form (1B) ☐ Regulated Research Institutional/Industrial Setting Form (1C) (when applicable after completed experiment) Continuation/Research Progression Form (7) (when applicable) Additional forms required if the project includes the use of one or more of the following (check all that apply): ☐ **Humans** (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.) ☐ Human Participants Form (4) or appropriate Institutional IRB documentation ☐ Sample of Informed Consent Form (when applicable and/or required by the IRB) ☐ Qualified Scientist Form (2) (when applicable and/or required by the IRB) ☐ **Vertebrate Animals** (Requires prior approval, see full text of the rules.) ☐ Vertebrate Animal Form (5A)—for projects conducted in a school/home/field research site (SRC prior approval required.) ☐ Vertebrate Animal Form (5B)—for projects conducted at a Regulated Research Institution. (Institutional Animal Care and Use Committee (IACUC) approval required prior experimentation.) ☐ Qualified Scientist Form (2) (Required for all vertebrate animal projects at a regulated research site or when applicable) ☐ Potentially Hazardous Biological Agents (Requires prior approval by SRC, IACUC or Institutional Biosafety Committee (IBC), see full text of the rules.) ☐ Potentially Hazardous Biological Agents Risk Assessment Form (6A) ☐ Human and Vertebrate Animal Tissue Form (6B)—to be completed in addition to Form 6A when project involves the use of fresh or frozen tissue, primary cell cultures, blood, blood products and body fluids. ☐ Qualified Scientist Form (2) (when applicable) ☐ Hazardous Chemicals, Activities and Devices (No prior approval required, see full text of the rules.) ☐ Risk Assessment Form (3) ☐ Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable) Note: The following are exempt from prior review but require a risk assessment: projects involving protists, archae and similar microorganisms, for projects using manure for composting, fuel production or other non-culturing experiments, for projects using color change coliform water test kits, microbial fuel cells, and for projects involving decomposing vertebrate organisms. Adult Sponsor's Printed Name Date of Review Signature Phone Email

# Student Checklist (1A) This form is required for ALL projects.

1.	a. Student/Team Leader:	Grade:
	Email:	Phone:
	b. Team Member:	c. Team Member:
2.	Title of Project:	
3.	School:	. School Phone:
	School Address:	
4.	Adult Sponsor:	Phone/Email:
5.	Does this project need pre-approval? ☐ Yes ☐ N	o Tentative start date:
	Is this a continuation/progression from a previous year?  If Yes:  a. Attach the previous year's   Abstract   And   b. Explain how this project is new and different from Form (7)  This year's laboratory experiment/data collection:	
	Actual Start Date: (mm/dd/yy)	End Date: (mm/dd/yy)
8.	Where will you conduct your experimentation? (che	ck all that apply)  ☐ Home ☐ Other:
9.	List name and address of all non-school work site(s):	
Na	me: ————	
Ad	dress:	
Ph	one:	
10	. Complete a Research Plan/Project Summary follow	wing the Research Plan instructions and attach to this

11. An abstract is required for all projects after experimentation.

form.

### Research Plan and Post Project Summary Instructions

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

- 1. The Research Plan is a succinct detailing of the rationale, research question(s), methodology, and risk assessment of your research project and should be completed before experimentation. For all projects requiring preapproval, this document must be reviewed and approved by the appropriate approval committee (e.g. IRB, IACUC, SRC) before experimentation. ALL changes made to the original plan should be added to the final document as part of the Post Project Summary. For projects not requiring preapproval, this document may be completed either pre- or post-experimentation.
- 2. All projects should complete a Post Project Summary after experimentation.

#### The Research Plan and Post Project Summary 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 the following in detail:
  - **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.
  - Discussion of Results and Conclusions: Discuss the data/results and the conclusions that can be drawn.
- **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

#### 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

Approval Form (1B)
A completed form is required for each student, including all team members.

	1.	To	Be	Comp	leted	by	Student	and	<b>Parent</b>
--	----	----	----	------	-------	----	---------	-----	---------------

a. Student Acknowledgment:

SRC/IRB Chair's Printed Signature		Approval (mm/dd/yy) prior to experimentation.)		Signature	Date of Approval (mm,	/dd/vv)
SRC/IRB Chair's Printed						
SRC/IRB Chair's Printed				SRC Chair's Printed N	ame	
	Name					
vertebrates or potentially hazardous biological agents).  The SRC/IRB has carefully studied this project's <b>Research Plan</b> and all the required forms are included. My signature indicates approval of the <b>Research Plan</b> before the student begins experimentation.		OR	institution ( <b>not ho</b> reviewed and appropriate the state of the state	s conducted at a regulated research home or high school, etc.), was oproved by the proper institutional perimentation and complies with the Attach (1C) and required institutional IACUC, IRB).		
a. Required for proj approval BEFORE	ects requiring p ects that need p experimentation	rior SRC/IRB APPRO prior SRC/IRB on (humans,		b. Required for I Research Inst	ppropriate.) research conducted at all Regu itutions with no prior fair SRC/	
Parent/Guardian's Prin	ted Name	Signature			Date Acknowledged (mm/dd, (Must be prior to experimentat	
		ave read and underst icipating in this resea			ole dangers involved in the <b>Res</b>	earch
Student's Printed Nam		Signature			Date Acknowledged (mm/dd (Must be prior to experimentat	ion.)
<ul> <li>I have read</li> <li>Scientific fraud and molagiarism, forgery, usorojects will fail to que</li> </ul>	h. and will abide b nisconduct are n se or presentati nalify for compe	on of other research tition in affiliated fai	leve er's	tement l of research or cor work as one's own,	npetition. Such practices inclu and fabrication of data. Fraud	de ulent

SRC Approval After Experimentation and Before Competition at Regional/State/National Fair I certify that this project adheres to the approved Research Plan and complies with all Intel ISEF Rules.					
Regional SRC Chair's Printed Name	Signature	Date of Approval			
State/National SRC Chair's Printed Name (where applicable)	Signature	Date of Approval			

# Regulated Research Institutional/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 <u>)</u>	
Title of Project	
To be completed by the Supervising Adult in the Setting (NOT the Studer (Responses must remain on the form as it is required to be displayed at student's	•
The student(s) conducted research at my work site:	
	iment(s)/conduct research s □ No
2. Is this research a subset of your work?	s □ No
<ol> <li>How did the student get the idea for her/his project?</li> <li>(e.g. Was the project assigned, picked from a list, an original student idea, etc.)</li> </ol>	)
<ol> <li>Did the student(s) work on the project as a part of a research group? ☐ Yes If yes, how large was the group and what kind of research group was it (studer</li> </ol>	
<ol> <li>What specific procedures or equipment did the student(s) actually use for the Please list and describe. (Do not list procedures student only observed.)</li> </ol>	project?
6. How independent or creative was the student's/students' work?	
Student research projects dealing with human participants, vertebrate animals agents require review and approval by an institutional regulatory board (IRB/IA 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)	<u> </u>			
To be completed by the Qualified S	 Scientist:			
Scientist Name:				
Educational Background:		Degree(s):		
Experience/Training as relates to the st	udent's area of researd	ch:		
Position:				
Address:	 Email/Phon	e:		
1) Have you reviewed the Intel ISEF ru	-		☐ Yes	□No
<ol> <li>Will any of the following be used?         <ul> <li>a. Human participants</li> <li>b. Vertebrate animals</li> <li>c. Potentially hazardous biological including blood and blood producted.</li> <li>d. DEA-controlled substances</li> </ul> </li> <li>Was this study a sub-set of a larger standard will you directly supervise the study.</li> </ol>	study?	ms, rDNA and tissues,	☐ Yes	<ul> <li>□ No</li> <li>□ No</li> <li>□ No</li> <li>□ No</li> <li>□ No</li> <li>□ No</li> </ul>
a. If no, who will directly supervise b. Experience/Training of the Desi		gnated 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.		when the Qualified	Scientis iewed the I ues to be us sion.	t cannot directly supervise. Research Plan and have been sed by this student, and I will
Qualified Scientist's Printed Name		Signature		Date of Approval
Signature Date of	f 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					
1. Identify and assess the risks involved in this project.					
2. Describe the safety precautions and procedures that will be used to redu	uce the risks.				
3. List all hazardous chemicals, activities, or devices that will be used; iden pre-approval (see Potentially Hazardous Biological Agent rules).	tify microorganisms exempt from				
1. 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 I agree with the risk assessment and safety precautions and procedures described above Research Plan and will provide direct supervision.					
Designated Supervisor's Printed Name Signature	Date of Review (mm/dd/yy)				
Position & Institution Phone or en	nail contact information				
Experience/Training as relates to the student's area of research					

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		
Must be completed by Student Researcher(s) in collaboration with the 1.   I have submitted my Research Plan which addresses ALL areas Instructions.	indicated in the Human Participants Section of the Research Plan my project or other documents provided to human participants. led. led by the IRB.		
BELOW — IRI	B USE ONLY		
5. Written Parental Permission required for minor participand  ☐ Yes ☐ No ☐ Not app 6. Written Informed Consent required for participants 18 yea ☐ Yes ☐ No ☐ Not app ☐ Approved with Expedited Review (1 signature required). Study in	and the following conditions: (All 5 must be answered) and the following conditions: (All 5 must be answered) all Risk		
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/Professional License		
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.

Parent/Guardian Printed Name:	Signature:
Parental/Guardian Permission (if applicable)	Date Reviewed & Signed:
Research Participant Printed Name:	Signature:
Adult Informed Consent or Minor Assent	Date Reviewed & Signed:
By signing this form I am attesting that I have read and to participate or permission for my child to participate	d understand the information above and I freely give my consent/assent e.
	ou decide not to participate there will not be any negative consequences. may stop participating at any time and you may decide not to answer any
Adult Sponsor/QS/DS:	Phone/email:
If you have any questions about this study, feel free to	o contact:
How confidentiality will be maintained:	
Benefits:	
Potential Risks of Study:	
Time required for participation:	
If you participate, you will be asked to:	
Purpose of the project:	
I am asking for your voluntary participation in my scie If you would like to participate, please sign in the app	ence fair project. Please read the following information about the project. propriate area below.
Title of Project:	
Student Researcher(s):	
if the form is serving to document parental permission	on, a copy of any survey of questionnaire must be attached.

### 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	s used.				
. 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. Add an additional page as necessary.					
3. What will happen to the animals after experimentation?					
4. Attach a copy of wildlife licenses or approval forms, as app	olicable				
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 Comm Level of Supervision Required for agricultural, behavioral o					
☐ Designated Supervisor REQUIRED. Please have applicable person					
☐ Veterinarian and Designated Supervisor REQUIRED. Please have app					
	RED. Please have applicable persons sign below and have the Qualified				
The SRC has carefully reviewed this study and finds it is an appropriate stude Local or Affiliate Fair SRC Pre-Approval Signature:	ly that may be conducted in a non-regulated research site.				
SRC Chair Printed Name Signature	Date of Approval (must be prior to experimentation (mm/dd/yy)				
To be completed by Veterinarian:  ☐ I have reviewed this research and animal husbandry with the student before the start of experimentation.  ☐ I have approved the use and dosages of prescription drugs and/or nutritional supplements.  ☐ I will provide veterinary medical and nursing care in case of illness or emergency.	To be completed by Designated Supervisor or Qualified Scientist when applicable:  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 will directly supervise the experiment.				
Printed Name Email/Phone	Printed Name Email/Phone				
Signature Date of Approval	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. Form must be completed and signed after experimentation.)

St	Student's Name(s)						
Tif	tle of Project						
	itle and Protocol Number of IACUC Approved Project						
 To	b be completed by Qualified Scientist or Principal Investigator:						
	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.	Did the student's project also involve the use of tissues?  No Yes; complete Forms 6A and 6B						
5.	What laboratory training, including dates, was provided to the student?						
6.	5. 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.)							
<ol> <li>Identify potentially hazardous biological ager risk group of each microorganism.</li> </ol>	nts to be used in this experiment. Include the source, quantity and the biosafety level						
2. Describe the site of experimentation including	g 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 culture	ed materials and other potentially hazardous biological agents.						
<ol> <li>To be completed by Qualified Scientist or Designated Supervisor</li> <li>What training will the student receive for this project?</li> <li>Do you concur with the biosafety information and recommendation provided by the student researcher above?         <ul> <li>Yes</li> <li>No If no, please explain.</li> </ul> </li> <li>Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable)</li> </ol>							
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 n	nust 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. Attached is institutional documentation certifying the above. The student has received proper training and the project complies with Intel ISEF rules.  Date of SRC approval							
SRC Chair's Printed Name	Signature						
Sixe Chair's Frinted Name	Jigilature						

### **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)	Student's Name(s)								
Title of Project									
To be completed by Student Researcher(s):									
<ul> <li>□ Fresh or frozen tissu</li> <li>□ Fresh organ or other</li> <li>□ Blood</li> <li>□ Body fluids</li> <li>□ Primary cell/tissue of</li> </ul>	body part	ck all that apply.							
2. Where will the above tiss	ue(s) be obtained. If using an es	tablished cell line include source and catalog number.							
		idy conducted at a research institution attach a copy of the ion, the title of the study, the IACUC approval number and							
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)

Components	Current Research Project	Previous Research Project
I. Title	•	2014–2015
		2013–2014
2. Change in		2014–2015
goal/purpose/ objective		2013–2014
3. Changes in methodology		2014–2015
methodology		2013–2014
1. Variables		2014–2015
studied		2013–2014
5. Additional		2014–2015
changes		2013–2014
ttached are: 2014–2015 Abstrac	ct and Research Plan	□ 2013–2014 Abstract

The Intel International Science and Engineering Fair encourages students to tackle challenging scientific questions and develop the skills needed to solve the problems of tomorrow.

#### **Society for Science & the Public**

Society for Science & the Public (SSP) is one of the oldest nonprofit organizations in the U.S. dedicated to public engagement in science and science education. Established in 1921, SSP is a membership society and a leading advocate for the understanding and appreciation of science and the vital role it plays in human advancement.

Through its acclaimed education competitions and its award-winning Science News Media Group, SSP is committed to inform, educate, and inspire.

#### societyforscience.org

To learn more about the Intel International Science and Engineering Fair, visit: **student.societyforscience.org/intel-isef** 

#### **Intel Corporation**

The foundation of tomorrow's innovation is education. That's why making quality education available to more students around the world—with the help of technology—has inspired Intel's commitment to education for 40 years. We do more than make contributions. Intel gets directly involved in developing and helping to change policy, training teachers, offering free curricula, providing kids with a place to explore technology, and encouraging young innovators. Intel believes that students at all levels everywhere deserve to have the skills they need to become part of the next generation of innovators.

In the last decade, Intel has invested more than \$1 billion, and Intel employees have donated more than four million hours, toward improving education in more than 75 countries, regions, and territories. We are actively involved in education programs, advocacy, and technology access to help tomorrow's innovators.

intel.com/education

Society for Science & the Public

1719 N Street, NW Washington, D.C. 20036-2801 202.785.2255 telephone 202.785.1243 fax student.societyforscience.org/intel-isef

