Intel International Science and Engineering Fair

International Rules and Guidelines 2018

International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs 2017–2018

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For ALL Projects

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

The International Rules and Guidelines for Science Fairs is available at student.societyforscience.org/intel-isef 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 2018
Pittsburgh, PA, USA, May 13–18, 2018

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
https://apps2.societyforscience.org/StudentScience/Student/FindAFair

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

For general 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

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

1. 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;
   b. not have reached age 20 on or before May 1 preceding the Intel ISEF.

3. English is the official language of the Intel ISEF. Student project boards and abstracts must be in English.

4. 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 2017.

5. 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.

6. 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.

7. Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.

8. All sciences (physical, life, social) are represented at the Intel ISEF. Review a complete list of categories and sub-categories with definitions.

9. 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

1. 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.

5. 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, genetically altered genetically-altered, 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 Display & Safety 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

1. 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.**

2. Every student must complete the Student Checklist (1A), a Research Plan/Project Summary and Approval Form (1B) and review the project with the Adult Sponsor in coordination with completion by the Adult Sponsor of the Checklist for Adult Sponsor (1).

3. 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.

4. After initial IRB/SRC approval (if required), any proposed changes in the Student Checklist (1A) and Research Plan/ Project Summary must be re-approved before laboratory experimentation/data collection resumes.

5. 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.

6. Any continuing project must document that the additional research is new and different. (Continuation Projects Form (7)).

7. 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.

8. 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).

9. 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.

10. 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

1. 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 2017 and ending May 2018.

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.

3. 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"). Previous year's databooks, research papers and supporting documents may be at the booth, but not openly displayed, 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 Continuation/ Research Progression Project Form (7) 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.
   b. 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 the same judging criteria as individual projects.

4. 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/ Project Summary and other required forms.

5. Full names of all team members must appear on the abstract and forms.

Contact the Science Education Programs or the Scientific Review Committee 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 Student Checklist (1A) and Research Plan/Project Summary to insure 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 and/or a Designated Supervisor.

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 consist of a minimum of **three** members including the following:

- An educator
- A school administrator (preferably principal or vice principal)
- A medical or mental health professional. The medical or mental health professional may be a medical doctor, nurse practitioner, physician's assistant, doctor of pharmacy, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor. The medical or mental health professional on the IRB may change depending on the nature of the study. This person must be knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study.

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.

To avoid conflict of interest, 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.

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 Human Participant Form (4). 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.

Expedited Review: An expedited review by one member of the IRB may be conducted for projects that meet one of the criteria listed below. The IRB member reviewing the project will determine whether appropriate safety precautions will be employed and whether the project meets criteria for expedited review. If a project submitted for expedited review does not meet the criteria specified below, the project must undergo full IRB review. The IRB member reviewing the project must have the expertise necessary to make such a decision and/or receive advisement from the appropriate expert.

- Student-designed Invention, Prototype, Computer Application, or Engineering/Design Project: The data received in these types of projects must be only in direct reference to the design. Personal data are not collected and the testing does not pose a health or safety hazard. NOTE: The expedited review process may not be used if the invention is tested medically for treatment, diagnosis or intervention.
- Any other human participant study that does not involve student-designed invention in which the student is the only subject of his/her own research and the project 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: https://apps2.societyforscience.org/StudentScience/Student/FindAFair.

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 Affiliated Fair. Projects which were conducted at a Regulated Research Institution, industrial setting or any work site other than home, school or field and which were reviewed and approved by the proper institutional board before experimentation, must also be approved by the Affiliated Fair SRC.

An SRC must consist of a minimum of three persons, including the following:

1. a biomedical scientist with an earned doctoral degree
2. an educator
3. 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.

To avoid conflict of interest, 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:

- evidence of literature search and appropriate attribution
- evidence of proper supervision
- 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)
- evidence of search for alternatives to animal use
- humane treatment of animals
- compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents and hazardous chemicals, activities or devices
- documentation of substantial expansion for continuation projects
- compliance with the Intel ISEF ethics statement

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 projects 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:

1. 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.

Members of the Intel ISEF Scientific Review Committee 2018:

Ms. Susan Appel
Mr. Henry Disston
Dr. Jennifer Green
Dr. Paula Johnson
Dr. Timothy Martin
Mrs. Evelyn Montalvo
Dr. Jason Shuffitt
Mrs. Andrea Spencer

Human Participants Rules

Rules involving human participants

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

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

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

1. Student-designed Invention, Prototype, Computer Applications or Engineering/Design Project in which the student is the only person testing the invention, prototype or computer application and the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed. The use of human participants (other than the student researcher him/herself) for this testing requires IRB review and approval (see page 10).

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

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

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

Rules

1. The use of human participants in science projects is allowable under the conditions and rules in the following sections. Based upon the U.S. Code of Federal Regulations (45 CFR 46), the definition of a **human participant** is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information. **These projects require IRB review and preapproval** and may also require documentation of written informed consent/assent/parental permission. Examples of studies that are considered "human participant research" requiring IRB preapproval include:
   a. Participants in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
   b. Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
   c. Studies in which the researcher is the subject of the research (Expedited Review may be used under certain conditions, see page 9)
   d. Testing of student designed invention, prototype or computer application by human participants other than student researcher (Expedited Review may be used under certain conditions, see page 9)
   e. Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables)
   f. Behavioral observations that
      1) involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
      2) occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
      3) involve the recording of personally identifiable information

2. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan/Project Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment information on page 11 and the online Risk Assessment Guide (https://student.societyforscience.org/human-participants#riskass) for additional guidance.

3. The research study should be in compliance with all privacy laws (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and U.S. 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/Project Summary 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. Risk Assessment information on page 11 and the online Risk Assessment Guide (https://student.societyforscience.org/human-participants#riskass) 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.
b. 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.
c. 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.
e. The student researcher may request that the IRB waive the requirement for written informed consent/parental permission in his/her research plan if the project meets specific requirements. See section on IRB waivers for more information about situations in which written parental permission and/or written informed consent can be waived by the IRB.

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/Project Summary and all of the Intel ISEF rules.

12. The following forms are required for studies involving human participants:
    a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
    b. Human Participants Form (4) with applicable consents and survey(s)
    c. Regulated Research Institution Form (1C), when applicable
    d. Qualified Scientist Form (2), when applicable
    e. Risk Assessment (3) when applicable

IRB Waiver of Written Informed Consent/Parental Permission

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:

- 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.
- 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.
- 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 only one member of the IRB may be conducted for projects that meet one of the criteria listed below. The IRB member reviewing the project will determine whether appropriate safety precautions will be employed and whether the project meets criteria for expedited review. If a project submitted for expedited review does not meet the criteria specified below, the project must undergo full IRB review. The IRB member reviewing the project must have the expertise necessary to make such a decision and/or receive advisement from an appropriate expert.

- Student-designed Invention, Prototype, Computer Application, or Engineering/Design Project in which the human participants other than (but possibly including) the student researcher are used to determine whether the invention/application works as intended. The data received in these types of projects is only in direct reference to the design. Personal data are not collected and the testing does not pose a health or safety hazard. (See below for further clarification.)
- Any other human participant study that does not involve student-designed invention in which the student is the only subject of his/her own research and the project does not involve more than minimal risk.

Human Participant Involvement in Student-designed Invention, Prototype, Computer Application & Engineering/Design Projects

Student-designed invention, prototype, computer application and engineering/design projects that involve testing of the invention by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype. To be considered for Exempt Status or Expedited Review, the data collected/feedback received must be a direct reference to the invention/prototype (i.e., personal data cannot be collected) and the testing may not pose a health or safety risk.

- Exempt Status can be used when the student researcher is the only person testing the invention/prototype. It is recommended that a Risk Assessment Form (3) be completed.
- Expedited Review process may only be used for projects that involve human participants to test a student designed invention or prototype in which the feedback obtained is only related to the invention.
- Full IRB Review is necessary if the activities involved in testing of the invention or prototype are more than minimal risk or involve collection of personal information from participants.
- Full IRB Review is necessary if the testing of the invention, prototype or project involves a medical intervention (as defined by the FDA or Medical Practices Act) and should be conducted in a Registered Research Institution with IRB approval from the institution.

Human Participant Risk Assessment

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

All human participant projects are considered to have some level of risk.

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 (https://student.societyforscience.org/human-participants#riskass) and Online Survey Consent Procedures (https://member.societyforscience.org/document.doc?id=40) 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. Health and well-being is of high priority when students conduct research with animal subjects.

The Society 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. (Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of an IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.) 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

1. 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
   c. Bird and reptile eggs up to three days (72 hours) prior to hatching
   d. All other nonhuman vertebrates (including fish) at hatching or birth.

   Exception: Because of their delayed cognitive neural development, zebrafish embryos may be used up to seven days (168 hours) post-fertilization.

2. 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.
   b. **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 local OR affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any 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.

6. 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 or Designated Supervisor, who is qualified to determine the illness, or by 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.

9. 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 or studies with the intent to study toxic effects of a substance on a vertebrate animal.
    b. 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.

13. 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/Project Summary 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.
c. 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.

1. 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 Institution (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 local or affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research and animal husbandry plan is required. This certification, as well as SRC approval, is required before experimentation 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.

5. The final disposition of the animals must be conducted in a responsible and ethical manner, and must be described on Vertebrate Animal Form (5A).

6. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site. Livestock or fish raised for food using standard agricultural/aquacultural production practices may be euthanized by a qualified adult for carcass evaluation.

7. The following forms are required:
    a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, 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 that 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 projects 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 Regulated Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

1. 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 affiliated fair SRCs 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.

3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals that is not mitigated by approved anesthetics, analgesics and/or tranquilizers are prohibited.

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/Project Summary, 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.
   f. 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)

1. The following types of studies involve BSL-1 organisms and are exempt from prior SRC review and require no additional forms:
   a. Studies involving baker's yeast and brewer's yeast, except in rDNA studies.
   b. Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing, oil-eating, 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 microbial 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 slime molds and edible mushrooms.
   f. Studies involving *E. coli k–12* which are done at school and are not recombinant DNA studies.

2. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
   a. Studies involving protists, archaea and known non-pathogenic microorganisms.
   b. Research using manure for composting, fuel production, or other non-culturing experiments.
   c. 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.

3. 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) if the Regulated Research Institution requires the review. The research must be supervised by a Qualified Scientist. For a high school BSL-2 laboratory, the SRC must review and approve.
   e. 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. Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted. Students may not genetically engineer organisms with multiple drug resistance traits for the intended purpose of investigation of the pathology or treatment of antibiotic-resistant infections. Insertion of antibiotic-resistance traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals, or plants is strictly prohibited.
   g. Laboratory studies culturing known MRSA (Methicillin-resistant *Staphylococcus aureus*), VRE (Vancomycin-resistant enterococci) and KPC *(Klebsiella pneumonia)* must have a written justification for usage and 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.
   i. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
   j. 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/Project Summary 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/Project Summary, 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.)

1. 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 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).
   c. The sealed petri dish is disposed of via autoclaving or disinfection under the supervision of the Designated Supervisor.

2. 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, plants and/or animals 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:

1. All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems, including commercially available kits, 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. 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.

3. 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.

4. Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses) is prohibited.

5. All genome editing studies that include alteration of germline cells, insertion of gene drives, use of rapid trait develpment systems (RTDS®), etc., should be categorized as a BSL-2 study and must be conducted at an RRI and approved by the IBC from the institution. Qualified scientists are expected to ensure that student research protocols address appropriate intrinsic and extrinsic containment precautions.

6. Introduction or disposal of non-native, genetically-altered, and/or invasive species (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. Students and adult sponsors should reference their local, state and national regulations and quarantine lists.

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 (except those known to be toxic or hazardous)
   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/Project Summary.
   c. 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.
   f. Fossilized tissue or archeological specimens.
   g. Prepared fixed tissue

2. 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/Project Summary.

3. 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. Use of tissues obtained from

research conducted at a Regulated Research Institution requires a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval. Use of tissues obtained from agricultural/aquacultural studies require prior SRC approval.

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. (See vertebrate animal rules.)

5. The collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 8) from a non-infectious source with little likelihood of microorganisms present must be considered Biosafety level 1 studies and must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.

6. The collection and examination of fresh/frozen tissues or body fluids or meat, meat by-products, pasteurized milk or eggs NOT obtained from food stores, restaurants, or packing houses may contain microorganisms. Because of the increased risk from unknown potentially hazardous agents, these studies must be considered biosafety level 2 studies conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist.

7. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered BSL-2.

8. All studies involving human or wild animal blood or blood products should be considered at a minimum a Biosafety level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Known BSL-3 or BSL-4 blood is prohibited. 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.

9. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.

10. Any study involving the collection and examination of body fluids may contain biological agents belonging to BSL-3 or BSL-4 is prohibited.

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.)
5. Assessment of the experience and expertise of the adult(s) supervising the student.
6. 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/Project Summary.
   b. 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. 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 tumefaciens*, *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 pneumoniae, Salmonella choleraesui*s.

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 an appropriate biosafety 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.