

2023-2024 High School Manual

NOTE: All students should use <u>mahs.zfairs.com</u> for project review and approval regardless of region.

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1. The Experience

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A High School Science & Engineering Fair

The Massachusetts Science & Engineering Fair (MSEF) gives high school students throughout Massachusetts a unique opportunity to compete for college scholarships, awards, honors programs, and other exciting prizes. But better yet, it brings them something even more precious: a valuable learning experience.

Each year, young scientists and engineers from public, private and parochial high schools (grades 9-12) pursue specialized fields of science by working on individualized research projects, either as part of their core curriculum or through independent study. These projects broaden scientific and engineering awareness and allow students to delve deeply into areas of special interest giving them a chance to explore, to gather information, to think critically, to arrive at conclusions, and to present ideas in a competitive forum. Science and engineering projects help develop higher level thinking skills.

Involvement in science and engineering projects provides students with opportunities to problem-solve, an understanding of and familiarity with the scientific method/engineering design process, and a basis of empirical knowledge, that carries over into many other parts of their lives. Curiosity and interest stimulate respect for evidence and develop a sense of stewardship. The science and engineering process demands an open mind and the use of analysis to process information. The student learns that success in investigation and research requires persistence and that such persistence can be both fun and rewarding.

Communities, through their local school systems, often share in the recognition their students receive, and through the guidance of parents, teachers, mentors, and Qualified Scientists, students are directed toward more advanced study, helping to maintain our scientific and engineering leadership now and for future generations. Taking part in the MSEF is a rewarding experience. It is an opportunity for students to learn and provides an opportunity for students to grow.

The Science & Engineering Process

The most critical aspect of a project is the way the student explores and manages the project. A simple project can offer a great experimental challenge to the imaginative student. Visit the <u>scifair.com</u> website for more information and resources.



OBSERVE: Choosing a Project

Student projects should be of an experimental nature —either investigating a research question or solving a challenge. The main areas for evaluation are the approach, the thought processes used in completing the project and the student's mastery of the topic and concepts. The strongest projects are often driven by student interest and what is personally meaningful to them.



PLAN: Research and Design

The next key step to planning a project is determining your 'testable question' or the 'problem to solve'. It needs to be something that can be observed and measured.

Then determine how you will address it. This is your research or design plan, where you identify what is feasible in the timeframe, what materials you need and the process you need to follow.



EXPLORE: Experimentation and Investigation

Students will need to experiment and investigate according to the plan they devised in the previous step. This may involve creating their prototype, testing, and revising and conducting multiple trials. Data collection and recording observations is critical in this step. In this phase it is important for students to know how to ask for help and learn from the unexpected.



EXPLAIN: Communication and Presentation

Students must analyze, interpret, and represent their work to tell the story of their project in a few different ways. Students will need to create graphs & tables, written reports as well as poster presentations. Students also will need to present their work through a practiced presentation as well as prepare for Q&A with judges and volunteers.

2. MSEF Ethics Statement Back to Table of Contents

Massachusetts Science & Engineering Fair, Inc. has adopted an ethics statement that each student is required to adhere to and will be asked to sign as a part of the research plan and application process.

The Statement

The primary reason that science/engineering project work enables such a wide range of learning to take place for each individual student is that the students themselves "own the question". Students pose a scientific/engineering problem and seek the necessary avenues to find a solution. When students work with a mentor either at school, in a lab or wherever project work takes place, *adults* working with students should bear in mind that it is the student's project. The mentor's job is to help students acquire background information; teach the techniques required to test the purpose or hypothesis and above all to look out for the safety of young scientists.

The mentor should <u>not</u> suggest or assign a specific topic to the student (the idea must come from the student), take data for the student (unless the student is willing to give credit to the data taker and does not claim the data as their own) or analyze the data for the student. These actions take away the opportunity for students to do these activities on their own and devalue student science/engineering project work in general. The motive for introducing science and engineering projects to young people is to help encourage responsible future scientists. *The behavior of adult mentors should model the honesty and integrity expected of scientists in our world.*

Before experimentation begins each student is required to complete a Research Plan, which includes signing the Ethics Statement that the student will, "adhere to all MSEF/ISEF rules when conducting research." Students may compete in only one MSEF affiliated fair, except when proceeding to the state fair from their affiliated Regional Fair. Students are only eligible to compete in their assigned science and engineering fair region, which is determined by the MSEF. *The student(s) will be judged only on the most recent year's research.*

Any act of plagiarism associated with science project work exhibited at the Massachusetts Science & Engineering Fair will lead to disqualification. Webster's New Collegiate Dictionary defines plagiarize as "to steal and pass off (the ideas or words of another) as one's own: use (a created production) without crediting the source: present as new and original an idea or product derived from an existing source."

In terms of science/engineering project work this means the student MUST:

- Complete all the necessary paperwork and permission forms, before, during and after experimentation honestly.
- Document their work in a dated notebook recording development of the project including all references, procedures, original data and other relevant material.
- Include a bibliography as part of their background research.
- Cite the author of any original statement that is not their own.
- Give credit to anyone giving assistance to the student. If another person(s) performed any part(s) of the experiment, data, collection, etc., credit must be given in the student's journal/log, display, and report.

In the lab - It is generally assumed that work discussed at science and engineering fairs is the work of the student. When this is not the case the student needs to make this very clear in their oral and written presentations of the project.

Photographs and Visuals - Any photographs included in the student's paper or on their presentation board are assumed to have been taken by the student. Any photographs NOT taken by the student MUST be clearly labeled giving credit to the photographer. This includes any visuals taken from magazines, newspapers, journals, the internet or texts where appropriate permission must be solicited and included. The use of photographs of persons requires 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 the research."

Scientific/engineering 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 and MSEF reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

Students MUST NOT:

- In any way falsify a permission form or scientific paper.
- Use another person's results or thoughts as their own even with the permission of this person. This includes work done by a family member or a mentor.
- Use information or data obtained from the internet without proper citation.
 - o Enter a project for a second or third year with only minor changes.

B. New 2024: Statement on grievences, accusations of wrong-doing, and protections to scientific integrity

Statement on Scientific Integrity

It is the expectation that the Ethics statement will be reviewed by students, teachers, parents, mentors, and supervisors so that they are individually and collectively aware of and monitoring for scientific integrity.

If an issue of concern arises related to scientific integrity or other grievance such that it needs to be brought to MSEF, the following process should be followed.

Email info@scifair.com

Subject: Grievance/ Accusation of wrong-doing

Body of email:

- Include your First and Last Name
- Your affiliation: school or company
- Your contact information (phone and email)
- The Fair at which the concern is placed/originated
- Indicate whether you are a: Student Participant, Parent, Teacher, Advisor/Mentor, or Concerned Citizen
- Please provide a brief description of the issue. Be sure to include your concern, any actions that have been taken, any responses received (or not), etc.
- Please indicate any other people that you have already spoken with about your concern.

Please note:

- Grievances shared more than 60 days after a Fair may not be possible to address, as MSEF does not have access to some student paperwork after that time.
- MSEF will keep the identity of the reporting individual anonymous in any resulting communication
- MSEF is not obligated to share any subsequent details about the resolution with the individual/institution that issues the
 grievance.
- If action is warranted, MSEF will coordinate with the fair, teacher, and student for corrective action.
- If anonymous information is received, no action will be taken.

Use and Abuse of Artificial Intelligence

We recognize that there are new tools that can support idea generation, writing, and data collection. It is MSEF's expectation that projects are always the students' own work. Students and teachers can work together to determine if the use of supports that rely on artificial intelligence are appropriate for use. This should follow any school policies and be based on maintaining scientific integrity and avoiding plagiarism.

See also policies that can be found at www.scifair.com/fairs including:

Harrassment Policy

Policy for Reasonable Accomodation of Qualified Students with Disabilities

Student Eligibility Policy

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The Student Researcher(s)

The student researcher is responsible for all aspects of the research project:

- Enlisting the aid of any required supervisory adults (Teacher, Adult Sponsor, Qualified Scientist, etc.), obtaining necessary approvals (SRC, IRB, etc.)
- Following the International and Massachusetts Rules & Guidelines and obtaining all necessary approvals (SRC, IRB, etc.) and completing all appropriate documentation
- Performing the project (which may include, but is not limited to) experimentation, data collection, engineering, data analysis, and any other process or procedures related to the project
- Understanding and abiding by the Ethics Statement and attesting to this understanding on Approval Form

Teacher - NEW for 2024

Students must select a school and teacher to support their participation. In many cases, the teacher is also the Adult Sponsor on the program (see below). Communication through zFairs and from the SRC goes to the Teacher.

The teacher is responsible for:

- Communicating with MSEF and Regional Fairs about students' participation in the Fair
- Monitoring any communication with the SRC for project approval follow-up as needed.
- Making sure students have follow-through, communication and are aware of rules and expectations

If students do not have support of a school:

- Homeschool students can participate with a licensed homeschool parent as 'teacher'
- Students can pursue a project in collaboration with an out-of-school time provider or STEM educator connected to an organization, like a library or club.
- Students should contact MSEF for more details at info@scifair.com.

The Adult Sponsor- In most cases, the adult sponsor is also the teacher. This should be the default.

Qualifications:

- An Adult Sponsor may be a teacher, parent, professor, and/or other professional scientist
- Should be knowledgeable in the area of student research, be familiar with the regulations around procedures and
 materials that apply to the student project, particularly when involving human participants, vertebrate animals,
 potentially hazardous biological agents or hazardous chemicals, devices, or activities.
- Should have close contact with the student throughout the timeline of the project.

Responsibilities:

The Adult Sponsor is responsible for:

- Working with the student to evaluate any possible risks involved to ensure the health and safety of the student conducting the research and the humans and/or animals involved in the study.
- Reviewing the student's Student Checklist (1A) and Research Plan/Project Summary to ensure that:
 - o experimentation follows local, state, and Federal laws and MSEF/ISEF rules
 - o forms are completed by other required adults
 - o any required Qualified Scientist meets the criteria in the MSEF/ISEF Rules and Guidelines
 - the student's research is eligible for entry in MSEF/ISEF

The Qualified Scientist

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Qualifications:

• Earned a doctoral/professional degree in a scientific discipline related to student's area of research AND/OR Individual with extensive experience and expertise in the student's area of research

- Must be thoroughly familiar with the regulations that govern the student's area of research including all local, state, Federal regulations and laws.
- Can also serve as the Adult Sponsor if that person meets both sets of qualifications
- A teacher may be eligible to serve as the Qualified Scientist
- May live elsewhere and not be local to the student, in which case, a Designated Supervisor has been appointed and trained to serve as the onsite supervisor for the specific student project.

Responsibilities:

The Qualified Scientist is responsible for:

- Reviewing the MSEF/ISEF rules relevant to the project and approving the student's research plan or engineering design prior to the start of experimentation
 - o Completing the required documentation which may include the Regulated Research Institutional Setting Form (1C), the Qualified Scientist Form (2), or the Risk Assessment Form (3), when applicable.
- Providing direct supervision throughout the timeline of the project or coordinating with a Designated Supervisor to serve in this capacity
- Ensuring the proper training of the Student Researcher and/or Designated Supervisor in the necessary procedures
- If located outside of Massachusetts, reviewing any differences in rules and regulations for Massachusetts students.

The Designated Supervisor

Qualifications:

- Does not need an advanced degree
- Must be familiar with the student's project and agree to any training necessary
- May also serve as the Adult Sponsor for the project
- If the project involves the use of Vertebrate Animals (where behavior/habitat is influenced by humans), must be knowledgeable about the humane care and handling of the animals

Responsibilities:

The Designated Supervisor is responsible for:

- Providing direct supervision of the student experimentation
- Completing the required documentation the Designated Supervisor box on the Qualified Scientist Form (2) when applicable
- Reviewing and completing the Risk Assessment Form (3) when needed

Review Committees

To avoid conflict of interest, no <u>Adult Sponsor</u>, parent or other relative of the student(s), the <u>Qualified Scientist</u>, or the <u>Designated</u> Supervisor who oversees the project may serve on the SRC reviewing that project.

Both the MSEF SRC and ISEF SRC are made up of adults knowledgeable about research regulations. In addition to the review of all projects, committee members answer questions about rules throughout the year from students and teachers.

- The MSEF SRC can be contacted at SRC@scifair.com
- The ISEF SRC can be contacted at SRC@societyforscience.org

The Scientific Review Committee (SRC)

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.

ALL proposed research projects involving any of the **Restricted Areas of Research** (work with human subjects, with vertebrate animals, with potentially hazardous biological agents, or with any hazardous chemicals/activities/devices) must be reviewed and approved BEFORE experimentation begins.

ALL projects, including those previously reviewed and approved by an SRC/IRB, must be reviewed, and approved by the SRC after experimentation and before competition in a Fair.

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

- a biomedical scientist with an earned graduate degree
- an educator
- Additional members are recommended to diversify and to increase the expertise of the committee.

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.

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

- Evidence of proper supervision
- Completed forms, signatures, research dates, and preapproval dates (when required)
- Evidence of proper team composition
- Compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents and/or hazardous chemicals, activities, or devices
- Compliance with ISEF ethics statement
- Use of accepted and appropriate research techniques
- Evidence that risks have been properly assessed
- Evidence of search for alternatives to animal use
- Humane treatment of animals
- Documentation of substantial expansion for continuation projects
- Evidence of appropriate literature search and attribution

Students:

Make sure your research plan covers these elements, as appropriate, to streamline the review process!

The ISEF Scientific Review Committee (Regeneron ISEF SRC)

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

Note: Students selected for participation will need to work with MSEF for a quick response to submit forms by the ISEF deadlines.

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 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

For most projects, an IRB is an informal collection of three individuals who can review projects at the localized setting (the school). The composition of this group may change for individual projects based on needed expertise. Students and teachers should work together to collect the signatures from the appropriate individuals.

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 Human Participant Form 4 and can be used in lieu of the signature of that expert.

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 ISEF rules.

Overriding IRB Approval: 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 assesses 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 ISEF SRC in questionable cases.

Regulated Research Institutions/Industrial Settings Review Committees

A **Regulated Research Institution** (RRI) 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.

It is critical that students working in institutions outside the United States communicate with BOTH their foreign research mentors and a **teacher** or mentor in the United States to ensure that the students are complying with both local safety regulations in the country they are working in and follow the Massachusetts regulations. Regulations for minors working in a lab are often stricter than those for an undergraduate or graduate student in the same lab. <u>Mentors who are not aware of the additional restrictions on minors may unknowingly authorize work that will not be eligible for competition in MSEF.</u> Safety protocols should refer to US guidelines for researchers (ie. the designations for biological safety levels) so that the US based reviewers can understand if proper safety procedures are in place before the work commences.

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

Independent or private laboratories, such as those established to support student researchers do not meet the requirements of oversight or committee infrastructure to be considered Regulated Research Institutions (RRI). Therefore, such laboratories should be considered the same as high school laboratories as it pertains to the International Rules and the types of projects able to be conducted in this setting. For purposes of documentation, such facilities may complete the Regulated Research Institution/ Industrial Setting Form 1C to address the adult supervision and conditions of research.

4. Official Rules and Requirements

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- Approval and Documentation
- Continuation/Research Progression of Projects
- Team Projects

General

- 1. All students competing in MSEF, or its affiliated Regional Fairs, must adhere to all rules as set forth in this document.
- 2. All projects must adhere to the Ethics Statement.
- 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.
- 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, 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. A project may include no more than 12 months of continuous research and may not include research performed before January of the year prior to the fair. (e.g., projects in the 2050 Fair cannot begin before January 2049)
- 8. Projects that are demonstrations, library research or informational projects, explanation models or kit building are not appropriate for competition in MSEF.
- 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. These details must be explained thoroughly on form 1C and in the research plan and other forms as appropriate.

Approval and Documentation

- 1) Project documentation should begin before experimentation with the current forms available.
- 2) Every student must complete the <u>Student Checklist (1A)</u>, a <u>Research Plan/Project Summary</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>.
- 3) Projects involving **Restricted Areas of Research** (work with human subjects, with vertebrate animals, with potentially hazardous biological agents, or with *any* hazardous chemicals/activities/devices) must be reviewed and approved by the Scientific Review Committee (SRC) **prior to the start of experimentation** (pre-approval).
 - (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.)
- 4) A **Qualified Scientist** is required for ALL studies involving **Restricted Areas of Research** (work with human subjects, with vertebrate animals, with potentially hazardous biological agents, or with any hazardous chemicals/activities/devices) AND those that require pre-approval by an SRC.

- 5) If students attending **summer institutes** or **summer science training programs** plan to submit their summer project work to a Science & Engineering Fair, they must have the Qualified Scientist and the Scientific Review Committee (SRC) approve the research plan BEFORE the research begins.
- 6) After initial IRB/SRC approval (if required), any proposed changes in the <u>Student Checklist (1A)</u> and/or the <u>Research Plan/Project Summary</u> must be **re-approved** before laboratory experimentation/data collection resumes. Contact <u>src@scifair.com</u> to submit an addendum and revised paperwork.
- 7) Projects which are continuations of a previous year's work **and** which also require IRB/SRC approval must undergo the review process with the current year <u>Research Plan/Project Summary</u> prior to experimentation/data collection for the current year.
- 8) Any continuing project must document that the additional research is new and different by completing a Continuation/Research Progression Projects Form (7). This form must be displayed with the project during competition.
- 9) If work was conducted either virtually or on site at a regulated research institution, industrial setting, or any work site other than home, school, or a field site at any time during the current project year, the Regulated Research Institutional/Industrial Setting Form (1C) must be completed. This form must be displayed with the project during competition.
 - i) Note: If working in a lab, the expectation is that your project is your own work and your own design. The lab may sponsor your project as an independent study separate from any lab- tech assignment.
- 10) After experimentation, each student or team must submit a (maximum) 250-word **abstract** which summarizes the current year's work. The abstract must describe research conducted by the student, not by the supervising adult(s).
- 11) A project **notebook** is required and is part of the judging process and scoring at regional and state fairs. **Project notebooks** should demonstrate evidence of your project development including data collection and research. Each student should keep their own project notebook. These can be digital or hand-written.
- 12) 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 final review must occur **after experimentation** and **before competition**.

Continuation/ Research Progression of Projects

- a) 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 of the previous year and ending in May of the current year.
- b) 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.
- c) 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 data books, research papers and supporting documents may be at the project display if properly labeled as such.
- d) 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.
- e) All projects must be **reviewed and approved each year** and forms must be completed for the new year.

f) Retention of all prior years' paperwork is required and must be presented to the MSEF SRC upon request. Each page of the previous year's forms must be clearly labeled in the upper right-hand corner with the appropriate year.

Team Projects

- 1. Teams must have no more than three members.
- 2. 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.
- 3. Teams composed of members that attend different high schools are eligible to compete in MSEF and its affiliated Regional Fairs as an entry through the school of enrollment for the Team Leader. The teacher of record must be employed by the same school as the Team Leader. The following team compositions are allowed:
 - a. Students attending different high schools in the same Massachusetts Region.
 - b. Students attending different high schools in different Massachusetts Regions.
 - c. Students attending different high schools in different states as long as the Team Leader attends a Massachusetts High School.
 - d. Students attending different high schools in different countries as long as the Team Leader attends a Massachusetts High School.

Note: Any Multi-school team project may only participate in one (1) affiliated Regional Fair.

- 4. 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 <u>Student Checklist</u> (1A).
- 5. 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.
 - a. Teams may not have more than three members at a local fair and then eliminate members to qualify for the regional, state, or international fairs.
 - b. All members of the team must be present at the local, regional, state, and international fairs to compete.
 - c. In a future research 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.
- 6. Each team member must submit an Approval Form (1B). All other forms are submitted jointly.
- 7. Full names of all team members must appear on the forms, Research Plan/Project Summary, and Abstract.
- 8. The methods or procedures in the Research Plan/Project Summary should include an outline of each team member's task(s).

- I. Hazardous Chemicals, Activities or Devices
- II. Human Subjects
- III. Vertebrate Animals
- IV. Potentially Hazardous Biological Agents (PHBAs)

General Rules

- 1. Projects involving **Restricted Areas of Research** must be reviewed and approved by the Scientific Review Committee (RSRC) **prior to the start of experimentation** (pre-approval).
- 2. A Qualified Scientist is required for ALL studies involving Restricted Areas of Research that require pre-approval by an SRC.
- 3. Students should follow the process below for creating accounts, uploading paperwork and seeking approvals.
 - Make sure your teacher and/or adult sponsor have reviewed your Research Plan.
 - Teachers will need to create an account on the Statewide SRC zFairs before students can set up accounts.
 - Set up your account online platform (<u>MAHS.zfairs.com</u>) according to the posted directions. Consult the tutorials at <u>scifair.com/resources</u> and reach out to <u>info@scifair.com</u> and your region with questions. Use a personal email if your school blocks external emails.
 - Once you have your research plan, identify the **paperwork** you will need for your project. See the <u>manuals</u> for more information. zFairs will generate forms that are required based on information in your account.

ALL PROJECTS:

- Checklist for Adult Sponsor (1),
- Student Checklist (1A),
- Research Plan/ Project Summary, and Approval Form (1B)

Regulated Research Institution Form (1C), when applicable

Qualified Scientist Form (2), when applicable

Risk Assessment (3), when applicable

Human Subjects (4), when applicable, must be printed, signed and uploaded

Vertebrate Animal (5A, 5B), when applicable

PHBA Risk Assessment Form (6A), when applicable

Human and Vertebrate Animal Tissue Form (6B), for all studies involving tissues and body fluids **Continuation Form (7)**, for projects that build on earlier projects

- Have your research plan and any required paperwork approved
 - All projects must first be approved by your adult sponsor through the signature on form 1A before experimentation.
 - o If your project involves the <u>Restricted Area of Research</u>, you must have the approval of the Scientific Review Committee (SRC) <u>before starting the experimentation</u>.
 - Summer projects in restricted areas must also follow this pre-approval process BEFORE EXPERIMENTATION. Email src@scifair.com for approval
- All projects that will be participating in a Fair need approval by the Statewide SRC before participating in a Regional or State Fair. Submit forms once your research plan is complete. Teachers should request approval through the portal when your forms are ready.
 - The final deadline for pre-approval projects is December 18, 2023. However, you should submit forms and plans to SRC as soon as possible so they are approved before experimentation begins, especially if the project requires several months of work.
 - o If your project does NOT require SRC pre-approval, submit to zFairs before February 5, 2023.

Section I - Hazardous Chemicals, Activities or Devices

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Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms, and explosives, regulated drones, radiation, etc. SEE ALSO Appendix A: Guidance for Risk Assessment: Hazardous Chemicals and Devices SEE ALSO Appendix D: Guidance for Risk Assessment: Engineering and Invention Projects

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. If students are using tools or devices that are in common use in the classroom or home and students are familiar with their use, they MAY be exempt from pre-approval (consult appendix A and email src@scifair.com for clarification). Form 3 is still recommended for final approval to ensure safety procedures were in place.

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 school, local, regional and/or state level fairs.

Rules for ALL Projects Involving Hazardous Chemicals, Activities and Devices

- 1. The student researcher must conduct a risk assessment in collaboration with a <u>Designated Supervisor</u> or <u>Qualified Scientist</u> prior to experimentation. This risk assessment should be documented in the research plan to include the risk assessment process, supervision, safety precautions and appropriate methods of disposal. This risk assessment is also documented on <u>Risk Assessment Form 3</u>.
- 2. The use of hazardous chemicals and devices and involvement in hazardous activities **require direct supervision** by a <u>Designated Supervisor</u>, except those involving DEA-controlled substances, which require supervision by a <u>Qualified Scientist</u>.
- 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 Regional, and MSEF 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. (Proper chemical, sharps and other hazardous materials disposal must follow local, state, federal guidelines.)
- 6. 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 Form (2), when applicable
 - d. Risk Assessment Form (3)

There are additional rules for the following regulated substances:

- A. DEA-controlled Substances
- B. Prescription Drugs
- C. Alcohol & Tobacco
- D. Firearms and Explosives
- E. Regulated Drones
- F. Radiation

A. 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 (www.dea.gov) 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.

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

B. Prescription Drugs

In the United States, the Food and Drug Administration tightly regulates the issuance of prescriptions and thus they are controlled substances. State laws further regulate the use of prescription drugs and it is unlawful for any person knowingly or intentionally to possess a controlled substance unless it was obtained directly from a valid prescription or order of a practitioner while acting in the course of their professional practice. It is also unlawful to use the prescription for persons or purposes outside of the original prescription. All applicable federal, state and country laws must be followed.

- 1. Students are prohibited from the use of prescription drugs in their study outside of the authority of a practitioner or researcher that has obtained the controlled substance with appropriate approvals and is using the substance for the purpose for which it was prescribed.
 - a. Such studies must be conducted with a Qualified Scientist and a Risk Assessment Form 3 is required documentation.
 - b. Students are further prohibited from providing prescription drugs to human participants.
- 2. In the case of prescription drugs administered to vertebrate animals, this may only be done under a veterinarian's supervision and with prescriptions provided for this specific purpose.

C. 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.

- 1. Fermentation studies in which *minute* quantities of ethyl alcohol are produced are permitted.
- 2. The <u>Designated Supervisor</u> is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
- 3. 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.
- 4. 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 or a Regulated Research Institution and follow all local and country laws. See the Alcohol and Tobacco Tax and Trade Bureau (TTB) website for details. (www.ttb.gov)

D. Firearms and Explosives

The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) (www.atf.gov), 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.

- 1. Projects involving firearms and explosives are allowable **when conducted with the direct supervision** of a <u>Designated</u> 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 firearms unless they are intended to be used as weapons. However, they must be treated as hazardous devices.

E. Regulated Drones

Projects involving unmanned aircraft systems (UAS)/drones must follow all state, Federal, and country laws. See the Federal Aviation Administration (FAA) for more details (www.faa.gov.uas/registration).

Current U.S. law requires all forms of drones to be registered with the FAA.

F. Radiation

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.

- 1. 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.
- 2. 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.
- 3. 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.
- 4. 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.

SEE ALSO Appendix B: Guidance for Risk Assessment: Human Participants

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 human participants and the student researcher. Health and well-being are of the highest priority when students conduct research with human participants.

According to Code of Federal Regulation 45, CFR 46, a **human participant** is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individuals(s) or (2) identifiable private information.

Examples of projects that are considered "human participant research" include:

- Participants in physical activities (e.g., physical exertion, any medical procedure)
- 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, prototype, or computer application 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)
- Behavioral observations that
 - o involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
 - o occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
 - o involve the recording of personally identifiable information.

Exempt Studies (Do Not Require IRB Pre-approval or Human Participants Paperwork)

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

- 1. Student-designed Invention, Prototype, Computer Applications, Engineering/Design Project or Consumer Product Testing in which the student researcher is the only person testing the invention, prototype, computer application or consumer product and the testing does not pose a health or safety hazard.
 - a. The exemption can also apply when the human participant testing is a single adult guardian or Adult Sponsor/QS/DS when the testing requires an adult tester.
 - b. It is required that a Risk Assessment Form (3) be completed for all such projects.
 - c. IRB review and pre-approval is required if the project involves more than the student researcher or any introduction of a human variable or factor in the testing of a consumer product/invention/prototype/application (e.g., amount of sleep, strength or endurance of tester, etc.).
- 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:
 - the professional providing the data certifies in writing that the data have been appropriately deidentified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
 - the affiliated Regional Fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s)

Rules

- 1. Student researchers must complete ALL elements of the Human Participants portion of the <u>Research Plan/Project</u> Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. Refer to the <u>Guidance on Risk Assessment</u> in Appendix B for additional guidance.
- 2. Student research involving human participants **must be reviewed and approved** by an Institutional Review Board (IRB) **before any interaction** (e.g., recruitment, data collection) with human participants may begin. It is the responsibility of the IRB to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for the student researcher and participants.
 - a. Projects that are conducted at school, at home or in the community that are not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the School IRB before the student may begin recruiting and/or interacting with human participants. The School IRB must assess the risk and document its determination of risk on Human Participants Form 4.
 - b. Projects that are conducted at a Regulated Research Institution (RRI) (e.g., university, hospital, medical center, government lab) must have IRB approval from the RRI. A copy of the IRB approval for the project must be obtained. A letter from an adult mentor and/or Qualified Scientist is not sufficient documentation of the RRI IRB review and approval process.
- 3. The student must comply with all determinations made by the School or RRI IRB before beginning any interaction with human participants (e.g., recruitment, data collection).
 - a. If the IRB requires a Qualified Scientist (QS), a <u>Qualified Scientist Form 2</u> must be completed by the QS before any interaction with human participants. The School IRB will review this completed form before approving the project.
 - b. If the IRB requires a Designated Supervisor (DS), a <u>Qualified Scientist Form 2</u> must be completed before any interaction with human participants. The School IRB will review this completed form before approving the project.
 - c. See rule #4 below regarding required procedures for obtaining informed consent/assent and/or parental permission.
- 4. Participation in research may begin only after research participants have voluntarily given **informed consent/assent** (in some cases with parental permission). 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 School IRB will determine whether the consent/assent/ parental permission may be a) verbal or implicit or b) must be written. See the online <u>Risk Assessment Guide</u> provided by ISEF 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** and that they are **free to stop participating at any time** (i.e., they may participate or decline to participate, with no adverse consequences of non-participation or aborted participation).
- c. Informed consent may not involve coercion.
- 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.
- 5. The research study **must be in compliance with all privacy laws** (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and the U.S. Health Insurance Portability and Accountability Act (HIPAA)) when they apply to the project involves medical information).
- 6. Students are **prohibited** from independently **diagnosing** disease, **administering** medication, and/or **performing** medical procedures on human participants.
 - a. A student may **observe** and collect data for analysis of medical procedures, medication/treatment efficacy, and diagnosis of illness, only under the direct supervision of a licensed health care provider/professional.
 - b. This Healthcare provider/professional must be named in the research plan/ protocol approved by the IRB. The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc.) of the state or country in which he/she is conducting the research.
 - c. Students are **prohibited from providing diagnostic or medical information** to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.
- 7. 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)).
- 8. 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.
- 9. 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.
 - a. Studies that involve the use of minors in conducting online surveys must have Informed Consent and the parent/guardian of the minor must provide written parental permission before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.
 - b. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be delineated in the Research Plan.

For suggestions as to how to comply with 9a and 9b above please see the Online Survey Consent Procedures.

10. After initial IRB approval, a student with **any proposed changes** in the Research Plan **must repeat the approval process** and regain approval before resuming interaction (recruitment, data collection) with human participants.

- 11. After experimentation and before competition, the affiliated Statewide SRC will review for compliance with all rules.
- 12. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/ Project Summary, and Approval Form (1B)
 - b. Human Participants Form (4)
 - OR (if applicable): Regulated Research Institution Form (1C) and

the IRB approval form from the RRI and all applicable consents and survey(s)

- c. Qualified Scientist Form (2)
- d. 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, anonymous data collection, and if it is one of the following:

- 1. Research involving normal educational practices
- 2. 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.
- 3. 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.
- 4. 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.

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

Student-designed invention, prototype, computer application and engineering/design projects that involve testing of the invention or consumer product by any human participant **require attention to the potential risks** to the individual(s) testing or trying out the invention/prototype.

- 1. IRB review and pre-approval is required when the student- designed invention, prototype, application, etc. is **tested by human participants other than the student researcher(s) or single adult guardian/adult sponsor/QS/DS** when the testing requires an adult tester. This includes surveys conducted regarding potential use, review of the invention or consumer product and/or opinions regarding the project/product.
- 2. Human participants testing of an invention, prototype or project that **involves a medical diagnosis or intervention** (as defined by the FDA or Medical Practices Act) must adhere to Rule 6 of the Human Participant Rules regarding prohibition of medical procedures and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention being studied.
- 3. A <u>Risk Assessment Form 3</u> is required for all projects that involve human participant testing of any project involving student-designed inventions, prototypes, or consumer products.

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 are of high priority when students conduct research with animal subjects.

Massachusetts Science & Engineering Fair, Inc. (MSEF) promotes humane attitudes toward all animals used in scientific investigation. MSEF opposes projects that involve cruelty or abusive treatment, either during the preparation process or in the actual demonstration at the Fair. The basic aim of projects using live organisms is to achieve an understanding of life processes. Therefore, experimentation must be conducted in a manner that fosters a **humane regard for animals** and a **respect for life**.

According to Massachusetts State Law:

Chapter 272, Section 80G. No school principal, administrator or teacher shall allow any live vertebrate to be used in any elementary or high school under state control or supported wholly or partly by public money of the state as part of a scientific experiment or for any other purpose in which said vertebrates are experimentally medicated or drugged in a manner to cause painful reactions or to induce painful or lethal pathological conditions, or in which said vertebrates are injured through any other type of treatment, experiment or procedure including but not limited to anesthetization or electric shock, or where the normal health of said animal is interfered with or where pain or distress is caused.

Therefore,

- 1. No vertebrate animals can be sacrificed (killed) for the purpose of student research or to obtain tissue for a student's research.
- 2. No studies with the intent to cause duress, pain, injury, distress, or death are allowed.
- 3. No studies with the intent to study the toxic effects of a substance on a vertebrate animal are allowed.

MSEF **strongly endorses** the use of **non-animal research methods** and encourages students to use alternatives to animal research, which must be explored and discussed in the research plan. The guiding principles for the use of animals in research include the following "Four R's":

- **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.
- Refine the experimental protocol to eliminate any potential pain or distress to the animals.
- **Respect** animals and their contribution to research.

If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals.

Vertebrate Animals, as covered by these rules, are defined as:

- 1. Live, non-human vertebrate mammalian embryos or fetuses
- 2. Tadpoles
- 3. Bird and reptile eggs starting three days (72 hours) prior to hatching

4. All other non-human vertebrates (including fish) at hatching or birth.

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Exception: Because of their delayed cognitive neural development, zebrafish embryos may be used up to seven days (168 hours) post-fertilization and not be considered a vertebrate. However, regardless of time of treatment, survival past the 7 days must be considered a vertebrate animal and the entire study is subject to all of the rules below.

Exempt Studies (Do Not Require SRC Preapproval)

Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:

- 1. There is no interaction with the animals being observed
- 2. There is no manipulation of the animal environment in any way, and
- 3. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.

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 pertaining to tissue studies are including in the next section on Potentially Hazardous Biological Agents (PHBAs)*.

All projects involving vertebrate animals **must adhere to the rules below** AND to the rules in **either Section A** (School/Home/Field Site) or **Section B** (Regulated Research Institute), depending on the nature of the study and the research site.

Rules for ALL Vertebrate Animal Studies

- 1. 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 **eliminate** 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.
- 2. All vertebrate animal studies must be reviewed and approved before experimentation begins.
 - a. 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.
 - b. The Statewide SRC serves in this capacity for vertebrate animal 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.
- 3. 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.
- 4. Research projects which cause slight pain or distress are <u>prohibited</u>. 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 <u>Qualified Scientist</u> or <u>Designated Supervisor</u>, 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.

- 5. **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.
- 6. All animals must be monitored for signs of distress.
 - a. Because significant weight loss is one sign of stress, weight must be recorded at least weekly with 15% being the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal. If weighing of animals cannot be done in a fashion that is safe for both the researcher and the animal, then an explanation and approval by an SRC or IACUC needs to be included in the research plan, as well as an alternative method(s) to address signs of distress.
 - b. Additionally, body conditioning scoring (BCS) systems are available for most species of animals utilized in research and agriculture and are an objective method for assessing the overall health status of the research subject, with or without weight loss. A BCS system should be included in the design of any study utilizing live vertebrate animals and results regularly recorded.
- 7. 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.
- 8. 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.
- 9. Animals must be obtained from licensed laboratory animal breeders. Pet store animals, except fish, are inappropriate because their genetic and nutritional background, as well as disease potential, is unknown.
 - a. 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.
 - b. 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.
 - c. The use of electrofishing is permissible only if conducted by a trained supervisor; students are prohibited from performing electrofishing.

- 10. A <u>Qualified Scientist</u> or <u>Designated Supervisor</u> must **directly supervise all research** involving vertebrate animals, except for observational studies.
- 11. 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.

Section A Rules: 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:

- 1. Studies of animals in their natural environment.
- 2. Studies of animals in zoological parks.
- 3. Studies of livestock that use standard agricultural practices.
- 4. 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.

Any vertebrate animal studies that do not meet the above guidelines must be conducted in a Regulated Research Institutions. *See Section B Rules*.

- 2. Animals must be treated kindly and cared for properly.
 - a. Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species.
 - b. They must be given a continuous, clean (uncontaminated) water and food supply.
 - c. Cages, pens, and fish tanks must be cleaned frequently.
 - d. Proper care must be provided at all times, including weekends, holidays, and vacation periods.
 - e. Animals must be observed daily to assess their health and well-being.
 - f. A <u>Designated Supervisor</u> is required to oversee the daily husbandry of the animals.
 - g. 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 SRC must determine if a veterinarian's certification of the research plan and animal husbandry plans is required. This certification, as well as SRC approval, is required before experimentation and is documented on <u>Vertebrate Animal Form 5A</u>. 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 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.
- 7. Intentionally left blank.
- 8. 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)

Section B Rules: Additional Rules for Projects Conducted in a Regulated Research Institution

All studies not meeting the criteria in Section A that are otherwise permissible under these 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 a 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 Regulated Research Institution are not permitted for participation in MSEF; therefor adherence to RRI rules is required, but may not be sufficient for MSEF.

- 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 SRC must also review the project to certify that the research project complies with MSEF Rules. This SRC review should occur before experimentation begins, if possible.
- 2. Euthanasia for tissue removal and/or pathological analysis is **not permitted** for a project conducted in a Regulated Research Institution.
- 3. Intentionally left blank.
- 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

Section IV - Potentially Hazardous Biological Agents (PHBAs)

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Includes microorganisms (bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA technologies, human or animal fresh/frozen tissues, blood, or body fluids.

SEE ALSO Appendix C: Guidance for Risk Assessment: Potentially Hazardous Biological Agents (PHBAs)

Students are permitted to do 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 Potentially Hazardous Biological Agents Risk Assessment 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 proposed laboratory facility is properly equipped and all personnel are trained and appropriate supervision is planned.

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** (unknown microorganisms), **Section B** (rDNA Technology), or **Section C** (Tissues and Body Fluids).

Exempt Tissues (no SRC pre-approval required)

The following types of tissue do not need to be treated as potentially hazardous biological agents (PHBAs):

- 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 <u>Research Plan</u>.
- c. Human capillary/blood collection (i.e., finger stick) of the student researcher to themself; blood collection from **any other human participants** must be reviewed and approved by an IRB.
- d. Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from **food stores**, **restaurants**, **or packing houses**
- e. Hair, hooves, nails, and feathers
- f. Teeth that have been sterilized to kill any blood-borne pathogen that may be present
- g. Fossilized tissue or archeological specimens
- h. Prepared fixed tissue

Exempt Studies (no SRC pre-approval required)

The following types of studies are exempt from requiring SRC pre-approval *as listed below*, but **may be subject to additional rules dependent upon the design of the project**. Student Researchers and Adult Sponsors are required to still refer to the Rules for ALL projects and sections A-C of the PHBA rules to be aware of additional rules for projects that involve unknown organisms, recombinant DNA (rDNA) technologies, tissues, fluids, blood, or blood products **before deciding upon a final biosafety level** (BSL) designation for projects.

- 1. The following types of studies are **exempt from prior SRC review**, but require a Risk Assessment Form 3:
 - a. Studies involving protists and archaea.
 - 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 in which the device is sealed during experimentation and disposed of properly at the conclusion of the study.
- 2. The following types of studies involve BSL-1 organisms and are **exempt from prior SRC review** and require **no additional forms**:
 - a. Studies involving fermentation of baker's yeast and brewer's yeast, except in rDNA studies.
 - b. Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing bacteria, oil-eating bacteria, or algaeeating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment.)
 - c. Studies involving water or soil microbes not concentrated in media conducive to their microbial growth.
 - 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* (and other strains of *E. coli* used solely as a food source for *C. elegans*) that are **performed at school** and are not subject to additional rules for recombinant DNA studies or use of antibiotic resistant organisms.

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

- 1. Prior review and approval are required for the use of
 - a. potentially hazardous microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites)
 - b. recombinant DNA (rDNA) technologies
 - c. human or animal fresh/frozen tissues, blood, or body fluids
- 2. An affiliated 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.
- 3. 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 Statewide SRC.
- 4. 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 <u>Designated Supervisor</u> or a <u>Qualified Scientist</u>. The student must be properly trained in standard microbiological practices.
- 5. 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.
 - a. For a **high school BSL-2 laboratory**, the SRC must review and approve. The research must be supervised by a Qualified Scientist.
- 6. Students are **prohibited from designing or participating in BSL-3 or BSL-4** research.

- 7. Laboratory studies designed to culture known clinically significant **multidrug resistant organisms (MDROs)** must have a written justification for usage and be conducted at a Regulated Research Institution laboratory with a minimum of BSL-2 containment and documented IBC review and approval. Representative examples include but are not limited to the following known agents: MRSA (Methicillin- Resistant *Staphylococcus aureus*), VISA/VRSA (Vancomycin Intermediate or Resistant *Staphylococcus aureus*), VRE (Vancomycin-Resistant *Enterobacteriaceae*), ESBLs (Extended Spectrum Beta-Lactamase producing gram negative organisms), and fungi (yeasts or molds) with known resistance to antifungal agents.
- 8. Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted, with the following exceptions:
 - a. Students are prohibited from the 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.
 - b. Students are prohibited from designing or selecting for multiple drug resistant organisms (MDROs) to investigate the pathology, development, or treatment of antibiotic-resistant infections.
- 9. Extreme caution must be exercised when **selecting and sub-culturing antibiotic-resistant organisms**. Studies using such organisms, including BSL-1 organisms that may have originally been exempt from prior SRC approval, **require at least BSL-2 containment**.
- 10. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
- 11. Naturally occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
- 12. All potentially hazardous biological agents (PHBAs) must be properly disposed at the end of experimentation in accordance with their biosafety level.
 - a. 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/or other manufacturer recommendations are acceptable.
- 13. Any proposed changes in the Research Plan by the student after initial local or affiliated SRC approval must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
- 14. The following forms are required:
 - a. <u>Checklist for Adult Sponsor (1)</u>, <u>Student Checklist (1A)</u>, <u>Research Plan/ Project Summary</u>, and <u>Approval Form (1B)</u>
 - b. Regulated Research Institution Form (1C), when applicable
 - c. Qualified Scientist Form (2),
 - d. Risk Assessment (3), when applicable
 - e. PHBA Risk Assessment Form (6A),
 - f. Human and Vertebrate Animal Tissue Form (6B), for all studies involving tissues and body fluids

Section A Rules: 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 another standard non-breakable container) and sealed.

- 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 <u>Designated</u> 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 precautions.

Section B Rules: 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 the SRC**.

- 1. 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 <u>Qualified Scientist</u> or <u>Designated Supervisor</u> and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli K-12*, *S. cerevisiae*, 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.
 - a. All genome editing studies that include alteration of germline cells, insertion of gene drives, use of rapid trait development 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. The <u>Qualified Scientist</u> is expected to ensure that student research protocols address appropriate intrinsic and extrinsic containment precautions.
- 5. **Introduction or disposal** of any species that is non-native, genetically altered, and/or invasive (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.

Section C Rules: 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. 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 <u>Research Plan/Project</u> Summary.
- 2. If tissues are obtained from an animal that was euthanized for a purpose **other than** the student's project, it is considered a tissue study and the PHBA rules apply (it is not a vertebrate animal study).
 - a. Use of the tissues obtained from research at a Regulated Research Institution requires **documentation of the IACUC approval** for the original animal study.
 - b. Use of tissues obtained from agricultural/aquacultural studies require prior SRC approval.

- 3. Intentionally left blank.
- 4. The collection and examination of **fresh/frozen tissue and/or body fluids**, (not including blood or blood products; see rule 7 below) 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 <u>Qualified Scientist</u> or trained Designated Supervisor.
- 5. The collection and examination of fresh/frozen tissues or body fluids or meat, meat byproducts, 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 <u>Qualified Scientist</u>.
- 6. **Human breast milk** of unknown origin (unless certified free of HIV and Hepatitis C) and **domestic unpasteurized animal milk** are considered BSL-2.
- 7. 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 <u>Qualified Scientist</u>.
 - a. Known BSL-3 or BSL-4 blood is prohibited.
 - b. Studies involving domestic animal blood may be considered a BSL-1 level study.
 - c. All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z.
 - d. 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. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.
- 9. Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or BSL-4 is **prohibited**.
- 10. 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.
- 11. 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.

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- Science & Engineering Fair Expectations and Policies
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MSEF Network: Why and How

The Massachusetts Science & Engineering Fair (MSEF) is the culmination of programming for high school students who have produced science or engineering projects, exhibited in local school or Regional Fairs and advanced to statewide competition.

A one-day event held annually, the Fair event is a valuable learning experience and provides students with the opportunity to win awards and scholarships and participate in additional science-oriented activities. The Massachusetts Department of Elementary and Secondary Education supports the opportunities available through participation in MSEF.

Beyond the event, Science & Engineering Fairs provide a unique journey for each student to explore personally meaningful questions, paving the way to academic growth and personal self-discovery. Each year, thousands of middle and high school students develop independent research questions, plan investigations, collect data, and share their stories with fellow students, teachers, and communities.

During the fair, students have an opportunity to showcase all their hard work and creativity through oral presentations and responding to questions from the judges, students, and members of their community. Although science and engineering fairs still involve an element of competition, this experience celebrates each student's learning journey. Receiving meaningful feedback from their peers and professionals in a STEM field is a powerful experience that has a lasting positive impact on students

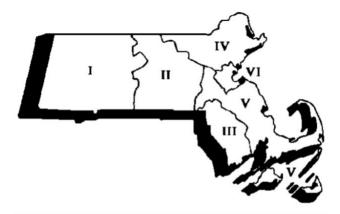
Local

Many high schools across the state sponsor their own Science & Engineering Fairs at the school, district, or community level. These local Fairs give students a chance to share with classmates their ideas, discoveries, and enthusiasms for science. Local Fairs provide an excellent training ground for students to sharpen communication and presentation skills. Each high school in the Commonwealth may send two projects directly to the State Fair.

Regional

Six regional fairs are held in March. Students are encouraged to participate in their respective regional fairs as this provides the student with an opportunity to meet students from other schools and sharpen communication skills. Schools that want to participate in a regional fair should contact the Regional Chair for registration information.

Each regional fair can certify and send projects based on participation numbers at the regional fair and with a maximum set each year. Each school may also send two projects directly to the State Fair. If one of the regional winners is unable to participate in the State Fair, the student must notify the Regional Chair who will designate another candidate. It is important to note that a winner in a regional fair is ineligible for the MSEF if s/he has participated in a regional fair outside the school's assigned region.



Geographic breakdown of the Massachusetts State Science & Engineering Fair network

The six MA regional fairs, respective Chairpersons, and towns, cities and regional high schools in each region are available on the website: www.scifair.com

Massachusetts Science & Engineering Fair: State Fair

Massachusetts Science & Engineering Fair, Inc. conducts an annual program of competitive science and engineering fairs open to high school (grades 9-12) and middle school (grades 6-8) students from all public, private, parochial, and home schools. This manual covers only the program for high schools. The MSEF program is composed of six separate regional fairs and one state fair, thereby providing a competitive hierarchical path upward, from school to the regional, state, and even the International Science and Engineering Fair (ISEF). Student projects are judged at all fairs, the results are announced, and awards are presented at public ceremonies.

International Science & Engineering Fair (ISEF)

The Massachusetts Science & Engineering Fair is an affiliated fair of the International Science and Engineering Fair (ISEF). Participation at ISEF is based on participation and scoring at the regional fairs or the state fair. Combined, Masscahusetts typically sends fifteen projects to ISEF. ISEF designates the number of projects that each fair can send.

Hosted annually in a North American city, ISEF hosts almost 1,700 student exhibitors from more than 70 countries and many states in the U.S. The weeklong program provides all participants with the opportunity to join with their national and international compatriots to share and exchange knowledge and develop lasting friendships.

Massachusetts follows rules and requirements of ISEF fairs so that all students could be eligible to be a Massachusetts delegate if they are chosen through their fair placement.

Science & Engineering Fair Expectations and Policies

MSEF is open to students from all public, private, and home schools (grades 9-12) throughout the state. Schools are encouraged to send participants to their respective regional fairs. Schools should contact the appropriate regional fair director for details. Each regional fair sends a percentage of student projects based on participation and placement at the regional fairs. If one of the region's state fair entries chooses not to attend the state fair, only the region can determine the replacement. In addition to the regional fair entries, each school can send two additional projects directly to the state fair as a 'direct entry'.

- The completion of the Research Plan with accompanying required Approval and Consent Forms is required to certify the project in terms of safety and integrity. All students should have approval of a qualified adult (usually a teacher) before beginning experimentation. Some projects need additional approval before experimentation.
- The final approval before participation in a regional or state fair. All projects must be reviewed and approved by MSEF and regions before participation in the fairs to confirm compliance. This typically occurs in February after projects are complete and before the regional fairs.
- Review the Science Fair Ready Checklist at <u>www.scifair.com/resources</u> for more details and resources.

Eligibility/Limitations

- 1. Each regional fair has an affiliation agreement with MSEF that determines the number of projects they can send to the state fair.
- 2. A student must meet both of the following:
 - a. be in grades 9-12 or equivalent; and
 - b. not have reached age 20 on or before May 1 preceding the fair
- 3. English is the official language of MSEF. Student project boards and abstracts must be in English. Judging takes place in English. If a translator is necessary, please contact MSEF.
- 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 of the previous year.
- 5. Team projects must have no more than three members. Teams competing at MSEF must be composed of members who all meet MSEF eligibility.
- 6. Students may compete in only one affiliated regional fair each year.
- 7. All sciences and engineering disciplines are represented at MSEF. Review a complete list of categories and sub-categories with definitions in the Appendix or at www.scifair.com/resources.

Timeline for Participation

- 1. The present project year includes research conducted over a maximum, continuous 12-month period between January 1st of the previous year and May of the year of the fair.
- 2. Projects in Restricted Areas of Research requiring SRC pre-approval must be submitted through zFairs to the Statewide SRC before experimentation begins https://mahs.zfairs.com. See the appropriate zFairs site for dates of review and deadlines.
- 3. Experimentation and data collection can begin only after forms have been completed, submitted, and approved by the Statewide SRC if the research topic is in a restricted area.

- 4. School fairs typically occur during January and February. School fairs must be held by the first week in March.
- 5. **Regional fairs** will be held by the second week in March. Check www.scifair.com for actual dates and locations of regional fairs
- 6. Information on how to access the online information for the **state fair** will be provided to regional winners and schools participating in direct entry.
- Massachusetts Science & Engineering Fair State Fair is typically the last week or March or first week of April. Watch for the official Fair Date announcement on www.scifair.com. The 2024 Fair will be held Friday, April 5th at Gillette Stadium in Foxborough.

Please note:

MSEF, Inc. is responsible for all decisions relative to project acceptance. All decisions are final.

MSEF, Inc. assumes no responsibility for project acceptance decisions made at the school or regional levels

Student Risk

Projects shall be accepted for display upon the express condition that neither the Massachusetts Science & Engineering Fair, Inc., Gillette Stadium, nor any other Fair sponsor be held responsible for the loss or theft of, or any damage to exhibits or exhibitor's personal property.

Student Obligations

Students must participate fully in all Fair activities including the Awards Ceremony. During judging and exhibition times, the students must remain with their projects. If a personal emergency occurs during the Fair, a student must notify a MSEF designated committee member at the Registration Table who will contact MSEF staff.

Student Expenses

MSEF and all its sponsors assume no responsibility for travel, lodging, or other activities of the state fair exhibitors. These responsibilities lie with the local school authorities and/or with the students' parents and guardians.

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If the MSEF Safety Committee and the Gillette Stadium professional staff consider the presence or operation of any equipment or material to be dangerous or unsafe, they shall have the right to prohibit the presence or operation of such equipment or material. Exhibitors should plan to demonstrate the safe use of hazardous materials through photographs, videos, charts, diagrams, and other simulations such as facsimiles.

All Science & Engineering Fair participants must attend to the safety aspects of their project, as follows:

- No exhibit may be larger than 122 centimeters (cm) wide X 76 cm deep X 274 cm high from the floor. If the exhibit will be set on a table, the height cannot exceed 198 cm above the table.
 - No oversized projects will be permitted.
 - Due to safety and fire regulations, no portion of the project may occupy aisle space.
- The weight of the exhibit apparatus should not exceed what a typical folding table can support. Tape, tacks, and other such materials and wall space are not available. Students should construct their exhibit so that wall space is not necessary. Exhibitors must provide their own tape, thumbtacks, stapler and any other necessary tools
- The following items cannot be included on the board or visual display: any awards, medals, personal websites, social media addresses, emails, QR codes, the name of any industrial/educational institution where the project was completed, school name, postal addresses, or telephone numbers.
- No display lighting is permitted.
- No running water is available.
- Quantities of water must be limited to small break-resistant containers/tanks and secondary containers used. The student shall protect experiments using any combination of water and electricity, by a Ground Fault Circuit Interrupter (GFCI).
- Anything that could be hazardous is prohibited, including the following:
 - 1. live animals and poisonous plants
 - 2. pathogenic microbial agents, e.g. viruses, bacteria, fungi
 - 3. microbial agents used in recombinant DNA experiments
 - 4. hypodermic needles, syringes, razor blades, and other sharp items
 - 5. all chemical substances except water and saline
 - 6. any instruments containing mercury, e.g. thermometers
 - 7. glass bottles and lab ware, either empty or containing any substance (must be replaced by break-resistant containers or placed in secondary containers)
 - 8. drugs, over-the-counter medications, antibiotics, and vitamins
 - 9. The following restrictions apply to acceptable chemical and microbial specimens:
 - All acceptable specimens to be used in the project must be fully and clearly labeled.
 - Abbreviations or formulas should not be used.
 - All acceptable specimens should be transported and displayed in break-resistant containers.
- All parts of the exhibit must be structurally sound and constructed of durable materials.
- Push buttons and levers must be securely mounted to the exhibit. They cannot be attached to tables or walls.
- All power-driven parts must be suitably guarded to prevent unauthorized or accidental access.
- All wiring of electrical apparatus must conform to the Massachusetts and National Electric Code. If in doubt, consult a licensed electrician.
- All exhibits that require an external source of electricity for operation must be designed for a standard 110–125 volt AC supply.
- Antenna lines and long leads cannot be used.
- All wiring, switches, power cords and metal parts carrying current in an AC circuit must be properly selected for load requirements and soldered or fixed under UL approved connectors with insulated connecting wires. No exposed wires, switches, joints, or non-insulated fasteners will be permitted.
- The power supply cord for the electrical apparatus must be no longer than six feet and must terminate in a three-pronged outlet. All power supplies and electrical equipment must be grounded and connected to a Ground Fault Circuit Interrupter (GFCI).
- High voltage areas and any areas which could present an electrical hazard must be completely enclosed by a protective barrier equipped with a safety interlock to cut off all power if the cover, door, barrier is opened or removed.
- Bare wire and exposed knife-type switches are permitted on 12-volt DC circuits or less. UL approved standard enclosed switches are required for all other electrical installations.
- Wet-cell batteries with open tops are not permitted. Closed-cell or dry-cell batteries are permissible.
- Compressed gases must be handled in compliance with standards established by the Compressed Gas Association.
- The operation of pressure vessels and pressurized systems is permitted providing all parts conform to the Massachusetts Safety Code for such items. Similarly, vacuum systems present an implosion hazard and all vacuum vessels must be determined to be capable of tolerating a high vacuum pressure environment.

- Any exhibit producing temperatures exceeding 100 degrees C. (212 degrees F.) must be adequately insulated from its surroundings. Asbestos-free insulation materials should be used.
- Because of the fire and burn hazard, there must be no open flame, torch or burner in the display area.
- Projects involving ionizing radiation, such as x-rays and radioactive materials, must be equipped with minimum safeguards as required by the Massachusetts Department of Public Health and the U.S. Nuclear Regulatory Commission.
- Lasers, welders, high-intensity visible light, infrared and ultraviolet radiation and other non-ionizing radiation must be displayed with safeguards as required by the U.S. Department of Labor, Occupational Health and Safety Standards and by the Massachusetts Department of Public Health. Class III and Class IV lasers are prohibited.
 - A source for information on laser standards and research is:

U.S. Food and Drug Administration Office of Compliance and Surveillance 1390 Piccard Drive, Rockville, MD 20850 phone (301) 427-1172

- All microwave and radio frequency sources must be designed and operated in compliance with state and federal regulations as well as applicable standards of the American National Standards Institute.
- Robotics projects should have interlocks or other controls
- Participants may only present judges with a copy of their official abstract that was submitted at the time of registration and appears in the abstract book. Students may not present judges with and other hand-out items, such as flyers, pens, flash drives, pins, disks, CD's business cards, brochures, etc.

Any <u>Student</u>, <u>Adult Sponsor</u>, <u>Qualified Scientist</u>, or <u>Designated Supervisor</u> who has a question about a project's compliance to these rules should contact the MSEF Safety Committee.

Note: Students may petition the MSEF Safety Committee for exceptions before March 15th of the year of the fair in written correspondence to info@scifair.com.

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Award Recognition Program

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MSEF is fortunate to have many corporations, educational institutions, professional organizations, and individuals whose generosity has helped MSEF to provide a generous award program.

As registered MSEF entrants, students automatically become candidates for awards. Customary criteria used for award distribution include, but is not limited to, scoring results, prize values and individual student preferences. There is no consideration given to financial need. Massachusetts Science & Engineering Fair, Inc. retains the sole responsibility for award distribution and all decisions are final.

Awards and Recognition at the regional fairs is at the discretion of the regional committees.

Description of Awards

Through the generosity of MSEF donors, there are several award categories – monetary, college scholarships, experiential, educational and miscellaneous. Following is a brief description of each category:

Placement Awards

These awards are presented to the top placing students at the state fair according to combined scores from judges. The top placement awards typically are monetary awards.

Special Awards

Special awards are determined based on a combination of topic and placement and are typically sponsored by an MSEF partner or funder. These awards weight the topic and approach of the project more heavily than overall placement. In many cases, special award judges review projects at the fair to identify a winner.

Monetary

Cash prizes are disbursed by check within four weeks following the Fair. MSEF, Inc. will not be held responsible for cash awards if or when a winner does not cash award check within sixty (60) days from date of issue. Note: Team project awards are usually monetary and are divided evenly between the project participants.

College Scholarships

Customarily, college or university scholarships are in the form of tuition-fee reductions. Individual donor institutions establish their respective admission requirements, renewal criteria and "payout" procedures. These scholarships are neither interchangeable nor exchangeable. They are all contingent upon acceptance at the university and MSEF plays no role in that selection process.

Experience Awards

These awards involve educational travel, professional research internships and other opportunities where the student is directly involved in a scientific or technological environment. Typically, these awards have included the National Youth Science Camp in West Virginia, and non-paid research internships at Massachusetts (usually Boston area) corporate sites.

Educational Programs

These programs include waiver or reduction of tuition fees for special courses at local colleges, universities, and other institutions. Professional organizations also waive registration fees to seminars and courses.

Alternate Winners

MSEF, Inc. selects alternate winners for some of the awards within the College Scholarship, Experience and Educational award categories. Winners are asked to notify MSEF if they do not accept/plan to use an award. MSEF, Inc. and/or the award donor will contact the alternate winner. Alternate winners should periodically contact MSEF headquarters to inquire about the status of the award

6. Appendix Back to Table of Contents

Appendix A: Guidance for Risk Assessment: Hazardous Chemicals and Devices

Appendix B: Guidance for Risk Assessment: Human Participants

Appendix C: Guidance for Risk Assessment: Potentially Hazardous Biological Agents (PHBAs)

Appendix D: Guidance for Risk Assessment: Engineering and Invention Projects

Appendix E: Project Categories – Updated for 2024

Appendix F: Glossary

Use these guidelines to perform a Risk Assessment when using POTENTIALLY Hazardous Chemicals and Devices.

A. Hazardous Chemicals

A proper <u>Risk Assessment Form 3</u> for chemicals must include a review of the following factors:

- 1. **Toxicity** the tendency of a chemical to be hazardous to health when inhaled, swallowed, injected or in contact with the skin.
 - a. Human health toxicity includes acute and chronic hazards when inhaled, swallowed, injected or in contact with the skin.
 - b. Environmental health includes aquatic toxicity (both acute and chronic), toxicity to mammals and birds, and impact on ecosystems.
- Reactivity the tendency of a chemical to undergo chemical change, including instability and reactivity with other substances or conditions (i.e., reaction with water, air, temperature, pressure).
- 3. **Flammability** the tendency of a chemical to give off vapors which readily ignite when used under normal working conditions (ambient temperatures).

Combustible substances can include:

- a. Chemical solvents that produce vapors which readily ignite when used under normal working conditions.
- Combustible solids (small particles, powders, or substances easily ignited by fire or an ignition source)
- 4. **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 Safety Data Sheets provided by the vendor (SDS) to **ensure that proper safety precautions are taken**. Some SDS sheets (e.g., Flinn) rank the degree of hazard associated with a chemical.

The risk assessment (documented on <u>Form 3</u>) must include **proper disposal methods** for the chemicals used in an experiment. The Flinn Catalog 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.

B. Hazardous Devices

The documentation of <u>Risk Assessment Form 3</u> is required when a student researcher works with:

- potentially hazardous/dangerous equipment and/or other devices that,
- 2. require a moderate to high level of expertise to ensure their safe usage.

Examples:

- <u>Definitely Hazardous (complete Form 3)</u>
 high vacuum equipment, heated oil baths, NMR equipment, and high-temperature ovens
- Maybe Hazardous

 (if the student has experience with it, no Form 3 required)

 Bunsen burners, hot plates, saws, drills, etc.
- <u>Potentially Hazardous (recommended Form 3)</u>
 any student designed inventions or prototypes

C. Radiation

The documentation of <u>Risk Assessment Form 3</u> is required when a student researcher works with:

- radiation beyond that normally encountered in everyday life
- ionizing radiation (e.g., X rays, gamma rays)

Environmentally Responsible Chemistry

The mission of environmentally responsible (green) chemistry is to avoid the use or production of hazardous substances during the 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 and avoiding the use of reactive substances

Appendix B: Guidance for Risk Assessment: Human Participants

Use the guidelines below when designing or reviewing projects with Human Participants.

The goal is to (1) minimize risk, (2) determine how to protect privacy,

and (3) determine how to obtain consent/assent from participants.

Refer to the <u>Guidance in Risk Assessment & Risk Reduction</u> and <u>Guidelines for Online Survey Consent Procedures</u> documents for more detailed information and explanation of rules and examples.

1. All human participant projects are considered to have some level of risk. The goal is to REDUCE the risk to participants.

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those *ordinarily encountered by a potential participant in daily life* or during performance of routine physical or psychological examinations or tests. physical, psychological or possibility of sharing a person's private information must be very small to be considered no more than minimal risk.

More than minimal risk exists when the (1) possibility of physical or psychological harm, (2) the harm related to breach of confidentiality, or (3) the risk of invasion of privacy is greater than what is typically encountered in everyday life.

- o Examples of Studies with **Greater than Minimal PHYSICAL Risk:**
 - Exercise other than ordinarily encountered in everyday life
 - 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 any known or potential allergies or medical conditions among any participants, the nature of the study, and local norms.
 - Exposure to any potentially hazardous material.
- Examples of Studies with 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:
 - 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
 - viewing violent or distressing video images

2. Confidentiality and 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.

Use this information to complete <u>PHBA Risk Assessment Form 6A</u>.

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. (See "Classification of Biological Agents" below.)
- 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" below.)
- 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 agents, level of biological containment available and the expertise of the <u>Qualified Scientist</u> or <u>Designated Supervisor</u> 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 <u>Form 6A</u> that the student received appropriate training and the project complies with ISEF rules.

Classification of Biological Agents Risk Groups

Biological agents 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 luteus, 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 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**.

Appendix D: Guidance for Risk Assessment: Engineering and Invention Projects

Use this information to help examine the components of an Engineering Project and potential areas that will require pre-approval and/or extra safety precautions.

This has been developed as a checklist with a series of questions to consider as you begin and design an engineering or invention project.

Consider the answers to the questions below. If the response is yes, then the project may fall under more specific rules and those sections of the Rules & Guidelines should be consulted.

Will 	us Chemicals, Activities and Devices your project involve any of the following? DEA-controlled Substances Firearms and Explosives Prescription Drugs Alcohol & Tobacco Regulated Drones Radiation
	If any are checked, see Hazardous Chemicals, Activities or Devices Rules (page 12)
 	Testing with Human Participants ☐ Are you going to test your project (device, app, invention, prototype, etc.)? ☐ If yes, does it require persons to interact with it other than yourself or adult sponsor/supervisor? ☐ Do you intend to gather background knowledge through a survey or interviews to understand the potential use and needs for your project design? ☐ Are you going to ask for opinions or suggestions on your project design at any point of the project? ☐ Does your project intend to gather personal data/have a health benefit to the user? If any are checked, see Human Participant Rules (page 15)
Vertebra	ate Animals
I	☐ Does your project include any interaction with vertebrate animals in any phase of the project?
	If any are checked, see Vertebrate Animal Rules (page 19)
1	Illy Hazardous Biological Agents ☐ Does your project include any collection, examination, or handling of microorganisms, and/or fresh or frozen tissue, primary cell cultures, blood, blood products or body fluids? ☐ Are you going to culture or isolate any substance, known or unknown?
	If any are checked, see Potentially Hazardous Biological Agents Rules (page 24)

<u>Appendix E: Project Categories – Updated for 2024</u>

Multiple qualified judges will review each project. In order for the judging to be conducted fairly and accurately, it is important that students properly categorize their project. What is your project about? And then, what are the steps you would use to achieve a result? If you discover your project is misaligned by February 1st you can contact MSEF to recategorize your project. You **cannot** adjust categories between fairs.

- **Behavioral and Social Sciences:** The study of thought processes and behavior of humans or other animals studied through observational and experimental methods. *Includes: psychology, educational testing, animal behavior, neuroscience, sociology, and anthropology.*
- **Biochemistry:** The study of the chemical basis of processes occurring in living organisms, including the processes by which these substances enter into, or are formed in, the organisms and react with each other and the environment. *Includes: analytical biochemistry, general biochemistry, structural biochemistry,* and *medicinal biochemistry*.
- **Biology: Cellular, Molecular, or Microbiology:** The study of the structure, function, intracellular pathways, and formation of cells. Studies involve understanding life and cellular processes specifically at the molecular level. Microbiology is the study of microorganisms as well as antimicrobial and antibiotic substances. *Includes: cell physiology, cellular immunology, neurobiology, genetics, virology, and microbial genetics.*
- **Biology: Evolution, Plant and Animal Science:** The study of animals and plants such as structure, physiology, development, evolution and classification. *Includes: pathology, genetics and breeding, nutrition and growth.*
- Chemistry: The study of the composition of substances, their structure, their behavior, reactions, analysis and synthesis. Other topics in this category include: physical chemistry, organic chemistry, inorganic chemistry, modern materials science, computational chemistry, and environmental chemistry.
- Computer Science and Technology: Including systems software, robotics, and intelligent machines, this category is for the study
 or development of software, information processes or methodologies to demonstrate, analyze, or control a process or solution.
 Additionally studies in which the use of machine intelligence to reduce the reliance on human intervention. *Includes:*algorithms, cybersecurity, databases, system languages, mobile apps, machine learning, robot kinematics.
- **Astronomy and Space Science:** The science regarding the celestial bodies and the observation and interpretation of the radiation received in the vicinity of the earth from the component parts of the universe. Other topics in this category include: optical astronomy, radio astronomy, astrophysics, astrometry and astrophotography.
- Engineering: Electrical and Mechanical: This category includes embedded systems as well as static and dynamic engineering. Studies involving electrical systems in which information is conveyed via signals and waveforms for purposes of enhancing communications, control and/or sensing. Studies may also focus on the science and engineering that involve movement or structure. The movement will be a result of forces; the structure will be stable due to the equilibrium of forces. Includes: circuits, networking and data communications, optics, sensors and signal processing, aeronautical, automotive, civil, industrial engineering, or civil engineering.
- Engineering: Biomedical This category is for projects that apply engineering practices to solve biological or medical problems. Projects may create methodologies and/or construct apparatus or biomolecules to obtain data, take measurements, or build understanding of biomedical systems. Includes: biomaterials, biomechanics, biomolecular engineering, biomedical devices, or biomedical sensors or imagining. Note: Student projects may not independently diagnose disease.
- **Engineering: Environmental** This category is for projects that apply engineering practices to develop processes or infrastructure to solve environmental problems in water systems, waste, systems, pollution control, or climate resilience. *Includes: pollution control, bioremediation, water resources management, land restoration, climate adaptation or mitigation.*
- Earth and Environmental Science: Focused on geosciences, ecology and related environmental systems, this category covers the study of weather, climate, rock formations, mineral resources, soils, atmosphere, and biomes, as well as the study of environments and the impact of changes (natural or as a result of human interaction) on ecosystems. Includes: pollution sources (air, water and land), natural resource consumption, climate science, and invasive species, a quatic science, climate science, geology, geophysics, physical oceanography, meteorology, seismology, mineralogy and topography.
- Mathematics (includes computational modeling): This category is for both theoretical and applied mathematics projects. This includes the study of measurement, properties, and relationships of quantities and sets, using numbers and symbols. Students may use both inductive or deductive reasoning. Includes: computational modeling, data science, number theory, probability and statistics, and game theory.
- **Physics:** The study of matter, energy, and the interactions between the two that do not involve change in composition. Topics covered by physics include: aerodynamics and hydrodynamics, solid-state theory, optics, acoustics, particle, nuclear, atomic, plasma, thermodynamics, semiconductors, magnetism, quantum mechanics, and biophysics.

Appendix F: Glossary

- abstract: A brief (200-250 words) summary of the background, methodology, results, and conclusions of a project.
- Adult Sponsor: An adult under whose close supervision the student is working in a lab. The Adult Sponsor may be a teacher, parent, professor, or scientist/engineer, but must have a solid background in science/engineering. The Adult Sponsor may also be a Qualified Scientist, but if the Adult Sponsor is not familiar with local, state, or federal regulations that affect the project, an individual with the necessary expertise should serve in this role as the Qualified Scientist. The Adult Sponsor may also serve as the Designated Supervisor.
- <u>APA format</u>: (High School) Writing and citation style for academic documents determined by the American Psychological Association.
- **anonymity:** Human subjects that participate in research should have their identities protected. If participants are kept anonymous, even the researcher cannot link data collected to individual subjects. See also **confidentiality**.
- appendix: A section at the end of a lab report that contains additional information. A final science and engineering fair lab report may include none, one, or several appendices. Examples of information that may be included in an appendix include copies of tests or surveys given to participants, scripts of directions, or other protocols not included in the procedure.
- background research paper: A summary of the important scientific principles behind the student's project. The purpose of the research is for the student to develop strong understanding of relevant science content in order to develop a strong experimental question or engineering goal, construct a sound hypothesis or select relevant design criteria, analyze data, and draw valid conclusions. This is not the same as a research plan or project proposal.
- confidentiality: If a student researcher collects data in a way that could link that data to a specific individual subject, this information must be protected. Raw data should be de-identified and thus anonymous when analyzed by the student researcher. Consent forms should also be kept separate from the collected data and only be accessible to the student, adult sponsor, and/or Qualified Scientist. Do not submit completed consent forms to an IRB or SRC, only a blank sample copy. See also anonymity.
- controlled substance: Controlled substances are those controlled by the DEA, the BATF, or the FDA such as alcohol, tobacco, illegal or prescription drugs, firearms, fireworks, explosives, etc. High school students working with controlled substances must work under direct supervision of a Qualified Scientist. See also hazardous activities and hazardous chemicals and devices.
- **Designated Supervisor:** An adult who directly supervises a student's project work. The **Adult Sponsor** may serve as the Designated Supervisor. The Designated Supervisor must be familiar with and trained in the student's area of research. The Adult Sponsor may serve as the Designated Supervisor.
- Designated Supervisor Form: (Form D in Middle School, Form 2 in High School) completed and signed by the Qualified Scientist, Designated Supervisor, or Adult Sponsor where the potential risks involved in the student's project are described and the steps taken to reduce risks and ensure safety are detailed. See also Risk Assessment Form for High School.
- **display board:** A visual presentation of the most important highlights of the student's science fair project, used as a support during the oral presentation of the project. The display board is usually on a standard 3-foot by 4-foot tri fold board, or two display boards stacked together.
- **ethics statement:** A statement signed by the student, parents, adult sponsors and qualified scientist where they agree to abide by the MSEF and ISEF rules and regulations, which include requirements that students are honest about their work, document their research, cite sources, give credit, and present work (including research, experimentation, and documentation) only done by the student.

- human subjects: Project plans that include human subjects must include details of how potential subjects will be identified, where and how subjects will be recruited, how informed consent will be obtained, and how subjects' anonymity or confidentiality will be maintained. These plans must include copies of any surveys, tests, images, videos, etc. that will be used. In high school these research plans must be reviewed by an IRB at their school.
- hazardous activities: Any activity that entails more than normal risk. Examples include working with high voltage, open flames, radiation, lasers, high temperature ovens, power tools etc. High school students may engage in some hazardous activities, but must first complete a Risk Assessment Form under the supervision of a Designated Supervisor or Qualified Scientist.
- hazardous chemicals and devices: Any chemical or device that involves more than normal risk. These include substances and devices that are controlled by local, state, federal, and/or international laws and regulations. Examples include illegal and prescription drugs, corrosive chemicals, toxic, highly reactive, flammable, or carcinogenic chemicals, alcohol, tobacco, firearms, explosives, radioactive materials, high vacuum devices, etc. High school students may work with other hazardous chemicals and devices, but must first complete a Risk Assessment Form (Form 3) under the supervision of a Designated Supervisor or Qualified Scientist.
- **informed consent:** All human subjects must be given the opportunity to decide if they are willing or not willing to participate in a research project. The written form for Informed Consent that the student researcher creates must include a summary of what participants will be asked to do, any risks or discomforts that may occur, and the statement that they are free to withdraw their participation at any time. Potential participants who are younger than 18 must also have a parent or guardian sign their consent. (**For high school, see Form 4.**).
- Institutional Animal Care and Use Committee (IACUC): The institutional animal oversight review and approval body for all animal studies that occur at a Regulated Research Institution. Students working at an outisde lab or institution and using vertebrate animals or their tissues and cells must provide a certificate of approval from the IACUC for that research institution.
- Institutional Review Board (IRB): A group of qualified individuals from the student's school that review any science fair projects that involve human participants. The IRB checks projects to ensure that informed consent is obtained from each subject, and that participation in the project does not endanger subjects or the student researcher physically or psychologically.
- <u>ISEF</u>: (High School) The Regeneron International Science and Engineering Fair, owned and operated by Society for Science. Students who earn top prizes at affiliated regional and state competitions are eligible to compete in ISEF.
- laboratory notebook (see project notebook)
- lab report: The complete project report, including a title page, abstract (high school), table of contents (high school), research question or engineering goal, variables (experimental projects), hypothesis or design criteria, background research, materials list, procedure, results and data analysis (including relevant tables and graphs), conclusion, acknowledgements, and works cited.
- materials: A list of specific materials, tools, and equipment that is used for the project.
- methodology (see procedure)
- <u>MSEF</u>: Massachusetts Science & Engineering Fair
- procedure: A step-by-step sequence that describes in detail how the experiment will be conducted or how the engineering prototype will be constructed. In an experimental project, the procedure includes how the experimental group(s) and the control group will be set up, how the independent variable will be manipulated, how controlled variables will be kept constant, and how the dependent variable will be measured. In an engineering project, the procedure includes detailed instructions on how to construct the first prototype as well as how the prototype will be tested and compared to the engineering goal and design criteria. (See also methodology).

- **project logbook or project notebook:** An often <u>handwritten</u>, detailed documentation of the student's project from start to finish, including the student's original thoughts on the selection of the project, background research, plan, data, and reflections. The project logbook should be in a bound notebook, and each page is numbered and dated.
- **project proposal:** In an experimental project, a summary of the proposed experimental question, materials, and procedure.
- Qualified Scientist: A qualified scientist/engineer with an advanced degree (PhD, MD, or Masters with additional experience/expertise) who supervises the student's compliance with local, state, or federal regulations related to the student's research. The Qualified Scientist may be the same person as the Adult Sponsor. If the Qualified Scientist is not local to the student, then a Designated Supervisor must oversee the student's research.
- **research plan:** A detailed summary of the background research, relevance, and rationale for the project, research question or engineering goal, expected outcomes, hypothesis(es), planned procedures, and potential risks and planned safety procedures, to be submitted to the **Scientific Review Committee (SRC)** <u>prior</u> to beginning the project.
- Risk Assessment Form: Before beginning a project that involves hazardous chemicals, activities, or devices, the student researcher, together with the Designated Supervisor/Qualified Scientist must complete form 2 and form 3 to detail the potential risks involved in the project as well as the steps that will be taken to minimize risks and dispose of chemicals safely. (See also Designated Supervisor Form).
- Scientific Review Committee (SRC): A group of qualified persons who are responsible for reviewing student science and engineering fair project proposals and research plans to ensure that the proposed projects meet legal and safety standards and regulations.
- SRC pre-approval: Certain types of research will be designated as requiring "SRC pre-approval". For these projects, the student must submit a complete research plan along with the required forms BEFORE they begin their experiment or collect data. This review is to ensure that the student meets all rules and requirements for safety and ethics. This review is done by the statewide SRC. Once given approval, the student can begin their experiment. In some cases, the SRC may require further explanation from the student on a form or in the research plan to ensure safety or to make a project compliant with rules. Once the edits or amendments are made, the project is re-submitted for review and pre-approval.
- SRC final approval: This stage of project review occurs after the project is completed and is part of entry into a science fair competition (Regional, State, and International). This review is for projects that did not require SRC pre-approval as well as projects that were already reviewed for pre-approval. Projects are reviewed for compliance with rules and regulations and will either "qualify" or "fail to qualify" for the science fair competition.
- **vertebrate animals:** Animals that have backbones, including fish, amphibians, reptiles, birds, and mammals, their embryos, fetuses, tadpoles, and newly hatched eggs. *High school students who choose to use vertebrate animals or their tissues and cells, must include either a Form 5A or 5B with their research plan to detail their justification of the use of vertebrate animals rather than a nonvertebrate alternative, the benefits of the research, and the humane care and treatment of the animals. No experiments that cause pain, distress, or death to vertebrate animals may be conducted.*
 - Projects that involve non-intrusive, non-invasive <u>observational</u> studies of vertebrate animals in homes, farms, ranches, schools, or in the field may be conducted in High School.
- works cited: An alphabetical, formatted listing of all of the sources used for information in a paper. The works cited is a separate page at the end of the background research paper, or, if the research paper is included in the lab report, at the end of the lab report. Also known as a bibliography. Students should have 3-5 works cited. Science and engineering fair works cited are usually formatted using APA style. See also APA format.

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