REQUIRED RESEARCH FORMS

GUIDE & CHECKLIST

Forms required for all grade 6-12 Georgia STEM research projects to be eligible for regional and state level fairs.

All projects (grades 6-12) competing in regional fairs in Georgia and the statewide Georgia Science & Engineering Fair must follow the <u>ISEF Rules & Guidelines</u>. The rules delineate forms and protocol that help ensure that the proposed student research is safe, ethical, and approved by a parent, teacher, and field professionals.



It is the responsibility of the student and the Adult Sponsor to know the rules and evaluate the proposed project to determine whether it requires special forms and approval before experimentation begins, as is the case for most projects using human participants, vertebrate animals, or potentially hazardous biological agents. Students are encouraged to use the ISEF Rules Wizard and consult with the local SRC/IRB to ensure they have followed all rules and completed all forms. Failure to adhere to ISEF Rules & Guidelines may result in disqualification at any stage of competition, including revocation of honors and awards.

See <u>ISEF Rules & Guidelines</u> for definition of terms, including Qualified Scientist (QS), Designated Supervisor (DS), Regulated Research Institution (RRI), Scientific Review Committee (SRC), and Institutional Review Board (IRB).

The ISEF Rules & Guidelines full text can be found at www.societyforscience.org/

DO	WNLOAD ALL	Forms required for EVERY project:
	GSEF Participation Agreement	(Required for state-level fair [GSEF]; school/regional fairs may require a different form for participation at those levels.) Not technically a research form, but required for <u>every student</u> participating in GSEF (not just one per project).
	Official GSEF Abstract Form	(Required for state fair [GSEF]; school/regional fairs may have different Abstract requirements.) Summarizes the most important ideas about your project and allows judges to quickly determine its nature and scope.
	Checklist for Adult Sponsor [Form 1]	DO BEFORE EXPERIMENTATION Adult Sponsor (with Student) reviews what forms and approvals are required to ensure project's compliance with ISEF rules, as well as local, state, and federal laws. Note: The Adult Sponsor may not serve on the SRC/IRB that reviews the project before and/or after experimentation.
	Student Checklist [Form 1A]	DO BEFORE EXPERIMENTATION Student provides basic details about research and experimentation. Must be accompanied by Research Plan / Project Summary (see below).
	Research Plan / Project Summary (free-typed; not a form)	DO BEFORE EXPERIMENTATION The Research Plan / Project Summary is written before experimentation to detail rationale, research question, methodology, and risk assessment. Any changes made during research can be added to the original Plan as an addendum, recognizing that some changes may require returning to SRC/IRB for review and approval.
	Approval [Form 1B] One form per student (not per project).	DO BEFORE EXPERIMENTATION Student, parent/guardian, and SRC (if required) consent to and approve the project. Must be signed by student and parent/guardian <u>BEFORE EXPERIMENTATION</u> . Must be signed by SRC in (2a) <u>BEFORE EXPERIMENTATION</u> if research involves human participants, vertebrate animals, or PHBAs and was not conducted at a RRI. For projects involving human participants, vertebrate animals, or PHBAs conducted at a RRI, SRC signs in (2b) after experimentation confirming institutional pre-approval and compliance with ISEF rules. Regional Fair SRC signs in section (3) after experimentation and prior to competition.
Additional forms required for specific types of research: Some types of research require approval prior to experimentation. See <u>ISEF Rules Wizard</u> and following page for guidance.		
	Regulated Research Institution/ Industrial Setting [Form 1C]	Required for research conducted at a <i>college/university, medical facility, industrial setting,</i> or other <i>lab/research setting</i> other than home, school or field. Completed by supervising adult at RRI after experimentation.
	Qualified Scientist [Form 2]	DO BEFORE EXPERIMENTATION Required for research with human participants, vertebrate animals, potentially hazard-ous biological agents, or DEA-controlled substances. Completed by QS/DS BEFORE EXPERIMENTATION.
	Risk Assessment [Form 3]	DO BEFORE EXPERIMENTATION Required for projects involving hazardous chemicals, activities, devices, or DEA-controlled substances, some human participants projects, and some PHBA projects, including protists, composting, coliform test kits, decomposition of vertebrate organisms, and microbial fuel cells. Recommended for student-designed inventions/prototypes. Completed by Student and signed by QS/DS BEFORE EXPERIMENTATION.
	Human Participants [Form 4] (sample consent form)	NEED IRB APPROVAL BEFORE EXPERIMENTATION Required for research involving <i>human participants</i> . Includes surveys, testing/providing feedback on invention/prototype/application, and cases where the researcher is the subject of the research. MUST BE APPROVED BY <u>FULL</u> IRB (ALL THREE SIGNATURES) <u>BEFORE EXPERIMENTATION</u> . IRB determines risk, supervision, and consent required.
	Vertebrate Animal [Form 5A] or Vertebrate Animal [Form 5B]	NEED SRC APPROVAL BEFORE EXPERIMENTATION Required for research involving vertebrate animals. 5A is for research conducted at home/school/field, which MUST BE APPROVED BY SRC BEFORE EXPERIMENTATION. SRC determines level of supervision required (DS, QS, and/or veterinarian). 5B is for research conducted at a RRI, which must be approved by institution's IACUC. 5B is completed and signed by QS/PI after experimentation.
	Potentially Hazardous Biological Agents (PHBAs)	NEED SRC APPROVAL BEFORE EXPERIMENTATION Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products, or body fluids. QS/DS selects box describing research setting and required approvals.
	[Form 6A]	MUST BE APPROVED BY SRC/IACUC/IBC <u>BEFORE EXPERIMENTATION</u> . SRC indicates agreement/approval before experimentation if <i>not</i> done at RRI or after experimentation if done at RRI.
	Human/Animal Tissue [Form 6B]	

PROJECTS REQUIRING APPROVAL PRIOR TO EXPERIMENTATION

All projects must have Forms 1, 1A, 1B, Abstract and Research Plan. Projects using human participants, vertebrate animals, or potentially hazardous biological agents require additional forms and MUST BE APPROVED BEFORE EXPERIMENTATION BEGINS. This guide can help determine what approvals are required but does not account for all situations and is not an exhaustive list of requirements. Additional forms are also required for projects that expand on student's past work, use a Qualified Scientist, are conducted at a RRI*, or involve hazardous chemicals, activities, or devices.

*Projects conducted at a **Regulated Research Institution (RRI)** have different requirements than those conducted at home, school, or in the field. RRIs include laboratories (government, college/university, commercial), medical facilities, hospitals, and industrial settings such as manufacturing facilities.

Review the ISEF Rules & Guidelines before beginning research: www.societyforscience.org/isef/international-rules

See rules for clarification of terms, including Qualified Scientist, Regulated Research Institution (RRI), Scientific Review Committee (SRC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC).

Project Component Required Approvals and Forms See ISEF Rules & Guidelines for complete rules **HUMAN PARTICIPANTS** If conducted at home/school/field: If conducted at a RRI: ☑ Project must be approved by the school ☑ Project must be approved by the RRI's IRB A human participants project is any project that involves observing or collecting data from or about humans, including: IRB before experimentation begins. before experimentation begins. • Having participant do a physical activity, even if low-risk ☑ Human Participants [Form 4] **☑** Regulated Research Institution [Form 1C] (e.g., physical exertion, tasting a substance) ☑ Qualified Scientist [Form 2] - if applicable ☑ Qualified Scientist [Form 2] - if applicable • Psychological, educational, and opinion studies (including surveys, questionnaires, tests) ☑ Risk Assessment [Form 3] - if applicable ☑ Risk Assessment [Form 3] - if applicable Study in which the student researcher is the subject of their EXEMPTIONS - The following projects are exempt from IRB pre-approval: own research (e.g., measuring heart rate) 1. Student-designed Invention, Prototype, Computer Applications, Engineering/Design Project or Consumer • Testing of student-designed invention, prototype, computer Product Testing in which the student researcher is the only person testing and testing does not pose health or application, etc. by anyone other than student researcher safety hazard. Risk Assessment [Form 3] is required for these projects. **PLEASE NOTE** This exemption DOES NOT APPLY if the project involves more than the student researcher or any introduction of a human Data/record review projects that include data that are not variable or factor in the testing (e.g., amount of sleep, strength or endurance of tester, etc.). IRB review de-identified/anonymous (e.g., includes name, birth date, and pre-approval would be required in this case. phone number, or other identifying details) Data/record review studies (e.g., baseball or crime statistics) using preexisting, publicly available data sets that Behavioral observations that a) involve interaction with do not involve any interaction with humans or the collection of data from humans for the purpose of the project. individuals or where the researcher has changed the Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) where researcher has environment (e.g., posted a sign, placed an object): no interaction with the individuals being observed, the researcher does not manipulate the environment in any b) occur in non-public or restricted access settings (e.g., way, and the researcher does not record any personally identifiable data. day care, doctor's office); or c) involve recording personally Projects in which the student receives pre-existing/retrospective data in a de-identified/anonymous format (must identifiable information be certified by professional providing data and reviewed by SRC). VERTEBRATE ANIMALS If conducted at a RRI: If conducted at home/school/field: ☑ Project must be approved by SRC Vertebrate animal studies involve any of the following: ☑ Project must be approved by the RRI's before experimentation begins. IACUC before experimentation begins. 1. Live, nonhuman vertebrate mammalian embryos or fetuses 2. Tadpoles ☑ Vertebrate Animal [Form 5A] ✓ Vertebrate Animal [Form 5B] 3. Bird and reptile eggs starting 72 hours prior to hatching ☑ Qualified Scientist [Form 2] - if applicable ☑ Regulated Research Institution [Form 1C] 4. All other nonhuman vertebrates (including fish) at hatching ☑ Qualified Scientist [Form 2] - if applicable Research conducted at home/school/field must involve only EXEMPTIONS - Behavioral observations are exempt from SRC pre-approval if ALL of the following apply: agricultural, behavioral, observational or supplemental nutria. There is no interaction with the animals being observed, tional studies on animals AND only non-invasive and nonb. There is no manipulation of the animal environment in any way, and intrusive methods that do not negatively affect an animal's health or well-being. c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations. POTENTIALLY HAZARDOUS If conducted at home/school/field: If conducted at a RRI: BIOLOGICAL AGENTS (PHBAs) ☑ Project must be approved by SRC ☑ Project must be approved by the RRI's IBC/IACUC before experimentation begins* before experimentation begins. Potentially hazardous biological agents (PHBA) studies involve microorganisms (including bacteria, viruses, viroids, ☑ PHBA Risk Assessment [Form 6A] ☑ PHBA Risk Assessment [Form 6A] prions, rickettsia, fungi, and parasites), recombinant DNA ☑ Human and Vertebrate Animal Tissue ☑ Human and Vertebrate Animal Tissue (rDNA) technologies or human or animal fresh/frozen tissues, [Form 6B] - if applicable [Form 6B] - if applicable blood, or body fluids. ☑ Qualified Scientist [Form 2] - if applicable ☑ Regulated Research Institution [Form 1C] A project is considered a tissue (PHBA) study and not a vertebrate animal study if the tissue is obtained from an ☑ Qualified Scientist [Form 2] - if applicable animal that was euthanized for a purpose other than the student's project. EXEMPTIONS - The following are exempt from prior SRC review but require Risk Assessment [Form 3]: protists and archaea; manure for composting, fuel production, or other non-culturing experiment; commercially available Experimentation involving the culturing of potentially color change coliform detection test kits (sealed, properly disposed); decomposition of vertebrate organisms; microhazardous biological agents, even BSL-1 organisms, is

bial fuel cells (sealed, properly disposed)

EXEMPTIONS - The following involve BSL-1 organisms, are exempt from prior SRC review, and require no additional forms: fermentation of baker's yeast and brewer's yeast (except rDNA studies); Lactobacillus, Bacillus thuringiensis, nitrogen-fixing, oil-eating, and algae-eating bacteria introduced into natural environment (not exempt if cultured); water or soil microbes not concentrated in media conducive to microbial growth; mold growth on food if experiment is terminated at evidence of mold; slime molds, edible mushrooms; E. coli k–12 (and other strains used

*Note regarding PHBA projects conducted at a RRI: PHBA projects must be approved by the RRI's IBC/IACUC before experimentation begins. If the RRI does not require prior review and approval, then the project must be reviewed and approved by an SRC before experimentation begins.

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