# SENIOR DIVISION RULES QUICK REFERENCE AND FORMS CHECK

#### **FORMS**

All Senior Division projects require forms 1, 1A, and 1B. The list below consists of forms that are required for projects depending on the experimentation being done. The lists for what types of projects require those forms is not a complete list. For a complete list, check the <u>ISEF rule book</u>.

- 1. Hazardous Materials, Activities, Devices: Risk Assessment Form (3)
  - a. Chemicals, poison, acid, petroleum products, paint, glue, fertilizer etc.
  - b. Power tools, knives, sharp or dangerous objects, machinery
  - c. Fire, heat, oven, burner, radiation, electricity, flammable materials/substances
  - d. Any other potentially dangerous situation or activity
  - e. Exempt Micro-Biology, E-coli k12, algae, bio-fuel, bio-fuel cells, etc.
  - f. Projects that involve human participant testing of any project involving student- designed inventions, prototypes or consumer products
- 2. Human Participant Study: Human Participant Form (4) (IRB Pre-Approval)
  - a. Surveys, tests, opinion studies, etc.
  - **b.** Tasting, smelling, exercise, etc.
  - c. Medical procedures, blood sugar, blood pressure, DNA kit, etc.
  - d. Using other people to test a product you created or purchased
  - e. Any research involving humans (including yourself) as test subjects
- 3. Vertebrate Animal Study: Vertebrate Form (5A) or (5B) (SRC Pre-Approval)
  - a. Involves any vertebrate animal (dog, cat, fish, chicken, birds, reptiles, etc.)
- 4. Biological Agents (microbiology): Hazardous Biological Agents Form (6A) (SRC Pre-Approval)
  - a. Culturing bacteria, mold, or other microorganisms (can't be done at home)
  - b. Prions (must work in regulated research institution with qualified scientist)
  - c. E-Coli K-12 does NOT NEED this form, but must be done in a lab
- 5. Vertebrate Tissue: Biological Agents Form (6A) & Tissue Form (6B) (SRC Pre-Approval)
  - a. Blood, blood products (from vertebrate animals or humans)
  - b. Saliva/other bodily fluids (from vertebrate animals or humans)
  - c. Cell or Tissue (from vertebrate animals or humans)

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- 6. Research Done outside home, school or field or with significant contribution from a mentor other than the teacher (including virtual assistance by a mentor): **Regulated Research/Industrial Form (IC)** 
  - a. Place of business or commercial/private property (stores, churches, offices, facilities, gyms, hair salon etc.)
  - b. Industrial Location (welding shops, machine shop, mechanic shop, etc.)
  - c. School or University other than the one you attend
- 7. Continuation Project: Continuation Form (7)
  - a. Project related to previous year's research

### **RULES QUICK CHECK: COMMON PAPERWORK MISTAKES**

The rules explained below are some that came up during regional and state fair review of projects. This is not a complete list of rules. This is just meant as a reminder of some of the rules most missed. Please review <u>all rules</u> prior to reviewing student paperwork.

- I. Human Participant Study:
  - **a.** Students who work at a Regulated Research Institution (RRI) must have Institutional Review Board (IRB) approval from the RRI. The school IRB is not sufficient. A copy of the RRI IRB approval must be uploaded in Scienteer.
  - **b.** Students are prohibited from diagnosing medical conditions, performing medical procedures, or administering medication to human subjects. They may collect data as an observer under direct supervision of a licensed professional at an RRI. The licensed professional must be named in the research plan and approved by the RRI IRB.
  - c. On-line surveys require participant consent and must include a statement similar to the one provided by ISEF: "There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question." Surveys should require participants to click a button or type a response indicating consent after the statement is read.
  - **d.** Form 4 should not have "Not Applicable" selected for any of the age groups of participants. A form 4 indicates that there are human participants, so the IRB needs to select the correct age groups depending on the project and select whether or not written consent is required for those age groups.
  - e. Engineering projects that use human participants, other than the student and a single adult guardian/sponsor, to test or analyze their product require a Form 4 with IRB review. Also, if students test their own engineering product and it requires them to do a physical activity, they need a Form 4 with IRB review.
  - **f.** The above exemption for students testing their own engineering product that does not require a Form 4 does not extend to projects where students are using themselves as a test subject in an experiment.

#### **Examples:**

Project Type	Project Explanation	Human Involvement	Form 4 Requirement
Engineering	Computer software created by student researcher	20 Students tested the software	Required
Engineering Computer software created by student researcher		Researcher or teacher tested software	Exempt
Engineering	Student created system where video game only works when a bicycle is used	Researcher or teacher tested the system and there is a physical component	Required
Experiment	Blood pressure tested while playing different video games	Researcher	Required
Experiment	Bacteria cultured from hands after using different hand sanitizers	Researcher	Required

#### 2. Vertebrate Animal Study:

- a. Studies performed at a Regulated Research Institution (RRI) require review by an Institutional Animal Care and Use Committee (IACUC). The IACUC review must be uploaded to STEM Wizard. The IACUC must have the student's name on it or include a letter from the IACUC allowing the student to work on the project.
- b. Students are not allowed to cause pain, distress, or death to animals in their study. An IACUC may allow this type of study, but it will not be allowed at our fair.

#### 3. Biological Agents (microbiology):

a. Culturing bacteria, mold, or other microorganisms can't be done at home.

#### 4. Regulated Research/Industrial Form (IC)

- a. Form IC must be completed by the supervising adult at the university or place of business where the research was done, not by the student or teacher.
- b. **NEW for 2023\*** A Form IC should be filled out by any researcher at an institution who significantly assists a student with their project even if the student works remotely.

## **Senior Division - <u>ISEF Forms with Signatures</u>**

Use this document to determine who can sign each ISEF Form.

Form	ISEF							
Needed	Form	Section	Needed By	Dated	Signature Needed	Who Can Sign Here	Name	Email Address
				Prior To Start				
				Date on Form	Adult Sponsor	Teacher or Adult in		
X	1		All Students	1A, Section 7	(Teacher)	Charge		
					Student (For a Team			
					Project, there should be			
					a Form 1B for each			
					student with their			
				Prior To Start	parent's signature. Save			
				Date on Form	as 1 pdf before			
X	1B	1a	All Students	1A, Section 7	uploading)	Student		
				Prior To Start				
				Date on Form				
X	1B	1b	All Students	1A, Section 7	Parent	Parent		
						SRC Chair - A		
						biomedical scientist		
						with an earned		
						graduate degree or		
			Required for projects that			IRB Chair - Usually the		
			need prior SRC/IRB			medical or mental		
			approval BEFORE			health professional on		
			experimentation			the IRB. <b>This can not</b>		
			,	Prior To Start		be the teacher or		
			potentially hazardous	Date on Form		anyone related to		
	1B	2a	biological agents).	1A, Section 7	SRC or IRB Chair	the student(s).		

				1		
				Regional SRC Chair -		
				Projects advanced in		
				STEM Wizard will have		
			AFTER End	this approval after ALL		
			Date on Form	forms are approved. If		
			1A, Section 7	project advances to		
		Projects advancing to	and BEFORE	ISEF, the document will		
		their Regional Science	Competition	need an actual		
1B	3	Fair	Date	signature.		
				State SRC Chair -		
				Projects advanced in		
				STEM Wizard will have		
			AFTER End	this approval after ALL		
			Date on Form	forms are approved. If		
			1A, Section 7	project advances to		
			and BEFORE	ISEF, the document will		
		Projects advancing to	Competition	need an actual		
1B	3	TXSEF	Date	signature.		
					Mentor, Supervising	
		Students who work with a			Adult, or Whoever	
		mentor (other than			gave permission for	
		teacher) virtually or on			the student to work at	
		site or who work at a			that location. <b>This</b>	
		research institution,		Mentor, Supervising	should not be the	
		industrial setting, or any		Adult, or Whoever gave	teacher or parent	
		place other that home,	AFTER End	permission for the	(unless it is the	
		school, or field (such as a	Date on Form	student to work at that	parent's lab or	
1C		park or open field).	1A, Section 7	location	business).	

2	]	Prior To Start Date on Form 1A, Section 7	Qualified Scientist. This signature is required if the project needs form 2.	Person who earned a professional degree or has extensive experience in the student's area of research and will supervise the student or coordinate with a designated supervisor to serve in that capacity	
2	May be required for research involving human participants, vertebrate animals, potentially hazardous biological agents, and hazardous substances and devices. ONLY Need this signature if Qualified Scientist isn't supervising the student.	Prior To Start Date on Form 1A, Section 7	Designated Supervisor signs ONLY if the Qualified Scientist won't be able to directly supervise the student.	Person familiar with student's project that will directly supervise work	
3	Recommended for all projects. May be required for projects involving Human Participants, Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents.	Prior To Start Date on Form 1A, Section 7	Designated Supervisor or Qualified Scientist who will supervise the student during experimentation.	Person who will supervise the student during experimentation	

	Required for all research		Medical or Mental		
	involving human		Health Professional (a		
	participants not at a		psychologist, medical		
	Regulated Research		doctor, licensed social		
	Institution. If at a		worker, licensed clinical		
	Regulated Research		professional counselor,	Medical or Mental	
	Institution, use		physician's assistant,	Health Professional on	
	institutional IRB approval		doctor of pharmacy, or	IRB. <b>This can not be</b>	
	forms for documentation	Prior To Start	registered nurse) with	the teacher or	
	of prior review and	Date on Form	expertise related to this	anyone related to	
4	approval.	1A, Section 7	project.	the student(s).	
	Required for all research				
	involving human				
	participants not at a				
	Regulated Research				
	Institution. If at a				
	Regulated Research				
	Institution, use				
	institutional IRB approval				
		Prior To Start		Another teacher. <b>Can</b>	
		Date on Form	Educator (can not be	not be the adult	
	of prior review and		`		
4	approval.	1A, Section 7	adult sponsor/teacher)	sponsor.	
	Required for all research				
	involving human				
	participants not at a				
	Regulated Research				
	Institution. If at a				
	Regulated Research				
	Institution, use				
	institutional IRB approval	Prior To Start		Preferably the	
	forms for documentation	Date on Form		Principal or Assistant	
4	of prior approval.	1A, Section 7	School Administrator	Principal	

5A	Required for all research involving vertebrate animals that is conducted in a school/home/field research site.	Prior To Start Date on Form 1A, Section 7	SRC Chair	A biomedical scientist with an earned graduate degree. This can not be the teacher or anyone related to the student(s).	
5A	May be required for all research involving vertebrate animals that is conducted in a school/home/field research site.	Prior To Start Date on Form 1A, Section 7	Veterinarian	Veterinarian	
5A	May be required for all research involving vertebrate animals that is conducted in a school/home/field research site.	Prior To Start Date on Form 1A, Section 7	Designated Supervisor or Qualified Scientist who will supervise the student during experimentation.	Person who will supervise the student during experimentation	
5B	Required for all research involving vertebrate animals that is conducted at a Regulated Research Institution. You must include IACUC approval form dated before experimentation.	AFTER End Date on Form 1A, Section 7	Qualified Scientist or Principal Investigator	Person who supervised the student during experimentation	

6A	3	Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.	Prior To Start Date on Form 1A, Section 7	Designated Supervisor or Qualified Scientist who will supervise the student during experimentation.	Person who will supervise the student during experimentation	
6A	4	Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids.	Prior To Start Date on Form 1A, Section 7	SRC Chair	A biomedical scientist with an earned graduate degree. This can not be the teacher or anyone related to the student(s).	
6B		are completed. All	Prior To Start Date on Form 1A, Section 7	Designated Supervisor or Qualified Scientist who will supervise the student during experimentation.	Person who will supervise the student during experimentation	

	listed above must also complete Form 6A.				
	Required for projects that				
	are a				
	continuation/progression				
	in the same field of study				
	as a previous project. This				
	form must be				
	accompanied by the				
	previous year's abstract	Prior To Start			
	and Research	Date on Form			
7	Plan/Project Summary.	1A, Section 7	Student	Student	