

Human Participants Form (4)

Required for all research involving human participants not at a Regulated Research Institution. If at a Regulated Research Institution, use institutional approval forms for documentation of prior review and approval. (IRB approval required before experimentation.)

Student's Name(s)

Adult Sponsor

Must be completed by Student Researcher(s) in consultation with a Qualified Scientist:

- 1. I have submitted my Research Plan which adheres to the Research Plan Instructions.
- 2. I have attached any surveys or questionnaires I will be using in my project.
 - Any published instrument(s) used was /were legally obtained.
- 3. I have attached an informed consent that I would use if required by the IRB.
- 4. Yes No Are you working with a Qualified Scientist? If yes, attach the Qualified Scientist Form 2

Form 4 is required for all projects involving human participants and must be completed prior to experimentation.

Must be completed by Institutional Review Board/Scientific Review Committee:

Research Plan must address the following:

Check one of the following:

Research project involving human participants and/or requested

Research project involving human participants

1. Risk Level (check one)

2. Qualified Scientist

3. Written Minor Assent

Yes

4. Written Parental Permission

Yes

5. Written Informed Consent

Yes

The project's Research Plan must be reviewed and approved by an Institutional Review Board/Scientific Review Committee. The IRB/SRC determines if the experiment's participants are required to provide assent, written parental permission, or written informed consent by checking the appropriate boxes. If the student's school does not have an IRB/SRC, Coriell can act as the SRC and approve the project. If the reviewing body determines assent, written parental permission, or written informed consent must be obtained from participants, the student needs to complete the Human Informed Consent Form and administer prior to experimentation.

IRB SIGNATURES (All 3 signatories must be a qualified scientist or related professional. I attest that I have reviewed the research plan and

Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)

Printed Name

Degree/Professional License

Signature

(Must be prior to experimentation.)

Educator

Printed Name

Signature

(Must be prior to experimentation.)

The IRB must hand-complete and sign the bottom section of Form 4. Note: the project's Adult Sponsor, Designated Supervisor, or Qualified Scientist cannot serve as a member of the IRB and cannot sign Form 4.

School Administrator

Printed Name

Degree

Signature

Date of Approval (Must be prior to experimentation.)

Human Informed Consent Form

Instructions to the student researcher:
This form is used for the IRB/Scientific Review Committee consultation with the student researcher.
This form is used for the IRB/Scientific Review Committee informed consent process.

- When written informed consent is required:
- Students

If the form is serving as:

Student Researcher(s): _____

Title of Project: _____

If the Institutional Review Board/Scientific Review Committee determines a project involving human participants requires written minor assent, written parental permission, or written informed consent from participants over the age of 18, the student must develop a Human Informed Consent Form and administer to participants prior to experimentation. Students are required to collect the completed forms from study participants.

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

All of the Human Informed Consent Form fields are required and must be completed by the student.

Potential Risks of Study: _____

Benefits: _____

How confidentiality will be maintained: _____

If you have any questions about the project, please contact the student researcher.

Adult Sponsor: _____

If the IRB/SRC determines the student needs to obtain written parental permission from study participants, the student must include a copy of the experiment's survey or questionnaire when applicable so the parent may review the materials.

Voluntary Participation:

Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent or Minor Assent

Printed Name of Research Participant: _____

Date Reviewed & Signed: _____

Signature: _____

Parental/Guardian Permission: _____

Parent/Guardian Printed Name: _____

Although not a requirement, students should have completed copies of the form available on Fair Day to support their research.