

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 Contact

Must be completed by Student Researcher(s) in collaboration with

- I have submitted my Research Plan which addresses the following instructions.
- I have attached any surveys or questionnaires I will be using in my project or other documents provided to human participants.
 Any published instrument(s) used was /were legally obtained.
- I have attached an informed consent that I would use if required by the IRB.
- 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 for approval to be valid. (If not approved, the project cannot proceed.)

Approved with Full Consent

(All 5 must be answered)

1. Risk Level (check one)

2. Qualified Scientist

3. Written Minor Assent

Yes

4. Written Parental Permission

Yes

5. Written Informed Consent

Yes

Approved with Expedited Review

Human participants

are no health or safety risks

Student is the only subject

The project's Research Plan must be reviewed and approved by an Institutional Review Board. The IRB determines if the experiment's participants are required to provide assent, written parental permission, or written informed consent by checking the appropriate boxes. If your school doesn't already have an IRB in place, it's easy to establish one: for example, your school nurse can sign as the Medical or Mental Health Professional, while two school officials can sign as the Educator or School Administrator. 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 signatures required unless expedited review checked above) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project, that the checkboxes above have been completed to indicate the IRB determination and that I agree with the decisions above.

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

Printed Name

Signature

Educator

Printed Name

Signature

School Administrator

Printed Name

Degree

Signature

Date of Approval (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. If the Expedited Review box is checked and the project meets the requirements (student is the subject or participants provide feedback only and no risks or privacy violations are involved), only one reviewer needs to sign Form 4.

Human Informed Consent Form

Instructions to the Student Researcher:
This form was developed in consultation with the Institutional Review Board/Scientific Review Committee. This form is used to obtain written informed consent from participants.

- When written informed consent is required.
- Students must obtain written informed consent from participants over the age of 18.

If the form is serving as a minor assent form, it should be attached to the Human Informed Consent Form.

Student Researcher Name: _____
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 providing this information to you for your information.

Please read the following information and check the appropriate box below.

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

Time required for participation: _____

Potential Risks of Study: _____

Benefits: _____

How confidentiality will be maintained: _____

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

Adult Sponsor/QS/DS: _____

Phone/email: _____

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

Date Reviewed & Signed: _____

Printed Name of Researcher: _____

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.