Human Participants Research

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CREST-Jane Goodall Science Symposium

Supplemental

Guidelines & Requirements

for your

ISEF Research Plan

When doing research with human participants, you need to follow all the local, state and federal rules and guidelines that apply to university-level studies. Your research plan must include information that shows how you will follow those guidelines. A special committee will review your plan, determine its risk level, and approve your project before you begin experimenting. This committee is called the Institutional Review Board, or IRB, and includes teachers, school administrators, and health professionals (nurses, doctors, psychologists) who have volunteered to review student projects to make sure participants and researchers are not harmed in any way by the research.

In this packet, you'll find:

1. A list of extra requirements that must be included in your research plan, from the Society for Science and the Public's ISEF rulebook.
2. An explanation of how to figure out the risk level for your project, from the ISEF rulebook. Any risk level that is determined by the IRB to be "more than minimal" will require extra supervision and paperwork.
3. A form you should fill out to obtain informed consent from your participants. When this form is approved, copies can be given to each of your study participants. They will read it and sign to show they are agreeing to be part of your study.
4. Information about the ethical guidelines for doing research with human participants, from the National Institutes of Health. These guidelines should be followed for any project that involves human test subjects. In this packet, we've included their full booklet, titled *Research Ethics: How to Treat People Who Participate in Research*. We strongly encourage you to read the full packet before you start writing your research plan.

CHECKLIST: Requirements for ISEF research plans involving human participants

adapted from: https://member.societyforscience.org/document.doc?id=642

The following items must be covered in the procedure and risk assessment sections of your research plan. BE SURE you have included each item in these two lists before you submit your plan for review!:

In the Procedure section, include all these points:

- ☐ Participants: Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
- ☐ Recruitment: Where will you find your participants? How will they be invited to participate?
- ☐ Methods: What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
- ☐ Informed Consent Process: Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

Be sure to attach all surveys, questionnaires, tests, and recruitment materials to your research plan!

In the Risk Assessment section, include all these points:

- ☐ Risks. What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize the risks?
- ☐ Benefits. List any benefits to society or each participant.
- ☐ • Protection of Privacy: Will any identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be

collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?

More info >>>

How will the IRB committee evaluate the risk level for your project?

https://student.societyforscience.org/human-participants

Use this information to see whether your risk level is *no more than minimal* or *more than minimal*. Which level do you believe applies to your project?

Human Participant Risk Assessment

Projects involving *no more than minimal risk* and those with *more than minimal risk* are allowed under the following guidelines:

- ***No more than minimal risk*** exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.
- ***More than minimal risk*** exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).
    1. **Examples of Greater than Minimal Physical Risk**
        a. Exercise other than ordinarily encountered in everyday life
        b. 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 the nature of the study and local norms.
        c. Exposure to any potentially hazardous material.

    2. **Examples of 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. Some examples include: 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; or viewing violent or distressing video images.

    3. **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.

4. **Risk Groups**

   If the research study includes participants from any of the following groups, the IRB and student research must consider whether the nature of the study requires special protections or accommodations:

   a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
   b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA).

How do you obtain proof of informed consent from your study participants?

https://student.societyforscience.org/human-participants#informed

Unless data collection is truly anonymous - meaning that even you do not know who participated in your study - the IRB will likely require you to obtain signed consent forms from your participants. These are called informed consent forms, because they have information about your study as well as a place to sign. These forms also tell participants about their rights to refuse to participate at any time, and how their data will be protected and kept private.

ISEF provides a generic form for your use; there's a blank copy in this packet. You may find it and fill it out online at https://member.societyforscience.org/document.doc?id=654 . You may instead tear out the form in this packet and handwrite your study information in the blanks. Write legibly, in ink! You may also design your own form if you prefer, but you must include the information shown on the ISEF Human Informed Consent form here. If participants are <18 years of age, you will likely need to get parental permission to participate, as well. Both parents and students will need to sign the form. The IRB will make the final determination about this requirement.