Human Participants Guidelines

https://www.societyforscience.org/isef/international-rules/human-participants/

The following rules were developed to help pre-college student researchers adhere to the federal regulations governing professional scientists and to protect the welfare of both human participants and the student researcher. Health and well-being is of the highest priority when students conduct research with human participants.

According to Code of Federal Regulation 45, CFR 46, a human participant is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individuals(s) or (2) identifiable private information.

Examples of projects that are considered "human participant research" include:

- Participants in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
- Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
- Studies in which the researcher is the subject of the research
- Testing of student designed invention, prototype or computer application by human participants other than student researcher
- Data/record review projects that include data that are not de- identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables)
- Behavioral observations that
    - involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
    - occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
    - involve the recording of personally identifiable information.

Rules

1. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan/Project Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment info on page 11 and the online **Risk Assessment Guide** for additional guidance.

2. Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) (See page 5) before any interaction (e.g., recruitment, data collection) with human participants may begin. It is the responsibility of the IRB to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for the student researcher and participants.

a. Projects that are conducted at school, at home or in the community that are not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the School IRB before the student may begin recruiting and/or interacting with human participants. The School IRB must assess the risk and document its determination of risk on Form 4.

b. Projects that are conducted at a Regulated Research Institution (RRI) (e.g., university, hospital, medical center, government lab) must have IRB approval from the RRI. A copy of the IRB approval for the project must be obtained. A letter from an adult mentor and/or Qualified Scientist is not sufficient documentation of the RRI IRB review and approval process.

3. The student must comply with all determinations made by the School or RRI IRB before beginning any interaction with human participants (e.g., recruitment, data collection).

- a. If the IRB requires a Qualified Scientist (QS), Form 2 must be completed by the QS before any interaction with human participants. The School IRB will review this completed form before approving the project.
- b. If the IRB requires a Designated Supervisor (DS), Form 3 must be completed before any interaction with human participants. The School IRB will review this completed form before approving the project.
- c. See rule #4 below regarding required procedures for obtaining informed consent/assent and/or parental permission.

4. Participation in research may begin only after research participants have voluntarily given informed consent/assent (in some cases with parental permission). Adult research participants may give their own consent. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing permission.

The School IRB will determine whether the consent/assent/ parental permission may be a) verbal or implicit or b) must be written. See the Risk Assessment info on page 9 and the online **Risk Assessment Guide** for further explanation of informed consent.

a. Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
b. Participants must be informed that their participation is voluntary and that they are free to stop participating at any time (i.e., they may participate or decline to participate, with no adverse consequences of non- participation or aborted participation).
c. Informed consent may not involve coercion.
d. When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
e. The student researcher may request that the IRB waive the requirement for written informed consent/parental permission in his/her research plan if the project meets specific requirements. See section on IRB waivers for more information about situations in which written parental permission and/or written informed consent can be waived by the IRB.

5. The research study must be in compliance with all privacy laws (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and the U.S. Health Insurance Portability and Accountability Act (HIPAA)) when they apply to the project (e.g. the project involves medical information).

6. Students are prohibited from independently diagnosing disease, administering medication, and/or performing medical procedures on human participants.

- a. A student may observe and collect data for analysis of medical procedures, medication/treatment efficacy, and diagnosis of illness, only under the direct supervision of a licensed health care provider/professional.
- b. This Healthcare provider/professional must be named in the research plan/ protocol approved by the IRB. The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc) of the state or country in which he/she is conducting the research.

7. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).

8. All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.

9. Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the **Online Survey Consent Procedures**.

10. After initial IRB approval, a student with any proposed changes in the Research Plan must repeat the approval process and regain approval before resuming interaction (recruitment, data collection) with human participants.

11. After experimentation and before competition, the Affiliated Fair SRC will review for compliance with all rules.

12. The following forms are required:

- a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/ Project Summary, and Approval Form (1B)
- b. Human Participants Form (4) or IRB approval form from an RRI and all applicable consents and survey(s)
- c. Regulated Research Institution Form (1C), when applicable
- d. Qualified Scientist Form (2), when applicable
- e. Risk Assessment (3), when applicable

IRB Waiver of Written Informed Consent/Parental Permission

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involves only minimal risk and anonymous data collection and if it is one of the following:

1. Research involving normal educational practices

2. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.

3. Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

4. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

Human Participant Involvement in Student-designed Invention, Prototype, Computer Application & Engineering/Design Projects

Student-designed invention, prototype, computer application and engineering/design projects that involve testing of the invention by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype.

1. IRB review and pre-approval is necessary when the student- designed invention, prototype, application, etc. is tested by human participants other than the student researcher(s) or Adult

Sponsor/QS/DS when the testing requires an adult tester. Surveys conducted regarding potential use, review of the product and/or opinions regarding the project, as defined by the FDA or Medical Practices Act, and tested on Human Participants must be supervised by a Qualified Scientist.
2. A Risk Assessment Form 3 is recommended for all student- designed inventions or prototypes.

Exempt Studies (Do Not Require IRB Pre-approval or Human Participants Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for ISEF and affiliated fairs are:

1. Student-designed Invention, Prototype, Computer Applications or Engineering/Design Project in which the student is the only person testing the invention, prototype or computer application and the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed. The use of human participants (other than the student researcher him/herself) for this testing requires IRB review and approval.
2. Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.
3. Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
   a. the researcher has no interaction with the individuals being observed
   b. the researcher does not manipulate the environment in any way and
   c. the researcher does not record any personally identifiable data.
4. Projects in which the student receives pre-existing/retrospective data in a **de-identified/anonymous** format which complies with both of the following conditions:
   - a. the professional providing the data certifies in writing that the data have been appropriately de-identified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
   - b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Human Participant & IRB Resources

Use this information to determine the level of risk involved in a study involving human participants.

All human participant projects are considered to have some level of risk.

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**

- Exercise other than ordinarily encountered in everyday life
- ngestion, 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.
- 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**

- 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.
- 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:

- 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.)
- 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).

See the online Risk Assessment Guide and Online Survey Consent Procedures for more detailed information on risk assessment.

Sources of Information: Human Participants

1. Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)
http://ohsr.od.nih.gov/guidelines/45cfr46.html

2. Dunn, C. M. and Chadwick, G. L., Protecting Study Volunteers in Research, 3rd Edition (2004). Boston, MA: Thomson Centerwatch. ISBN 1-930624-44-1. Can be purchased from: www.amazon.com

3. NIH tutorial, "Protecting Human Research Participants", http://phrp.nihtraining.com/users/PHRP.pdf

4. Belmont Report, April 18, 1979, www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

5. Standards for Educational and Psychological Testing. (1999). Washington, DC: AERA, APA, NCME.
www.apa.org/science/programs/testing/standards.aspx

6. American Psychological Association, 750 First Street, NE Washington, DC 20002-4242
phone: 202-336-5500; 800-374-2721, www.apa.org

Information for students: www.apa.org/science/leadership/students/information.aspx
Information regarding publications: www.apa.org/pubs/index.aspx

7. Educational and Psychological Testing, Testing Office for the APA Science Directorate
phone: 202-336-6000, email: testing@apa.org, www.apa.org/science/programs/testing/index.aspx

8. The Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. §§ 6501–6506)
www.ftc.gov/privacy/coppafaqs.shtm