Youth Science Canada
Sciences jeunesse Canada

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Participation of Humans in Research – Significant Risk

1 Introduction

1.1 A Significant Risk Project involves conditions where the risk of harm is greater, or is potentially greater, than that encountered in everyday life. Low Risk projects are defined in the Participation of Humans in Research – Low Risk policy. All other projects are, by definition, Significant Risk Projects.

1.2 The implementation of this policy is described on the web site of the Youth Science Canada National Ethics and Safety Committee. This material must be read by both students and their supervisors.

1.3 All students must submit a Research Plan to the Chair of the Regional STEM fair Ethics Committee before starting their experiments.

2 Definitions

2.1 Human Research refers to any project that involves the generation of data about persons.

2.2 A Student Researcher is an elementary or secondary school student who takes data, collects information, or assists in research activities involving humans, usually as part of work on a project.

2.3 A Participant is a person who takes part in a project or activity as a source of primary data and bears any risk as the research is being carried out. The Student Researcher may also be a Participant.

2.4 An Adult Supervisor is a parent, teacher, professor, scientist, or other STEM professional responsible for ensuring that the student is aware of the ethical issues involved in the project and providing guidance and advice to ensure that Youth Science Canada policy is followed. The Adult Supervisor is responsible for ensuring that the student's research is eligible for entry into a regional STEM fair, Canada-Wide Science Fair, or other youth STEM project competitions or events. Every project involving the participation of humans requires an Adult Supervisor.

2.5 A Scientific Supervisor, who will usually have an advanced degree, must be involved in a Significant Risk project, which often takes place in a university, institutional, industrial or government laboratory. The Scientific Supervisor is responsible for ensuring that (a) all provincial and federal laws governing safety, handling of materials, and procedures are followed; (b) that all applicable policies concerning research ethics and the participation of humans are known to the student and adult supervisor and are followed. The Scientific Supervisor may be the Adult Supervisor.

3 Significant Risk Projects

3.1 Drugs

a) Definition of a "drug": "drug" includes any substance or mixture of substances manufactured, sold, or represented for use in:

1) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in humans or animals,
2) restoring, correcting, or modifying organic functions in humans or animals;
3) disinfection in premises in which food is manufactured, prepared, or kept. (Ref. 1)

b) Drugs may be used in a Human Participant experiment exhibited at a STEM fair only if carried out in a Hospital, University, Medical or other similar Laboratory under the direction of a Scientific Supervisor. The study must be approved by the appropriate Scientific Review Committee that reviews the research at the Institution, and this must be documented by a letter that forms part of the application to the School, Regional or Canada-Wide Science Fair, or any event organized by, or coming under the auspices of Youth Science Canada. No other studies involving the use of Drugs on human participants, as defined above by Federal Regulations, may be exhibited at any STEM fair or similar event.

3.2 Invasive Procedures and Bodily Tissues

a) Invasive procedures, such as taking blood or tissue samples, or use of human bodily tissue or other bodily fluids, are permitted in an experiment exhibited at a STEM fair only if carried out in a Hospital, University, Medical or other similar Laboratory under the direction of a Scientific Supervisor. The project must be approved by the appropriate Scientific Review Committee that reviews the research at the Institution, and this must be documented by a letter that forms part of the application to the School, Regional or Canada-Wide Science Fair, or similar YSC event.

3.3 Ingestion Projects

a) Projects involving ingestion of food or drink, defined as consumption through eating or drinking, are considered Significant Risk when they involve:
1) articles not manufactured, sold or represented as food or drink for humans.
2) foods that contain additives exceeding the Recommended Daily Intake (RDI) normally associated with those foods.
3) foods not considered to be basic, common, or everyday foods.
4) products that are licensed Natural Health Products. These products are identified by a Health Canada Natural Product Number (NPN) or Exemption Number (EN) and are listed in the Health Canada Natural Health Product Database (Ref 2).

b) Significant Risk Ingestion projects are allowed only if carried out under professional supervision at a laboratory with its own internal Ethics Review Committee, such as a university or hospital laboratory.

c) Some provinces have put in place rules that govern ingestion of food by the public, and these take precedence over the rules in this section. Students doing ingestion projects must know the applicable procedures required for the safe handling of food.

3.4 Cannabis

a) It is illegal for anyone under the age of 18 to possess cannabis. Any project that requires a student to possess cannabis is not permitted at a STEM fair.

3.5 Ingestion Projects - Forbidden

a) The following ingestion projects are not eligible to participate in any event sponsored by Youth Science Canada:
1) Projects that involve the consumption of alcohol.
2) Projects that involve the consumption of cannabis.

3.6 Exercise

a) Projects involving exercise beyond normal everyday activities are Significant Risk projects. They require a Scientific Supervisor with a degree in medicine or with training in exercise, such as a degree in kinesiology or appropriate coaching qualifications. All participants in projects involving physical exercise beyond normal everyday activities must submit the Physical Exercise Permission Form, which is based on the recommendations of the American College of Sports Medicine. (Ref.3)

3.7 Permitted Exceptions

a) The projects listed in this section are eligible for presentation at STEM fairs and are permitted exceptions to the rules above.
   1) Tests on saliva, sweat, tears and urine.
   2) Taking of cheek swabs.
   3) Projects investigating commercial antiperspirant, mouthwash, sunscreen, or toothpaste.
   4) The following exception is permitted only when a qualified health care practitioner (such as a physician, nurse, dentist, or pharmacist) is supervising the project: Blood testing data collected using personal glucose monitors commonly available at pharmacies.

4 Informed Consent

4.1 Human participants must be assured that they are safe, that they are treated with respect and dignity, and that the information they provide will be kept confidential. These ethical safeguards are primarily the responsibility of the Student Researcher and their Adult Supervisor. The process of providing this information is called "Informed Consent".

4.2 The Adult Supervisor is responsible for supervision of ethical as well as scientific aspects of a Significant Risk project, and the Scientific Supervisor is responsible for ensuring that all applicable policies concerning research ethics and the participation of humans are known to the Student and Adult Supervisor and are followed. Both the Adult Supervisor and Scientific Supervisor must sign the Human Participants – Significant Risk Form ensuring that the essential elements of ethics review: consent, confidentiality, and the right to withdraw have been considered.

4.3 Participants must give informed consent before taking part in any Human Research. The research and their participation in it must be explained to children in words they will understand. It must also be explained to children that they do not have to participate unless they want to, even if their parents have approved. Agreement to participate (assent) must be documented for each participant. Children over 9 years can be invited to indicate their assent by co-signing the same form their parent signed. Younger children can provide assent orally, but the researcher must document it.

4.4 If the Participant is under the age of majority (18 or 19 depending on the province/territory), then the parent or guardian must also sign the Informed Consent Permission Form.

4.5 If the Participant is over the age of majority (18 or 19 depending on the province/territory) but is unable to consent for themselves, the Participant's legal guardian must sign the consent form. Assent of the Participant must also be documented.

4.6 Informed Consent - Letter of Information

a) Answers to questions 1 to 12 must appear in the Letter of Information to ensure that Participants have been properly informed of all appropriate ethical issues:
    1) What is the name(s) of the investigator(s); school; project title; the Adult Supervisor's name, email address and telephone number.
    2) What is the purpose of this research?
    3) What are the benefits to the participant from participating?
    4) What are the risks to the participant from participating?
    5) What time commitment is required?
    6) What remuneration or reward will be provided? It is the policy of Youth Science Canada that incentives shall not be offered for participation in Student Research.
    7) How will the confidentiality of the data be guaranteed?
    8) Is the right to withdraw clearly communicated? Explain in the Letter of Information that the participant has the right to withdraw at any time for any reason without consequences of any kind.
    9) How does the participant communicate a decision to withdraw from the study?
    10) How will the results of the research be communicated to the participant?
    11) Are there any other issues that need to be included in the Letter of Information?
    12) Has the project been reviewed and received ethics approval from the appropriate committee? (A positive answer is mandatory for Significant Risk projects.)

4.7 Informed Consent - Permission Form

a) The Informed Consent - Permission form is a short document that contains:
    1) The printed name and signature of the Participant.
    2) The printed name and signature of the person obtaining the Informed Consent.
    3) The signature of a parent or guardian.
    4) A statement that the Participant has received and understood the Informed Consent - Letter of Information.
    5) The date.

4.8 Confidentiality

a) The confidentiality and anonymity of all participants must be maintained. Use coded systems of references; no identifying information may be used. Appropriate safeguards for storage and access to data must be planned. The date all identifiable data will be destroyed must be given to the participants.

5 Display

5.1 The project display may include pictures of participants if prior permission has been obtained in writing. Projects dealing with forensic science topics must preserve the anonymity of any human victims, and project displays must avoid sensational or gratuitous macabre images.

6 Forms

6.1 A Participation of Humans- Significant Risk Approval Form must be submitted to the Regional STEM fair and/or Canada-Wide Science Fair at registration for any Significant Risk project, along with any applicable Letter of Information, Blank Permission Form, and Sample Survey.

7 References

1. Definition of a Drug The definitions are in alphabetical order on this page. Look for “Drug”. Accessed 01 November 2022
2. Natural Health Products Data Base Accessed 01 November 2022
3. Guidelines for Exercise Testing and Prescription 11th Edition. 2021 ISBN 9781975150189. This text is written for professionals.