

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 Participation of Humans in Research – Low Risk. 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 [2]. This material must be read by both students and their supervisors.

1.3 All students wishing to undertake a project of significant risk must submit a Research Plan to the Chair of the Regional Science 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 one who takes data or collects information or assists in research activities involving humans.

2.3 A *Participant* is a person who takes part in a project or activity and so is a source of primary data, and bears any risk as the research is being carried out.

2.4 The *Adult Supervisor*, a parent, teacher, professor, or scientist is responsible for ensuring that the student is aware of the ethical issues involved in the project and provides 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 the CWSF and related or other events sponsored by Youth Science Canada. Every project involving the participation of humans or the use of animals requires an Adult Supervisor.

2.5 The *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

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 beings or animals;
3. disinfection in premises in which food is manufactured, prepared or kept. (Ref. 1)

Drugs may be used in any experiment exhibited at a Science 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 Science Fair or similar event.

3.2 Invasive Procedures and Bodily Tissues

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 Science 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 - Allowed

1. 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 human beings;
 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).
2. 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.
3. 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 Ingestion Projects - Forbidden

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.

3.5 Exercise

Projects involving exercise beyond normal everyday activities are considered to be Significant Risk projects. They require a Scientific Supervisor with training in exercise, such as a degree in kinesiology or appropriate coaching qualifications. Exercise testing must follow the Guidelines for Exercise Testing and Prescription [3], a publication of the American College of Sports Medicine. (Ref. 3)

3.6 Permitted Exceptions

The projects listed in this section are eligible for presentation at science fairs, and are permitted exceptions to the rules above for students in **grades 10-12**.

1. Tests on saliva, sweat, tears and urine.
2. Taking of cheek swabs.
3. Projects investigating 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 Participants must give informed consent before taking part in any science fair project. The project and their participation in it have to 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.

4.2 Informed Consent

Answers to the questions (1) to (17) must appear to ensure that the participants have been properly informed of all appropriate ethical issues:

1. What are 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. No remuneration or reward will be paid. It is the policy of Youth Science Canada that incentives not be offered for participation in projects displayed at either Regional Science Fairs or the Canada-Wide Science Fair.
7. How will the confidentiality of the data be guaranteed?
8. Is the following clearly explained? *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?
12. Has the project been reviewed and received ethics approval from the appropriate committee?
(A positive answer is mandatory for Significant Risk projects.)
13. The printed name and signature of the Participant
14. The printed name and signature of the person obtaining the Informed Consent.
15. The signature of a parent or guardian.
16. A statement that the Participant has received and understood the *Informed Consent*.
17. The date.

An Informed Consent Form (2C) is available at www.cysf.org.

4.4 Confidentiality

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 the data will be destroyed must be given.

5 Display

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

A Significant Risk project requires submission of a Research Plan, an Ethics and Due Care Form (2A), a Significant Risk Form (2B), and an Informed Consent form (2C).

All forms are available from www.CYSF.org.

7 References (available at www.ysc.org)

1. Definition of a Drug: [5] The definitions are in alphabetical order on this page. Look for “Drug”. Accessed 30 June 2015
2. Natural Health Products Data Base [6] [6] Accessed 30 June 2015
3. Exercise Testing. [3]

Source URL: <https://www.youthscience.ca/policy/participation-humans-research-significant-risk>

Links

[1] http://www.youthscience.ca/node/728#Low_Risk_Project_Definition

[2] <http://youthscience.ca/node/8183>

[3] <http://youthscience.ca/node/8198>

[4] <http://youthscience.ca/node/8197>

[5] <http://www.laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html>

[6] <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>