

Participation of Humans in Research – Significant Risk

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Policy Section:	4.1 Youth Science & Technology Research – Ethics
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Related Policies:	4.1.1.1 Participation of Humans in Research – Low Risk 4.1.2 Use of Animals in Research
Contact:	Chair, National Ethics Committee

1 Introduction

- 1.1 *A Significant Risk Project* involves conditions where the risk of harm is greater, or is potentially greater, than those encountered in everyday life. Where there is doubt, projects shall be classified as Significant Risk Projects.
- 1.2 Science fairs often include excellent projects involving human research participants. These projects are usually based in the social and behavioural sciences such as psychology, sociology, and education, and in related health sciences such as physiology, kinesiology and nursing.
- 1.3 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 science fair student researchers and their supervisors. To help them carry out these responsibilities in accordance with national standards, Youth Science Canada provides a set of guidelines and a procedure for review of the ethical aspects of projects. Student researchers and their supervisors are encouraged to read these before starting to design their research program.
- 1.4 There are restrictions on the use of human participants in scientific research. Youth Science Canada wants to ensure that all projects by young scientists involving the participation of humans with an element of risk are supervised, and to ensure that all appropriate safety and ethical concerns are addressed.
- 1.5 This policy has three goals:
 - a) To present the information young scientists, their supervisors and Regional Science Fair Committees need to understand the ethical issues.
 - b) To make it as easy as possible for young scientists to follow appropriate guidelines for projects that involve ethical issues.
 - c) To define clearly the rules that finalists at the Canada Wide Science Fair (CWSF) must follow.
- 1.6 Implementation

The implementation of this policy is described on the web site of the Youth Science Canada Ethics Committee: <http://ethics.youthscience.ca>. Extensive information is provided there. This material must be read by both students and their advisors.

2 Definitions of Human Research, Student Researcher, Participant, Adult Supervisor, Scientific Supervisor.

- 2.1 *Human Research* refers to any project that involves the generation of data about persons. An example of a non-invasive project is exercise testing. Examples of invasive procedures include blood sampling and tissue sampling.
- 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 Human Participants - Significant Risk

- 3.1 Supervision
 - a) The Adult Supervisor, and if appropriate the Scientific Supervisor, is responsible for ensuring the safe, ethical and legal conduct of projects dealing with human participants.
 - b) Before starting research, the student must seek permission for the research by submitting the Research Plan – Significant Risk Projects¹. This form must be reviewed by at least one person knowledgeable about ethics, preferably a member of the RSF Ethics Committee.
 - c) After the research is complete, Form 4.1B *Application for Review of Research with Human Participants – Significant Risk* must be completed and included with the project registration. Projects involving human participants that are deemed to be unethical may be disqualified. Young scientists or their supervisors unsure about the acceptability of a proposed project should contact their Regional Science Fair. The Chair of the RSF Ethics Committee can access appropriate authorities familiar with current regulations and relevant aspects regarding scientific merit. The Chair can provide guidance and suggestions to ensure that the project follows the rules that govern ethical research.

3.2 Drugs

- a) Definition of a “drug”: “*drug*” includes any substance or mixture of substances manufactured, sold, or represented for use in:
 - (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in humans or animals,
 - (ii) restoring, correcting, or modifying organic functions in humans beings or animals;
 - (iii) disinfection in premises in which food is manufactured, prepared or kept.²
- b) 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, as defined above by Federal Regulations, may be exhibited at any Science Fair or similar event.

3.3 Invasive Procedures

- a) Invasive procedures, such as taking blood samples or that involve bodily tissue or other bodily fluids, 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 similar YSC event.

3.4 Ingestion Projects

- a) 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 should be encouraged to explore the procedures required for the safe handling of food.
- 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.

4 Ethics Review Requirements

- 4.1 Youth Science Canada requires that all research involving human participants entered in the Canada-Wide Science Fair, a Youth Science Canada affiliated Regional Science Fair or other event under its auspices, satisfy ethics and safety rules. This ensures that the safety and welfare of the participants as well as the researchers are considered and protected.
- 4.2 The ethics of human participation in research changes over time, and are subject to Federal and Provincial laws. These take precedence over the rules in this document.
- 4.3 The ethics review process must involve (i) the student’s Scientific Supervisor, and (ii) at least one other person who is knowledgeable in the ethics issues involved, and who will usually be a member of the Ethics Committee of the Regional Science Fair. This will

provide the student researcher with an appreciation of the requirements and safeguards existing in law regarding experimentation involving humans.

- 4.4 The term *Significant Risk* covers projects with a range of level and sophistication. To illustrate, here are two extremes:
- a) Significant risk projects such as a study of the effects of using a treadmill on heart rate, can be supervised by a teacher with qualifications such as a first degree in kinesiology or certification as a coach.
 - b) Significant risk projects which are complex or involve participants with special needs, or belong to special groups such as those who have been diagnosed with autism, must be supervised by a professor in a University or similarly highly qualified individual who is trained and is authorized to supervise such studies. These projects will normally be carried out in a research laboratory with its own internal Scientific Review Committee (SRC), who must approve the project. In this case, the Scientific Supervisor will be a staff member of the institution. The rules of the research institution may be more stringent than the rules given here, and must be followed.
- 4.5 Regional Science Fairs, but not individual students, may refer significant risk projects to the National Ethics Committee for advice and a ruling on the appropriate level of supervision.

5 Informed Consent

- 5.1 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.
- 5.2 Informed Consent - Letter of Information

Answers to the questions a) to l) must appear in the *Letter of Information* to ensure that the participants have been properly informed of all appropriate ethical issues:

- a) What are the name(s) of the investigator(s); school; project title; the Adult Supervisor's name, email address and telephone number;
- b) What is the purpose of this research?
- c) What are the benefits to the participant from participating?
- d) What are the risks to the participant from participating?
- e) What time commitment is required?
- f) 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.
- g) How will the confidentiality of the data be guaranteed?
- h) Is the following clearly explained in the Letter of Information? *The participant has the right to withdraw at any time for any reason without consequences of any kind.*
- i) How does the participant communicate a decision to withdraw from the study?
- j) How will the results of the research be communicated to the participant?

- k) Are there any other issues that need to be included in the *Letter of Information*?
- l) Has the project been reviewed and received ethics approval from the appropriate committee? (A positive answer is mandatory.)

A sample for *Informed Consent - Letter of Information* is available for download from the web site of the Youth Science Canada web site, given in Section 8 below.

5.3 Informed Consent - Permission Form

The Informed Consent - Permission form is a short document that contains:

- a) The printed name and signature of the Participant.
- b) The printed name and signature of the person obtaining the Informed Consent.
- c) A statement that the Participant has received and understood the *Informed Consent - Letter of Information*.
- d) The date.

A sample *Informed Consent – Permission Form* is available for download from the web site of the Youth Science Canada web site, given in Section 8 below.

6 Confidentiality

- 6.1 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.

7 Display

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

8 Forms

- 8.1 All forms are available from both the Download section of the CWSF Registration System, and from the Ethics Committee web site:

<http://ethics.youthscience.ca>

- a) Form 4.1B – Significant Risk – Approval
- b) Informed Consent - Letter of Information – blank
- c) Informed Consent – Permission Form – blank

9 Acknowledgements

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10 References

¹ <http://ethics.youthscience.ca/node/91>

² http://laws.justice.gc.ca/en/showdoc/cs/F-27/bo-ga:s_2/20090615/en#anchorbo-ga:s_2

The definitions are in alphabetical order on this page. Look for “Drug”. Accessed 20 August 2010