



Participation of Humans in Research – Low Risk

Policy Number:	4.1.1.1
Policy Section:	4.1 Youth Science & Technology Research – Ethics
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Related Policies:	4.1.1.2 Participation of Humans in Research – High Risk; 4.1.2 Use of Animals in Research
Contact:	Chair, National Ethics Committee

1 Introduction

- 1.1 A *Low Risk Project* - involves conditions where the risks of harm are not greater or more likely than those encountered in everyday life.
- 1.2 All other projects involving humans are to be treated as *Significant Risk Projects*, and must follow Policy 4.1.1.2 *Participation of Humans in Research – Significant Risk*.
- 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.
- 1.4 Supervising Low Risk Projects

It is sufficient to have the adult supervisor assume responsibility for supervision of ethical as well as scientific aspects of the project, and also complete Form 4.1A Human Participants – Low Risk ensuring that the essential elements of ethics review: consent, confidentiality and the right to withdraw are considered.

2 Low Risk Projects

- 2.1 Surveys of Attitudes and Beliefs, Skill Tests, or Observations of Behaviour
 - a) These are all Low Risk Projects. Be aware however that not all survey/skill testing studies are automatically low risk. For example, a project to measure the Body Mass Index of a class could cause considerable discomfort to students who perceive themselves to be overweight. Skill testing could be a difficult experience for a participant who scores well below the group average. It is the responsibility of the adult supervisor to ensure that participants are not put at risk, either physically or emotionally. Mechanisms such as discussion and debriefing should be used to minimize any remaining risk.
- 2.2 Sensory Food Projects
 - a) Such projects are designed only to assess the sensory characteristics of a food, defined by the Food and Drugs Act (1953) as:

- (i) any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatsoever;
- (ii) the foods to be considered are basic foods for which no health benefits are to be claimed, and contain permitted additives not exceeding recommended daily allowance guidelines (RDI) normally associated with those foods.
- b) Sensory evaluations of foods for which health benefits will be claimed or tested are classified as Significant Risk.
- c) Sensory evaluation of foods should only be conducted in participants who are not taking prescription medications, to minimize the risk of drug-food interactions.

2.3 Sports Drinks – Yes

- a) Sports drinks such as Gatorade or Powerade re-hydrate the body. These sports drinks also provide sugars, which the body burns to create energy and replenish electrolytes. Electrolytes maintain salt and potassium balances in the body. Sports drinks may be used in Science Fair Projects.

2.4 Energy Drinks – No

- a) Health Canada has concerns about the safe use of energy drinks¹. Thus Energy Drinks may **not** be used in science fair projects.

2.5 Absorption through the skin

- a) Projects that involve absorption through the skin must satisfy the rules for a low risk project. Thus a project comparing different ways of removing bacteria using different brands of hand sanitizer is legal. A project that involves putting benzene on the skin is not.

2.6 Natural Herbal Products – No

- a) Natural Herbal Products that are purported to produce a physiological response may not be used in a science fair project.

2.7 Medications (prescription and non-prescription) – No

- a) All medications, even those available without a prescription, are considered drugs. 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.

3 Informed Consent

- 3.1 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.

3.2 Informed Consent - Letter of Information

Answers to the questions a) to k) 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*?

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 6 below.

3.3 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 6 below.

3.4 For surveys only, consent may be assumed by the completion of the survey; however, a detailed explanatory letter should accompany the survey, and provide identical information as listed above.

3.5 Informed Consent Forms signed by the parent or guardian is mandatory for all sensory food projects, because of the risk of allergic reactions unknown to the teacher.

4 Confidentiality

4.1 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.

5 Display

5.1 The project display may include pictures of participants if prior permission has been obtained.

6 Forms

All forms are available from both the Documentation section of the CWSF Registration System, and from the Ethics Committee web site: ethics.youthscience.ca.

- a) Form 4.1A – Low Risk – Approval

- b) Informed Consent - Letter of Information – sample
- c) Informed Consent – Permission Form – sample

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References

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- ¹ <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/boissons-energ-drinks-eng.php>
[Accessed 20 August 2010](#)