Youth Science Canada
Sciences jeunesse Canada

**Document Name** Participation of Humans in Research-Low Risk
**Effective Date** 2012-10-01
**Approved By** Reni Barlow – Executive Director

# Participation of Humans in Research – Low Risk

## 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. A Low Risk Project is one that fits one of these five criteria:

a) Some surveys
b) Some food and drink projects
c) Some caffeinated beverage projects
d) Some absorption through the skin projects
e) Some exercise projects

See Section 3 for more details.

1.2 All other projects involving humans are considered Significant Risk Projects and must comply with the Participation of Humans in Research – Significant Risk policy.

## 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.

## 3 Low Risk Projects

3.1 Surveys of attitudes and beliefs, skill tests, or observations of behaviour

a) These are generally 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 are not comfortable with their body weight. 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.

3.2 Food and Drink Projects

a) Projects involving the consumption of food or drink are considered low risk when they are designed only to assess the characteristics and effects of a food. Food is defined as "…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". (Food and Drugs Act (R.S.C., 1985, c. F-27) (Ref. 1)

b) The foods to be considered must be basic or common foods that contain permitted additives not exceeding Recommended Daily Intake (RDI) guidelines normally associated with those foods.

c) Evaluation of foods in youth (under the age of 19 years) must only involve participants who are not taking prescription medications, to minimize the risk of drug-food interactions.

d) Some provinces have rules that govern ingestion of food by the public; 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.

3.3 Caffeinated Beverages

a) The daily limits of caffeine intake are:

1) 200 mg caffeine per day for Participants aged 13 and older.

2) 85 mg caffeine per day for Participants aged 10 to 12.

3) No research involving caffeinated foods or drinks is permitted with Participants under 10 years of age.

b) Caffeine is found in soft drinks, coffee, tea, iced coffee, energy drinks, and many other food and drink products. It is the responsibility of the student researcher and the adult supervisor to ensure that the daily limits are not exceeded. Health Canada has expressed concerns about excessive intake of caffeine by Canadians, especially children and youth (Ref. 2). Thus, the ingestion of caffeine must be closely monitored and kept within reasonable limits according to Health Canada recommendations.

3.4 Absorption through the skin

a) Projects that involve absorption through the skin must satisfy the rules for a low risk project and involve a risk of harm no greater than that encountered in everyday life. Thus, research comparing different ways of removing bacteria using different brands of hand sanitizer would be permitted. Research that involves putting a toxic substance like benzene on the skin would not.

3.5 Exercise Testing

a) All exercise testing beyond normal everyday activities is considered Significant Risk and must comply with the Participation of Humans in Research – Significant Risk policy.

3.6 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. 3)

b) All projects involving Drugs are considered Significant Risk and must comply with the Participation of Humans in Research – Significant Risk policy.

## 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 low-risk project, and for signing the Human Participants - Low 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 In the case of activities that are clearly of very low risk such as observational surveys or having participants listen to music, informed consent may be assumed by the simple act of agreeing to participate. Parents or guardians must still be provided with the Letter of Information beforehand, even though their signed informed consent will not be sought. The teacher or other supervising adult is responsible for deciding if signed informed consent is required for these types of projects.

4.7 Signed informed consent forms are mandatory for all food and drink projects because the risk of allergic reactions is unknown.

4.8 Informed Consent - Letter of Information

a) Answers to questions 1 to 11 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 Student Researcher(s); school; project title; 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?

b) A sample Informed Consent - Letter of Information is available for download from the Youth Science Canada Policy Portal.

4.9 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 requesting 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.

b) A sample Informed Consent - Permission Form is available for download from the Youth Science Canada Policy Portal.

4.10 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.

## 5 Display

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

## 6 Forms

6.1 An Approval of Low Risk Projects Form must be submitted to the Regional STEM Fair and Canada-Wide Science Fair at registration for any low risk project, along with any applicable Letter of Information, Blank Permission Form, and Sample Survey.

## 7 References


1. Definition of Food Accessed 11 August 2022
2. Health Canada article on Caffeine Accessed 11 August 2022
3. Definition of a Drug The definitions are in alphabetical order on this page. Look for “Drug”. Accessed 27 October 2022