Humans in Research
Low Risk Regulations

NOTE: These regulations are based on the Youth Science Canada policy.

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. Low Risk Projects are limited to:

- Some surveys
- Some food and drink projects
- Some caffeinated beverage projects
- Some absorption through the skin projects
- Some exercise projects

Section 3.3 below has a detailed discussion of each of these. A project is not Low Risk just because you think no one will be harmed. It is a project that fits one of these five criteria.

1.2 All other projects involving humans are to be treated as *Significant Risk Projects*, and must follow our "*Humans in Research - Significant Risk*" regulations.

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. The Student Researcher may also be a Participant.

2.3 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 the WWSEF guidelines are followed. The Adult Supervisor is responsible for ensuring that the student's research is eligible for entry into the WWSEF, 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.

Low Risk Projects

3.1 Surveys of Attitudes and Beliefs, Skill Tests, or Observations of Behaviour

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 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.

3.2 Food and Drink Projects

1.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 common food. This is defined as "any article manufactured, sold or represented for use as food or drink for human beings".
2.The foods to be considered are basic or common foods that contain permitted additives not exceeding Recommended Daily Intake (RDI) guidelines normally associated with those foods.
3.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.
4.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.

3.3 Caffeinated Beverages.

The daily limits of caffeine intake for Science Fair Projects are:

1.200 mg caffeine per day for subjects aged 13 and older.
2.85 mg caffeine per day for subjects aged 10 to 12.
3.No Projects involving caffeinated foods or drinks are permitted in subjects under 10 years of age.
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 above daily limits are not exceeded in any Science Fair Project. The *Youth Science Canada* website contains links an background information on Caffeine that should be referenced before undertaking any project involving caffeinated drinks. Health Canada has expressed concerns about excessive intake of caffeine by Canadians, especially children and youth. Thus the ingestion of caffeine in Science Fair Projects must be closely monitored and kept within reasonable limits according to Health Canada recommendations.

3.4 Absorption through the skin

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 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.

3.5 Exercise Testing

All Exercise Testing beyond normal every day activities is considered Significant Risk, and must be carried out according to the Humans ion Research Significant Risk Exercise Regulations**.**

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 science fair student researchers and their supervisors. 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 also sign Form 4.1A Humans in Research – Low Risk ensuring that the essential elements of ethics review: consent, confidentiality and the right to withdraw are considered.

4.3 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.

4.4 If the participant is under the age of 18, then the parent or guardian must also sign the Informed Consent Permission Form.

4.5 If the participant is over the age of 18, but not able 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 some surveys, or such as having participants listen to music, Informed Consent may be assumed by the simple act of agreeing to participate. The parents or guardians must still be provided beforehand with the Letter of Information, 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.

Signed Informed Consent Forms by a parent are mandatory in all cases for food and drink projects, because of the risk of allergic reactions unknown to the teacher.

4.7 Informed Consent - Letter of Information

Answers to the questions 1) to 11) must appear in the *Letter of Information* 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.
7. How will the confidentiality of the data be guaranteed?
8. 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*.
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*?

4.8 Informed Consent – Permission Form

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.

4.9 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 only if prior permission has been obtained in writing.

6 Forms

6.1 Form 4.1A - Approval of the Humans in Research - Low Risk Projects Form – must be submitted to the Regional Science Fair (WWSEF) 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 30 June 2015
2. Health Canada article on Caffeine Accessed 30 June 2015

Humans in Research - Low Risk
Research Plan Template

NOTE:This template is based on the available Youth Science Canada template.

It is a simple way of making sure that what you are doing is ethical and taking the best care of the human subjects involved. This Template should be completed BEFORE you start your project.

Develop and share this plan with your adult supervisor(s). If you enter this project in the WWSEF, you may be required to show this plan to the WWSEF Ethics Chair and judges.

Print a copy of the Research Plan, Fill it out, and give it to your Adult Supervisor for Approval.

Instructions:
1. Adult Supervisor: Who will be supporting you in the project?
2. Data Collection When will you start and stop collecting data from the subject(s)?
3. Location Where will you be collecting the data?
4. Purpose Briefly explain the research you did to support your idea.
5. Explain the procedure you will be using.
6. Risks What are the potential risks in your project? Write a complete and clear description of all known or anticipated risks and how you will address them.
7. What are the potential benefits? Your project must have some benefit in order to justify using humans. Describe known and/or potential benefits to the humans and/or society. If this idea has been already tested, come up with a new idea.
8. Is this a continuation of a previous project? If so give a brief summary of the previous project.

Humans Low Risk Research Plan

School				
Project Title				
Exhibitor 1	**First Name**		**Last Name**	
	Phone		**Email**	
Exhibitor 2	**First Name**		**Last Name**	
	Phone		**Email**	
Adult Supervisor	**First Name**		**Last Name**	
	Phone		**Email**	
	Role	(eg. Teacher, Parent, etc.) > > >		

Data Collection

Start Date	
End Date	

Location: _____

Purpose: _____

_____

In the following, please be brief, but include important information.

Procedure: _____

_____

_____

_____

_____

_____

_____

Risks: _____

Potential Benefits: _____

Is this a continuation of a previous project? _____

Informed Consent
Letter of Information

Dear _____

I am a student who is preparing to enter the Waterloo-Wellington Science and Engineering Fair. The information I collect will be used for this project. This letter provides the information required for you to make an informed decision about whether to participate.

Researcher and Advisors:
Student Researcher(s): _____ _____

Adult Supervisor: _____ School: _____

Project Title: _____

Purpose of the Research: _____

_____

What You Will Be Asked to Do in the Research: _____

_____

_____

Benefits from Participating: _____

_____

Risks in Participating: _____

_____

Time Commitment Required: _____ **Remuneration** There is no remuneration for participating in this project.

Confidentiality of Data
All the information will be stored by the researcher, and will be protected. All paper records will be shredded, and all electronic raw data files will be deleted at the end of the project using deletion software, so that the data cannot be recovered. At the Science Fair, all information will be presented anonymously. No participant will be identified.

Withdrawing from the project: You have the right to withdraw from the project at any time and for any reason. Contact the Adult Supervisor by telephone or email if you would like to do this.

Results
A summary of the results of this research will be available to you after the Science Fair is over.

Informed Consent Permission Form

Project Title: _____

Project Exhibitor(s): _____ _____

Date: _____

I have received and read the *Letter of Information for Informed Consent* for this Science Fair Project, which is mine to keep. All my questions have been answered to my satisfaction, and I agree to participate in this research.

Name of Participant (print): _____

Signature of Participant: _____

Name of Parent of Guardian * (print): _____

Signature of Parent of Guardian * : _____

Name of person obtaining consent (print): _____

Signature of person obtaining consent: _____

Note:

* If the participant is under the age of 18, then a parent or guardian must also give permission by signing this form.

This Informed Consent Form contains confidential data, and so must be secured at the home of the Adult Supervisor, whose signature on the Human Participation Form confirms that Informed Consent has been obtained.

All Informed Consent Forms must be shredded after the project is no longer needed for Science Fairs.

Instructions for using Form 4.1A
Humans in Research Low Risk Approval

1. **Form 4.1A**
   Submit this form to your adult supervisor. This form certifies that a low risk project involving the participation of humans is in full compliance with WWSEF regulations *Humans in Research Low Risk.*

2. **Documentation**
   The following documents must be given to the Adult Supervisor, along with Form 4.1A:
   a. The Research Plan
   b. The Survey (if your project involves a survey)
   c. The Information Letter that would be given to all potential participants
   d. The Informed Consent (a blank sample of your permission form)

3. **Instructions for Exhibitors**
   a. Print the form.
   b. Complete the table.
   c. Get it signed with all required signatures.
   d. Store the original signed copy of Form 4.1A in a safe place.
   e. Make a paper copy of the completed signed form and keep it with your project at all times.
   f. Have the following documents with your project when it is on display:
      i. Your Information Letter that you gave to every participant in your project
      ii. A blank sample of your Informed Consent form that each participant signed before they participated in the experiment
      iii. Your Survey , if your project involves one.

Form 4.1A
Humans in Research Low Risk Approval

This form certifies that a low risk project involving the participation of humans is in full compliance with WWSEF regulations *Humans in Research – Low Risk*.

School				
Project Title				
Exhibitor 1	**First Name**		**Last Name**	
	Phone		**Email**	
Exhibitor 2	**First Name**		**Last Name**	
	Phone		**Email**	
Adult Supervisor	**First Name**		**Last Name**	
	Phone		**Email**	
	Role	(eg. Teacher, Parent, etc.)		

Request for Ethics Approval

I/We have read and understand the WWSEF *Humans in Research - Low Risk* Regulations.

_____ _____ _____ _____

Exhibitor 1 signature Date Exhibitor 2 signature Date

Ethics Approval

I certify that this Low Risk project involving human participation is in full compliance with WWSEF regulations *Humans in Research - Low Risk* and that it is eligible for the WWSEF and the Canada-Wide Science Fair.

_____ _____

Adult Supervisor signature Date