Humans in Research
Significant Risk Regulations

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

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.
1.2 All students must submit a Research Plan to the WWSEF Ethics Chair before starting their experiments.
NOTE: There are 5 categories of low-risk projects described in the Low Risk Human regulations. Make sure that you check them out in case your project could be classified as Low Risk. ALL OTHER PROJECTS are, by definition, Significant Risk Projects.

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 the WWSEF regulations 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.
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.
> 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 (WWSEF) 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 (WWSEF) 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:

- articles not manufactured, sold or represented as food or drink for human beings;
- foods that contain additives exceeding the Recommended Daily Intake (RDI) normally associated with those foods;
- foods not considered to be basic, common or everyday foods.
- 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 Cannabis

It is illegal for anyone under the age of 18 to possess cannabis. Any project that requires a student to possess cannabis is not permitted at a science fair.

3.5 Ingestion Projects - Forbidden

The following ingestion projects are not eligible to participate in any event sponsored by WWSEF and Youth Science Canada:

1.Projects that involve the consumption of alcohol.
2.Projects that involve the consumption of cannabis.

3.6 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, a publication of the American College of Sports Medicine.

3.7 Permitted Exceptions

The projects listed in this section are eligible for presentation at science fairs, and are permitted exceptions to the rules above.

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 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.

4.3 Informed Consent - Letter of Information

Answers to the questions (1) to (l2) 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.Payment for participation in research is discouraged. The decision as to whether to offer a nominal payment, either in cash or kind, is at the discretion of the student researcher, and must be approved by the adult supervisor.
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*?
12.Has the project been reviewed and received ethics approval from the appropriate committee? (A positive answer is mandatory for Significant Risk projects.)

4.4 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.

4.5 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

6.1 Form 4.1B and a completed Research Plan must be submitted to the Ethics Chair of WWSEF before proceeding with a project. These forms must be available for both the regional (WWSEF) science fair and for the Canada-Wide Science Fair, along with any applicable Letter of Information, Blank Permission Form, and Sample Survey.

Exercise Testing Regulations

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

1. Key Reference
The key reference for exercise testing is the text *Guidelines for Exercise Testing and Prescription,* a publication of the American College of Sports Medicine, now in its eighth edition, 2010. It is published by Lippincott Williams and Wilkins; ISBN=978-0-7817-6903-7. This text is written for professionals in the field. This material is abstracted from Chapter Two.

2. Risk Stratification.

a. Minimum Risk. Individuals classified as minimum risk are those who do not have signs/symptoms of, and have not been diagnosed with, cardiovascular, pulmonary and/or metabolic disease. They have no more than one cardiovascular disease risk factor – see section 4. The risk of an acute cardiovascular event in this population is low, and a physical activity /exercise program may be pursued safely without the necessity for medical examination and clearance.

b. Moderate Risk. Individuals classified as moderate risk do not have signs/symptoms of, and have not been diagnosed with, diagnosed cardiovascular, pulmonary and/or metabolic disease but have two or more cardiovascular disease risk factors.

c. Maximum Risk. Individuals classified as maximum risk are those who have one or more signs/symptoms of or diagnosed cardiovascular, pulmonary, and/or metabolic disease.

3. Participation in Science Fair Projects

a. Only individuals classified as Minimum Risk may participate in science fair projects.

b. Individuals classified as Moderate or Maximum Risk may NOT participate in science fair projects.

4. Artherosclerotic Cardiovascular Disease Risk Factor Thresholds

Positive Risk Factors	Defining Criteria
Age	**Men: ≥ 45 years; Women: ≥ 55 years**
Family History	**Myocardial Infarction, coronary revascularization or sudden death before 55 years in the father or other first degree male relative, or before 65 years old in the mother or other first degree female relative.**
Cigarette Smoking	**Current cigarette smoker, or those who have quit within the last 6 months or those exposed to tobacco smoke.**
Sedentary Life Style	**Not participating in at least 30 minutes of moderate intensity physical activity on at least three days a week for at least three months.**
Obesity	**Body mass index ≥ 30 kg.m2 or waist girth > 102 cm for men and > 88 cm for women.**

Hypertension	**Systolic Blood Pressure > 140 mm Hg and / or diastolic blood pressure > 90 mm Hg confirmed by a minimum of two measurements taken at least 24 hours apart. *Or* on antihypertensive medication.**
Dylipidemia	**Low density lipoprotein (LDL-C) cholesterol ≥ 130 mg·dL-1*or* high-density lipoprotein (HDL-C) < 40 mg·dL-1 *or* or on lipid-lowering medication. See the text above for further details**
Prediabetes	**Impaired fasting glucose (IFG) = fasting plasma glucose ≥ 100 mg·dL-1 See the text above for further details.**

5. Risk Stratification

Minimum Risk Allowed Asymptomatic ≤ 1 Risk Factor	**Moderate Risk Not Allowed Asymptomatic ≥ 2 Risk Factors**	**Maximum Risk Not Allowed Symptomatic, or known cardiac, pulmonary or metabolic disease**
Medical Exam & Graded Exercise Testing before Exercise Moderate Exercise: Not Necessary Vigorous Exercise: Not Necessary	**Medical Exam & Graded Exercise Testing before Exercise** Moderate Exercise: Not Necessary Vigorous Exercise: Recommended	**Medical Exam & Graded Exercise Testing before Exercise** Moderate Exercise Recommended Vigorous Exercise: Recommended
MD Supervision of Exercise Test Sub maximum: Not necessary Maximum: not necessary	**MD Supervision of Exercise Test** Sub maximum: Not necessary Maximum: recommended	**MD Supervision of Exercise Test** Sub maximum: recommended Maximum: recommended

a. Moderate Exercise: Moderate intensity exercise; 40 -60% of VO2 max ; 3-6 METs' [i]"an intensity well within the individuals capacity, one which can be comfortably sustained for a prolonged period of time (45 minutes).
b. Vigorous Exercise: Vigorous Intensity Exercise; > 60% of VO2 max ; > 6 METs; "exercise intense enough to represent a substantial cardiorespiratory challenge".
c. Not Necessary: reflects the notion that a medical examination, exercise test, and physician supervision f exercise testing would not be essential in the pre-participation screening, however they should not be viewed as inappropriate.
d. Recommended: when MD supervision of exercise testing is "Recommended" the MD should be in close proximity and readily available should there be an emergent need.

[i] MET: Metabolic Equivalent of Task (MET). See for example: http://en.wikipedia.org/wiki/Metabolic_equivalent

Humans in Research - Significant 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 and scientific supervisor(s). If you enter this project in the WWSEF, you will be required to show this plan to the WWSEF Ethics Chair and possibly to judges.

Print a copy of the Research Plan, Fill it out, and send it to the WWSEF Ethics Chair for Approval.

Instructions:

1. Adult and Scientific Supervisor(s) Who will be supporting you in the project? When working with humans under significant risk conditions, it is important to have a Scientific Supervisor. Your adult supervisor can be your scientific advisor too, if they are qualified to advise you in the type of project that you are doing.
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 Significant 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.) > > > >		
Scientific Supervisor	**First Name**		**Last Name**	
	Phone		**Email**	
	Role	(Professional affiliation) > > > > >		

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: _____

Scientific Supervisor _____

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 4.1B
Humans in Research Significant Risk Approval

1. **Form 4.1B**
   Submit this form to your supervisors. This form certifies that a significant risk project involving the participation of humans is in full compliance with WWSEF regulations *Humans in Research Significant Risk.*

2. **Documentation**
   The following documents must be made available to the Chair of WWSEF Ethics Committee, along with Form 4.1B:
   a. The completed Research Plan
   b. The Survey (if your proposal 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. **Ethics Committee**
   There are several Ethics Committees available to certify projects
   a. The WWSEF Ethics Committee. In complex cases, the WWSEF Committee, but not the student, may wish to contact the National Ethics & Safety Committee.
   b. The Scientific Review Committee (SRC) at the university, hospital, government or commercial laboratory where this research will be carried out. A copy of the letter from the Scientific Review Committee to the Director of the laboratory approving the research may be submitted in place of the signature of the Chair of the Ethics Committee on Form 4.1B.

4. **Instructions for Exhibitors**
   a. Print the form.
   b. Complete the table.
   c. Get it signed with all required signatures.
   d. Scan or photograph the form and the completed Research Plan and email them to ethics@wwsef.ca.
      If approved, you will receive an email from the WWSEF Ethics Committee. The form giving approval will be returned to you at WWSEF.
      If not approved, you will be contacted to help redesign your project.
   e. Store the original signed copy of Form 4.1B in a safe place.
   f. Make a paper copy of the completed signed form and keep it with your project at all times.
   g. 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. The signed Informed Consent forms that each participant signed before they participated in the experiment
      iii. Your Survey, if your project involves one.

Form 4.1B
Humans in Research Significant 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 – Significant 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.) **> > > >**		
Scientific Supervisor	**First Name**		**Last Name**	
	Phone		**Email**	
	Role	(Professional affiliation) **> > > > >**		

Request for Ethics Approval

I/We have read and understand the WWSEF *Significant Risk Human Regulations*.

Exhibitor 1 signature _____ Date _____ Exhibitor 2 signature _____ Date _____

Request for Ethics Approval

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

Adult Supervisor signature _____ Date _____ Affiliation of Adult Supervisor _____

Scientific Supervisor signature _____ Date _____ Affiliation of Scientific Supervisor _____

Ethics Approval by Chair of the WWSEF Ethics Committee

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

WWSEF Ethics Committee Chair Signature _____ Date _____