YOUTH SCIENCE FOUNDATION CANADA
FONDATION SCIENCES JEUNESSE CANADA

Use of Human Participants in Research

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Policy Section:	4.1 Youth Science & Technology Research – Ethics
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Related Policies:	4.1.2 Use of Animals in Research
Contact:	National Judge-in-Chief

1 Introduction

1.1 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.

1.2 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, YSF 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 projects.

1.3 There are restrictions on the use of human participants in scientific research. YSF 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. At the same time, YSF Canada does not want to impose a burdensome set of procedures on young scientists, their teachers or parents where the project carries minimal risk.

1.4 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 must follow.

2 Definitions of Human Research, Researcher, Participant, Adult Supervisor and Scientific Supervisor

2.1 *Human Research* refers to any project that involves the generation of data about persons beyond that which is necessary for the person's well being. This includes non-invasive methods such as: surveys, interviews, observations of, or field work with,

individuals, administration of psychometric and other tests, examination of records, and exercise testing. It may also involve invasive procedures, such as blood sampling and tissue sampling.

2.2 A *Researcher* is a student data or information collector, or assistant, involved in research activities involving humans.

2.3 A *Participant* is a person, who by virtue of his/her participation in a data-generating situation or activity, 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 YSF Canada policy is followed. The Adult Supervisor is responsible for ensuring that the student's research is eligible for entry into the CWSF. All projects involving the participation of humans or the use of animals require an Adult Supervisor.

2.5 The *Scientific Supervisor*, who will usually have an advanced degree, is involved in a project where there is more than minimal risk, which often takes place in a university, institutional or industrial setting. The Scientific Supervisor is responsible for ensuring that all provincial and federal laws governing safety, material and procedures are followed. The Scientific Supervisor may be the Adult Supervisor.

3 Statement of Ethics Review Requirements

3.1 Youth Science Foundation Canada requires that all research involving human participants entered in the Canada-Wide Science Fair, or a YSF-Canada affiliated Regional Science Fair, satisfy ethics and safety rules. This ensures that the safety and welfare of the participants as well as the researchers are considered and protected.

3.2 This policy applies to all projects involving human participation. Simple surveys of attitudes and beliefs or skill tests are considered low risk projects. All other projects are considered significant risk projects.

3.3 For complex or high risk projects, often carried out in a university or research institute setting, the ethics review process should involve the student’s Scientific Supervisor, often a member of a bona fide research institution or hospital practiced in the ethics of human research, and 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. Universities have their own Ethics Committees, often called Scientific Review Boards (SRB), which must approve the project. University rules may be more stringent that the rules given here, and must be followed. Projects may also be referred to YSF Canada's Ethics Committee. Students and their supervisors involved in complex or high risk projects must follow the process described in Section 8.

3.4 Form 4.1C - Science Project Human/Animal Research Approval Form – must be submitted to the Canada-Wide Science Fair Host Committee for any project involving the use of human participants.

4 Informed Consent:

4.1 Participants must give informed consent to participate in any science fair project before it begins. 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 any 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 Details which must appear in the letter of Informed Consent to ensure the participants have been properly informed and have given free consent, without pressure to participate include:

a) name(s) of investigator(s), school, project title, Adult Supervisor, his/her address and telephone number;
b) purpose of the research;
c) description of benefits from participating;
d) description of risks from participating
e) details of time commitment required;
f) details of any remuneration;
g) plans to ensure the confidentiality of data;
h) details about their right to withdraw at any time without fear of reprisal;
i) information about how to communicate a decision to withdraw from the study,
j) a statement that the project has been reviewed and received ethics approval from whatever authority was consulted.
k) details of how feedback will be given to participants;
A sample Informed Consent Form is provided in the Appendix, form 4.1D.

4.3 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.

5 Confidentiality

5.1 The confidentiality and anonymity of all participants must be maintained. Use coded systems of references; no identifying information may be used. Also, appropriate safeguards for storage and access to data, or destruction of data, must be planned.

6 Display

6.1 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.

7 Human Participants - Low Risk

7.1 Low-risk projects are surveys of attitudes and beliefs, skill tests, or observations of behaviour with the participants' consent. 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.

7.2 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.

8 Human Participants - Significant Risk

8.1 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. 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, who can access appropriate authorities familiar with current regulations and relevant aspects regarding scientific merit, and for guidance and suggestions in performing the work. The following instructions will provide assistance in completing the form as well as providing additional guidelines for the conduct of research involving humans.

8.2 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.[1]

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. No other studies involving the use of Drugs, as defined above by Federal Regulations, may be exhibited at any Science Fair.

8.3 Invasive Procedures

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.

8.4 Completing the Form 4.1B "Application for Review of Research with Human Participation Involving Significant Risk.

a) Student Researcher(s): The student researcher(s) who will collect the data. All students involved must be listed, even if assisting the principal investigator(s).

b) Title of Project: The title of the project should be succinct, yet clearly describe the focus of the project.

c) Adult Supervisor: The adult supervises and accepts responsibility for ensuring that YSF Canada policy is followed. The name, address and telephone number of the Adult Supervisor must be given.

d) Scientific Supervisor: The scientific supervisor is responsible for ensuring that all provincial and federal laws governing safety, material, and procedures are followed. The name, address and telephone number of the Scientific Supervisor must be given.

e) Purpose of this Project: The purpose describes the reason for conducting the project, and briefly outlines literature that has shaped the project proposal. The general procedure to be used in the research is outlined.

f) Participants in this Project: describe the participants' age range, gender, numbers required and other identifying characteristics.

g) How will the Participants be Recruited? Special consideration is needed for the involvement of children or other vulnerable participants. Describe the source of the participants and the manner in which they will be recruited. Attach a copy of any covering letter. Studies involving students and/or teachers often require the explicit permission of Board of Education officials.

   Researchers are reminded of the potential for certain participant groups to experience or perceive undue pressure to volunteer as research participants, and are to minimize this perception. Members of distinct cultural groups, legally incompetent people and children are examples of special populations that require special effort to ensure that informed consent is being given. Include details of any compensation for participation in the study. It should not be so high as to induce a person to volunteer, or cause a person to continue in a study past the point at which he/she would otherwise stop.

h) What are the Participants expected to do? Describe procedures in detail and in terms that can be understood by reviewers without specialized knowledge of the research area. Attach a copy of all test materials and indicate the time required for participation in the study.

i) Studies involving exercise testing must include a description of all tests, a copy of the medical screening form used to determine that the potential participants are in good health, and a statement about exclusion criteria. Describe arrangements for supervision of the testing by a qualified health care professional. The American College of Sports Medicine Guidelines for Exercise Testing and Prescription recommends that professional medical personnel supervise certain kinds of exercise testing. Table 2.7 from the 1995 edition of this guide is reproduced in Appendix 4.1A. YSF Canada requires that these guidelines be followed.

j) What Are the Potential Risks? A complete and clear description of all known or anticipated risks of participation, whether physiological, psychological, economic and/or social in nature must be provided. Indicate how risk will be minimized to the extent reasonably possible. In cases of tasks involving psychological risk, indicate preparations to deal with any negative impact attributable to participation in the study.

k) What are the Potential Benefits? All studies must have some benefit in order to justify their conduct. Thus, a description of known and/or potential benefits to the participants and/or society is required.

l) How will Informed Consent be Obtained? Attach a copy of the sample letters of Informed Consent.

m) Anonymity of the Participants and confidentially of data. Describe how these goals will be met.

Feedback to Participants: Feedback of the findings to the participants, their parents and/or teachers should be part of the plan. If deception is used, provide details about the nature of the deception and why it was needed. Participants in such a study must receive adequate and immediate debriefing at the end of their participation. This debriefing, provided orally and as a written handout, should explain why the deception was required, offer the opportunity to answer any questions and then seek their written consent to use all information obtained from them.

Additional Attachments: parent permission letters and pre-exercise medical screening forms must be included as appendices to the Application for Review of Research with Human Participants.

References

1. Departmental Consolidation of the Food and Drugs Act and the Food and Drug Regulations with Amendments to 2004_10_01. Issued by the Department of Health. Minister of Public Works and Government Services Canada.

http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/e_a-contnt.pdf.

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4.1.1 Appendices

A. American College of Sports Medicine Guidelines for Exercise Testing

4.1.1 Forms

A. Form 4.1A Approval of Low Risk Projects involving Human Participation

This form is required for projects such as surveys of attitudes or beliefs, or skill tests to ensure that all the ethical issues will be considered and that the young scientist will follow the policy.

B. Form 4.1B Application For Review of Research with Human Participants Involving Significant Risk

This form is required to ensure that all the ethical issues will be considered and that the young scientist will follow the policy.

C. Form 4.1C Science Project Human/Animal Research Approval Form

This form is required to ensure that all the ethical issues have been considered and that the CWSF finalist has followed the policy.

D. Form 4.1D Science Project Informed Consent Form

Human participants involved in Science Fair projects must usually provide informed consent in writing. This is an example.

For projects by young scientists (elementary/secondary grades) and for science fairs, testing may ONLY be done on Apparently Healthy individuals. The Increased Risk and Known Disease areas are greyed-out for this reason but are included for reference.

ACSM Recommendation for (A) Medical Examination and Exercise Testing Prior to Participation and (B) Physician Supervision of Exercise Tests

A. Medical examination and clinical exercise test recommended prior to:

	Apparently healthy		Increased Risk[1]		Known Disease[2]
	Younger[3]	Older	No Symptoms	Symptoms	
Moderate exercise[4]	No[5]	No	No	Yes	Yes
Vigorous exercise[6]	No	Yes[7]	Yes	Yes	Yes

B. Physician supervision recommended during exercise test:

	Apparently healthy		Increased Risk[1]		Known Disease[2]
	Younger[3]	Older	No Symptoms	Symptoms	
Submaximal testing	No[5]	No	No	Yes	Yes
Maximal testing	No	Yes[7]	Yes	Yes	Yes

[1] Persons with two or more risk factors (see Table 2-2) or one or more signs or symptoms (see Table 2-1).
[2] Persons with known cardiac. pulmonary, or metabolic disease.
[3] Younger implies < 40 years for men. <50 years for women.
[4] Moderate exercise as defined by an intensity of 40% to 60% $VO_{2\ MAX}$; if intensity is uncertain, moderate exercise may alternately be defined as an intensity well within the individual's current capacity, one which can be comfortably sustained for a prolonged period of time, that is, 60 minutes, which has a gradual initiation and progression, and is generally non-competitive.
[5] A “No” response means that an item is deemed “not necessary”. The “No” response does not mean that the item should not be done.
[6] Vigorous exercise is defined by an exercise intensity > 60% $VO_{2\ MAX}$; if intensity is uncertain, moderate exercise may alternately he defined as exercise intense enough to represent a substantial cardiorespiratory challenge or if it results in fatigue within 20 minutes.
[7] A “Yes” response means that an item is recommended. For physician supervision, this suggests that a physician is in close proximity and readily available should there be an emergent need.

Reference: American College of Sports Medicine’s Guidelines for Exercise Testing and Prescription 5th Edition, Table 2.7, pg 25, (1995).

Approval of Low Risk Projects involving Human Participation

(e.g., surveys of attitudes, beliefs or skill tests)

Student Name (1): **Address:** **Phone:** **Email:**	**Student Name (2):** **Address:** **Phone:** **Email:**

School, City:

Project Title:

Purpose of this Research

Prior to consent and assent being granted, the parents or guardians and the participants have had the opportunity to ask questions about the project, and any concerns have been addressed.	**Yes**	**No**
The Parents of the participants have given their consent.	**Yes**	**No**
The Participants have given their assent.	**Yes**	**No**
The Participants understand that they are free to withdraw at any time.	**Yes**	**No**
The Participants will be given the results of the project.	**Yes**	**No**

The confidentiality of data. The results of this research will be given with all information about individual participants removed. No personal information will be stored on a computer. All information on paper that could be use to identify individuals will be shredded at the end of the research project.

Declaration of the Adult Supervisor

I am familiar with the ethical issues that are involved with involving Human Participation in low-risk procedures such as surveys of attitudes and beliefs or skill tests. I confirm that this research satisfies the rules that govern such projects

Name _____ **Telephone** _____

Address _____

Email _____

Date _____ **Signature** _____

Application For Review of Research with Human Participants Involving Significant Risk

Print or type, attach additional sheets as necessary. Include with Project Registration and keep a copy in the Project notebook. This form must be completed and the project approved before experiments begin.

Student Name (1): Address: Phone: Email:	Student Name (2): Address: Phone: Email:

School, City:

Project Title:

Adult Supervisor:
Name:

Address: Phone:
Email:

Professional Qualifications:

Scientific Supervisor (if applicable):
Name:

Address: Phone:
Email:

Professional Qualifications:

Summary of Proposed Research:

1. Briefly describe the purpose of this project.

2. Who, and what number of participants will be involved in this project?

3. How will the participants be recruited for this project? (Attach a copy of any recruitment notice or letter)

4. Outline what the participants will be expected to do. (e.g. surveys, interviews, etc.) Attach a copy of test materials, surveys, questionnaires or interview questions to be used.

5. What are the potential risks (physical, psychological, emotional) to the participants in this project?
6. What are the potential benefits of this project (e.g. to the participants, to society)?
7. Will informed consent of the participants be obtained in writing? If not, explain why. Attach a copy of the informed consent form to be used.
8. How will you ensure anonymity of the participants and confidentiality of their data?
9. Describe your plans to provide feedback or a summary of the study to the participants.
10. Additional Attachments: Sample letters of consent, parent permission letters and pre-medical screening forms should be attached.

Signatures:
I have read the YSF Canada policy on the Use of Human Participants in Research and agree to comply with the policy. Further, I agree to notify the Regional Science Fair of any changes to this project.

Who	Signature	Date
Student Researcher 1		
Student Researcher 2		
Adult Supervisor		
Ethics Review Committee Comments:		
Ethics Committee Chair		

Science Project Human/Animal Research Approval Form

This form certifies that a project involving the use of vertebrate animals, animal or human tissues, or human participants, meets the standards required by Youth Science Foundation Canada (YSF). The signature of the student certifies that the rules of the YSF have been read, understood and followed at the level appropriate for this project. The signature of the Adult Supervisor certifies that the project meets the rules of YSF. The signature of the Scientific Supervisor, if applicable, certifies that appropriate professional supervision was provided and, if relevant, also meets the rules and safety regulations that govern the research activities at the institution where the research was carried out.

Name of student _____

Title of Project _____

This project involves:

Use of Vertebrate Animals	___ Yes	___ No
Animal or Human Tissue	___ Yes	___ No
Participation of Humans	___ Yes	___ No

Declaration by the Student Researcher:

I declare that I have read the rules that relate to my project and that I understand them at a level that is appropriate. My project satisfies the rules of Youth Science Foundation Canada.

Signature _____

Date: _____ Phone: _____ Email: _____

Declaration by the Adult Supervisor:

I declare that I have read the rules of the YSF that relate to this project, and that all ethical and safety regulations have been satisfied.

Name (print) _____Signature _____

Date: _____ Phone: _____ Email: _____

Declaration by the Scientific Supervisor:

I declare that I have read the rules of the YSF that relate to this project, that appropriate professional supervision has been provided, and that all ethical and safety regulations have been fulfilled.

Name (print) _____Signature _____

Date: _____ Phone: _____ Email: _____

Science Project Informed Consent Form

You are invited to take part in a research study. Before you decide to be a part of this study, you need to understand the risks and benefits. This consent form provides information about the research study. If you agree to take part in the research study, you will be asked to sign this consent form. This process is known as *Informed Consent.*

Student Name (1): **Address:** **Phone:**	**Student Name (2):** **Address:** **Phone:**

School, City:

Project Title:

Adult Supervisor:
Name:

Address: Phone:

Purpose of this Research

Your benefits from participating.

Your risks from participating.

Your time commitment

Your remuneration

The confidentiality of your data

The results of this research will be given with all information about individual participants removed. No personal information will be stored on a computer. All information on paper that could be use to identify individuals will be shredded at the end of the research project.

Withdrawal

Your participation is voluntary, and you have the right to withdraw at any time for any reason. If you wish to do so, please send a message to the Adult Supervisor.

Review

This project has been reviewed by the Ethics Committee of the _____ Regional Science Fair, and has received their permission to proceed.

Feedback. The results of this research will be provided to you in the following way:

By signing below, you are agreeing to participate in this study.

Name _____

Signature _____ **Date** _____

If this participant is under the age of 18, permission of a parent or guardian is also required:

I give permission for the person named above to participate in this study

Name_____ **Signature**_____

Phone _____ **Date** _____