

Policy 20: Use of Human Participants in Research

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Approved By:	Evaluations Committee, Ethics and Due Care Committee
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Date of Next Review:	

20.1 INTRODUCTION

20.1.1 The Calgary Youth Science Fair Society (CYSFS) has adopted the Youth Science Canada (YSC) policy with minor changes in wording to reflect CYSFS procedures.

20.1.2 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.

20.1.3 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. To help them carry out these responsibilities in accordance with national standards, YSC 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.

20.1.4 There are restrictions on the use of human participants in scientific research. YSC 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, YSC does not want to impose a burdensome set of procedures on young scientists, their teachers or parents when the project carries minimal risk.

20.1.5 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; and
- c) to define clearly the rules that finalists at the Canada-Wide Science Fair (CWSF) must follow.

20.2. DEFINITIONS OF HUMAN RESEARCH, RESEARCHER, PARTICIPANT, ADULT SUPERVISOR AND SCIENTIFIC SUPERVISOR

20.2.1 "Human Research" refers to any project that involves the generation of data about persons

20.2.2 A "Student Researcher" is one who takes data or collects information or assists in research activities involving humans

20.2.3 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.

20.2.4 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 YSC policy is followed. The Adult Supervisor is responsible for ensuring that the student's research is eligible for entry into the CWSF and related or other events sponsored by YSC. Every project involving the participation of humans or the use of animals requires an Adult Supervisor.

20.3 STATEMENT OF ETHICS REVIEW REQUIREMENTS

- 20.3.1 Youth Science Canada requires that all research involving human participants entered in the Canada-Wide Science Fair, or a YSC-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.
- 20.3.2 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.
- 20.3.3 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), and must approve the project. University rules may be more stringent than the rules given here, and must be followed. Projects may also be referred to YSC's Ethics Committee. Students and their supervisors involved in complex or high risk projects must follow the process described in Section 8.
- 20.3.4 Prior to beginning any research involving humans, Form CYSF-2A (Ethics and Due Care) must be submitted to the CYSF Ethics and Due Care Committee. Additionally, Form CYSF-2B (Participation of Humans in Research – Significant Risk) must be submitted to the CYSF Ethics and Due Care Committee for any significant risk project involving the use of human participants (see 20.3.2 for definition of 'significant risk'). Final decision regarding assignment of level of risk rests with the Ethics and Due Care Committee

20.4 INFORMED CONSENT:

- 20.4.1 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".
- 20.4.2 The Adult Supervisor is responsible for supervision of ethical as well as scientific aspects of a Low Risk Project, and also sign Ethics and Due Care Form 2A, ensuring that the essential elements of ethics review, consent, confidentiality and the right to withdraw are considered.
- 20.4.3 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 signing Informed Consent Form 2C. Younger children can provide assent orally but the researcher must document it.
- 20.4.4 The parent or guardian must also sign the Informed Consent Form (2C).

20.4.5 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 CYSF Ethics and Due Care Committee must agree before research proceeds that signatures on an Informed Consent form are not necessary for a specific project.

20.4.6 Details that must appear on a Letter of Information (should CYSF Ethics and Due Care Committee judge that a project is *very low risk*) to ensure the participants have been properly informed and have given free consent, without pressure to participate include:

- a) names(s) of investigator(s), school, project title, Adult Supervisor, his/her email 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) 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 the confidentiality of the data will be guaranteed;
- h) it must be clearly stated that the participant has the right to withdraw at any time and 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?;

An Informed Consent Form, Form CYSF 2C, is provided at www.cysf.org.

20.5 CONFIDENTIALITY

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.

20.6 DISPLAY

The project display may include pictures of participants only 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.

20.7 PARTICIPATION OF HUMANS IN RESEARCH—LOW RISK

20.7.1 Introduction

- a) *A Low Risk Project* - involves conditions where the risks of harm are not greater or more likely than those encountered in everyday life.
- b) All other projects involving humans are to be treated as *Significant Risk Projects*, and must follow Policy 20.8 *Participation of Humans in Research – Significant Risk*.
- c) 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.

20.7.2 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 the Ethics and Due Care Form (CYSF-2A) and the Informed Consent Form (CYSF-2C), ensuring that the essential elements of ethics review: consent, confidentiality and the right to withdraw are considered.

20.7.3 Types of Low Risk Projects

- a) Surveys of Attitudes and Beliefs, Skill Tests, or Observations of Behavior. 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.
- b) Food and Drink Projects. Such projects 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” (Food and Drugs Act [R.S.C., 1985, c. F-27]):
 - i. The foods to be considered are basic or common foods that contain permitted additives not exceeding Recommended Daily Intake (RDA) guidelines normally associated with those foods.
 - ii. 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.
 - iii. 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.

PARTIAL LISTING OF ACCEPTABLE/NOT ACCEPTABLE LOW RISK FOOD/DRINK PROJECTS:

Sports Drinks – **Yes**

- 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.

Energy Drinks – **No**

- Health Canada has concerns about the safe use of energy drinks¹. Thus Energy Drinks may **not** be used in Science Fair Projects.

Absorption through the skin

- 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 **acceptable**. A project that involves putting benzene on the skin is **not acceptable**.

Natural Herbal Products – **No**

- Natural Herbal Products that are purported to produce a physiological response may not be used in a Low Risk science fair project (see Significant Risk – Natural Herbal Products).

Medications (prescription and non-prescription) – **No**

- All medications, even those available without a prescription, are considered drugs. Drugs may be used 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.

20.8 HUMAN PARTICIPANTS—SIGNIFICANT RISK

20.8.1 INTRODUCTION

A *Significant Risk Project* involves conditions where the risk of harm is greater, or is potentially greater, than that encountered in everyday life. Where there is doubt, projects shall be classified as Significant Risk Projects.

20.8.2 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 Youth Science Canada policy is followed. The Adult Supervisor is responsible for ensuring that the student's research is eligible for entry into the 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.

20.8.3 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.

20.8.4 Drugs (Definition of a Drug: <http://www.laws-lois.justice.gc.ca/eng/acts/F-27/page-1.html>).

- 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 or animals;
 - iii) disinfection in premises in which food is manufactured, prepared or kept.
- 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 on human participants, as defined above by Federal Regulations, may be exhibited at any Science Fair or similar event.

20.8.5 Invasive Procedures and Bodily Tissues

Invasive procedures, such as taking blood 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, Canada-Wide Science Fair, or similar YSC event.

20.8.6 Ingestion Projects – May be Allowed for older students

1. Projects involving ingestion of food or drink, defined as consumption through eating or drinking, are considered Significant Risk when they involve:
 - a) articles not manufactured, sold or represented as food or drink for human beings;
 - b) foods that contain additives exceeding the Recommended Daily Intake (RDI) normally associated with those foods;
 - c) foods not considered to be basic, common or everyday foods;
 - d) 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 (<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>).
 - e) 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;
 - f) 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.

20.8.7 Ingestion Projects – Forbidden

The following ingestion projects are not eligible to participate in any event sponsored by the Calgary Youth Science Fair Society or Youth Science Canada:

1. Projects that involve the consumption of alcohol.

20.8.8 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 [3], a publication of the American College of Sports Medicine. (Ref. <http://youthscience.ca/node/8198>).

20.8.9 **Your Significant Risk -- Research Proposal (CYSF 2B) must be submitted with forms CYSF 2A and CYSF 2C.**

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