POLICY 20: USE OF HUMAN PARTICIPANTS IN RESEARCH

Policy Number:	20
Approved By:	Evaluations Committee, Ethics and Due Care Committee
Date Approved:	Dec. 2010; Feb. 2012, Reviewed Only September 2017
Date of Next Review:	September 2021

20.1 PREAMBLE

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 in order 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) and to define clearly the rules that finalists at the Canada-Wide Science Fair must follow.

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

20.2.1 In this policy “CYSFS” will mean “Calgary Youth Science Fair Society”, “CYSF” will mean the “Calgary Youth Science Fair”, “student” will refer to any young person who has been chosen to attend a CYSFS event as a Science Fair competitor, “YSC” will mean “Youth Science Canada”, and “CWSF” will mean Canada-Wide Science Fair.

20.2.2 “Human Research” refers to any project that involves the generation of data about persons.

20.2.3 A “Student Researcher” is one who takes data or collects information or assists in research activities involving humans.

20.2.4 A “Participant” is a person who takes part in a project or activity and so is a source of primary data, and may bear risk as the research is being carried out.

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

20.2.6 The “Scientific Supervisor”, who will usually have an advanced degree, must be involved in a project when there is significant risk. Such project often takes place in a university, institutional or industrial setting 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.

20.3 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 (such as CYSF), satisfies their 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 (i.e CYSFS’s Ethics and Due Care Committee). 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 also 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 20.8 (Significant Risk).

20.3.4 Prior to beginning any research involving humans, Ethics and Due Care Form 2A must

be submitted to the CYSFS Ethics and Due Care Committee. Additionally, Use of Human Participants Significant Risk— Approval Form 2B must be submitted to the CYSFS 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 Participants must give informed consent before taking part in any science fair project (they must sign Informed Consent form 2C). The project 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 of age 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.

20.4.2 If the participant is under the Age of Majority (18 in Alberta), then the parent or guardian must also sign the Informed Consent Form (CYSF Form 2C).

20.4.3 Details that must appear in the Informed Consent form (2C) 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) a statement that 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) plans to ensure the confidentiality of data;

h) a clear statement that the participant has the right to withdraw at any time for any reason without consequences of any kind;

i) the procedure for a participant to communicate a decision to withdraw from the study;

j) a statement that the project has been reviewed and received ethics approval, as well as the authority who provided that approval;

k) the procedure in which the results of the research will be communicated to the participant; and

l) any other issues which need to be included, as specified by YSC, CYSFS, or any other reviewing body. A sample of Informed Consent Form 2C is available at www.CYSF.org.

20.4.4 For low risk surveys only, consent may be assumed by the completion of the survey; however, a detailed explanatory letter (Letter of Information) should accompany the survey, and provide identical information as listed above. It is possible for surveys to fall into the significant risk category in which case Use of Human Participants Significant Risk—Approval Form 2B (page 47) and Informed Consent Form 2C (page 48) are required. A final decision on assignment of level of risk rests with the Ethics and Due Care Committee.

20.5 CONFIDENTIALITY

20.5.1 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.

20.6 DISPLAY

20.6.1 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.

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 Section 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 2A and the Informed Consent Form 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 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.

b) Food and Drink Projects. 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 that include:

    (i) Projects involving ingestion of food or drink, defined as consumption through eating or drinking, are considered Low Risk when they are designed only to assess the characteristics and effects of a common food, defined in part by the Food and Drugs Act (R.S.C., 1985, c. F-27) a as "any article manufactured, sold or represented for use as food or drink for human beings".

    (ii) 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.

    (iii) 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.

    (iv) The foods to be considered are basic foods for which no health benefits are to be claimed, and contain permitted additives not exceeding recommended daily allowance guidelines (RDI) normally associated with those foods.

PARTIAL LISTING OF ACCEPTABLE/NOT ACCEPTABLE 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 drinks[1]. 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 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.

Natural Herbal Products – **No**

The ingestion of licensed Natural Health Products is not permitted in Science Fair Projects. These products are identified by a Health Canada Natural Product Number (NPN), Homeopathic Medicine Number (DIN-HM), or Exemption Number (EN) and are listed in the Health Canada Natural Health Product Database.

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

All medications, even those available without a prescription, are considered drugs. Projects involving drugs are deemed to be Significant Risk projects.

Alcohol – **No**

Projects that involve the consumption of Alcohol are not permitted.

Cannabis – **No**

Projects that involve the consumption of cannabis or cannabis products are not permitted

Exercise Testing

All Exercise Testing beyond normal every day activities is considered Significant Risk, and must be carried out under YSC policy 4.1.1.2.

20.8 HUMAN PARTICIPANTS – SIGNIFICANT RISK

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

20.8.2 The Adult Supervisor, and if appropriate, the Scientific Supervisor, are responsible for ensuring the safe, ethical and legal conduct of projects dealing with human participants.

Use of Human Participants Significant Risk—Approval Form 2B (page 47) must be completed and included with the project registration. Projects involving human participants that are deemed to be unethical will be disqualified. Young scientists or their supervisors unsure about the acceptability of a proposed project should contact the Ethics and Due Care Committee 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.

20.8.3 The term “drug” is defined as any substance or mixture of substances manufactured, sold, or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals; the restoring, correcting, or modifying organic functions in humans beings or animals; and the 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 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.

20.8.4 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, or other YSC event.

20.8.5 Your Research Proposal must contain the following information and be submitted with:

a) Ethics and Due Care Form 2A

b) Use of Human Participants Significant Risk—Approval Form 2B

c) Informed Consent Form 2C

d) Additional information required includes:

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

(ii) The Adult Supervisor: The name, address and telephone number of the adult who will supervise and accept responsibility for ensuring that YSC and CYSFS policies are followed;

(iii) The Scientific Supervisor: The name, address and telephone number of the scientific supervisor responsible for ensuring that all provincial and federal laws governing safety, material, and procedures are followed;

(iv) The Purpose of this Project: The reason for conducting the project, a brief outline of the literature that has shaped the project proposal and an outline of the general procedure to be used in the research;

(v) The Participants in this Project: A description of the participants' age range, gender, numbers required and other identifying characteristics;

(vi) The Recruitment Procedures: the source of the participants and the manner in which they will be recruited, with a copy of any covering letter. Special consideration is needed for the involvement of children or other vulnerable participants. . 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. Please also note that no remuneration may be offered for participation in projects;

(vii) The Participants' Role: A detailed description of any procedures involving human participants, in terms that can be understood by reviewers without specialized knowledge of the research area. The submission should also include a copy of all test materials and an estimate of the time required for participation in the study;

(viii) The Exercise testing additional information: 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. The submission should also include a description of 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 120205 edition of this guide is reproduced on page 49. CYSF requires that these guidelines be followed;

(ix) The Assessment of 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;

(x) The Potential Benefits: A description of potential benefits to the participants and/or society. (All studies must have some benefit in order to justify their conduct;

(xi) The Informed Consent letter: A copy of the letter of Informed Consent planned to be used in the project;

(xii) The Anonymity of the Participants and confidentiality of data. A description of how these will be ensured; (Feedback to Participants: A description of how the results of the project will be communicated to the participants, their parents and/or teachers;

(xiii) Additional requirements for projects involving deception: If the project involves deception of the subjects, the submission should include details about the nature of the deception and why it was needed. The submission should also include details of the plans for debriefing of the subjects. 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;

(xiv) 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.

Acknowledgements
The development of this policy benefited from the valuable advice given by the following:

Carl von Baeyer, Dept of Psychology, University of Saskatchewan
Tom Crawford, Dofasco Inc, Bay Area Regional Science & Engineering Fair
Bill Ross, Faculty of Medicine, University of Ottawa
Louis Silcox, Waterloo-Wellington Regional Science Fair
Fred Smith, Faculty of Science, Memorial University Newfoundland
Judith Soon, Faculty of Pharmaceutical Sciences, University of British Columbia
Susan Sykes, Office of Human Research, University of Waterloo
Patrick Whippey, Dep. of Physics and Astronomy, University of Western Ontario

FORMS APPENDED to POLICY 20

ETHICS AND DUE CARE FORM 2A

This form determines level of risk for the proposed research

USE OF HUMAN PARTICIPANTS SIGNIFICANT RISK—APPROVAL FORM 2B

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

INFORMED CONSENT FORM 2C

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