Human Participation – Significant Risk Research Plan

Youth Science Canada
Sciences jeunesse Canada

Insert your Title Here

1. Student Researchers and Advisors

	First	Last	Phone	Email	Affiliation
Student 1					
Student 2					
Adult Supervisor					
Scientific Supervisor					

2. Data Collection: Start Date End Date

3. Location where the data will be collected

4. Purpose

5. Participants

6. Recruiting

7. What will the Participants be asked to do?

8. Risks

9. What are the Potential Benefits?

10. Informed Consent

11. Anonymity

12. Feedback to Participants

13. Is this a continuation of a previous project?

14. Exercise Testing

Significant Risk Projects
Instructions

If your project is classified as a Significant Risk, you must prepare this Research Plan. This form must be reviewed by at least one person knowledgeable about ethics, preferably a member of the RSF Ethics Committee, who will review it to ensure that it complies with the policies of Youth Science Canada. The RSF Ethics Committee (but not the student) may submit complex projects to the National Ethics Committee. The maximum number of pages allowed is five.

1. **Student Researchers and Advisors** List the names, contact information, and affiliation of the student researchers, the Adult Supervisor and the Scientific Supervisor.
2. **Data Collection** Give the start and end dates of your data collection.
3. **Location** Give the location where you will be collecting your data.
4. **Purpose** The purpose describes the objective of the project, and briefly outlines the literature that has shaped the project proposal. The general procedure to be used in the research is outlined.
5. **Participants** Describe the participants' age range, gender, numbers required and any other identifying characteristics.
6. **Recruiting** How will the Participants be recruited? Give the criteria by which participants are (a) included and (b) excluded from the study. 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 the Information 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. No compensation may be given for participation in a science fair project.
7. **What will the Participants be asked to do?** Describe the 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. 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 at the end of this document. Youth Science Canada requires that these guidelines be followed.
8. **Risks** 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.

9. **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.
10. **Informed Consent** How will Informed Consent be obtained? Attach a copy of a sample Letters of Information and your Informed Consent form.
11. **Anonymity** Describe how the data will be kept secure, so that participants cannot afterwards be identified. Explain how you will present your findings at the Science Fair without revealing who participated in your research.
12. **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.
13. **Is this a continuation of a previous Project?** If so, give a brief summary of the previous project.
14. **Exercise Testing** The rules for exercise testing are given in the appendix.
15. **Send this completed form** by email to the Chair of the Ethics Committee or other official of your Regional Science Fair. If you cannot find the right email address from their web page, you can find a contact here: http://apps.ysf-fsj.ca/fairlocator/

Appendix: Rules for Exercise Testing

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[7]

[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% VO2 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% VO2 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.

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