**IRB TEMPLATE**

**SOCIAL-BEHAVIORAL ADULT PARTICIPANT INFORMED CONSENT**

The following instructions and examples are provided to assist in development of the Social-Behavioral Adult Participant Consent Form.

The following should be considered when developing the consent form:

* Consent forms must include clear identification of the responsible institution (Linfield College letterhead as shown above can be utilized or Departmental specific letterhead). Consent forms submitted without identification of the responsible institution will result in delay of approval of the project.
* All forms should be submitted suitable for reproduction (printed single sided or available electronically) using 12-point font and 1-inch margins.
* Each page of the consent form should be full without inappropriate divisions: sections can be split (some on one page, some on another page) so that large blank areas do not exist.
* The informed consent form must be written in the second person (I.e., “you”). When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision-making on the part of the potential participant.
* The informational content of the elements of informed consent should not be mixed or repeated unless necessary (e.g., reminding of safeguards when you discuss risk). Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the potential subject focus on each individual element of consent thereby streamlining the process.
* The consent form must be written in simple enough language so that it is readily understood by all of your participants. Normally the highest level of language used in the consent form should be understandable to someone with an eighth grade standard reading level. Scientific terms should be avoided when possible. If scientific terms will be included, the lay term or definition should be provided.
* Please remember, age of consent in Oregon is 18 years old. Anyone younger than 18 requires parental consent/youth assent or they may not participate.
* ***Before submitting the consent document for IRB approval, delete this page and all comments/instructions/boxes or non-applicable language.***

**IRB #:**

**Participant Study Title:**

A Randomized Trial to Determine the Differential Efficacy of Running and Walking on Indicators of Physical and Mental Health

***Optional: If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand.***

**Formal Study Title:**

The Effects of Running and Walking on Physical and Mental Health

***List the title in this section exactly as it appears on the IRB Application unless overly technical or the study involves deception in a way that the formal title won’t work.***

**Authorized Study Personnel:**

***List by name those personnel authorized to document consent as listed in the IRB Application. Use the following personnel labeling: Principal Investigator and Secondary Investigator(s). Include day phone numbers for all listed individuals. For greater than minimal risk studies, consider including night/home phone numbers and/or other direct contact mechanism. List other study personnel and contact information as appropriate.***

**Principal Investigator:** John Smith, B.A. Office: (503) 883-5555

**Secondary Investigator**: Jane Doe, Ph.D. Office (503) 883-6666

**Key Information:**

***The 2018 changes to the Common Rule (45 CFR 46) require that consent forms “must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.” This key information is only required to be included for non-exempt research (i.e., Expedited or Full Board review).***

If you agree to participate in this study, the project will involve:

* (Males/Females) between the ages of (Age range)
* Procedures will include (Summary of X procedures)
* (X) number of visits are required
* These visits will take a (X) amount of hours total
* There are/are no risks associated with this study
* You will be paid (X) amount for your participation
* You will be provided a copy of this consent form

**Invitation**

***Invite the prospective subject to participate in the study using the following standard invitation to participate.***

You are invited to take part in this research study conducted by [input - investigator names here] from the [input - department name here] Department at Linfield College. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

**Why are you being asked to be in this research study?**

***Explain succinctly and simplistically why the prospective subject is eligible to participate. As appropriate, major eligibility criteria may be included in this section.***

You are being asked to be in this study because you are a student athlete. You must be 18 years of age or older to participate and currently able to run/walk for at least one mile.

**What is the reason for doing this research study?**

***This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential subject understand why the research is being done. The information should be provided in simplistic language without reference to the subject. Make use of sub-headings to organize the remaining sections (e.g., “Purpose”).***

**PURPOSE**

Physical activity has been linked with benefits to physical and mental health. Because running and walking involve different levels of physical effort, their potential effects on physical and mental health may also be different. This research is designed to (1) better understand these effects and (2) determine whether walking or running is more effective at reducing stress and improving health (resting heart rate, blood pressure).

**What will be done during this research study?**

***Describe the procedures and their duration chronologically using simplistic language, short sentences or short paragraphs. The use of subheadings may help organize this section and increase readability for studies with a large number of procedures. Make use of sub-headings to organize (e.g., “Procedures”).***

**PROCEDURES**

You will be asked to do the following:

1. fill out a questionnaire (it should take about 10 minutes) to make sure you do not have any health concerns that may make you ineligible to participate and, if eligible a basic questionnaire to provide us with basic information (age, gender identity, physical activity, etc.)

2. complete baseline measures of health (blood pressure, weight, resting heart rate) and mental health (3 online surveys about depression, anxiety and stress) – should take about 30 minutes.

3. be willing to be randomly assigned to either walk or run three times a week with one of the research assistants

4. walk/run for 30 minutes (including warm-up and stretching) three times per week for 6 weeks

5. complete the same measures of health and mental health after completing 6-week walking/running program – about 30 minutes.

Thus, you will spend a total of about 1 ½ hours across 6 weeks engaged in physical activity and 45 minutes filling out questionnaires before you start the program and about 30 minutes after you finish the program.

**\*\*If you want your project to be exempt under Category 3 (Benign Behavioral Intervention) but your project will involve deception, in any way (either unaware or misled about the nature or purposes of the research), you need to include a prospective agreement to have your project possibly considered exempt. Here is one example of a statement you might include:\*\***

This study requires that you may be unaware of or misled regarding the nature of the research but still consent to participate. Please note that as a safeguard to your willingness to participate without full knowledge the researchers will: fully explain the purpose of the study, the reasons for not telling you everything about the study before you participated and be available to answer any questions you might have. Additionally, as a part of this debriefing discussion if you no longer want your data to be used you may withdraw your participation at that time.

**\*\*If audio- or videotaping will be used, the participant must be informed of taping and, if applicable, given the option to agree to the recording. Explain who will have access to these tapes, whether the information will be identifiable, how long the tapes will be maintained, and when the time comes, how they will be destroyed. Here is one example of a statement you might include:\*\***

At each session the researcher will be recording [specify what – the interview, you doing each movement, etc.] using a [specify what will be used – iphone, handheld recorder]. The recording will be used for [explain how audio/photo/video recordings will be used for study purposes – to ensure accurate recording of their answers, to allow their movements to be later coded, etc.]. [Explain how you will maintain privacy/confidentiality] I will be using a pseudonym or first initial, whichever you prefer, to protect your privacy. These recordings will be labeled only with a code number, which will be kept in the Investigator's files and [explain what will happen with the tapes – after they are coded, once interviews are transcribed they will be destroyed].

If you agree to participate in this study, your signature on this consent form gives the researchers permission to collect and make use of the audio/video recordings for this study. You have the right to review the recordings and to request that all or any portion of the recording be erased.

**How will my [data/samples/images] be used?**

***If the research involves collection and/or sharing of data/biospecimens/images to other researchers include the following statements as applicable.***

***If the research involves collection and/or sharing of de-identified data/biospecimens/images to other researchers include the following statement.***

Your [data/samples/images] will be sent to researchers outside of Linfield College for [explain why the samples are being sent outside]. Any personal information that could identify you will be removed before the [data/samples/images] are shared.

***If the research involves collection and/or sharing of identifiable data/samples/images to other researchers include the following statement.***

Your [data/samples/images] will be sent to researchers outside of Linfield College for [explain why the samples are being sent outside]. The [data/samples/images] that are sent to these researchers will contain identifiable information including [describe the identifiable information that will be associated with the data]. Identifiable information is being sent to these researchers because [explain the purpose of sending identifiable data to researchers outside Linfield College].

**What are the possible risks of being in this research study?**

***Identify each procedure with a subheading and then state the associated risk(s) using simplistic language. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Make use of sub-headings to organize (e.g., “Possible Risks and Discomforts”).***

**POSSIBLE RISKS and DISCOMFORTS**

It is possible that filling out the questionnaires will cause emotional and/or psychological discomfort because they ask sensitive questions about your moods, stress levels and physical activity. You may decline to answer any questions or sections of the questionnaires that make you too uncomfortable at any time. You may experience fatigue, sore muscles of the legs or shortness of breath while walking/running. You may stop at any time during the program. Stretching before and after this physical activity should minimize these problems.

***Alternately, if there are no known risks, use the below standard clause.***

There are no known risks to you from being in this research study beyond what you might experience your typical daily experiences.

**What are the possible benefits to you?**

***If direct subject benefits can reasonably be anticipated as a result of participating in the study, then describe these possible benefits. Conclude with the following standard clause. Make use of sub-heading (e.g., “Possible Benefits of Participating”)***

[Describe benefits]. However, you may or may not get any benefit from being in this study.

***If direct subject benefits are NOT anticipated, then use the following standard clause.***

You are not expected to get any direct benefit from being in this study.

**What are the possible benefits to other people?**

***State the possible benefits to society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective subjects’ position.***

**POSSIBLE BENEFITS OF PARTICIPATING**

[Describe benefits – You may notice improvements in your well-being and physical health as a result of participating in the study’s 6-week program]. However, you may not get any benefit from being in this research study. The benefits to science and/or society may include better understanding of how different forms of physical activity may improve health and mental health.

**What are the alternatives to being in this research study?**

***Describe in reasonable detail, alternatives the prospective subject may have available. If there are no alternatives, this section does not need to be included.***

Instead of being in this research study you can [include alternative – e.g., you can walk or run on your own].

**What will being in this research study cost you?**

***This section should state the financial obligations the subject may incur as a result of participating in the study. If there are no financial obligations to the subject, then use the following standard clause.***

There is no cost to you to be in this research study.

**Will you be compensated for being in this research study?**

***If the subject will receive compensation for participating in the research, state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required. If no compensation will be provided, state that. Include information about whether they might receive credit or course credit and, if known, indicate how many credits it is worth. Make use of sub-headings to organize (e.g., “Compensation”)***

**COMPENSATION**

Examples:

You will receive $20.00 for completing all study-related questionnaires and the 6-week program.

OR

You will be entered into an end-of-the-year cash drawing for one of three prizes (list here).

Additionally, some professors offer course credit or extra credit opportunities in their classes for participating in research.

**What should you do if you have a problem during this research study?**

***Your estimation of risk determines what additional information you will include in this section. For studies classified as minimal risk, use the following standard clause. Make use of sub-headings to organize (e.g., “Welfare”)***

**YOUR WELFARE**

Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If you experiencing psychological distress please also make use of the counseling center (503-883–2535; Walker 103).

*[Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information].*

***For studies classified as greater than minimal risk, use the following standard clause.***

If you have a problem or experience harm as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form. If needed, seek immediate emergency care for this problem. Please note, it is the policy of Linfield College not to pay for any required care. Agreeing to this does not mean you have given up any of your legal rights.

*[Think about also providing resources to participants dependent on the project parameters. For example, provide them with student health or wellness contact information*].

**How will information about you be protected?**

***Begin with the following standard clause.* *Make use of sub-headings to organize (e.g., “Confidentiality”)***

Reasonable steps will be taken to protect your privacy and the confidentiality of your data.

***Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective subject, follow the introductory standard clause above with a brief description of the precautions which will be utilized to protect the data.***

***For projects that collect paper-records use this standard clause.***

**CONFIDENTIALITY**

The data will be stored in a locked cabinet in the investigator’s office (Room XX) and will only be seen by the research team during the study and for XX years after the study is complete.

***For projects that collect electronic records use this standard clause. Describe the security in detail so the participant can understand what protections are in place.***

The data will be stored electronically through a secure server and will only be seen by the research team during the study and for XX years after the study is complete.

***Finally, for all protocols, conclude with the following standard clause.***

The only persons who will have access to your research records are the researchers working directly on this study (and listed above), the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings but the data will be reported as group or summarized data and your identity will be kept strictly confidential.

**What are your rights as a research subject?**

***Use the following standard clause. Make use of sub-headings to organize (e.g., “Your Rights as a Participant”)***

**YOUR RIGHTS AS A PARTICIPANT**

You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study. For study related questions, please contact the investigator(s) listed at the beginning of this form. Participation in this study is voluntary. You can decide not to be in this research study, or you can stop being in this research study (“withdraw’) at any time before, during, or after the research begins for any reason.

Deciding not to be in this research study or deciding to withdraw (or skip any portions of the study that cause discomfort) will not affect your relationship with the investigator or with Linfield College (list others as applicable).

You will not lose any benefits to which you are entitled.

For questions concerning your rights or complaints about the research contact the chair of the Institutional Review Board (IRB):

* Phone: 503-883-2684
* Email: tatompki@linfield.edu

**Documentation of informed consent**

***Use the following standard clause if you are obtaining signed/written consent. Make use of sub-headings (e.g., “INFORMED CONSENT STATEMENT”)***

**INFORMED CONSENT STATEMENT**

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I am at least 18 years of age or older and hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I have been given a copy of this form.

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Participant Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant name

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Witness Signature