**Notes are provided in red. Please delete these notes and reformat to black for your proposal material (a blank copy of this proposal is also available)**

**Title of the Proposed Research:**

Click or tap here to enter text.

**Principal Investigator or Faculty/Staff Sponsor *(name, department, and email):***

This person should be a Longwood employee with an @longwood.edu email address and will be designated as the communicating investigator.

**NOTES: The Principal Investigator should be a Longwood employee. This person is responsible for:**

* **submitting the proposal to the IRB and managing all IRB communications;**
* **the ethical conduct of co-investigators;**
* **the safe and ethical deployment of the approved protocol;**
* **promptly notifying the IRB of amendments to an approved proposal;**
* **promptly notifying the IRB of unanticipated problems, or serious or continuing noncompliance;**
* **responding to reports of unanticipated problems, or serious or continuing noncompliance;**
* **obtaining and submitting letters of support/permission from external agencies where research is taking place (if applicable); and**
* **maintaining records of IRB approval and communications.**

**If you are a PI for student researchers, be aware that records of this research are held under your name and you are responsible for the quality of the research and proposal, and the ethical conduct of the student co-investigators. It is assumed that you have read and approved the student research proposal submitted with your name as the PI.**

**Co-investigators *(names and emails):***

**NOTES: Co-investigators can be students, faculty, or staff using @longwood.edu or @live.longwood.edu email addresses. You may name co-investigators from other institutions but IRB approval does not cover their research activities and they will not be included in communication. External co-investigators do not need to provide CITI certification in this proposal. They will be responsible for obtaining IRB approval from their home institution. See the Canvas page on Collaborating with Other Institutions for more information. Responsibilities of the co-investigators:**

* **the safe and ethical deployment of the approved protocol; and**
* **promptly notifying the Principal Investigator or the IRB of unanticipated problems, or serious or continuing noncompliance.**

**Is this proposal for secondary research using data obtained from a previously approved project under broad consent?**

[ ] No

[ ] Yes, provide the IRB reference number for the primary research and indicate whether broad consent was obtained in the primary study.

**NOTES: This question relates to research that is using data obtained in a previous study under Broad Consent. Broad consent is separate from consent for the (previous) primary study and allows researchers to use the data collected for that previous primary study for more research. If you have checked “Yes” then this proposal details the research study you are proposing that uses these previously obtained data. When you use data obtained under broad consent you will not need to re-consent subjects for this new study and IRB review will focus on data security and storage.**

**What is the goal, aim, or purpose of your study? *Include a hypothesis statement.***

**NOTES: What do you want to find out? What do you think you’re going to find out?**

**Are you applying for a waiver of informed consent or alteration of informed consent?**

[ ] No

[ ] Yes, I am applying for a waiver of consent.

[ ] Yes, I am applying for an alteration of consent.

If you have checked either “Yes” above please answer the following questions:

* **Is the research minimal risk?**

[ ]  Yes

[ ]  No

* **For alteration – what is the requested alteration?**

**An alteration of informed consent is the omission of one or more of the required elements *that apply to your methodology*. Which element(s) are you wanting to omit? Why do you want to omit this element?**

* **Can the research practicably be carried out without the requested waiver? Why or why not?**

**Why are you unable to obtain informed consent? It may be that you are using deception, therefore you cannot inform the subjects fully, or you may not have access to the subjects anymore or another situation where obtaining informed consent is prohibitively difficult. This section should show that the research would not be possible if you are required to obtain informed consent from the subjects.**

* **Does the requested waiver or alteration adversely affect the rights or welfare of the participants?**

**Yes or no, you can include explanation if you wish.**

* **If applicable, how will you debrief the subjects? If you are not debriefing the subjects, explain why.**

**When you use deception you will need a waiver of informed consent i.e. you have their consent but it is not considered informed because you have deceived them. You must debrief the subjects immediately/soon after conclusion of their participation and re-consent them i.e obtain informed consent. Leave blank if this does not apply.**

**NOTES: A waiver of consent is not a waiver of any rights of the subject. Language that waives rights should not appear in informed consent materials.**

**Subjects: *Describe the subjects, how the subjects are recruited and what safeguards are in place to protect the subjects from any foreseeable risks. Please describe your process for obtaining voluntary, informed consent (e.g. written, electronic?) if applicable?***

**NOTES:**

**Describe the target subject population, for example, Longwood seniors, adults who read the New York Times, children in Grades 3-5. Include your target number of subjects here.**

**How are you recruiting these subjects? Are you posting on social media, asking friends and family (convenience sampling), sending a recruitment email to your church/sports club/fly fishing meet up group?**

**What are the safeguards to protect your subjects from foreseeable risks? For example, subjects will complete an American Heart Association prescreening Questionnaire for cardiac risk; subjects will not provide any identifying information in the survey and survey responses will be stored on a password protected server only accessible by the researchers; the researcher will leave the room while subjects complete their surveys (or choose not to participate) to avoid any undue influence. Basically, what are you doing to maintain subject safety, welfare, rights, and privacy? What are you doing to make sure nothing goes wrong? Your answers will be specific to your research.**

**How are you obtaining voluntary informed consent? Electronic? If you are obtaining consent electronically, how will you ensure the subjects have a copy of what they consented to (which also has your contact information if they have concerns)? Will a file be provided on the e-consent page for subjects to download? Will you send it as part of your recruitment information? Are you obtaining consent using a paper consent form? Verbal consent as part of an interview study? How will you provide a copy of what they consented to after the interview? Will you send the consent material when you recruit your interview subjects? If you are applying for a waiver of consent because of the use of deception, describe how you will re-consent the subject AFTER the research procedures.**

**For Parental consent and child assent: describe how you will send information home to the parents and recruit them (their children) for the study. How will you obtain assent from the child? Will the child be completing the research with their parents or when they are at school/participating in a program?**

**Will the subjects be deceived in any way?**

[ ] No

[ ] Yes, please explain. Provide debrief materials in the Appendices.

**NOTES: When you need to use deception to achieve your research aims subjects are unable to provide INFORMED consent. Subjects should be debriefed after their participation in the research protocol is concluded and provided the opportunity to provide informed consent or withdraw their consent for the use of the data you have collected. More information about uses of deception and how this affects the IRB review and approval process is on Canvas. You will need to provide your debrief procedure and material in the appendices in addition to the post-procedure informed consent materials.**

**Is a request for broad consent included on the consent form?**

[ ] No

[ ] Yes

**NOTES: What is broad consent? When we create a research study we want to find something specific/answer a specific question or set of questions using the data we collect. This is the primary study. Your consent materials will ask the subjects to consent to the use of their data for this purpose. Often though, we see different patterns in the data and realize that we may be able to answer another question using these data. The subjects however, have not consented to the use of their data for this secondary purpose (because that was not part of the consent materials they signed).**

**Broad consent is a separate consent block that can be added to the consent material you provide subjects in the primary study. In this broad consent block you will ask the subjects if they consent to you using their data for research purposes beyond the primary study. It is a useful element to include if you are collecting a lot of data and think there could be further uses for the data. A subject must provide broad consent separately from consent for the primary study. A subject cannot consent to broad consent and NOT consent to the primary study (since the primary study is where the consent for the data collection resides). A subject can consent to the primary study and NOT consent to broad consent.**

**Broad consent must be noted and approved by the IRB. Later, when you complete your IRB application for the study using the data obtained under broad consent (i.e. secondary data) the IRB will go back to the original proposal to ensure that broad consent was appropriately obtained. The review for the secondary study will generally be a limited review of data management, security, and confidentiality. See Canvas for the items that need to be included in the Broad Consent request and examples of how broad consent could be presented to the subjects.**

**Data Management, Storage, and Confidentiality: *How will consent be obtained, stored, accessed, and secured?*  *How will the data be collected, stored, accessed, and secured? How long will the records be maintained (can be indefinite)?***

**Electronic data should be stored in password protected software. How will you store and secure hard copies of any data collection instruments (surveys, demographic information sheets, experimental datasheets etc…? Will these be locked in the PIs office? If a student researcher will be handling and storing hard copies of subject data, how will these data be secured when the student has possession of them? Here we want to ensure that a student who may take home a binder of data (especially if the data has identifying information) is going to secure these records appropriately. The IRB wants to see that you are maintaining the subjects’ confidentiality by handing the data you collect appropriately.**

**Are you collecting any biospecimens? *Biospecimens include blood, saliva, urine etc.***

[ ] No

[ ] Yes – Please detail the amount of specimen collected and method of collection. You must complete the Biosafety Proposal

**NOTES: There are specific criteria for the method, volume, and amount of biospecimens that a researcher can collect while still meeting the criteria for expedited review. See the Canvas page on Types of Research – Expedited Research Categories for detailed information.**

**Methods and Procedures: *Describe your methodology in plain English in a way that is understandable by people outside your discipline. Complex protocols may need to be broken down into parts.***

**NOTES: The best way to approach this section is to think of it like a recipe. If your study is complicated then think of this section like the individual recipes that produce a meal. What are the steps involved in the methodology (recipe for a dish, what are the dishes that make up the meal)? You may find it makes sense to break your protocol up into manageable parts. Repeated measures protocols may need a timeline to visualize when different data will be collected or sections that explain the experimental design and sections that explain the separate procedures. This section is not a literature review and class papers that focus on literature reviews do not translate well here. This is a technical section. We want to know what you are doing, step by step. Make sure to use plain language and define any abbreviations the first time you use them (or better yet, don’t use abbreviations). Don’t assume the IRB knows what a particular test is for. Provide a plain language explanation.**

**A survey example:**

**Longwood University seniors who are first-generation college students will be recruited for this study by convenience sampling, posting on social media (see appendices), and by posting the survey on the department student page. Subjects will complete informed consent within the survey then a panel of screening questions. Subjects that meet the screening criteria (students at Longwood, seniors, super-super seniors, first in their family to go to college) will answer questions related to experiences, goals, and opinions of their education. Subjects will also be asked about their role in their family and if this has changed as a result of their experiences and goals. Subjects will not provide any identifying data in the survey, but demographic information will be collected.**

**A lab example for a study that could involve a pre-test, intervention, then a post-test:**

**Experimental Design**

**Healthy volunteers will report to the lab twice for testing. In the first visit the subject will complete informed consent procedures, and the first (pre-training) set of experimental procedures (body composition measurements and Wingate anaerobic testing). Following the completion of testing the subject will receive instruction on the training procedures and will be shown how to record their data in the provided training journal. Subjects will receive a weekly email (shown in the appendices) to remind them of their training program and the training journal.**

**Subjects will return to the lab 4-5 weeks after their pre-training visit to complete the post-training measurements. Body composition measurements and Wingate anaerobic testing will be completed.**

**Experimental Procedures**

**Body composition measurements**

**Subjects will have their body weight, total body water, and body fat percentage measured using the InBody 770 Body Composition Analyzer. Subjects will remove their shoes and socks and stand on the InBody footplates while holding the hand electrodes. The InBody sends a small electrical current through the body to determine total body water and body fat percentage. This current cannot be felt by the subject and there are no risks associated with the test for healthy individuals. InBody Body Composition analyzers are widely used with no reported adverse events.**

**Wingate Anaerobic Testing**

**Subjects will report to the lab in the afternoon for testing. Body weight will be recorded, then the subject will be asked to warm-up on a lab bicycle for 5-10 minutes at a self-selected pace until they experience a light sweat. After the warm-up the subject will sit on the lab testing bicycle and the seat height and handlebar position will be adjusted until they are comfortable. When the subject indicates they are ready the testing software will be started.**

**The subject will be performing the Wingate Anaerobic Test. The Wingate Anaerobic test is common lab test in exercise physiology and human performance and measures lower body anaerobic power. This test is a 30 sec supramaximal (very intense) cycling test. The subject pedals as fast as they can against a resistance equivalent to 7.5% of their body weight. Power output during the test is recorded by the software. The testing software begins with a 20 second period at a fixed intensity of 100W (moderate intensity). At the end of this 20 sec period the subject will be instructed to pedal as fast as they can and the equipment will instantaneously increase the resistance on the bike to 7.5% of the subject’s body weight. The subject will then pedal as fast as they can for 30 sec. The subject will be given regular time checks and encouragement. At the end of the test the resistance on the bike will reduce to 100W and the subject will pedal as a self-selected pace to cool down.**

**Training**

**Subjects will complete three sprint training sessions per week. Subjects will be asked to run as fast as they can for four seconds then complete a self-paced jogging recovery for ~ 30-60 seconds. This sprint-recovery pattern will be completed five times for the training session. The subject will be able to complete the session in a location of their choice (running on a track or outside) on the days of their choice, but will be asked NOT to complete the sprint interval training on a treadmill. Subjects will record basic training information each week on the training journal provided (provide the training journal in the appendices – this would be treated like survey questions).**

**Risks:** ***What are the potential, foreseeable risks for participants? If a risk is identified, how are you mitigating this risk?***

**NOTES: The role of the IRB is to protect subjects’ rights and welfare and so the IRB specifically assesses potential risks and harms subjects may experience. No study is without risk. The federal language for minimal risk is:**

***Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

**If your study is minimal risk you can copy and edit this language into this section and into your consent forms. Make the language specific to your study, for example a survey is not a physical test so you would edit the language to exclude that: “It is anticipated that the risks of completing this survey are not greater in and of themselves than those ordinarily encountered in daily life or during the completion of routine psychological examinations or tests.” You may need to adjust the language for the target subject population’s reading level. Make sure that you are communicating the relevant information effectively.**

**Mitigating risk in a survey – some surveys of sensitive information carry the risk of discomfort or psychological harm for subjects. Careful assessment of the language choices and questions asked will be important for mitigating this risk. You may send a survey to an expert to assess the language choices or ask individuals from the target subject population to review the survey language and questions and provide feedback prior to submitting to the IRB (these individuals will not be completing the survey – i.e. providing data, they will be critiquing language and question choices – this can happen prior to IRB approval).**

**Third party information: When asking about family history be careful about what and how you ask questions. Asking if a family member has a health condition (and then asking who that family member is) is providing that family member’s private information without their consent.**

**Outlining risk does not mean the study can’t or won’t be approved as minimal risk!**

**For studies that involve greater than minimal risk – these studies must be reviewed by the full IRB but outlining the risks does not mean the study won’t be approved! For the Wingate methodology example above some of the risks are: cardiac events during exercise, fatigue, nausea, dizziness, fainting.**

**The consent form language could look like this: “The Wingate Anaerobic Test is a very intense test. You may experience fatigue, dizziness, nausea, and fainting. There is a risk of a cardiac event (e.g. heart attack, chest pain) during intense exercise. You will complete an American Heart Association Prescreening Questionnaire prior to the test to assess your risk of heart problems. The research team is trained to recognize and respond to any signs of cardiac problems or exercise intolerance.**

**Appendices:**

***Please include the following appendices:***

* Any subject recruitment materials (posters, flyers, emails, social media postings etc.)
* Informed consent materials (if applicable)
	+ For e-consent provide a link/screenshots/copy and paste.
	+ If using e-consent, include the consent document that will be provided to subjects after they agree to participate. This document may be emailed to the subject or provided in hard copy and may contain the required elements of informed consent in a different format.
* Survey/interview instruments (list of questions AND accessible link to online survey materials; if applicable)
	+ A copy of the questions as approved is needed for records.
	+ The IRB will test your skip logic for consent, please enable the survey for repeated use and the ability to go back within the survey for the review process. You can change these settings when you send the survey to your subjects.
* Any debriefing materials if deception is part of the study
* CITI Certificates for each of the named investigators
	+ PI should have Humans Subjects Research Supervisor from the HSR group
	+ Co-Investigators should have Human Subjects Research from the HSR group
	+ Please ensure that your certification remains current during the approval period

All documents should be merged into a single PDF file and submitted to IRB@longwood.edu by the principal investigator, with co-investigators copied on the email. This electronic communication will be accepted as an indication that all the named investigator(s) agree that the information provided to the committee is accurate and true to the best knowledge of the researcher(s), and that the researcher(s) have conformed to the above guidelines to the best abilities of the researcher(s).

Proposals that do not contain the required material or supporting documents will be returned to the Principal Investigator.

**Checklist**

[ ]  Complete proposal

[ ] …..CITI Certificates

[ ]  Subject Recruitment Materials

[ ]  Consent form(s)

**Survey Studies**

[ ]  Copy of survey questions

[ ]  Link to survey included (if applicable)

 [ ]  The link works

 [ ]  Survey settings allow skip logic to be tested multiple times

**Studies Using Deception**

[ ]  Debrief materials for research with deception

 [ ]  Post-participation informed consent

**For Studies Involving Children**

[ ]  Description of how you will recruit and inform parents

 [ ]  Parental consent form

[ ]  Child Assent materials if applicable

[ ]  Everything merged into one PDF (you can delete this checklist)