**Consent Template: Medical**

To provide the necessary information to enable individuals or their legally authorized representatives (LARs) to decide whether to agree to research participation, a comprehensive consent form is needed. For your convenience, a consent template is provided on the next page. **To reduce the potential for IRB revision requests and delayed study approval, please use our template.**

The contents of the consent template have been organized to facilitate comprehension. **Consent documents should be written in plain language, excluding technical terms, and generally at an 8th-grade reading level.** The reading level can be higher if the planned participant population tends to have a higher literacy rate than the general population. For more information on plain language, go to <http://www.plainlanguage.gov/>.

Please not the following:

1. Regulations now require consent forms for federally sponsored research projects to contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in a study. The key information must be presented first and must include the following:
	1. Identification of the project as a research study and that participation is voluntary
	2. Purpose of the research, duration of participation, and a description of research procedures
	3. Foreseeable risks or discomforts
	4. Expected benefits to subjects or others
	5. Alternative procedures or treatments that might benefit the subject
2. Text in [brackets] represents information about your study that you must add.
3. A forward slash (/) indicates that you must select an option specific to your study (e.g., “will/will not” or “I/we”) and remove the remaining option(s).
4. Additional instructions or sample text are provided in boxes.
5. Before you submit your consent document to the IRB, delete this cover page, all brackets, and the boxes. You’ll also need to remove any extra spaces created when the boxes were removed.
6. Please follow the **instructions in blue** below, revising or providing the information in **red**. You will need to remove the instructions as you go, including these instructions. The font color of your completed document should be **black**.
7. The finished document should reflect what you will give to prospective participants.
8. If your study involves multiple types of participants who will complete different procedures, you will need to create different consent forms for each participant group.
9. When you save your newly created consent documents, please use a file name that clearly identifies the document and the intended audience (e.g., consent(males), etc.).

For questions about consent, please contact the IRB at irb@liberty.edu.

**Consent**

Provide your study title, **ensuring that it matches the title you listed on your IRB application**. Regarding co-investigators, list any individuals who will be assisting you with your research. If you are a student, list your faculty sponsor as the principal investigator and yourself and any members of your study team as co-investigators. If you are a faculty member, list yourself as the principal investigator (PI).

**Title of the Project:** [Title]

**Principal Investigator:** [Your faculty sponsor’s name [List your sponsor’s role/affiliation with LU.] [Director of [\_\_\_]/Assistant Professor of [\_\_\_]/etc.], [Provide the name of your faculty sponsor’s academic school or department (e.g., Liberty University College of Osteopathic Medicine, School of Health Sciences, School of Nursing, etc.).] [\_\_\_], Liberty University

**Co-investigator(s):** [Your name and the names of any co-investigators, [List your affiliation with LU.] [Student/Graduate Student/Doctoral Candidate/Osteopathic Medical Student/etc.], [Provide the name of your academic school or department.] [\_\_\_], Liberty University

**Invitation to be Part of a Research Study**

The next section should include your participant criteria. Make sure that all participant eligibility requirements are listed and that **they match what is on your IRB application and recruitment document(s)**. An example is provided.

You are invited to participate in a research study. To participate, you must be [List your participant criteria.] [e.g., 18 years of age or older, male, and moderately physical fit, etc.]. Taking part in this research project is voluntary.

**Important Information about the Research Study**

This is the key information section described beside number one on the previous page. Please complete each bullet point by inserting the required information.

Things you should know:

* The purpose of the study is to [brief, concise study purpose]. If you choose to participate, you will be asked to [brief, concise study procedures]. This will take approximately [time estimate].
* [Retain and complete the following sentence if your study procedures will involve greater than minimal risk. Otherwise, you may remove it.] Risks or discomforts from this research include [brief, concise description of risks or discomforts].
* [Brief, concise description of potential direct benefits to subjects or statement that subjects are not expected to receive direct benefits].
* Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

**What is the study about and why is it being done?**

In one to two sentences and in plain language, please list the purpose of your study. Do not include details about your procedures as they will be discussed below.

The purpose of the study is [study purpose].

**What will happen if you take part in this study?**

\* Next, you will need to list your study procedures **in order** and **include expected time estimates for each**. You may provide an overall time estimate for total participation at the end of your procedures list if your study involves multiple procedures that will take place **during a single visit** (e.g., Exercise Science projects).

\* If you plan to implement an intervention and will be using a control and experimental group(s), you must notify your participants of how groups will be assigned (randomly or otherwise) and that participants may or may not receive the intervention as part of their participation. If control group participants will have the opportunity to receive the intervention after the study has concluded, provide related information.

\* If you choose to withhold information about study groups and group assignments, your study will involve deception, and you will need to note this on the Consent page of your IRB application and potentially create and submit a debriefing statement for IRB review.

\* Screening is not considered a study procedure, so **it should not** be listed in the below paragraph.

\* Please **do not list reading/signing the consent form as a procedure**.

\* If your study will involve photographing, video recording, or procedures involving images (e.g., CT scans, etc.) of participants and you plan to include the photographs/video/images in your paper/thesis/dissertation/publication or as part of a future presentation(s), your participants will need to sign a release form allowing you to do so.

If you agree to be in this study, I will ask you to do the following:

1. [First task/procedure] [Be sure to include a time estimate.]
2. [Second task/procedure (or delete this text)] [Be sure to include a time estimate.]
3. [Add additional tasks/procedures as needed (or delete this text)] [Be sure to include a time estimate.]

**How could you or others benefit from this study?**

\* Select the appropriate option below. Participants may receive a direct benefit if the study procedures involve a therapeutic intervention, the opportunity to obtain training they would not receive if they did not participate (e.g., diabetes education), or free medical testing.

\* You will also need to provide information about the expected benefits to society/your discipline/the literature.

[Option 1: No Direct Benefits] Participants should not expect to receive a direct benefit from taking part in this study.

Option 2: Direct Benefits] The direct benefits participants should expect to receive from taking part in this study are [description of the expected benefits].

Benefits to society include [description of expected benefits to society].

**What risks might you experience from being in this study?**

\* Select the appropriate option below, keeping in mind that risk can be psychological, physical, legal, social, and economic.

\* No study is without risk. Some studies involving marketed drugs, approved medical devices, and blood samples, and studies involving the collection of biological samples through non-invasive means are considered minimal risk.

\* Individuals participating in studies involving physical activity may risk injury, but if the participants will be healthy, fit individuals, such risks are still considered minimal.

\* Studies involving x-rays or microwaves and invasive procedures are considered greater than minimal risk.

\* The IRB will provide guidance regarding level of risk as needed.

[Option 1: Minimal risk] The expected risks from participating in this study are minimal, which means they are equal to the risks you would encounter in everyday life.

[Option 2: Minimal risk, but the possibility of injury exists.] The expected risks from participating in this study are minimal, which means they are equal to the risks you would encounter in everyday life. The risks involved in this study include [Describe any risks, including the likelihood of them occurring.] [(e.g., the possibility of muscle strain or soreness or a sprained ankle resulting from the vertical jumps.)]. To reduce risk, [I/the study team] will [Describe the steps you will take to mitigate the risks.] [(e.g., demonstrate proper form prior to the procedures, monitor participants during the procedure, and provide appropriate first aid should a participant be injured.)].

[Option 3: Greater than minimal risk] The risks involved in this study include [Describe any risks, including the likelihood of them occurring.] [risk information]. To reduce risk, [I/the study team] will [Describe the steps you will take to mitigate the risks.] [\_\_\_].

If your study will involve medical tests, retain the below paragraph.

[Incidental Findings: Should the medical tests associated with the study procedures indicate an urgent medical problem, the researcher will advise you to seek medical attention from a physician.  However, neither the Liberty principal investigator, nor any members of the research team willoffer a possible diagnosis or additional medical advice to you about your test results.]

If your study will involve activities, including exercise, that could result in an injury or are considered greater than minimal risk, retain the below paragraph.

[Injury or Illness: Liberty University will not provide medical treatment or financial compensation if you are injured or become ill from participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.]

**How will personal information be protected?**

**Please read the below definitions before completing this section:**

**\*Anonymous** means **you, the researcher,** **will not be able** to link your data (e.g., survey responses, grades, etc.) to the specific participants who provided or are associated with the data. \***Confidential** means **you will be able** to link individual participants to the information they provide or are associated with, but you will not disclose participant identities or how named or identifiable individuals responded.

The records of this study will be kept private. [Include the following sentence if the data will NOT be anonymous.] [Published reports will not include any information that will make it possible to identify a subject.] Research records will be stored securely, and only the researcher[s] will have access to the records.

[Include the following in this section:]

* [Based on your study procedures and the definitions provided above, retain the applicable statement, and remove the inapplicable statement. If your study will involve both anonymous (e.g., an anonymous online survey) and confidential data (e.g., coded biospecimens), retain both statements and specify which forms of data will be applicable to each (e.g., Participant responses *to the online survey* will be anonymous.).] Participant responses [will be anonymous./will be kept confidential by replacing names with codes.]
* [If your research will involve the collection of identifiable private information or identifiable biospecimens, include the appropriate statement from the below options.]

[Future Research: Your [information/biospecimens] collected as part of this research, could be used or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. If your [information/biospecimens] are used or distributed, identifiers [will/will not] be removed.]

**OR**

[Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.]

[We suggest using caution when implementing the second statement in your consent form, as it can be very challenging to keep subjects’ information or biospecimens from being used for future research. This is not to say the second statement should not be used; you will just need to be extra vigilant to make sure the information/biospecimens are used or not used in accordance with the consent form.]

* [Describe how and where data/biospecimens will be stored and if and when the data/biospecimens will be disposed of. If you will have both electronic and hardcopy data and biospecimens, include information associated with each type.] [Biospecimens will be [stored in a lab at [Name the location (e.g., hospital, university, etc.).] \_\_\_./destroyed once they have been analyzed.] [Data will be stored [on a password-locked computer/in a locked [drawer/file cabinet, etc.]. [If the data will be destroyed, include and complete the following sentence.] [After [three/five/seven] years, [all electronic records will be [deleted/etc.]] [and/or] [all hardcopy records will be shredded.] [**Note**: Data should be retained for at least three years after the completion of your study.]

**How will you be compensated for being part of the study?**

\* You may delete this section if participants will not be compensated, and you prefer not to mention the possibility of compensation on this form.

\* Please note, the purpose of compensation is to reimburse participants for their time, effort, or actual costs (e.g., fuel used to travel to and from an interview) spent completing your study procedures.

\* If you do plan to compensate participants, include payment/reimbursement/incentive information here. If participants will receive class points or some other token, include that information here.

\* Include information about when participants will be compensated, the conditions of payment, and whether monetary benefits will be pro-rated if a participant does not complete the study. Because participation in research is voluntary and participants have the right to end their participation during the study if they so choose, if a study involves more than one procedure, compensation should be prorated or even staggered (e.g., $5 to $10 per procedure as opposed to receiving a single payment of $20 or $25 after all procedures are completed.)

\* If you will provide a meal, snack, or refreshments for your participants, include related information below.

Participants [will/will not] be compensated for participating in this study. [If participants will be compensated, include payment/reimbursement/incentive information. Otherwise, remove the remaining information in this paragraph.] [At the conclusion of the [procedure/each procedure/etc.] participants will receive [a $\_\_ [Visa/Amazon/etc.] gift card/etc.]. [If participants will not be compensated for each procedure, but compensation will instead be pro-rated, include the following sentence.] [Any participant who chooses to withdraw from the study after beginning but before completing all study procedures will receive [a $\_\_ [Visa/Amazon/etc.] gift card/etc.]

[The IRS requires study payments of $600 or more to a single individual to be reported on tax returns. If you plan to compensate individual participants in excess of $600, you must notify participants that the compensation will be reportable to the IRS and will be considered taxable income. If you are not compensating individual participants in excess of $600, you may remove this paragraph:] [e.g., The compensation provided as a result of participating in this research may exceed $600. In such cases, this compensation must be reported to the IRS as taxable income.]

**What are the costs to you to be part of the study?**

Delete this section if it is not applicable to the study.

To participate in the research, you will need to pay for [expected costs (e.g., parking)].

**Is the researcher in a position of authority over participants, or does the researcher have a financial conflict of interest?**

Include the above heading and applicable below statement if you are in a perceived or actual position of authority over your planned participants (e.g., You are a professor, and participants will be students at the university where you teach.), or you or the organization funding the study may receive a direct financial benefit from the study results (e.g., **Delete this section if it is not applicable to your study.**

[Option 1: Professional/Grading Authority] The researcher serves as [a professor/supervisor/etc.] at [university/organization/etc.]. To limit potential or perceived conflicts, [Retain the applicable option.] [data collection will be anonymous, so the researcher will not know who participated/a research assistant will ensure that all data is stripped of identifiers before the researcher receives it/etc.] This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study. No action will be taken against an individual based on his or her decision to participate or not participate in this study.

[Option 2: Financial Interests]The researcher has a financial interest in the outcome of this study. The researcher [Retain the applicable option.] [is a [paid/unpaid] board member of the sponsoring organization/has stock in the sponsoring organization/is listed on a patent associated with this study/has received honoraria or travel reimbursement from the sponsoring organization during the last 12 months]. This study is funded by [sponsoring organization/firm/etc.]. [Sponsoring organization/firm/etc.] is providing [equipment/etc.] for the study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate or not participate in this study.

**Is study participation voluntary?**

The voluntary-participation wording **is required** for all research. Please review the options in red and select the appropriate options based on your study design.

Participation in this study is voluntary. Your decision whether to participate will not affect your current or future relations with Liberty University [Include the name(s) of any other institution(s) associated with your study from whom you had to gain permission or IRB approval.] [or \_\_\_\_\_]. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

**What should you do if you decide to withdraw from the study?**

The how-to-withdraw section **is required** for all research.

If you choose to withdraw from the study, please contact the [researcher/research assistant/etc.] at the email address/phone number included in the next paragraph. Should you choose to withdraw, data collected from you [will be included in the study/will be destroyed immediately and will not be included in this study].

**Whom do you contact if you have questions or concerns about the study?**

Please complete the below paragraph, listing all study personnel and providing at least one means of contacting you or a member of the study team.

The researcher[s] conducting this study [is/are] [your faculty sponsor’s name, your name, and the name(s) of any additional co-researcher(s)]. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact [him/her/them] at [phone number and/or email].

**Whom do you contact if you have questions about your rights as a research participant?**

**Do not** remove or alter the IRB’s contact information or the disclaimer.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researchers, **you are encouraged** to contact the IRB. Our physical address is Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA, 24515; our phone number is 434-592-5530, and our email address is irb@liberty.edu.

*Disclaimer: The Institutional Review Board (IRB) is tasked with ensuring that human subjects research will be conducted in an ethical manner as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.*

**Your Consent**

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. The researchers will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I have read and understood the above information. I have asked questions and have received answers. I consent to participate in the study.*

If you will be recording or photographing participants, retain the below checkbox and permission statement and remove the listed methods that do not apply to your study. **If you will NOT be recording your participant(s), please remove the checkbox and permission statement.**

[ ]  The researcher has my permission to [audio-record/video-record/photograph] me as part of my participation in this study.

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Printed Subject Name Signature & Date

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Printed Investigator Name Signature & Date

**Legally Authorized Representative Permission**

Delete this section if it is not applicable to your study. A legally authorized representative (LAR) is a family member or other individual who has the legal authority to make decisions on the part of an adult who is not capable of doing so because of a physical condition or cognitive disability.

By signing this document, you are agreeing to the person named below participating in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. The researcher[s] will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I have read and understood the above information. I have asked questions and have received answers. I agree for the person named below to take part in this study.*

If you will be recording or photographing participants, retain the below checkbox and permission statement and remove the listed methods that do not apply to your study. **If you will NOT be recording your participant(s), please remove the checkbox and permission statement.**

[ ]  The researcher has my permission to [audio-record/video-record/photograph] the person named below as part of their participation in this study.

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Printed Subject Name

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Printed LAR Name Relationship to Subject

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LAR Signature & Date

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Printed Investigator Name Signature & Date