**Consent Template: Blood Draw**

To provide the information necessary for potential subjects or their legally authorized representatives to make a decision about participating in research, consent is required.

Information in the consent document must be organized to facilitate comprehension. **Consent documents should be written in plain language, generally at the 8th-grade reading level.** The reading level can be higher if the target population tends to have a higher literacy rate than the general population.

We recommend the use of this template to create the consent document(s) for your study. Please note 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, if any
	4. Expected benefits to subjects or others, if any
	5. Alternative procedures or treatments that might benefit the subject
2. Text in [brackets] represents information about your study that you must add. Your study information should be written in plain language.
3. A backslash ( / ) indicates that you must make a selection depending on your study procedures (e.g., “will/will not” or “I/we”).
4. Additional instructions or sample text are provided in boxes.

Please follow the instructions provided below to prepare your consent form:

1. Follow the **instructions in blue**.
2. Revise or provide the information in **red**.
3. **Do not remove** the wording in **black**. It is required.
4. Before you submit your consent document to the IRB, remove the instructions, delete this page, and remove all brackets and boxes. The finished document should reflect what you will give to the subject. The font color of your completed document should be **black**.
5. If your study will involve multiple types of participants requiring different consent forms, save each file using a file name specific to each consent document, clearly identifying the type of consent and the intended audience (e.g., parental consent, control consent, etc.).

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

For more information on plain language, go to <http://www.plainlanguage.gov/>.

**Consent to Draw Blood for Research**

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

**Principal Investigator:** [Name, credentials, institutional affiliation]

[**Co-investigator(s):** Name(s), credentials, institutional affiliation]

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

You are invited to participate in a research study. In order to participate, you must be [age, occupation, etc.] [Provide all of your eligibility criteria. Your criteria should match what you provided on your IRB application]. Taking part in this research project is voluntary.

**Important Information about the Research Study**

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].
* 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?**

The purpose of the study is [study purpose].

In two to three 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.

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

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

1. [First task/procedure] [**Describe the amount of blood, location, how often, and any other information that participants may need to make an informed decision. 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**.]

Please **do not list reading/signing the consent form as a procedure**. If you are using control and experimental groups, 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 you choose to withhold information about study groups and group assignments, your study will involve deception, and you will need to note this on your IRB application and submit a debriefing statement.

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

**[Option 1: Direct Benefits]** The direct benefits participants should expect to receive from taking part in this study are [description of the expected benefits].

**[Option 2: No Direct Benefits]** Participants should not expect to receive a direct benefit from taking part in this study.

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

Select the appropriate option above. Participants should not expect to receive a direct benefit from participating unless the study procedures involve an intervention (e.g., diabetes education session).

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

A blood draw may lead to lightheadedness or fainting. It may also cause bruising, prolonged bleeding, and infection at the site where the blood was drawn. In order to minimize these risks, we will swab the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising.

To protect against infection, we will also provide instructions on how to care for the wound and watch it for signs of infection. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests as the researchers are not using this test to make a diagnosis.

**Injury or Illness:** Liberty University will not provide medical treatment or financial compensation if you are injured or become ill as a result of 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?**

The records of this study will be kept private. Published reports will not include any information that will make it possible to identify a subject. Blood samples and any associated records will be stored securely, and only the researcher[s] will have access to the samples and records.

[Include the following in this section:

* A statement describing procedures taken to protect the privacy of the participant(s) and the confidentiality of their samples: [e.g., Blood draws will be conducted in a location where others will not be able to observe. Participant samples will be kept confidential through the use of codes, so only members of the study team will know whose blood it is. After [period of time], what’s left of your blood sample will be destroyed.].
* If applicable, describe how and where records will be stored, how the records will be disposed of, and any anticipated use of the records in the future (e.g., studies, presentations, etc.). [e.g., Records will be stored on a password-locked computer and may be used in future presentations.] [**Note**: Data associated with a research study should be retained for three to five years upon completion of the study.]
* [Include the following sentence if the possibility of sharing the samples/records exists.] [Samples/information] collected from you may be shared for use in future research studies or with other researchers. If [samples/information] collected from you is shared, any information that could identify you, if applicable, will be removed before the [samples/information] is shared.

**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.

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

Participants [will/will not] be compensated for participating in this study. [If applicable, insert payment/reimbursement/incentive information here. If subjects 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 or not monetary benefits will be pro-rated if a subject does not complete the study.

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.]

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

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

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

**Delete this section if not applicable to the study.**

**What conflicts of interest exist in this study?**

**[Option 1: Professional/Grading Authority]** The researcher serves as [a teacher/professor/supervisor/etc.] at [organization/school/etc.]. To limit potential or perceived conflicts [someone other than the researcher will draw . . .a research assistant will ensure that all data is stripped of identifiers before the researcher receives it.] [If you plan to address the potential conflict using a method other than the two examples provided, please describe your method]. 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 in this study.

**[Option 2: Financial Interests]** The researcher has a financial interest in the outcome of this study. The researcher [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/drug/device/etc.] for the study. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.

Include this heading and statement if you need to disclose any conflicts of interest. This may include, but is not limited to (1) having a position of professional or grading authority over potential participants or (2) having financial interests related to the conduct or outcome of the study. **Delete this section if not applicable to the study.**

**Is study participation voluntary?**

Participation in this study is voluntary. Your decision whether to participate will not affect your current or future relations with Liberty University [or names(s) of any other cooperating institution(s)]. If you decide to participate, you are free to not answer any question or withdraw at any time [Insert the following statement if you are only conducting an anonymous survey: [prior to submitting the survey] Delete the statement if your data collection includes additional/other procedures than an anonymous survey.] without affecting those relationships.

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

**[Option 1: Anonymous Survey Research]** If you choose to withdraw from the study, please [exit the survey and close your internet browser.]—OR—[inform the researcher that you wish to discontinue your participation, and do not submit your study materials.] Your responses will not be recorded or included in the study.

**[Option 2: All Other Research]** If you choose to withdraw from the study, please contact the researcher at the email address/phone number included in the next paragraph. Should you choose to withdraw, data collected from you [, apart from focus group data,] will be destroyed immediately and will not be included in this study. [Focus group data will not be destroyed, but your contributions to the focus group will not be included in the study if you choose to withdraw.] [**Note:** Revise or remove the focus group information as needed.]

The “How to Withdraw from the Study” heading is required for all research. **Please review the above options and select the appropriate option based on your study design.**

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

The researcher[s] conducting this study [is/are] [your name and the name(s) of any 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]. You may also contact the researcher’s faculty sponsor, [name], at [email].

If the researcher is a faculty member, the sponsor name/email information may be removed.

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

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher[s], **you are encouraged** to contact the Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA 24515 or email at 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.*

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

**Your Consent**

For projects involving a waiver of signed consent, delete the text below this box and only include the following statement in this section:

**Before agreeing to be part of the research, please be sure that you understand what the study is about. [You will be given a copy of this document for your records/you can print a copy of the document for your records]. If you have any questions about the study later, you can contact the researcher/study team using the information provided above.**

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 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 consent to participate in the study.*

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

If your study involves audio recording, video recording, or photographing participants, retain the above checkbox and permission statement, leave the appropriate method of recording listed, and remove the method(s) you will not utilize. **If you will NOT be recording your participant(s), please remove the checkbox and permission statement.**

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Printed Subject Name

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Signature & Date

**Legally Authorized Representative Permission**

**Delete this section if not applicable to the study. Legally authorized representative (LAR) permission is needed for adult participants who are not capable of consenting.**

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.*

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

If your study involves audio recording, video recording, or photographing participants, retain the above checkbox and permission statement, leave the appropriate method of recording listed, and remove the method(s) you will not utilize. **If you will NOT be recording your participant(s), please remove the checkbox and permission statement.**

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Printed Subject Name

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Printed LAR Name and Relationship to Subject

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LAR Signature Date