

Consent Form

[Insert Title of Study]

Note to researcher**:** this template encompasses all the required and some additional elements of informed consent that are relevant to minimal risk research, as required by federal regulations. These requirements can be found on the [IRB’s website](https://research.cc.lehigh.edu/required-elements-informed-consent). If your research is greater than minimal risk, is a clinical trial, and/or is FDA-regulated, please check the website to ensure that all relevant required and additional elements are included in the final version submitted to the IRB.

Text that does not apply to your research should be deleted or modified as appropriate.

Delete all instructive text, which is in red, before submitting the informed consent for IRB review. Replace all bracketed text with your own text.

Please follow the IRB’s [Readability Guidance](https://research.cc.lehigh.edu/readability) when creating your consent form.

Informed consent documents that are longer than 4 pages are required to begin with a concise presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate. Skip the Key Information section for now. If the final consent form is less than four pages long once you have modified this template, delete this section. If the final consent form is longer than four pages, enter the following information.

**Key Information**

Study Purpose:

Major Requirements of the Study:

Significant Risks:

Potential Benefits:

Duration of Participation:

You are invited to be in a research study. The research is about how [briefly describe the study in layman’s terms]. You are invited to take part in this study because [explain how the subject was identified]. Before you agree to be in the study, please read this form and ask any questions you have. **Your participation is completely voluntary. This means that whether you take part in this research is completely up to you.**

**This study is being conducted by:** [Name of researchers, department, University affiliation].

If the Researcher is a Lehigh Student, use the following. Delete if not applicable:

**This study is being conducted by:** [Name of researchers, department, indicate University affiliation], under the direction of [Name of faculty adviser, department, indicate University affiliation]

Delete the following if the research is not funded:

**This study is sponsored by:** [Name of sponsor]

# Background Information

**The purpose of this study is:**

[Explain the research question and the purpose of the research using layman’s terms.]

# Procedures

**If you agree to be in this study, this is we will ask you to do:**

* [Give a detailed description of what participants will be asked to do. Use easily understandable terms.]
* [Describe the length of time for participation and frequency of procedures.]
* [Identify any procedures that are experimental. Describe assignment to study groups.]
* [Describe any data you will obtain that participants will not disclose themselves (e.g., educational records, medical records).]
* [Describe any audiovisual recording that will take place.]

If the study involves biospecimens, the following information must be included:

The research team [will/will not] return clinically relevant information to you. Clinically relevant information is information that may relate to your health.

[If clinically relevant research results will be returned, describe the circumstances under which this will be done.]
This research [will/will not] include whole genome sequencing. This means that researchers [will/will not] study your entire genetic makeup.

If the study is subject to the [European Union’s General Data Protection Regulations (GDPR)](https://research.cc.lehigh.edu/GDPR-Guidance), the following information must be included. Delete if not subject to the GDPR:

The researchers will collect the following personal data from you for the purposes of this research: [Provide a complete list of all personal data being collected from participants. E.g.: name, address, phone number(s), email address(es), IP address(es), photographs / videos, ID number(s), etc]*.* Your personal data collected for this research will be stored until [period for which the data will be stored or if undetermined, the method for determining the length of data storage]. In the future, your personal data may be used for [include specific details about any projected / planned future use of personal data].

# Risks and Benefits of being in the Study

**The study involves the following foreseeable risks:** [Describe all risks and explain the likelihood of the risk. This section must be consistent with the risks as explained in the IRB protocol. Keep in mind that loss of confidentiality is almost always a risk in research. If physical injuries or mental health risks are present, include a sentence that states whether treatment will be provided from the research team or from the research team’s resources.]

**The benefits to participation are:**[List direct benefits to subjects. If none, state. Note that compensation is not considered a benefit and should instead be described below. If appropriate, list the broader societal benefits. E.g. “More broadly, this study may help us learn more about (topic) and may help (future populations with a similar issues/future researchers design interventions to help with a topic).” This section must be consistent with the benefits as explained in the protocol submitted to the IRB.]

# Duration

**Your participation in the study involves the following time commitment:**[Explain the expected time commitment for all study-related tasks. Include information about any follow-ups with participants.]

# Compensation

**You will receive:**

[Describe the compensation. Explain when disbursement will occur and conditions of payment. Explain if monetary benefits will be prorated if the subject completes only part of the study or withdraws from the study before the study is complete. If subjects will receive class points or some other token, include that information here. If there is no compensation, please state this here.]

If biospecimens collected as part of this research project will be used for the research team or institution’s commercial profit, you must include the following statement. Delete if not applicable:

Even once any information that could identify you has been removed, your biospecimens may be used for [research team’s/sponsor’s/institution’s, etc.] commercial profit. You [will/will not] share in that commercial profit.

# Confidentiality

Participation in research involves some loss of privacy. There is a risk of breach of confidentiality (the unintentional release of your information). We will do our best keep information about you confidential. However, we cannot guarantee total privacy.

Your identity will not be revealed in any publications, presentations, or reports about this research study. Delete the following text if not applicable (this information is particularly applicable for research involving interviews/focus group/ethnographic/oral history research projects): However, it may be possible for someone to recognize your story or response. Include the following text if your research is in a group setting: We will ask all participants to keep the information they hear in this group confidential, but we cannot guarantee that everyone will do so.

We will collect your information through [audiovisual recordings, interviews, audio recordings, Qualtrics, email, etc.]. This information will be stored [in a restricted access folder on Dropbox.com, an encrypted, cloud-based storage system, a locked drawer in a restricted-access office, etc.].

[If the data includes identifiers that will be separated from the data and destroyed, state the timeframe for doing so].
[If the data is inherently identifying (e.g. voice and/or video recordings, extensive demographic data, etc.) state the timeframe for destruction of that data. Describe any information that will be stored indefinitely.]This informed consent form will be kept for [number of years, 3 is required minimum] years after the study is complete, and then it will be destroyed.

One of the following statements regarding future research use of de-identified information must be included. The first statement should be utilized in most situations, as this provides researchers flexibility regarding future secondary research use of de-identified datasets. For example, some journals may require researchers to submit de-identified data sets for replicability purposes.

The information you provide will be de-identified. This means that any information that could identify you will be removed. Your de-identified information may then be used for future research studies, without asking for your additional permission. Your de-identified information may also be distributed to other researchers for future research, without asking for your additional permission.
OR, if no such future research use of identifiable private information or biospecimens is possible or planned:The information you provide will be de-identified. This means that any information that could identify you will be removed. Your de-identified information will not be used or distributed for any future research studies.

Include the following text if using an online survey or data collection tool. Delete if not:

The research team does their best to keep your information confidential to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could access to your online responses. However, this risk is similar to a person’s everyday use of the internet.

Include the following section if your study has **not** received an NIH Certificate of Confidentiality. If you’ve received a Certificate of Confidentiality, replace the following section with the language in the “Certificates of Confidentiality” section, further below:

It is unlikely, but possible, that others (such as Lehigh University, [funding sponsor], or state or federal officials) may require us to share the information you give us to ensure the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so. If working with children, the elderly, disabled persons, or other vulnerable populations that carry a reporting requirement, please include the following statement*:* If the researchers learn that you are [abusing/neglecting/going to engage in self-harm/intend to harm another], state law requires the researchers report this [behavior/intention] to the authorities.

The section below is required for all NIH funded research, and any other research, with a Certificate of Confidentiality. Delete if you were not granted a Certificate of Confidentiality.
Certificates of Confidentiality:

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy.  With this Certificate, the researcher may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

* there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
* you have consented to the disclosure, including for your medical treatment; or
* the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

A Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The section below is required for all NIH funded clinical trials. Delete if the study is not a clinical trial:ClinicalTrials.gov:

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/%22%20%5Ct%20%22_blank), as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

# Voluntary Nature of the Study

**Participation in this study is entirely voluntary:**

If you decide not to participate there will be no penalty, and you will not lose benefits to which you are otherwise entitled. Your decision whether to participate will not affect your current or future relations with the Lehigh University. If you decide to participate, you are free to not answer any question or stop being the study at any time without affecting those relationships.

Delete this section if none, or if the research does not involve experimental procedures:
Appropriate alternatives:

[Disclose any appropriate alternative procedures or courses of treatment that may be advantageous to the participant.]

If the study involves a reported financial conflict of interest (fCOI), OR there is the potential appearance of a possible fCOI, the following section must be included:
Researcher Financial Conflict of Interest

[Describe the fCOI, including the name(s) of the research team member(s) who have an fCOI.]

You are given this information so that you can decide if this potential conflict of interest affects your willingness to participate in this study. If you have any questions, please contact [name of research contact without an fCOI] at [phone number], [email address]. They will answer any questions you may have.

If the study is subject to the [European Union’s General Data Protection Regulations](https://research.cc.lehigh.edu/GDPR-Guidance) (GDPR), the following section must be included:

# European Union’s General Data Protection Regulation (GDPR) Compliance

The relevant “Legal Basis” for the collection and/or processing of your personal data for research purposes is your consent to participate in this research study, as demonstrated by your signed affirmation of consent below. This consent form also serves as the “Privacy Notice” for the purposes of the GDPR.

Your consent to participate in this study and provide your personal data is voluntary. You have the right to withdraw your consent at any time and to have your personal data deleted, except in cases where there is a legal obligation for the researchers to maintain this data. Data may also be maintained by the researchers if it has been fully anonymized, and there no longer exists any means of reidentifying individual participants. You also have the right to obtain a copy of any personal data collected by the researchers as part of this study.

You may exercise your right to withdraw consent for the use of your personal data by contacting the Principal Investigator at [phone number], [email address].

Note: for research subject to GDPR, all participants must give active consent. For example, participants must sign the consent form or click an “I consent” button.

# Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Lehigh University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at [phone number], [email address]. If you have questions about your rights or would simply like to speak with someone other than the research team about the questions or concerns, please contact the IRB at (610) 758-2871 or inirb@lehigh.edu. All reports or correspondence will be kept confidential.

***You will be given a copy of this information to keep for your records.***

# Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

Include if minors are involved. Delete if subjects are adults:

Signature of Parent or Guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

Signature of Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_