



Consent Form

[Insert Title of Study]

Note to researchers**:** this template encompasses all required and some additional elements of informed consent that are relevant to research receiving expedited review, as required by federal regulations. These requirements can be found on the [IRB’s website](https://research.cc.lehigh.edu/required-elements-informed-consent). Informed consent requirements for research receiving exempt review can be found [here](https://research.cc.lehigh.edu/informed-consent-process-exempt-research).

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

Delete all instructive text, which is in red, before submitting the informed consent for IRB review. Review, delete, edit, and reformat all bracketed text as necessary.

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 once you have modified this template, delete this section. If the final consent form is longer than four pages, enter the following information:



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.]

We will do our best to protect your data [and biospecimens] during storage [and when they are shared]. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data [and biospecimens]. In either case, we cannot reduce the risk to zero.

**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 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.]

For projects involving data sharing:

You will not receive any direct benefit from sharing your data [and biospecimens]. However, sharing your data [and biospecimens] may contribute to research that could help others in the future.

# Duration

**Your participation in the study involves the following time commitment:**[Explain the expected time commitment for all study-related tasks. Include information about 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.

All payments to research participants must comply with the [University Business and Travel Expense Policy](https://financeadmin.lehigh.edu/sites/financeadmin.lehigh.edu/files/offices/controller/pdf/Business%20and%20Travel%20Expense%20Policy%20%28effective%208.28.2023%29.pdf). Researchers must ensure that no research subject receives more than $600 in compensation within a single calendar year from Lehigh. The PI must keep records of payments and also ask each participant if they are being paid for involvement in other research studies at Lehigh University. If a participant is paid for involvement in multiple studies, the PI must inform [Research Accounting](https://financeadmin.lehigh.edu/content/contact) of the annual amount paid to that participant for the study, along with the participant’s name and contact info.

If the name and contact info of participants will be provided to Research Accounting, please include the following statement; delete if not applicable:]

Compensation is considered taxable income per Federal tax law. Lehigh University is required by IRS

regulations to issue a Form 1099-MISC to any participants who receive $600 or more within a calendar year. In order to comply with IRS requirements, your name and contact information will be shared with Lehigh University if you are participating in multiple studies involving compensation by Lehigh University this calendar year.

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

We will do our best to protect your data [and biospecimens] during storage [and when they are shared]. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

We will not reveal your identity 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 takes place 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 identifying information that will be stored indefinitely.]

Include 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 your online responses. However, this risk is similar to a person’s everyday use of the internet. 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.

**Information Sharing**

If NO 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.

If de-identified information will be or may be used for future research:

If you agree to take part in this study, data [and biospecimens] will be collected from you. We would like to make your data [and biospecimens] available for other research studies that may be done in the future. Before your data [and biospecimens] are shared for other research studies, they will be de-identified. This means that any information that could identify you will be removed. Future research may be about topics similar to this study. However, research could also be about unrelated topics. These studies may be done by researchers at Lehigh University or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data [and biospecimens] for [insert time frame as indicated in the study protocol].

If the data are coded and can be linked back to the identity of the participant:

We will protect the confidentiality of your information to the extent possible. Your data [and biospecimens] will be coded to protect your identity before they are shared with other researchers. [Indicate who/which institution maintains the code key] will have a code key that can be used to link to your identifying information. The code key will be securely stored.

If the data cannot be easily linked back to the identity of the participant:
Your name and identifying information will be removed from any data [and biospecimens] you provide before the data are shared with other researchers. Researchers cannot easily link your identifying information to the data and biospecimens.

If data will be shared and access to datasets will be restricted:

Your data and biospecimens may be shared with researchers around the world. The decision to share your data and biospecimens is controlled by [indicate which entity has control (e.g., the PI, a data repository)]. To access your data [and biospecimens], future researchers must seek approval from [indicate which entity has control (e.g., the PI, a data repository)]. Future researchers must agree not to try to identify you.

If datasets will be shared with unrestricted access:

Your deidentified data and biospecimens will be shared in a way where anybody around the world can access them.

Include the following if your study has **not** received an NIH Certificate of Confidentiality.
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 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**

If thePrincipal Investigator has a conflict of interest related to this research: One or more of the investigators conducting this study have a financial interest in [name of company and/or describe intellectual property]. This means that it’s possible that results of this study could lead to personal profit for the individual investigator(s) and/or Lehigh University. Any questions you might have about this will be answered fully by the Lehigh University Office of Research Integrity at 610-758-2199.

If a member of the study team who is not the PI has a conflict of interest related to this research: One or more of the investigators conducting this study have a financial interest in [name of company and/or describe intellectual property]. This means that it’s possible that results of this study could lead to personal profit for the individual investigator(s) and/or Lehigh University. Any questions you might have about this will be answered fully by the Lehigh University Office of Research Integrity at 610-758-2199, or by the Principal Investigator, [name of Principal Investigator] at [telephone number of Principal Investigator], who has no financial interest in this research.

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.

When sharing of data and biospecimens will not be optional (i.e., where sharing is integral to the purpose of the study): Participating in this study means I agree to sharing my de-identified data [and biospecimens].

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

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

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

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

When sharing of data and biospecimens is optional:

It is your choice whether or not to let researchers share your de-identified data [and biospecimens] for research in the future. If you say “no,” you can still fully participate in this study. Please sign next to your choice:

YES, my data [and biospecimens] may be used in other research studies: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

NO, do NOT use my data [and biospecimens] in other research studies: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_