

# UNIVERSITY OF PENNSYLVANIA RESEARCH PARTICIPANT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

ALL INSTRUCTIONAL RED/BLUE TEXT SHOULD BE REMOVED OR REPLACED WITH STUDY SPECIFIC INFORMATION (including headers and footers)- PRIOR TO SUBMISSION TO THE IRB.

Research teams should start with the Penn template to draft consent forms, rather than starting with consent forms from previously approved research studies. This is to ensure clean formatting and that all current institutional template language is included.

Likewise, it is strongly recommended that Penn Medicine / Dental staff and others doing research under a covered entity (Penn Medicine / Penn Dental) utilize the biomedical template to ensure all required institutional language is included, even if the research may be social-behavioral in nature.

**PLEASE REVIEW THE HEALTH LITERACY GUIDANCE PRIOR TO DRAFTING CONSENT FORMS.**

- Protocol Title:** Insert Title of Research Study or Acronym
- Principal Investigator:** Insert Name of the Principal Investigator  
Address  
Insert Phone Numbers
- Emergency Contact:** Insert Emergency Contact  
Insert Phone Number/Pager, etc.
- Sponsor** Remove if N/A

## Research Study Summary for Potential Participants

*Informed consent must begin with "a concise and focused presentation of the key information that is most likely to assist a prospective participant, or legally authorized representative, in understanding the reasons why one might or might not want to participate in the research. Researchers are encouraged to utilize the IRB developed "Concise Summary Guidance".*

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to <INSERT GENERAL OVERVIEW OF THE PURPOSE AND, IF APPLICABLE, WHY POTENTIAL PARTICIPANTS ARE ELIGIBLE>.

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If you agree to join the study, you will be asked to complete the following research procedures: <PROVIDE LIST OF STUDY PROCEDURES>.

Your participation will last for <INSERT OVERALL DURATION AND ANY STATEMENT NEEDED ABOUT ONGOING FOLLOW-UP OR ACCESS TO DATA/BIOSPECIMENS>.

<INSERT STATEMENT OF POTENTIAL FOR BENEFIT, IF ANY>. The most common risks of participation are <INSERT LIST OF MOST COMMONLY EXPECTED OR MOST IMPACTFUL RISKS>.

<INSERT INFORMATION ABOUT ALTERNATIVES TO PARTICIPATION AND OTHER IMPACTFUL INFORMATION BASED ON THE RESEARCH BEING PROPOSED. YOU MAY ALSO UTILIZE THIS SUGGESTED LANGUAGE BELOW TO REMIND POTENTIAL PARTICIPANTS THAT THIS IS A SUMMARY ONLY AND THE MAIN ICF HAS A LOT MORE DETAIL NOT DISCUSSED HERE>

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

### Why am I being asked to volunteer?

- *The participant is being invited to participate in a research study and why he/she/they is being asked to volunteer.*
- *The participant will get a copy of the consent form*
- *The participant will be asked to sign this form if consent is given to participate.*
- *Ensure participant is aware that they do not have to participate in research being performed by their own doctor.*

You are being invited to participate in a research study because (*why he/she/they is being asked to volunteer.*).

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form.

*Additional suggested language for introduction when the participant is a minor or decisionally impaired adult:*

This consent form is written from the point of view of a research participant. If the parent or legal guardian of a minor or a legally authorized representative will be providing

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consent, the words "you" and "your" should be read as ("your child" or "the research participant").

### What is the purpose of this research study?

- *A concise explanation of the purpose of the research, incorporating any intent to assess safety +/- efficacy.*
- *Inform participants of any investigational drugs, devices, and/or procedures. If applicable, note that a drug/device is approved for another indication but clarify that the use of the drug/device in this study is experimental.*

### How long will I be in the study?

- *Expected duration of a participant's involvement with the study.*
- *Expected total duration of study.*
- *(optional) Total number of participants in study \*note: if this information is included add "How many other people will be in the study" to the title of this section.*
- *(optional) Include number of participants at Penn \*note: if this information is included add "How many other people will be in the study" to the title of this section.*

### What am I being asked to do?

- *Provide a full list of research procedures/interventions/tests following health literacy guidelines. Consider including number of times each test will occur, amount, exposure if appropriate, etc. in layman terminology. Bulleted and subheadings can be useful tools for organization of information that will aid with comprehension.*
- *Describe any clinical tests/procedures (e.g., lumbar puncture, endoscopy, etc.) in layman's terms.*
- *If research occurs within the context of clinical care: It is preferred that only the research procedures and risks be included in the consent form. However, if both clinical and research procedures are included, clearly identify which procedures are for research purposes only. Procedures done solely for clinical care may also reference a clinical consent if applicable.*
- *If the study includes randomization, use of placebo, cross-over design, or blinding: these should be described in lay terminology.*
- *If the study includes the collection of blood or other tissue: Include the amount to be collected in understandable terms (e.g., 1 tablespoon (15 ml) of blood) and the method of collection (e.g., through a vein in your arm).*
- *(optional) Consider complimenting text with a simple table, chart, picture or other additional materials as appropriate if it will aid with comprehension. Separate handouts require IRB approval.*

### What are the possible risks or discomforts?

- *Include the known risks, discomforts, or inconveniences from the research intervention/procedures/agent(s)/devices described in the section "What am I being asked to do?". When known, please structure in terms of likelihood /severity. Do not include risks of standard care procedures that are not part of the research.*

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- *If the study involves randomization, discuss the risk of randomization (e.g., receiving less effective treatment)*
- *This section may also be detailed in chart format and additional material inserted here or given as a handout. Any such materials require IRB approval.*
- *If the research involves a change from standard clinical care, describe any resultant risk, if applicable.*
- *Clarify that if the participant is injured, they should inform treating physician that they are in a research study.*
- *Include information on reproductive issues, if appropriate. NOTE: If male contraception methods or warnings are warranted, the appropriate information must be provided in this section as well.*
- *Do not make statements of proven safety unless that safety data is part of FDA-approved labeling. If the labeling safety data does not include data in the proposed study population for this study, make clear that there is no safety data in the population under study.*
- *For early phase and first in human research and as applicable: Include a statement that the research may involve risks that are currently unforeseeable.*
- *If protocol includes MRI for research purposes (with or without IV contrast agents), please refer to the required CAMRIS clause language for all required risk language: <http://www.med.upenn.edu/camris/consent.html>*
- *If protocol includes the administration of gadolinium based contrast agents please refer to the required CAMRIS clause language for the use of such agents: <https://www.med.upenn.edu/camris/consent.html>*

### **Reproductive risks**

*Language about reproductive risks is required if the study has possible risks to pregnant women and /or the fetus, or breastfeeding children. Sponsor provided language may be an acceptable replacement. **Delete this language if it is not applicable.***

Because of the effects of this [drug/device], there could be serious harm to unborn children or children who are breast-feeding. These effects could also harm the parent carrying the child. Therefore, you should not become pregnant while you are taking this [drug/device]. It is also possible that harmful side effects that are not yet known could happen to both the parent and unborn or breast-feeding child.

If you are currently pregnant, it is important that you inform the investigator because you will not be able participate in the study. If you are able to become pregnant, you will be given a pregnancy test before entry into the study. [Add details about required pregnancy testing in alignment with the protocol.]

*If long-term participation requires inclusion of contraception, include the following information. Sponsor provided language may be an acceptable replacement. **Delete this language if it is not applicable.***

You are asked to use a medically accepted method of birth control while you participate in the study. [Add details about required contraception in alignment with the protocol.] If

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you do become pregnant, you must tell the investigator and consult an obstetrician or maternal-fetal specialist.

**Reproductive Risks for studies involving MRIs**

*If protocol includes MRI for research purposes (with or without IV contrast agents), please refer to the CAMRIS clause language for all required reproductive risk language: <http://www.med.upenn.edu/camris/consent.html>*

**Risks of Genetic Testing**

*If protocol includes genetic testing of human genetic material for research purposes, please include the following language. Please see IRB SOP GA 102, 3.1.15 Research involving Genetic Information for definitions of genetic information and genetic testing.*  
This research includes genetic testing. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

*If protocol includes genetic testing of inherited traits for research purposes, please also include the following language. Please see IRB SOP GA 102, 3.1.15 Research involving Genetic Information for definitions of genetic information and genetic testing.*

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

**What if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

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**What are the possible benefits of the study?**

- *Do not include overly promissory statements for investigational agents where efficacy has not been established*
- *If direct participant benefits can reasonably be anticipated as a result of participating in the protocol (section II.16 of application), then describe these possible benefits. Conclude with the following standard clause:*

You may not get any benefit from being in this research study.

- *If direct participant benefits are NOT anticipated, then use the following standard clause:*
- *(optional) Anticipated benefits to society.*

You are not expected to get any benefit from being in this research study.

**What other choices do I have if I do not participate?**

- *Information on other treatments available.*
- *Alternatives to entering the study including, when appropriate, supportive care with no additional disease-directed therapy.*
- *A statement that they may discuss alternatives with their personal physician.*

**Will I be paid for being in this study?**

- *If there is no compensation for participation in this study, state that here.*
- *Describe any monetary compensation (\*payments/stipend) for time and effort, and / or if participants are being reimbursed for their travel.*
- *Include a breakdown of the total compensation [i.e. clarify if paid after each visit/procedure (pro-rated) or upon completion of the study, etc.].*
- *When using Greenphire ClinCard the following is required: HSERA Compensation section, Protocol, and the Informed consent payment section should all clearly state:*
  - *That "Greenphire ClinCard" will be used as a payment option as well as the compensation schedule*
  - *Whether social security number will be collected for Clin Card purposes (If you have obtained a waiver for collecting social security number, this should be specified in HSERA and the protocol not the ICF.)*
- *[If participants will receive monetary compensation for their participation by check or an amount of \$100 or more, include the following language]*

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

**Will I have to pay for anything?**

- *Note any products, procedures or tests that will be covered by the study.*
- *Note any products, procedures or tests that are not covered by the study, stating how they will be paid for (i.e., third party payer, etc.).*

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You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

### What happens if I am injured from being in the study?

*Include injury language for research that poses greater than minimal risks to participants. **This section can be deleted for minimal risk research.***

- *Provide contact information for research-related injury (i.e. can refer to the contact information noted in Consent header, if appropriate).*
- *Describe what treatment will be provided for research related injuries.*
- *Explain how treatment for research related injuries would be paid.*
- *Participant's responsibilities relating to research related injuries.*
- *Sponsor provided language may be an acceptable replacement. However, PLEASE NOTE: The consent cannot contain any exculpatory language per 45 CFR 46.116 and 45 CFR 50.20, i.e., language in which the participant is made to waive or appears to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.*

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

--- OR ---

*[If there is sponsor-specific injury language, add it here. However, for industry-sponsored research, the sponsor must pay for research related injury unless otherwise negotiated with the institution.]*

*For NCI supported cancer trials, consider including the following information:*

For more information on clinical trials and insurance coverage, visit the National Cancer Institute's website at <https://www.cancer.gov> and type "paying for clinical trials" into the website's search bar. Another way to get this information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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### When is the Study over? Can I leave the Study before it ends?

- Define when the overall study is to end.
- Explain what events could lead to early study closure.
- Note that the participant can elect to leave the study at any time. **Discuss the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.** This should include who to contact if they want to withdraw, and any requirements related to withdrawal (e.g., end of study visit).
- If early withdrawal could expose the participant to medical risks, describe and how those risks will be minimized or prevented (e.g. in a hypertensive study, it may be necessary to wean a participant off the study medication or to transition them to alternate therapy).

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

*[NOTE: It may be appropriate to tell a participant that, for safety reasons, if they withdraw from the study, they will be urged to return for final testing or end of study visit. Suggested language is below]*

If you decide to stop participating in the study, we encourage you to talk to your doctor first. It is important to tell the doctor if you are thinking about stopping so any risks to you can be minimized. A final study visit may be requested to ensure your safety.

### How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

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The confidentiality of your information will be protected in the following way during the study:

*[Explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the participant. For example, explain if data will be de-identified or coded, explain if it will be stored under lock and key, etc. Please note; the content of this section will vary according to the research design. There may be cause for more or less protections depending on the nature of the research.]*

### **Infectious Disease Testing and Reporting**

*[If your study involves testing for infectious diseases, please include the language in paragraphs two/three below]*

If you test positive for <add any reportable infectious diseases for which testing will be performed specifically for research, such as COVID-19, HIV, Hepatitis, etc.>, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit <https://hip.phila.gov/ReportDisease>. For more information about the requirements of reporting infectious diseases to the PA Health Department, please visit [www.health.pa.gov](http://www.health.pa.gov) and type 'Reportable Diseases' into the site search bar.

### **Certificate of Confidentiality**

- *[If your study is funded by the NIH or if you have otherwise obtained a Certificate of Confidentiality (COC) from the NIH, please include the language below.*
- *If you have a COC and you are entering information into the medical record, please review guidance online here: <https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/other-elements-research>. If you need to suppress information from release in the medical record, please review this Tip Sheet on placing a flag on a record, and contact [psom-ocr@pobox.upenn.edu](mailto:psom-ocr@pobox.upenn.edu) with any associated questions.*
- **Delete this section if your study is NOT NIH funded and/or you do not have a COC from the NIH.]**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your

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information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**Will information about this study be available to the public?**

*If this is a clinical trial that requires registration on [clinicaltrials.gov](http://clinicaltrials.gov), include the below regulatory statement in full:*

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

**What may happen to my information [include if applicable: and samples] collected on this study?**

*This section is intended to include consent language required by the 2018 common rule about 1) the primary research use of specimens as well as 2) storage of collected data and specimens for future secondary research uses.*

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Commented [A1]: Additional guidance added for clarification purposes.

**Definitions for Guidance:**

**Non-Identifiable**

- *Anonymous: The data/sample was collected without knowing the identity of the participant. There is no chance of re-identification.*
- *De-identified: The data/sample was collected knowing the identity of the participant, but identifiers were destroyed or are not accessible to the recipient. There is no chance of re-identification.*

**Identifiable**

- *Coded: The sample is assigned a unique random identifier that is separately linked to participant identifiers. Re-identification is possible.*
- *Identified: The sample contains participant identifiers (e.g., name, medical record number, etc.)*

**Collection of Identifiable Specimens**

*[To address §46.116(c)(7&9) include the following 2 elements of consent if the study involves collecting identifiable specimens (see definitions above- this applies to coded or identified specimens) such as a biopsy, tissue resection, blood, sputum, urine, bone marrow, buccal swab, etc.]*

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1. *“A statement that the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.” Suggested language:*

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Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are [no plans] [or insert plans] to tell you, or to pay you, or to give any compensation to you or your family.

2. *“A statement of whether the research might include whole genome sequencing” (if known or a possibility, this should be included along with the risks of genetic testing in the risks section. See <https://irb.upenn.edu/forms> for genetic testing risks template language). Suggested language:*

Whole genome sequencing (WGS) [may / will not] be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code. WGS can be conducted to determine changes and mutations in DNA. The significance of these results may not be well defined. Not all genetic variations affect one’s health.

### Future Use of Data and/or Specimens

*[To address §46.116(b) include 1 of the 3 following statements about whether there may be future use of data and, if applicable, specimens.]*

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***PLEASE NOTE:*** *It should be considered whether storage of data and/or specimens for future secondary research uses is optional or a required part of participation. Providing options is particularly important in studies that offer the prospect of direct benefit to avoid undue influence to participate. Please make clear within this section whether the storage for future secondary research uses is optional or a required element of participation. If optional: ensure the end of the consent form includes an area to indicate the participant’s decision.*

**Commented [A2]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

1. *“A statement that data and, if applicable, specimens will not be stored or distributed for future research studies.” Suggested language:*

Your information [and samples] will not be stored or shared for future research purposes.

OR

2. *“A statement that data and, if applicable, specimens will be de-identified, and could be stored and distributed for future research studies without additional informed consent.” Please refer to the definitions above. This only applies to anonymous and de-identified data. Please note any plans to store data or specimens in repositories, and what the access controls will be. Please note that CODED data (such as stored with a study ID or other unique identifier CANNOT be considered de-identified unless the linking set is destroyed prior to any sharing of data, or the link and all identifiers are deleted from the data disclosed). Suggested language:*

**Commented [A3]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

Your information [and samples] will be de-identified prior to storage for future use. De-identified means that all identifiers have been removed. The information [and samples] could be stored and shared for future research in this de-identified fashion. The information [and samples] may be shared with other researchers within Penn, or other

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research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information [and samples] only applies to the information [and samples] collected on this study. If you change your mind, we will not be able to destroy or withdraw your information [and samples] that were shared because all identifiers would have already been removed.

**Commented [A4]:** New template language added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

OR

3. *"A statement that identifiable data and, if applicable, specimens will be stored and distributed for future research studies without additional informed consent." Please refer to the definitions above. Please note any plans to store data or specimens in repositories, and what the access controls will be. This applies to coded or identified data when that information is stored locally at Penn or elsewhere. Suggested language:*

**Commented [A5]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

Your coded or identifiable information [and samples] will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information [and samples] only applies to the information [and samples] collected on this study.

**Commented [A6]:** Added clarifying guidance to address situations in which local site may maintain code/link but a sponsor or external site only gets de-identified data/specimens.

- o *[If statement 3 is included, please also include the following additional elements of consent]*
  - *"A statement about which identifiers will be retained and shared with data/specimens." If there are circumstances under which a code key may be used to re-link identifying information to data and biospecimens, consider including language to address this. Suggested language:*

The following identifiers will be retained with your information [and samples]: [detail the identifiers that will accompany data/specimens during storage and sharing, e.g., the linking ID code, date of birth, etc.].

**Commented [A7]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

- *"A description of the period of time that the data/ biospecimens may be stored, maintained, and used for research purposes." If indefinite, please state this. Suggested language:*

Your information [and samples] may be stored and used for future research purposes for an indefinite amount of time [or state alternate timeline].

- *"A general description of the types of research that may be conducted with the data/ specimens." Suggested language:*

There are no plans to tell you about any of the specific research that will be done. Possible future research may include: [include examples]

- *"The types of institutions or researchers that might conduct research with the data/specimens, including plans to store data or specimens in repositories."*

**Commented [A8]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

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[NOTE: The below text is required institutional language if there are or may be intentions to share data or specimens outside of the institution]. Suggested language:

**Commented [A9]:** Added guidance to clarify which language is required institutional language.

We may share your identifiable information [and samples] with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

- “A statement regarding whether participants will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research.” Suggested language:

We [will/will not] follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

**Commented [A10]:** Duplicative text removed.  
**Deleted:** We [will/will not] give you any results from these studies. ...

- “A statement regarding whether the research results of any future testing of specimens, will be disclosed to participants.” If results will be returned, specify the conditions. This is only necessary if identifiable specimens will be stored for future research.

You will [will/will not] be given the results from testing that may be performed on your identifiable specimens as a part of future research. [if results will be returned, please specify the conditions]

- Specifically related to the future use: “A description of how confidentiality will be maintained during storage/ sharing, reasonably foreseeable risks and benefits of future research use” [including, if applicable, stigmatization related to sharing of sensitive data], “who to contact about future use/storage and research related harms.” If secondary research may include WGS or genetic testing of specimens, please detail genetic testing risks if they are not otherwise in the consent form. Suggested language:

**Commented [A11]:** Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by [detail confidentiality measures, e.g., encryption, access controls, etc.].

**Commented [A12]:** Additional guidance added for clarification purposes.

You will likely not directly benefit from future research with your information [and samples]. Research with your identifiable information [and samples] may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information [and samples], or have changed your mind, you can contact [Name or office] at [Phone Number]. If you change your mind, [Note the following: 1) what will happen to the data / specimens when a participant withdraws (e.g., data / specimens will be destroyed), and 2) any limits to destruction of information / samples (e.g., if data / specimens are shared outside institution were de-identified, it may not be possible for them to be destroyed; if data/ specimens are being used for FDA-regulated secondary research, data and specimens

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may need to be maintained per federal regulations; limits on cessation of ongoing research, etc.]]

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Commented [A13]: Additional guidance added to align the Penn ICF Template with the NIH Guidance: Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing.

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### **Electronic Medical Record and Release of Study Related Information**

*[This language is required for research being conducted within Penn Medicine when research data and results may be placed into the electronic medical record or are otherwise built in the EMR. As a reminder, studies must be built into the EMR/ PennChart if the study will be utilizing PennChart EMR ordering, billing or recruitment capabilities.]*

#### **What is an Electronic Medical Record?**

An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record.

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

#### **What may be placed in the EMR?**

Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

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**Will I, as a participant, have access to research related information within the EMR?**

The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine’s patient portal – called MyPennMedicine (MPM).

*[Include in this section: Specify whether **information** such as procedures, notes, orders, and results etc. or any other study information that may be shared in a delayed manner, at the end of the study, or will not be shared with participants. Template language is included in the highlighted paragraph below. If there will be no delays in sharing study information within the EMR, the highlighted paragraph below does not have to be included. **This paragraph should discuss all research information in the EMR, not just results of tests/imaging.]***

***Please utilize this section to discuss only study information that is permitted to be placed in the medical record.***

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. Not sharing or delaying certain research information within your EMR may be necessary to protect the integrity of the trial results or for other reasons.

*<Add details about what information will be shared with research participants in a delayed manner, shared at the end of the study, and/or not shared at all. For example: "Your drug / intervention assignment and progress notes will be withheld until the end of the study, but test and imaging results will be shared with you in a delayed manner.">*

**Will I receive the results of research testing that may be relevant to my health?**

*[The 2018 common rule requires that participants be informed “regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.” This section is applicable to all Penn schools and centers.*

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*This applies to the any type of testing where individual results may be expected. This may include, but is not limited to, diagnostic psychological or neurological testing, testing of specimens using assays or other in vitro diagnostic tests, diagnostic imaging, results other diagnostic devices, etc.*

*If clinically relevant results will be returned, specify the conditions.*

*Please note the following about diagnostic test or imaging results:*

- o **Results that may be placed in the medical record:** Results from testing conducted in a laboratory or center that is part of the Penn Medicine HIPAA covered entity (i.e., the results would have been placed in the medical record, regardless of research participation). Results placed in

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the medical record are part of the designated record set and the patient has a right to review these results per HIPAA regulations.

- o **Results that may not be placed in the medical record:** Results from biospecimen testing conducted in a laboratory that is not part of the HIPAA covered entity OR results from testing conducted in a non-CLIA certified laboratory (i.e., the results would not have been placed in the medical record as part of clinical care).]
- o Please note the following related to compliance with FDA regulations: The plan to return results from investigational diagnostic devices, without confirmation by a medically established device or procedure may not be exempt from IDE regulations.]

**\*\*\*NOTE\*\*\* The above bullets should not be used as consent language as the text is not written to be understandable to research participants. This is intended as guidance to the research community ONLY. Please draft your own language utilizing the text below as needed.**

**If the study will NOT generate clinically relevant research results, include the following language.**

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

**If the study will generate clinically relevant research results, include the following language.**

Results that may be relevant to your healthcare may be released to you. <Add details about the conditions under which clinically relevant results will be released to participants.

- If inclusion in the Penn Medicine EMR is applicable, note that they will be released in the EMR and refer to the Electronic Medical Record and Release of Study Related Information section in regard to timing;
- If inclusion in the Penn Medicine EMR is not applicable (e.g., Penn Medicine hospital services are not being used), discuss how the results will be released (e.g., discussed with the participant individually or shared with their primary care or a specialist clinician.>

*The language below is optional template language for situations where incidental findings may be possible. Delete this section if incidental findings are not expected.*

**Incidental Findings**

It is possible that during the course of the research study, the research staff may notice an unexpected finding(s) or information related to your health. Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety. You may need to meet with professionals who have the expertise to help you learn more about these results. You can decide whether you want this information to be provided to you. The study team/study will not cover the costs of any follow-up consultations or actions.

**Penn Template HIPAA authorization language follows and is preferred over other institutional or Sponsor template HIPAA language. This language will apply to most prospective biomedical research that is using or generating health information as part of**

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*the study. If you are utilizing non-Penn HIPAA authorization language, you must still ensure that required institutional language from the Penn HIPAA template is still included.*

- You may delete the language if the research is not being conducted under a Penn covered entity (e.g., Penn Medicine and Penn Dental are covered entities).*
- If HIPAA language is not applicable and is removed, then please update the consent form title to reflect that.*

*This template language should be utilized by researchers from all hospitals, centers, and programs within Penn Medicine covered entity. Penn Medicine is comprised of the Perelman School of Medicine and the University of Pennsylvania Health System. **For a complete list, please click [here](#).** Penn Dental researchers should utilize the Penn Dental template, located on the IRB forms and template webpage.*

### **What information about me may be collected, used or shared with others?**

*Provide a description of the information to be used and/or disclosed for the research project. This may include, for example, information in the medical record, results of physical examinations, medical history, lab tests, or PHI identifiers such as name, dates, address, or social security number.*

- Name, address, telephone number, date of birth*
- Social Security number*
- Sex assigned at birth, gender*
- Personal and family medical history*
- Results from a physical examinations, tests or procedures*

### **Why is my information being used?**

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research*
- oversee the research*
- to see if the research was done right*
- to evaluate and manage research functions.*

### **Where may my information be stored?**

*[This language is required for Penn Medicine expedited and convened research studies]*

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

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### Who may use and share information about me?

The following individuals may use or share your information for this research study:

*List all names or all classes of persons involved in the research at Penn Medicine, e.g.,*

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

### Who, outside of Penn Medicine, might receive my information?

*First, list all names or all classes of persons involved in the research outside of Penn Medicine who might receive their information, e.g.,*

- *Those working under the direction of the investigator for the study, (e.g. under subcontracts).*
- *All research centers participating in the study, even if they are not part of Penn Medicine*
- *The funding sponsor and organizations supporting the sponsor*

*Second, list all entities that will have oversight over the research and might receive information or require access to the research records to ensure research was properly conducted. OHRP should always be listed.*

#### Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

*Add additional as appropriate when applicable:*

- *The Food and Drug Administration*
- *The NIH Office of Biotechnology Activities and their committees overseeing gene therapy research*
- *The study data and safety monitoring board*

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

### How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

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However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

### **Can I change my mind about giving permission for use of my information?**

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

### **What if I decide not to give permission to use and give out my health information?**

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

### **Financial Interest Disclosure**

**Delete this section if there is no financial conflict of interest to disclose.**

*If a member of the research team has identified a financial conflict of interest this information may be included in the consent form using one of the template disclosures listed below. These template disclosures are intended to serve as a guide. The template language may be modified to best inform participants of any financial conflicts of interest. For example, "the person leading this study" may be replaced with "Dr. XYZ, a member of the study team." Suggested Language:*

#### **Research Team Member Financial Conflict of Interest template language**

*Disclosure of Money received outside of the study:*

This research study is supported by money from *Company XYZ*. In addition, the person leading this research study receives extra money from *Company XYZ* for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches or writing reports. If you would like more information, please ask the researchers or the study coordinator.

*Researcher or the University Holds a Patent:*

The person leading this medical research study has invented a new (*drug, treatment, device, etc.*) that is being evaluated through this research. Therefore, the researcher could benefit financially from the results of this research study. If you would like more information, please ask the researchers or the study coordinator.

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### *Researcher Owns Equity*

This research study is designed to test a product made by *Company XYZ*. The person running this study has an investment in *Company XYZ*, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study. If you would like more information, please ask the researchers or the study coordinator.

### *Institutional Financial Conflict of Interest template language University Owns Equity*

This research study is designed to test a product made by *Company XYZ*. The University of Pennsylvania has an investment in *Company XYZ*, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the University of Pennsylvania could gain or lose money depending on the results of this study. If you would like more information, please ask the researchers or the study coordinator.

### *Other Institutional Financial Conflict of Interest*

The University of Pennsylvania has a significant financial interest in the study product (*name*) being evaluated in this study. In the event that the study product proves to be effective, the University of Pennsylvania will likely receive significant financial benefit.

### *For Gene Therapy Trials*

The University of Pennsylvania has a significant financial interest in the study drug being evaluated in this study. Some of these technologies have been licensed to *Company XYZ*. The University of Pennsylvania made a substantial monetary investment in *Company XYZ* and also holds stock in the company. In the event that the study drug proves to be effective, the University of Pennsylvania will likely receive significant financial benefit.

### *Generic Disclosure*

The person leading this medical research study might benefit financially from this study. Specifically, ... (*insert description of financial relationship*). If you would like more information, please ask the researchers or the study coordinator.

## **Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

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When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

\_\_\_\_\_  
Name of Participant **[print]**      Signature of Participant      Date  
*If participants are required to provide their legal (government) name, please consider implementing a dual-name consent documentation process so that participants who use a different name (such as some transgender individuals) have the ability to provide it.*

\_\_\_\_\_  
Name of Person Obtaining Consent **[print]**      Signature      Date  
*Use the authorization line below when Non-English speaking participants are incidentally encountered and enrolled via a short form process. See IRB SOP IC 703 Consent Documentation, Section 3.2 Obtaining Informed Consent from Non-English Speakers*  
*For use with Non-English Speaking participants / LARs utilizing a short-form process:*

\_\_\_\_\_  
Name of Witness (Please Print)      Signature of Witness      Date

\_\_\_\_\_  
Name of Interpreter (Please Print)      Signature of Interpreter      Date  
*(When available)*

*(Optional) Use the authorization line only in studies which are approved by the IRB to use representatives to authorize a participant's inclusion in research. Delete if not applicable.*  
*For participants unable to give authorization, the authorization is given by the following authorized participant representative:*

\_\_\_\_\_  
Authorized participant representative **[print]**      Authorized participant representative Signature      Date

Provide a brief description of above person authority to serve as the participant's authorized representative.

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TITLE OR ACRONYM

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