UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM
ALL INSTRUCTIONAL BLUE TEXT SHOULD BE REMOVED OR REPLACED WITH STUDY SPECIFIC INFORMATION (including headers and footers)– PRIOR TO SUBMISSION TO THE IRB.

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 Subjects
Informed consent must begin with "a concise and focused presentation of the key information that is most likely to assist a prospective subject, 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>.

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
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 subject is being invited to participate in a research study and why he/she is being asked to volunteer.
- The subject will get a copy of the consent form.
- The subject will be asked to sign this form if consent is given to participate.
- Ensure subject 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 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 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 subject’s involvement with the study.
- Expected total duration of study.
- (optional) Total number of subjects in study "note: if this information is included add "How may other people will be in the study" to the title of this section.
- (optional) Include number of subjects at Penn "note: if this information is included add "How may other people will be in the study" to the title of this section.

Version - Insert version date here

IRB Biomedical Research Informed Consent Template Version: 4/01/2021 (Remove this prior to IRB submission)
What am I being asked to do?
- A high level overview of the major elements of the study and what is expected of the subject (i.e. note here only the major procedures and milestones).
- Following the overview, provide a full list of procedures/tests by lay-term names. Consider including number of times each test will occur, amount, exposure if appropriate, etc. in easy layman terms.
- If some procedures are being done for clinical care and for research purposes, clearly identify which procedures are for research purposes.
- (optional) May be complimented by a simple table or chart or other additional materials may be inserted here or given as a handout. Any such materials require IRB approval.

What are the possible risks or discomforts?
- Known risks from the study agent. When known, please structure in terms of likelihood/severity. May also be detailed in chart format and additional material inserted here or given as a handout. Any such materials require IRB approval.
- Risks, discomforts/inconveniences of study-related procedures noted in the section “What am I being asked to do?” If standard of care is testing is being changed, describe any resultant risk, if applicable. May also be detailed in chart format and additional material inserted here or given as a handout. Any such materials require IRB approval.
- Clarify that if the subject 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.
- 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 the use of such agents: 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
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 mother. It is also possible that harmful side effects that are not yet known could happen to both the mother 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 serum pregnancy test before entry into the study. You are asked to use a medically accepted method of birth control while you participate in the study. You should not become pregnant while you are taking this drug/device. If 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

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**Risks of Genetic Testing**

- **If protocol includes genetic testing of human genetic material for research purposes, please include the following language**

  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**

  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.

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

- **If direct subject 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 subject benefits are NOT anticipated, then use the following standard clause:**

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

  **(optional) Anticipated benefits to society.**
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?
- Description of any monetary compensation (*payments/stipend), if subjects are being compensated for their time and travel.
- 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.)
- A break down the total compensation (i.e. clarify if paid after each visit/procedure or upon completion of the study, etc.).
- If there is no compensation for participation in this study, state that here. [If subjects 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.).

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?
(for research that poses greater than minimal risks to participants.)
- 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.
- Subject’s responsibilities relating to research related injuries.

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.

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 subject can elect to leave the study at any time.
- If early withdrawal could expose the subject 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 subject 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 anytime. Withdrawal will not interfere with your future care.

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.

[In addition to the text above, explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the subject. 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.]

[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>, 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 and type ‘Reportable Diseases’ into the site search bar.

Will information about this study be available to the public?
If this is a clinical trial that requires registration on clinicaltrials.gov include a statement about this.

Suggested language:
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

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

Definitions for Guidance:
Non-Identifiable
- Anonymous: The data/sample was collected without knowing the identity of the subject. There is no chance of re-identification.
- De-identified: The data/sample was collected knowing the identity of the subject, but identifiers were removed. There is no chance of re-identification.

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

Collection of Identifiable Specimens
[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.]

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:
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. See https://irb.upenn.edu/forms for genetic testing risks template language). Suggested language:
   Whole genome sequencing [may / will not] be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens
[Include 1 of the 3 following statements about whether there may be future use of data and, if applicable, specimens]

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. Suggested language:
   Your information [and samples] will be de-identified. 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 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.

   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. This applies to coded or identified data. Suggested language:
   Your 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.

   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. 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].

- 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.

- 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. Suggested 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.] [give examples as applicable, such as: other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others.]

- A statement regarding whether subjects 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. We [will/will not] give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

- 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. See the consent section Will I receive the results of research testing? For more guidance and template language.

- 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, who to contact about future use/storage and research related harms. Suggested language:
  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].

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].

Commented [A3]: Text added to facilitate sharing with various types of other individuals and researchers.

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- [give examples as applicable, such as: other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others.]

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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.

Will I, as a subject, 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 information related to your participation in the study (e.g., laboratory tests, imaging studies, and clinical procedures) that may be placed in your existing EMR maintained by Penn Medicine. Information related to your participation in clinical research will also be contained in the CTMS.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.
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 about test results, procedures, notes, orders, 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 subjects. Template language is included in the paragraph below. If there will be no delays in sharing study information within the EMR, the paragraph below does not have to be included]

Please utilize this section to discuss only study information that is permitted to be placed in the medical record. Please note the following about diagnostic test or imaging results:

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

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 will be shared with research participants in a delayed manner, shared at the end of the study, or not shared at all. For example: “test results will be shared with you in a delayed manner, but other study information (e.g., progress notes and research notes) will be withheld until the end of the study.”>

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

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

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 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.

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).

HIPAA authorization language follows. This language will apply to most prospective biomedical research.

• 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
• 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

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Where may my information be stored?

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.

Who may use and share information about me?

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

- 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

Commented [A12]: CTMS language has been moved here (previously was in the EMR section)
Commented [A13]: Guidance has been added as to when this language is required.
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.

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 Subject 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.

Who can I call with questions, complaints or if I’m concerned about my rights as a research subject?
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 subject, 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...
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 personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal 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 Subject (Please Print)       Signature of Subject              Date

Name of Person Obtaining Consent (Please Print)       Signature              Date

(Optional) Use the authorization line only in studies which are approved by the IRB to use representatives to authorize a subject's participation in research. Delete if not applicable.

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative [print] Authorized subject representative Signature

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

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