*INSTRUCTIONS: This language will apply to most prospective biomedical research.*

*Add the following template language to the informed consent document. Change the title of the form to: Informed Consent and HIPAA Authorization Form. Note in submission to the IRB that a combined form will be used for the research protocol. Be sure to remove all instructional blue text from the document.*

*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***](https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/other-elements-research)***.*** *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
* 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.

# 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.

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.