*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.*

# 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.

# 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 Dental, e.g.,*

* The investigator for the study and the study team
* Other authorized personnel at Penn Dental 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 Dental, might receive my information?

*First, list all names or all classes of persons involved in the research outside of Penn Dental 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 Dental*
* *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 Dental, 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 Dental procedures developed to protect your privacy.

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

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

Your information may be held in a research database. However, Penn Dental 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 Dental to use and disclose personal health information collected about you for research purposes as described above.