Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: *<<Insert Title of the Research Study>>*

Principal Investigator: *<<Insert the Name of the Primary Investigator>>*
<<Insert Address>>
<<Insert Phone Numbers>>

***Co-Investigators:** *<<Insert the Names of the Co-investigators>>*
<<Insert Phone Numbers>>

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. This authorization form gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting the University of the Sciences in Philadelphia to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of the Sciences in Philadelphia to disclose that personal health information to outside organizations or people involved with the processing of this study.

What personal health information is collected and used in this study, and might also be shared (disclosed)?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study: *[Modify this list as appropriate- delete or add items as necessary]*:

- Name
- Address
- Telephone number
- Family medical history
- Allergies
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- List all other tests and procedures that will be performed in the study *[these tests and procedures should be fully described in the existing ICF along with the associated risks and discomforts of the tests and procedures]*
- *[List any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites]*

Why is your personal health information being used?

Your personal contact information is important for the University of the Sciences in Philadelphia research team to contact you during the study. Your health information and results of tests and procedures are

being collected as part of this research study and for the advancement of medicine and clinical care. *The Principal Investigator may also use the results of these tests and procedures to treat you.*

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- The University of the Sciences in Philadelphia Institutional Review Board (the committee charged with overseeing research on human subjects
- Authorized members of the University of the Sciences in Philadelphia workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, etc.).

Who, outside of the University of the Sciences in Philadelphia, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following *[Modify this list as appropriate- delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information {the examples below are suggestions only}.]*:

- Other collaborating academic research center(s) *[list all academic centers and their roles in project {who are working with the investigators}]*
- Research data coordinating office and/or their representative: *[name that group or company [who will be responsible for collecting results and findings from all the centers}]*
- Research data management office and/or their representative: *[name that group or company]*
- Pharmaceutical Company and/or their representative: *[name that group or company {who will use the results for submissions to the Food and Drug Administration}]*
- Government agency and/or their representative: *[name that agency { who need to confirm the accuracy of the results submitted to the government or using government funds}]*
- Contract Research Organization: : *[name that company {whose job is to review and correct any mistakes before the results are given to the sponsor or government}]*
- Others: *[name the other group and why they will receive the results]*

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of the Sciences in Philadelphia the information may no longer be covered by the federal privacy protection regulations.

[Depending on how personal health information will be handled for a specific study, the following notes some example language that might also be included (if applicable):]

- In all disclosures outside of the University of the Sciences in Philadelphia, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- In records and information disclosed outside of the University of the Sciences in Philadelphia, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

How long will the University of the Sciences in Philadelphia be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of the Sciences in Philadelphia may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of the Sciences in Philadelphia Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

Will you be able to access your records?

You will be able to request access to your records when the study is completed.
[If applicable, for the majority of blinded studies or other studies where access will be denied:]
During your participation in this study, you will not be able to access your records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.
[If applicable, for open label studies and other studies for which access will not be denied:]
During your participation in this study, you will have access to any study information that is part of your medical record. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

[ONLY USE THE FOLLOWING PARAGRAPH IF APPLICABLE]
If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice

By signing this document you are permitting the University of the Sciences in Philadelphia to use and disclose personal health information collected about you for research purposes as described above.

_____	_____	_____
Subject's Name **[print]**	Subject's Signature	Date
_____	_____	_____
Person obtaining authorization **[print]**	Person obtaining authorization Signature	Date

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

_____	_____	_____
Authorized subject representative **[print]**	Authorized subject representative Signature	Date

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

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