**The MetroHealth System**

# HIPAA: Authorization to Use and Disclose Your Protected Health Information to

**Participate in a Research Study**

**Study Title:**

**IRB No.**

**Principal Investigator:**

Your medical information and billing records constitute Protected Health Information (“PHI”). By signing this form, you allow the researchers for this study to obtain, use, and share your PHI as described more below. Your permission to allow the use and disclosure of your PHI is required if you want to take part in this study. MetroHealth has rules and procedures to protect information about you. Federal and state laws also protect your privacy. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at The MetroHealth System (MetroHealth) or any benefits to which you are already entitled. You will receive a copy of this form for your records.

**What PHI will be obtained, used, or disclosed?**

Your health information may be used or disclosed in connection with this research study.

Health information that may be collected, used, or disclosed specific to this study includes the following:

*

Identifiers to be collected specific to this study include:

*

Existing information or information created during your participation in this study will be made available by MetroHealth.

**How will my PHI be used in the study?**

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* To make sure you can take part in the study.
* To make sure the study is done safely and properly
* To learn more about side effects
* To analyze the results of the study
*

**Do I have to sign this Authorization?**

You do not have to sign this form. However, if you do not sign this Authorization, you will not be able to participate in this research study. Your decision whether to sign this Authorization will not affect your ability to receive medical care outside the study.

**When does the Authorization end? If I sign the Authorization, can I revoke it?**

Your permission to use and disclose your PHI expires at the conclusion of this study. However, if you decide to participate in the study, you are free to withdraw your Authorization regarding the use and disclosure of your PHI (and to discontinue your participation in the study) at any time. If you revoke your Authorization, the researchers will continue to use the information that they previously collected, to the extent that MetroHealth has already acted based on this Authorization, but no new PHI about you will be collected for study purposes after revocation unless required by law.

To revoke this Authorization, you must notify MetroHealth by contacting the Principal Investigator       at the telephone number       or mailing your request here      ..

**Who may use or disclose my PHI?**

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at MetroHealth may see or give out your information. These include people who review research studies such as the Institutional Review Board (IRB) and other MetroHealth staff authorized to access your information.

**Who may receive or use my PHI?**

The parties listed in the last paragraph may disclose your PHI to the following parties for their use in connection with this research study: [Remove any parties that will not receive PHI and add any specific to this study.]

* The Office for Human Research Protections in the U.S. Department of Health and Human Services.
* The MetroHealth Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
* Authorized representatives from internal hospital operations (for example, quality assurance).
* The MetroHealth research study staff members.
* *If applicable*, (Name) drug company supporting the study.
* *If applicable*, The Food and Drug Administration (FDA) and the National Cancer Institute (NCI) in the US, and similar ones if other countries are involved in the study.
* *If applicable,* Your insurance company;
* *If applicable,* Data and Safety Monitoring Committee/Board (DSMC/DSMB), an independent group of experts that will review the data from this research throughout the study.

We will do our best to ensure your information is kept confidential and that the least amount of PHI required to conduct the study is used or disclosed to people outside MetroHealth. Please know that people outside MetroHealth who receive your information may not be covered by this promise and the information disclosed to them may no longer be protected.

**How will researchers protect my information?**

Your research information will be stored in a secure location. It will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

**What will happen to my information that is collected for this study?**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. MetroHealth has no control over the use of your information once it is released. This information may be used for purposes unrelated to this research and could potentially be used to identify you.

Your samples and/or data may be stored and shared for future research projects without further consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples and/or data, no one will know that it is related to you specifically, and we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other forums, but these results will not include your identifying information. Your records will be confidential, and your identity will not be shared in these forums without your express consent. If your name or other information that might identify you will be used in any publication or presentation, the researchers will ask for your separate written permission.

**Authorization for use and disclosure of PHI for Research**

The information in this Authorization regarding the use of my protected health information (PHI) for research has been explained to me. I have read this authorization form, or it has been read to me, and I have had the opportunity to ask any questions and clarify any information that I do not understand. I voluntarily agree to allow the use and disclosure of my protected health information in this study. I will be given a signed copy of this Authorization form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Subject or Legal Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authority of Legal Representative, if applicable

Date

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Authorization

 (This must be an individual named in the protocol)