# Study Title:

**We are asking you to let us use and share your health information in a research study.**

**Your health care will not change in any way if you say no.**

# Why are you asking me to sign this document?

To let the researchers from [insert name of institution or organization] use and share your health information for this study, sign this document. We will give you a copy.

# Why are you asking for my information?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

# What information will you use and share for the study?

If you agree, we will:

* Use and share information from [insert name of institution or organization].
* Use and share [describe in detail the information to be used, e.g., entire medical record, information from your record such as how often you visited the doctor or health care provider and the reason for the visits, what medicines you take, the results and your medical record number, sex, and date of birth].

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule, you can speak to our Privacy Officer at hipaa@cmich.edu .

# How will you use and share this information?

We will use your information only for the study described in this document.

We may share your information with [list anyone other than the researchers who will receive identifiable information.].

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this.

# What happens if I say no?

We will not use or share your information for this study. The care you receive from your health care provider will not change.

# What happens if I say yes, but change my mind later?

At any time, you can tell us to stop using and sharing health information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this, please ask. [Note to researcher: After permission is revoked, researchers are permitted to disclose health information in very limited circumstances that relate to protecting the integrity of the research. For such use and disclosure is permitted to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.]

If you want us to stop, you have to tell us in writing. Write or e-mail [insert name and address and e-mail]. If you have questions, contact [insert name and phone # and e-mail].

If you stop, the care you receive from your health care provider will not change.

# How long will my health information be used?

We expect our study to take at least [insert number] years. We will not use or share your information after the study is finished. [Note to researcher: If the information is being shared for any reason other than this research, that also requires a authorization (e.g., sharing a person's contact information for recruiting to other research projects), include the expiration date for the authorized activity, if different from this expiration date.]

# What if I have questions?

* If you have any questions about the study, call the head of the study, [insert name and phone #]. Please call if you have:
	+ Questions about your rights.
	+ Questions about how we will use and share your information.

You can also call the Institutional Review Board at 989-774-3477 to ask questions about this study.

By signing this document you are letting us use and share your health information for this study. [Add other uses as described in disclosures referenced above. For example: By signing the document you are giving us permission to contact you about participating in other research studies.]

# Authorization by Research Participant

My signature below indicates that I am 18 years of age or older and all my questions have been answered. I authorize use of my protected health information as described above.

|  |  |
| --- | --- |
| Name of Participant: |  |
| Signature of Participant: |  |
| Date: |  |

# Statement of Person Obtaining Authorization

I have discussed with this participant the procedure(s) described above. I believe he/she understands the contents of this consent document and is competent to give legally effective authorization to use his/her health information.

|  |  |
| --- | --- |
| Name: |  |
| Signature: |  |
| Date: |  |