Addendum to Consent Form

Authorization to Use and Release Personal Health Information (PHI) for

Researchers/Investigators/Study Doctor: *[fill in]*

Study Title: *[fill in]*

The federal government has created a new privacy rule called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It gives you the right to decide who can use and release your personal health information (also called "protected health information" or PHI). This form, called an "Authorization", explains your rights and how your health information will be used and released for this study.

Description and purpose of information to be released:
By signing this form, you will be allowing or "authorizing" the use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you at as part of this study. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

Who may receive, use or release information:
Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *[Name of PI, and co-investigators]* and his/her research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:
The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees *(if applicable)*
- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,
- Representatives of outside groups contracted by QMC Research Department for audits to make sure studies are done as approved.
- *[Collaborators at other institutions]*

- *[Outside data analysts]*
- *[List any other class of persons or organizations not affiliated with QMC to whom the subject's information might be disclosed]*

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

You will not be identified by name in any published reports, or scientific publications, or meetings.

Right to Withdraw or Stop Taking Part in the Study

You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.
If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

Access to Your Information

As is usually the case, you may see the information in your medical record; however, the records and information related only to the study that are kept separately will not be available to you until the study is finished. If you wish to review your study records after the completion fo the study, you should request this from the study doctor.

There is no expiration date to this authorization.

You will get a signed copy of this consent form to keep.

_____	_____	_____
Subject's Name (Print)	Subject's Signature	Date/ Time

If subject unable to sign:

_____	_____	_____
Representative's Name (Print)	Representative's Signature	Date/ Time

If signed by a personal representative of the subject, a description of the representative's legal authority to act on behalf of the subject must be stated below:

_____

_____	_____	_____
Witness' Name (Print)	Witness' Signature	Date/ Time

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I have explained this authorization to the above subject. In my judgment the subject is voluntarily and knowingly giving authorization and has the legal capacity to give authorization to take part in this research study.

_____	_____	_____
Investigator's Name (Print) (Individual obtaining Subject's consent)	Investigator's Signature	Date/ Time

_____	_____	_____
Translator's Name (if appropriate) (Print)	Translator's Signature	Date/ Time