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Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

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Research and the Health Insurance Portability & Accountability Act (HIPAA)

All research conducted by faculty/ staff of UHCMC and/or recruiting UH patients that will use and/or disclose protected health information (PHI) must abide by the Health Insurance Portability & Accountability Act (HIPAA). This regulation, also known as the "Privacy Rule", establishes conditions under which researchers may have access to and use an individual's PHI for research purposes.

Patients who come to UH for treatment are required to sign a clinical HIPAA Authorization. *The clinical HIPAA authorization may refer to potential future research uses but a signature on this document is not, in and of itself, sufficient with respect to use and/or disclosure of PHI for research purposes.* Additional determinations with respect to the need for a signed HIPAA Authorization for research purposes must be made.

If a subject is asked to sign a HIPAA Authorization for research purposes, the subject must receive a signed copy of the executed authorization. This means that investigators must retain one (1) original signed copy in the subject's research records AND a signed copy must also be given to the subject. If the HIPAA Authorization language is contained as part of the informed consent document, the subject must receive a signed copy of the informed consent document.

What happens if the HIPAA Authorization isn't signed?

Failure to comply with HIPAA (Privacy Rule) requirements for research studies may have an impact on the ability to use data collected in the research study since "permission" has not been obtained and documented. In cases where the HIPAA is not signed, this omission would be considered a deviation and is required to be reported to the UHCMC Research Privacy Board (RPB) and considered an allegation of non-compliance. Instances of non-compliance with HIPAA requirements will be referred to the UHCMC Privacy Officer for investigation and resolution that may include review by the UHCMC RPB.

Examples of non-compliance include (but not limited to):

- 1) Usage of an incorrect version of the HIPAA Authorization;
- 2) Usage of an unstamped HIPAA Authorization; and
- 3) Not obtaining HIPAA Authorization;

If non-compliance is found, the RPB will discuss continued use of the PHI collected without appropriate authorization.

Examples of possible findings include:

- 1) The use of PHI collected for all study participants affected is allowed. No further contact with previously enrolled subjects is necessary.
- 2) The use of PHI collected is allowed upon receipt of a signed HIPAA Authorization for all affected study participants.
- 3) The use of PHI collected for the all study participants affected is disallowed.

How to Avoid Non-Compliance with HIPAA Regulations

To help ensure compliance with the Privacy Rule requirements, consider the following:

- 1) Incorporate the HIPAA Authorization into the body of the informed consent document.
- 2) Create a checklist to remind the individual obtaining consent to obtain HIPAA Authorization