

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH
TITLE: Use and Disclosure of Protected Health Information Preparatory to Research**Last Revised:04/2015****Prior Version: 02/2015****SOP NUMBER: GA-102****Page 1 of 3****1. PURPOSE:**

To define the procedures necessary to use or disclose University Hospitals (UH) patient Protected Health Information (PHI) preparatory to research.

2. SCOPE:

This SOP applies to University Hospitals (UH) personnel who desire to use or disclose PHI preparatory to research (“Investigator”). Non-UH personnel is permitted to use PHI preparatory to research only if credentialed through the UHCMC [Research Credentialing](#) process and under the direction of a UH employee who has met the requirements of this SOP.

This SOP applies to UH patient PHI, whether in paper or electronic form.

3. RESPONSIBLE INDIVIDUALS:

UH employees interested in using and/or disclosing PHI preparatory to research are responsible for completing the required steps set forth below. Prior to giving access to PHI, UH employees and workforce members must take reasonable steps to ensure that the procedures stated herein have been followed by the Investigator.

4. DEFINITIONS:

Disclose means the release, transfer, provision of, access to, or divulgence of PHI to a person or entity *outside* UH

Preparatory to Research activities include:

- Preparing a research protocol;
- Developing a research hypothesis; and
- Identifying prospective research participants.

Protected Health Information (PHI) means information created or received by a UH entity related to (a) the past, present or future physical or mental health or condition of a patient; or (b) payment for the provision of healthcare to a patient that is transmitted or maintained in any form or medium. PHI contains identifiers, such as demographic or insurance information, medical record number, physician, admission date or photographic images, for which there is a reasonable basis to believe the information can be used to identify a patient. Any individually identifiable information of a person deceased more than 50 years is not PHI.

Use means sharing, employing, applying, utilizing, examining or analyzing PHI *within* UH.

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH TITLE: Use and Disclosure of Protected Health Information Preparatory to Research	Last Revised:02/2015 Prior Version: None
SOP NUMBER: GA-102	Page 2 of 3

5. POLICY STATEMENT:

An individual who desires to use or disclose PHI preparatory to research must agree to the following:

- The use or disclosure is sought solely to review PHI as necessary to prepare a research protocol, develop a research hypothesis; and/or identify prospective research participants.
- No PHI will be removed from the covered entity during the review. (*Remove* means the act of providing, transferring, or storing paper or electronic PHI offsite of UH premises. Examples include providing PHI on an external device for use offsite of UH premises; emailing PHI to a non-UH email account; and/or storing electronic PHI on Google.Docs); **and**
- The PHI that the researcher seeks to use or disclose is solely necessary for the research purpose.

6. PROCEDURES:

6.1. The Investigator who desires to use and/or disclose PHI preparatory to research, must complete and submit the Use and Disclosure of Protected Health Information Preparatory to Research Investigator’s Certification (“Certification Form”) to the UH Privacy Officer, Compliance@UHhospitals.org . By completing the Certification Form, the Investigator agrees to the following:

- 6.1.1. The Investigator is preparing and/or considering a research protocol;
- 6.1.2. In order to prepare or determine the feasibility of the research protocol, the Investigator requires access to certain PHI;
- 6.1.3. The requested PHI is necessary to prepare for the particular research;
- 6.1.4. The PHI requested is limited to only that which is essential to conduct the activity related to preparation of the proposed protocol;
- 6.1.5. The Investigator has provided a complete list of the names of the individual(s), who will be reviewing the information being sought;
- 6.1.6. At no time during the review will the Investigator or others remove the PHI from UH premises;
- 6.1.7. The Investigator will only disclose PHI to non-UH personnel who have been researched credentialed;
- 6.1.8. Neither the Investigator nor his/her staff will contact patients about the proposed study or conduct any research until the Investigator submits and receives IRB approval for the research protocol;
- 6.1.9. Review of PHI will commence only on or after the date of the approval of the Certification Form.
- 6.1.10. After the Certification Form expiration date, the Investigator will not use or disclose the PHI for research preparation, unless the Investigator has submitted a request for an extension and received approval from the UH Privacy Officer.

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH TITLE: Use and Disclosure of Protected Health Information Preparatory to Research	Last Revised:02/2015 Prior Version: None
SOP NUMBER: GA-102	Page 3 of 3

6.1.11. The Investigator will retain the PHI in accordance with the policies on human subject research, only if needed as part of an approved research protocol from UH.

6.1.12. The Investigator will abide by UH policies to ensure the privacy and security of UH PHI.

6.2. The Investigator maintains a copy of the Certification Form with the Investigator’s study documentation.

6.3. The Investigator may not use PHI obtained pursuant to this SOP to contact potential study subjects, unless the Investigator receives IRB approval for the study protocol.

6.4. After the Certification Form expiration date, the Investigator will not use or disclose the PHI for research preparation, unless the Investigator has submitted a request for an extension and received approval from the UH Privacy Officer. The Investigator will retain the PHI in accordance with the policies on human subject research, only if needed as part of an approved research protocol from UH. If no longer needed, the Investigator will destroy the PHI to ensure privacy and confidentiality of the PHI, in accordance with UH policies and procedures.

7. REFERENCES:

- [UH Policy R-3 Uses and Disclosure of Protected Health Information \(PHI for Research\)](#)
- [UH Policy PH-15 De-Identifying Protected Health Information \(PHI\)](#)
- [UH Policy PH-16 Limited Data Set: Permitted Purposes for Use/Disclosure](#)
- [Research SOP GA 103: UH Research Credentialing](#)

8. FORMS OR ATTACHMENTS:

- Use of Protected Health Information Preparatory to Research Investigator’s Certification Preparatory to Research Flowchart
- Research FAQ

APPROVALS