SOP: Preparatory to Research			
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HRP-056f	5/6/2020	Julie Moore	1 of 2

PURPOSE

To define the procedures necessary to access Protected Health Information (PHI) for reviews preparatory to research.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 10/10/2005
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

This procedure applies to all investigators who desire access to PHI for reviews preparatory to research at the University of South Florida (USF) and to USF health care providers who use PHI for reviews preparatory to research.

RESPONSIBILITIES

All investigators are responsible for following the procedures stated in this standard operating procedure (SOP). Prior to giving access to PHI belonging to a USF covered component, USF health care providers, and USF covered component workforce members must take reasonable steps to ensure that the procedures stated herein have been followed by the Investigator.

PROCEDURE

The Investigator who has the need to access PHI belonging to a USF covered component for purposes of reviews preparatory to research must complete and submit a preparatory to research request by completing the “HIPAA Research Privacy Program - Preparatory to Research Request Form” on the HIPAA Research Compliance Program website. For more information on determining whether a proposed use of PHI qualifies as a “review preparatory to research,” refer to HRP-056b - SOP - Evaluating a Research Study for HIPAA Compliance on the HIPAA Research Compliance Program website.

The HIPAA Research Privacy Officer in USF Research Integrity & Compliance verifies that the completed Preparatory to Research request is in compliance with this SOP. If changes are required, the HIPAA Research Privacy Officer corresponds with the Investigator. If no changes are required, the HIPAA Research Privacy Officer approves the request by signing the “HIPAA Research Privacy Program - Preparatory to Research Request Form” and returning it to the Investigator.

A copy of the approved preparatory to research request must be maintained with the Investigator's study documentation in the event a decision has been/is made to conduct the research study.

Upon notification of approval of a preparatory to research request, the Investigator may have access to the PHI. The PHI may not be removed from the premises of the USF covered component granting access.

If the source of the PHI being sought for reviews preparatory to research is a site other than one that belongs to a USF covered component, the Investigator must consult that particular site and follow the procedures that are in place for that site.

Review of psychotherapy notes must have a subject's authorization and may not be exempted from such pursuant to this SOP.

REFERENCES

45 CFR 164.512(i)(1)(ii)

HIPAA Research Privacy Program - Preparatory to Research Request Form