Center for Clinical & Outcomes Research Procedure:

Preparatory To Research

Version 1.0

Overview

For activities involved in preparing for research, Protected Health Information (PHI) may be used or disclosed to a researcher without an individual's authorization, a waiver or alteration or authorization, or a data use agreement. However the covered entity must obtain from the researcher that: (1) the use of disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research; (2) the PHI will not be removed from the covered entity in the course of review; and (3) the PHI for which use or access is requested is minimum necessary for the research.

Scope

The HIPAA Privacy Rule requires researchers who intend to use Protected Health Information (PHI) for activities preparatory to research to declare to Kaiser Permanente Georgia. This policy applies to any persons requesting access to or use of any PHI for research purposes.

Procedures

1. Preparatory to Research Activities conducted for the purpose of:
   - Preparing a research protocol;
   - Developing a hypothesis;
   - Writing a grant application; or
   - Identifying subjects or records of subjects who may be recruited for the research.
2. The Representation of Activities Preparatory to Research (RAPToR) form certifies that:
   - The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
   - The PHI will not be removed from Kaiser Permanente Georgia in the course of review; and
   - The PHI for which use or access is requested is the minimum necessary for the research.
3. The KPGA researcher and/or their delegate will complete the RAPToR form and obtain the Executive Director of CCOR's signature **prior** to accessing the data. If the PTR request is for a non-KPGA workforce member, then their KPGA Sponsor Investigator will need to sign and submit the form on their behalf.
4. The completed form will be given to the CCOR Executive Administrative Assistant, where they:
   - Will create and record a new tracking ID# located on page 2 of the RAPToR form;

- Will record the RAPToR on the electronic master tracking log for RAPToR's located on the **I:\CHRSE\Proposal Award Finance\PTR\RAPToR Log** folder; and
- Will scan and save the electronic copy of the RAPToR to the **I:\CHRSE\Proposal Award Finance\PTR**<**YYYY**> folder.
    - The electronic file will be saved as <**RAPToR#**>_<**PI Last Name**>_<**Date of RAPToR**>

Supporting Policies

- HIPAA Privacy Rule: Information for Researchers (https://privacyruleandresearch.nih.gov/)

Document Approval, Ownership, & History

This document will be reviewed every two years for accuracy, relevance, and completeness.

Document owner: Research Manager III

Version #	Distributed on:	Reviewed on/by:
Version 1.0	7/24/17	Marca Gurulé
Version 2.0		
Version 3.0		