Representation of Activities Preparatory to Research (RAPtoR)

Requestor's Name: _____ **Department & Location:** _____

Telephone: _____ **Email Address:** _____

Please specify the date by which PRELIMINARY DATA is needed: _____

This representation is valid for 12 months following the date upon which this RAPtoR is executed. If further review is necessary after that date, another RAPtoR will be required.

A. Health Information Portability and Accountability Act of 1996 (HIPAA) Privacy Rule imposes restrictions on the use of protected health information (PHI) in activities preparatory to research. Please select the purpose of this RAPtoR (check all that apply):

☐ To develop a research question
☐ To determine study feasibility
☐ To determine study eligibility (inclusion/exclusion) criteria
☐ To determine study participation of individual potential subjects

B. Please describe the specific Protected Health Information (PHI) data that will be examined in this review; please request only the minimum necessary PHI to meet your needs—as required by HIPAA:

C. In a few sentences, please describe the reason for which the researcher plans to examine data:

INTENTION TO USE DECEDENT PHI

Does any of the data to be collected include PHI of decedents? ☐ Yes or ☐ No

If Yes, please answer the following questions.

If No, skip to the ACKNOWLEDGEMENT & ATTESTATIONS Section.

In order to access PHI of decedents, the following three representations must be TRUE. Use the checkbox below to indicate that the statement is true.

☐ TRUE The use or disclosure is solely to review PHI on decedents (not to be compared with PHI of living human subjects).
☐ TRUE The PHI that is being requested is necessary for the research purposes.
☐ TRUE At the request of KPMAS, documentation will be provided of the deceased individuals of whom data has been accessed.

If the PHI will be viewed by an individual, not on KPMAS region's workforce, Privacy Rule disclosure accounting rules apply. Contact Chanika Nelson (chanika.m.nelson@kp.org) for instructions.

- PHI ☐ will or ☐ will NOT be viewed by an individual(s) who is not on KPMAS region's workforce.
- If PHI will be viewed by an individual(s) who is not on KPMAS region's workforce, will the data of more than 49 individuals be viewed? ☐ Yes or ☐ No

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ACKNOWLEDGEMENTS & ATTESTATIONS

I acknowledge that the HIPAA Privacy Rule imposes restrictions on the use of PHI in activities preparatory to research, defined as the:

- Development of research questions,
- Determination of study feasibility (in terms of the available number and eligibility of potential study participants),
- Development of eligibility (inclusion and exclusion) criteria, and
- Determination of eligibility for study participation of individual potential subjects.

I, therefore, attest that:

1. I will use only the PHI that is necessary to prepare a research protocol for grant preparation, IRB review, and/or for those preparatory to research activities listed above [B].
2. I will not remove any PHI, abstracted in the course of my review of PHI from Kaiser Foundation Health Plan of the Mid-Atlantic States and the Mid-Atlantic Permanente Medical Group entities under the HIPAA Privacy Rule.
3. I will not disclose the abstracted PHI under any circumstances to anyone outside of these covered entities.
4. I will apply the above conditions to PHI maintained by the Kaiser Foundation Health Plan of the Mid-Atlantic and the Mid-Atlantic Permanente Medical Group covered entities.

Principal Investigator:

Signature	Printed Name	Date

You will be notified if the Privacy Rule requirements stated above change. If a change in these requirements occurs, you may be required to file a revised attestation form.

Submit a signed and dated copy of this form to your department, section, center, or institute administrator and the original to:

Mid-Atlantic Permanente Medical Group
Attn: MAPRI/Research Privacy Officer
700-B 2nd Street, NE
Washington, DC 20002
Email: Chanika.M.Nelson@kp.org

Approval:

Signature	Printed Name	Date

A copy of this approved form should be retained for your records AND presented to the database custodian before permission is granted to access PHI as described above [B].

Please allow 7 business days for the processing and approval of this document.

Frequently Asked Questions: Reviews Preparatory to Research

1. **Q: 45 CFR Parts 160 and 164 under "Permitted uses and disclosures (reviews preparatory to research)", states "No protected health information is to be removed from the covered entity by the researcher in the course of the review." What is specifically not permitted to be removed from the building?**
   A: The HIPAA privacy regulations say that the information cannot be removed from the building. In addition to prohibiting physical records of PHI from removal, this means that copying information and then removing the copied information is also prohibited, which includes electronic copies of the records.

2. **Q: At what point do activities "preparatory to research" cross over to "research", such as asking questions from the patient to see if they are eligible versus having patients sign a release of medical information so that you can look through their medical records to see if they are eligible?**
   A: Activities prior to interactions with the potential subject (for example chart review to obtain names for screening) would be acceptable under Preparatory to Research. Once the contact is made, however, further information provided through interviews, tests or record reviews would be considered "screening procedures" that would be part of conducting the research and would require IRB approval.

3. **Q: I am getting access to PHI from another covered entity under the 'preparatory to research' rule. I have provided the other facility with a written representation as they require. Do I need to track disclosures?**
   A: You do not need to track the disclosures, but the other facility does. Disclosures (release of information outside a covered entity) made under representations (reviews preparatory to research or decedent research), as well as disclosures made under waivers, require tracking. So most likely you will have to satisfy the requirements established by that covered entity for tracking.

4. **Q: Is a review preparatory to research considered a disclosure or use by a covered entity under HIPAA?**
   A: A "use" is when the PHI is accessed by someone within KP; a "disclosure" is when the PHI is accessed by someone outside our covered entity. Only disclosures that are made without permission are subject to "disclosure accounting". Uses of PHI by the covered entity are not required to be tracked for accounting purposes. So if you do a preparatory to research activity and all you do falls under "use", no tracking is needed. If, however, you do any "disclosure" under that preparatory activity, then that would have to be tracked.

5. **Q: If, during the review of data, I find a viable research question, may I begin to establish my protocol and start acquiring and analyzing data?**
   A: Before you engage in any activities that fall under the definition of "research" you must apply for, and receive, IRB approval.

6. **Q: What definition of research should I be using?**
   A: Research is "...a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities that fall into this category may include:
   a. Collecting, compiling and analyzing data from computers, files or patients.
   b. Analyzing clinical data to discern patterns.
   c. Tracking data on different treatments or practices to compare results.
   d. Providing information about patients to vendors, outside providers or institutions so they may compile, analyze or compare evaluations (even if you have shared information in the past).
   e. Publishing or presenting information collected or analyzed in which KP member data is included.

7. **Q: If I am unsure if I need IRB approval, who should I contact?**
   A: Please contact LaTrina B. Neal, Director, Human Research Protections and IRB Administrator, at latrina.b.neal@kp.org.

8. **Q: What is HIPAA's "minimum necessary" requirement?**
   A: According to Health and Human Services, when using, disclosing or requesting PHI, reasonable efforts must be made to use, disclose or request only the minimum amount necessary for the intended purpose.
   When a covered entity, such as KP, receives, requests or stores PHI, it must identify:
   a. Those persons or classes of persons in the workforce (which includes employees, volunteers, trainees, contractors and employees of contractors) who need access to PHI to carry out their duties; and
   b. The category or categories of PHI to which access is needed.
   Based on these factors KP must establish appropriate conditions on access to PHI to ensure that:
   a. Only staff with a need for access to PHI has such access; and
   b. Staff shall only have access to the categories of PHI needed to carry out their assigned duties.

9. **Q: What is Decedent PHI?**
   A: The HIPAA Privacy Rule protects the individually identifiable health information about a decedent (deceased person) for 50 years following the date of death of the individual. For more information, click here.