**The University of Vermont Medical Center**

**Data Access for Reviews Preparatory to Research 45 CFR 164.512:**

The purpose of this memorandum is to clarify your recent request for access to protected health information for a review preparatory to research[[1]](#footnote-1). In order to honor your request, can you please confirm the following:

* The use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;[[2]](#footnote-2)
* No protected health information will be removed from UVM Medical Center/UVM Health Network in the course of the review (moving PHI to UVM systems is not permitted); and
* The protected health information for which access is sought is necessary for the research purposes.

If these statements are accurate, please provide a brief description of the proposed research project in the space provided below.

Name of principal investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person accessing PHI (if different): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dept.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anticipated beginning date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Anticipated ending date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Proposed research purpose/reason for data use: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Describe data needed to accomplish purpose: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Source for access/collection of data for review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Method for review of data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please e-mail this form to Lynn Combs, Network Manager of Compliance and Privacy at lynn.combs@uvmhealth.org. The Compliance and Privacy Office will follow-up as needed and/or advise when the request is approved.

If you have any questions or require any assistance responding to this request, please feel free to contact the UVM Medical Center Compliance and Privacy Office @ 802-847-3532.

1. The Department of Health & Human Services has defined a "review preparatory to research" as preliminary research activities necessary to assist in the development of a research hypothesis and/or aid in the recruitment of research participants (e.g., to determine whether UVM Medical Center has protected health information of prospective research participants that would meet the eligibility criteria for enrollment into a research study). [↑](#footnote-ref-1)
2. If you are a member of the UVMMC/UVMHN workforce, you may use the preparatory to research exception access patient information for the purposes of recruiting subjects for your research. If you are not a member of the UVMMC/UVMHN workforce or if the patient information needs to be removed from the UVMHN environment, you will need to obtain a Partial Waiver of HIPAA Authorization from the IRB to access patient information for the purposes of subject recruitment. [↑](#footnote-ref-2)