

DATA ACCESS FOR REVIEWS PREPARATORY TO RESEARCH

The purpose of this memorandum is to clarify your recent request for access to protected health information (PHI) for a review preparatory to research¹. In order to honor your request, each of the following statements must apply to your proposed research:

1. The use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.¹



2. No PHI will be removed from UVM Health Network systems in the course of the review (e.g. moving PHI to UVM systems is not permitted).²



3. The PHI for which access is sought is necessary for the research purposes.

IF ALL THREE STATEMENTS ARE ACCURATE FOR YOUR PROPOSED RESEARCH, PLEASE COMPLETE THE SECTION BELOW.

Note: if you are accessing or collecting PHI to conduct any research activities beyond validation of a study cohort or for recruitment purposes (i.e. full study data set) an IRB approved study protocol is required.

Provide the following information:

1. Name, email address, and department of Principal Investigator:
2. Name, email address, and department of person accessing PHI (if different from PI):
3. Actual or approximate dates for the proposed research (start & stop dates):
4. Brief description of the proposed research purpose/reason for the data use:
5. Description of the actual data needed to accomplish the purpose:
6. Source for access/collection of the data for review:
7. Method of review of data:

If you have any questions or require assistance completing this form, email DataGovernance@UVMHealth.org or contact the UVMHN Compliance & Privacy Office at 802-847-2667 or Compliance@UVMHealth.org.

Please email this completed form to DataGovernance@UVMHealth.org. The Data Governance Team within the Data Management Office will follow-up as needed and/or advise when the request is approved.

¹ The Department of Health & Human Services has defined, and specified in 45 CFR 164.512, 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 identify a prospective cohort of research participants that would meet the eligibility criteria for enrollment into a study via chart review using Medical Record Numbers). The Preparatory to Research form meets the requirements for a HIPAA allowed pathway to access PHI to prepare for a research study - **IRB approval is required to conduct a study using PHI for study subjects.**

² If you are a member of the UVMHC/UVMHN workforce, you may use the preparatory to research exception to access patient information for the purposes of recruiting subjects for your research. If you are not a member of the UVMHC/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.