

ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION (PHI)

The Privacy Rule issued under HIPAA (Health Insurance Portability & Accountability Act) requires that investigators conducting a research study that utilizes PHI must account for all disclosures of PHI when specific criteria apply. HIPAA's Privacy Rule requires that there must be an accounting of each disclosure including repeated disclosures; this is relevant for each initial study and any study modification that expands the content or amount of PHI being disclosed when all three of the following criteria apply to a research study:

1. PHI will be disclosed by the Investigator.

• Disclosure of PHI refers to the release, transfer, access to, or divulging of information in any other manner outside the entity that maintains the information (e.g. REDCap or other UVM systems or research collaborators external to UVMHN). Whereas, use of PHI refers to the sharing, employment, application, utilization, examination, or analysis of the information within the entity that maintains the information. Note, PHI obtained through a review preparatory to research is not to be removed (disclosed) from UVMHN systems.

2. The research disclosure involves at least 50 records (i.e. 50 unique patients/subjects)



3. One of the following circumstances applies:

- Provisioning of access to the PHI has been approved by an IRB/Privacy Board through a HIPAA Waiver of Authorization; the patient/subject has not given consent, OR
- •The research utilizes information for a population explicitly defined as requiring records for deceased individuals only; authorization on behalf of the individual has not been obtained

IF ALL THREE OF THE CRITERIA ABOVE APPLY TO YOUR RESEARCH STUDY, PLEASE COMPLETE THE SECTION BELOW.

Select the one that applies to your study: HIPAA Waived Research Research on Decedents

Provide the following information:

- 1. Study Title:
- 2. IRB Study Number:
- 3. Actual or approximate Date of disclosure, frequency of disclosure (e.g., quarterly, annually), and/or number of disclosures within a specified period:
- 4. Name, email address, and phone number of Person Making the Disclosure:
- 5. Name, email address, and phone number (if known) of the entity or person who received the PHI:
- 6. Name, email address, and phone number (if known) of the entity that sponsored the research (if applicable):
- 7. Description of the PHI disclosed (i.e. direct & indirect identifiers as defined by HIPAA):
- 8. A brief statement of the purpose of the disclosure, including a plain-language description of the research protocol, purpose & objectives of the research, and criteria for selecting the study population/records: