Use of Patient Information for Research – Special Considerations and Forms

Accessing PHI Preparatory to Research, and
Conducting Research on Decedents, and
Guidance for Accounting for Disclosures of PHI

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THE University of Vermont HEALTH NETWORK

Topics for Discussion

- HIPAA Pathways to Use PHI for Research (Lynn)
  - Preparatory to Research
  - Research on Decedents
- Accounting of Disclosures of PHI for Research (Lynn)
- IRB Forms/Documentation Related to Each Topic (Beth)

HIPAA Basics

What is Protected Health Information (PHI)

Protected Health Information (PHI) is all individually identifiable health information, whether oral or recorded in any form or medium, relating to the:

- Past, present, or future physical or mental condition of a patient
- Provision of healthcare
- Past, present, or future payment for the provision of healthcare to a patient

HIPAA "Identifiers"

- ❑ Names
- ❑ All geographic subdivisions smaller than a state
  - ➢ Includes cities, counties, street addresses, precinct, geocodes, etc.
  - ➢ Specific exemption for certain zip codes
- ❑ All elements of dates (except year) for dates that are directly related to an individual
  - ➢ Including birth date, admission date, discharge date, death date, and
  - ➢ all ages over 89 must be aggregated into a single category of age 90 or older
- ❑ Telephone numbers
- ❑ Fax numbers
- ❑ Email addresses
- ❑ Social security numbers
- ❑ Medical record numbers
- ❑ Health plan beneficiary numbers
- ❑ Account numbers
- ❑ Certificate/license numbers
- ❑ Vehicle identifiers and serial numbers, including license plate numbers
- ❑ Device identifiers and serial numbers
- ❑ URLs
- ❑ IP addresses
- ❑ Biometric identifiers, including finger and voice prints
- ❑ Full-face photographs and any comparable images
- ❑ Any other unique identifying number, characteristic, or code
  - ➢ Unique tattoo, birthmark, feature
  - ➢ Clinical trial subject number

What We Do with PHI

HIPAA defines how we can "**access,**" "**use**" and "**disclose**" PHI

Use of PHI – PHI stays within UVMHN

Use of PHI refers to sharing, employment, application, utilization, examination, or analysis of the information within the entity that maintains the information.

Disclosure of PHI – PHI leaves UVMHN

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, research collaborators external to UVMHN); certain disclosures of PHI must be accounted for by the covered entity.

- We also talk about "access" to PHI. Access, which is a subcategory of "use." All the rules and exceptions apply to access too but the person accessing the information does not "do" anything with the information. Today's focus is on uses and disclosures.

Primary HIPAA Rule

- Without the patient's written permission, PHI **cannot be accessed, used or shared (disclosed)** unless HIPAA makes an explicit exception that permits it.

- **Key question**: What is the HIPAA pathway that permits me to access, use or disclose PHI?
  - Examples of HIPAA "pathways" include patient authorization, treatment, public health surveillance, obtaining payment for services provided and hospital operations
  - 6 distinct HIPAA pathways allow for the use of patient data for research

6 “Pathways” for Use/Disclosure of PHI for Research

- Authorization from the research participant/subject
  - Requires IRB review
- Waiver of HIPAA authorization issued by IRB/Privacy Board
  - Requires IRB review
- PHI preparatory to research (PHI cannot be shared outside of UVMHN) (non-IRB review)
  - Does not require IRB review (form approved by UVMHN Data Governance)
  - May be required for recruiting for IRB-approved research
- Research on PHI belonging to decedents
  - Does not require IRB review (form approved by UVMHN Data Governance)
- Limited data set (containing no direct identifiers) and compliant DUA with researcher(s)/data recipients
  - Does not require IRB review but requires third party to prepare the data set (e.g., UVMHN DMO)
- De-identified data sets
  - Does not require IRB review but requires third party to prepare the data set (e.g., UVMHN DMO)

Pathways to Discuss Today

- PHI preparatory to research (PHI cannot be shared outside of UVMHN)
- Research on PHI belonging to decedents **(also accounting for these disclosures)**
- Waiver of HIPAA authorization issued by IRB/Privacy Board **(accounting for these disclosures)**

Data Access for Reviews Preparatory to Research

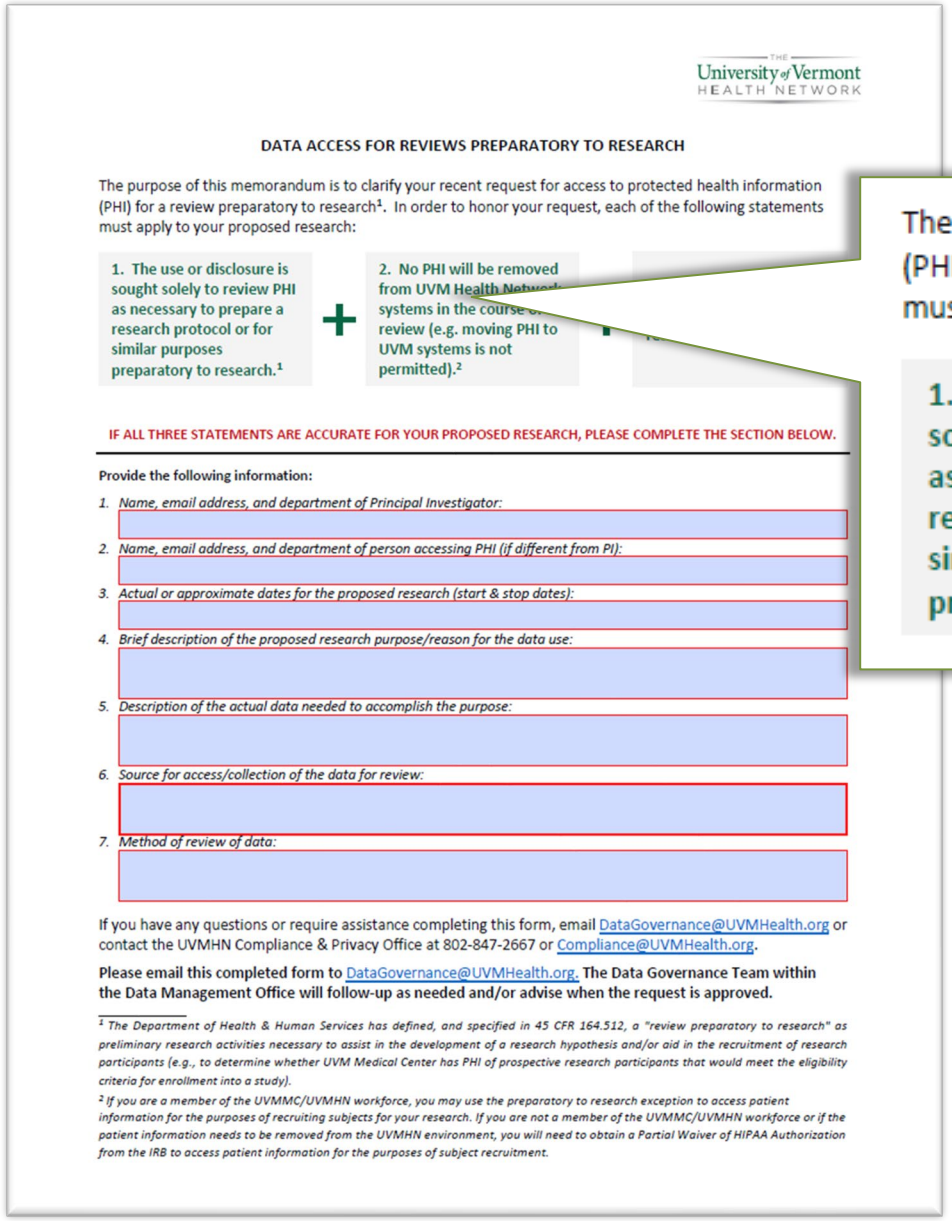
Includes preliminary research activities necessary to assist in the development of a research hypothesis and/or aid in the recruitment of research participants.

Researchers must submit attestation that confirms:

- 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;
- No protected health information will be removed from the covered entity; and
- The PHI sought is necessary for the research purposes.

Source: eCFR :: 45 CFR 164.512 – Research on decedent's information. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512

Reviews Preparatory to Research



University of Vermont HEALTH NETWORK

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 research[1]. 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]
+

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

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 determine whether UVM Medical Center has PHI of prospective research participants that would meet the eligibility criteria for enrollment into a study).

[2] If you are a member of the UVMMC/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 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.

The purpose of this memorandum is to clarify your recent request for access to protected health information (PHI) for a review preparatory to research[1]. 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.

<u>The purpose of the form is to verify:</u>

- ❑ Access to the PHI is for research purposes.
- ❑ The research purpose is limited in scope to preparing a study protocol or for study recruitment; research activities such as data collection or analysis are not permitted.
- ❑ PHI will be accessed only by UVMHN workforce members and downloaded & stored only within UVMHN systems; PHI must not be disclosed.

Preparatory to Research is not used for updating any aspect of an IRB approved study, UVMClick is the source of all approved documentation on IRB protocols!

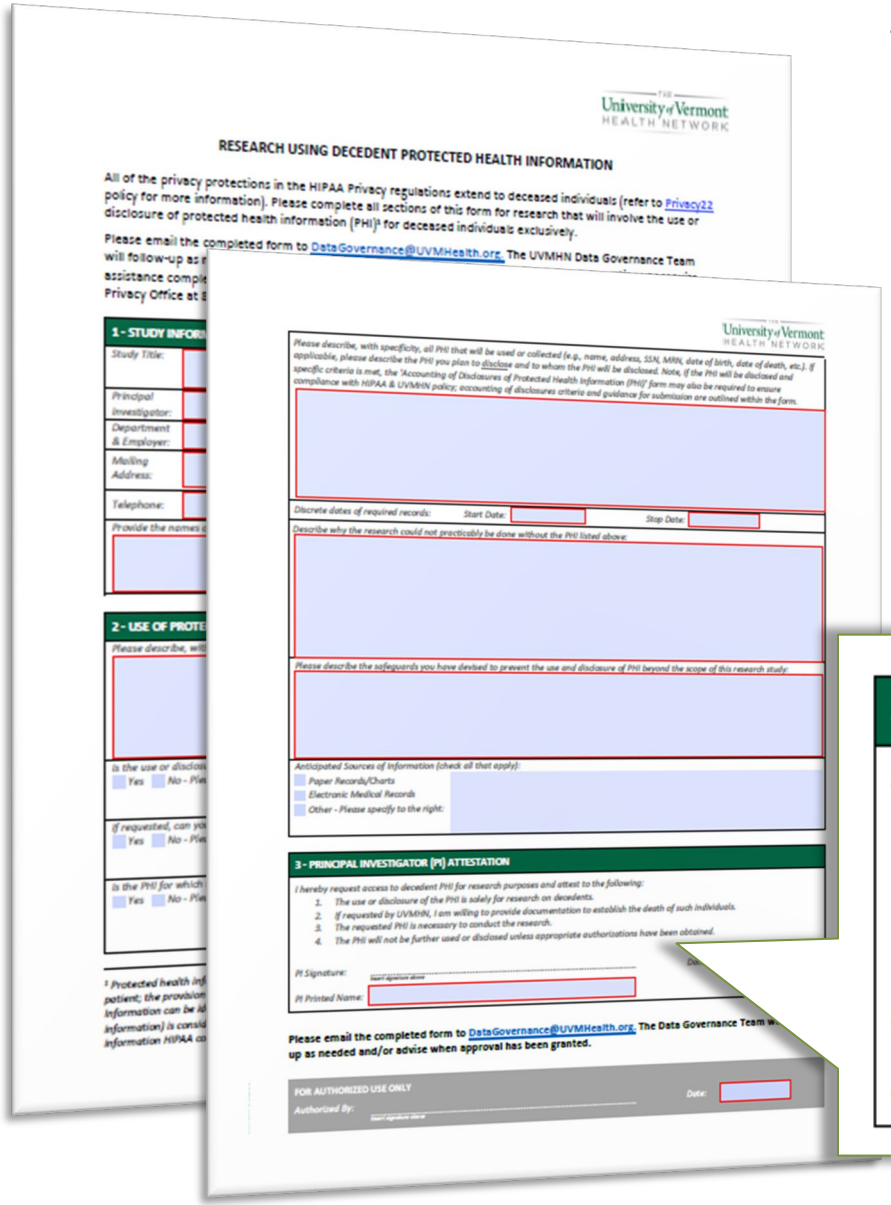
Research Using Decedent Protected Health Information

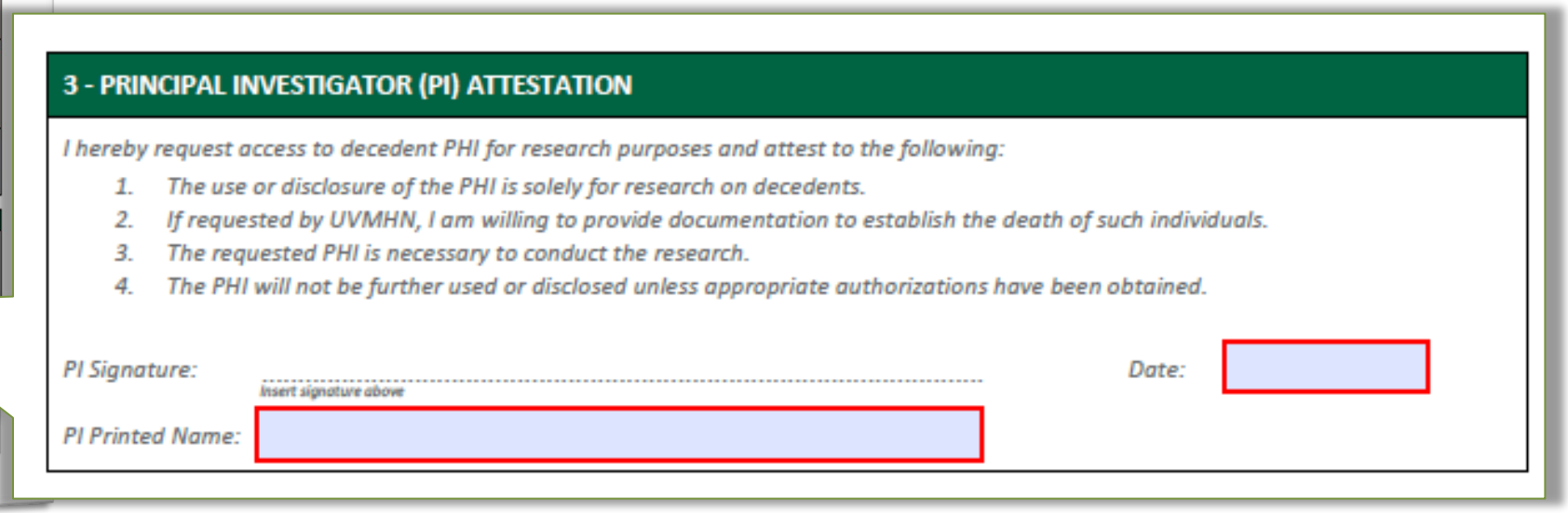
Researcher must submit attestation confirming:

- The use or disclosure sought is solely for research on the protected health information of decedents;
- Documentation, if requested by the covered entity, of the death of such individuals is provided; and
- The protected health information for which use or disclosure is sought is necessary for the research purposes.

Source: eCFR :: 45 CFR 164.512 – Research on decedent's information. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512

Research Using Decedent Protected Health Information





The purpose of the form is to:

- ❑ Collect general study & contact information
- ❑ Provide a description of the use or disclosure of PHI
- ❑ Ensure this decedent research is compliant with HIPAA and will not be further disclosed without appropriate authorization as attested to by the Principal Investigator

Patient's Right to Accounting of Disclosures

Accounting of Disclosures of Protected Health Information (PHI)

Patients are entitled to an "accounting of disclosures" of their PHI that UVMHN has made for the past 6 years, except for disclosures made for the following reasons:

- Treatment, payment and operations
- Pursuant to an authorization
- To the patient themselves
- For the facility directory or individuals involved in patient care
- Incidental to otherwise permitted uses or disclosures
- Made in a limited data set
- For national security or intelligence

Source: eCFR :: 45 CFR 164.528 -- Accounting of disclosures of protected health information. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.528

When do we have to account for research disclosures

- When information about 50 or more patients is disclosed

Either pursuant to:

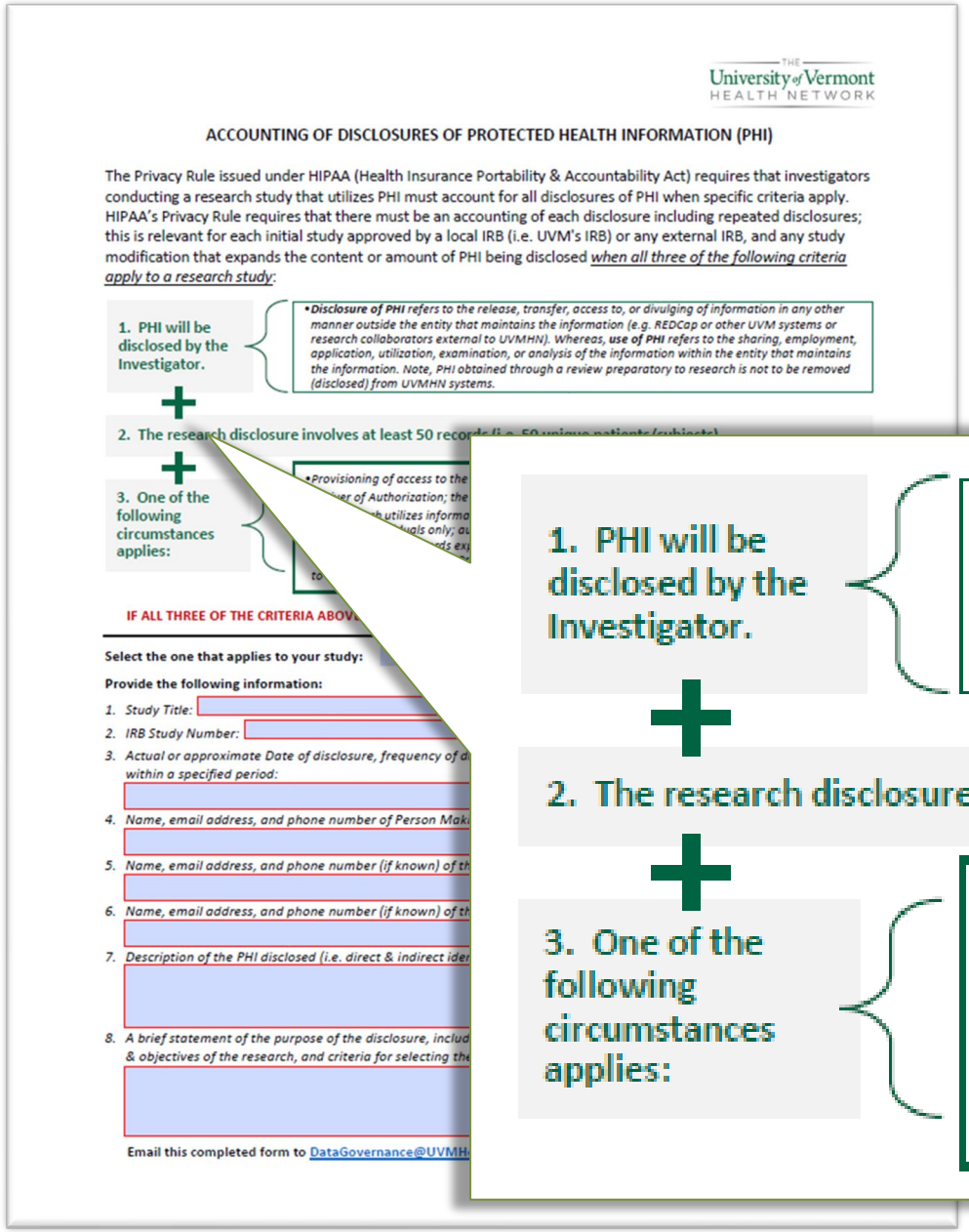
(1) a waiver of HIPAA authorization issued by IRB/Privacy Board, or

(2) research on PHI belonging to decedents (when data leave UVMHN)

What do we have to include in the accounting?

- Name of the protocol or other research activity
- Plain language description of the activity, including purpose of the research and the criteria for selecting the records
- Brief description of the PHI that was disclosed
- Date or time frame when the disclosures occurred (including date of last disclosure)
- Name, address and phone number sponsoring entity and researcher received the PHI
- Statement that PHI may or may not have been disclosed for a particular protocol or other activity

Accounting of Disclosures Qualifying Criteria



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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 approved by a local IRB (i.e. UVM's IRB) or any external IRB, 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 the research requires records explicitly from deceased individuals, also complete and email the 'Research Using Decedent Protected Health Information' form to DataGovernance@UVMHealth.org to ensure compliance with HIPAA & UVMHN policy.*

IF ALL THREE OF THE CRITERIA ABOV

Select the one that applies to your study:

Provide the following information:

1. Study Title:
2. IRB Study Number:
3. Actual or approximate Date of disclosure, frequency of d within a specified period:
4. Name, email address, and phone number of Person Maki
5. Name, email address, and phone number (if known) of th
6. Name, email address, and phone number (if known) of th
7. Description of the PHI disclosed (i.e. direct & indirect ide
8. A brief statement of the purpose of the disclosure, includ & objectives of the research, and criteria for selecting the

Email this completed form to DataGovernance@UVMH

Accounting is required when:

- ❑ PHI will be disclosed
- ❑ At least 50 unique patients/subjects in cohort
- ❑ Access approved via a HIPAA Waiver of Authorization, **or** is decedent research

How to Comply with These Requirements and Complete and Submit Needed Forms

Accessing PHI Preparatory to Research

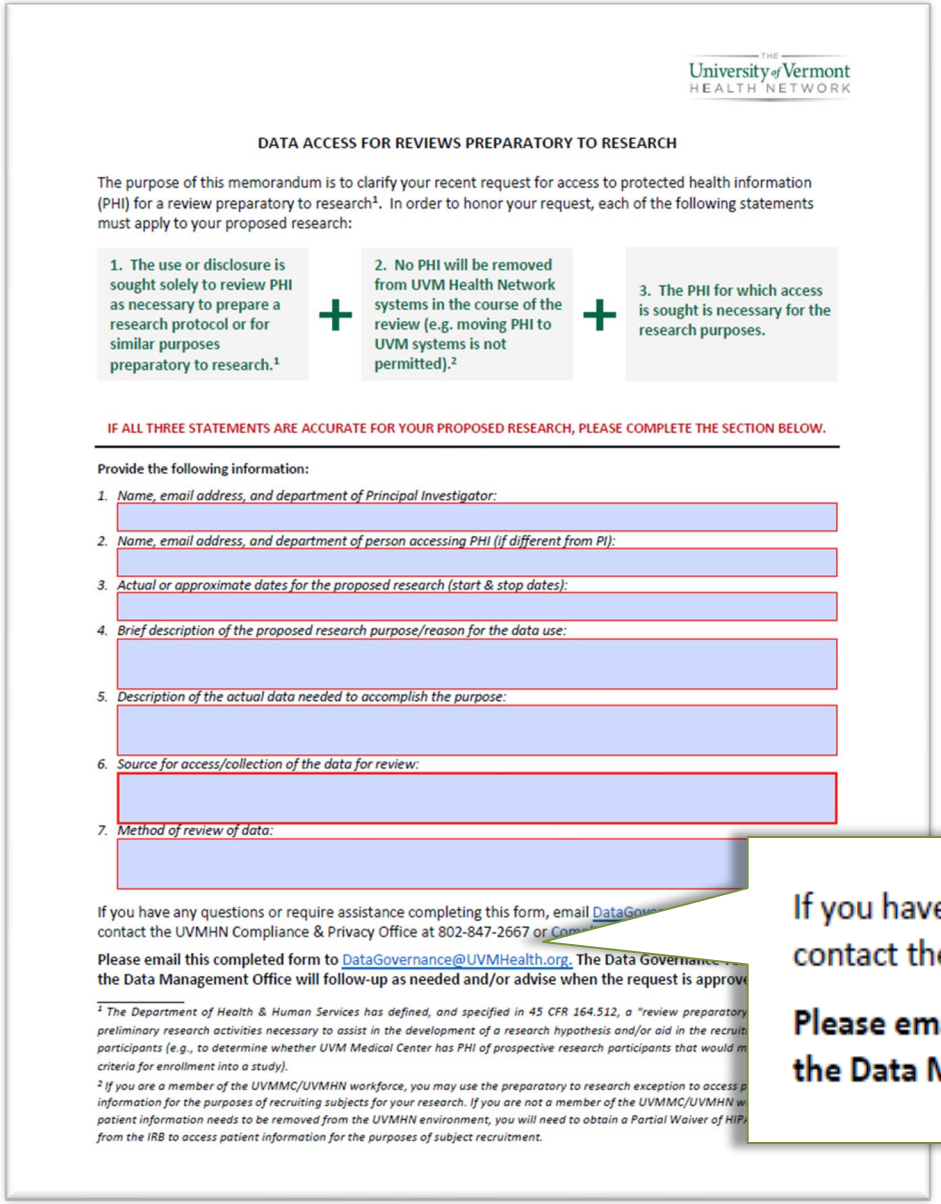
Conducting Research on Decedents

Accounting for Disclosures of PHI

Examples of When I Might Need a Preparatory to Research Form?

- When you need patient information to design a study, for example:
  - To determine the sample size of a cohort of patients who meet study eligibility criteria
  - Other inquires to help assess the feasibility of a study design:
    - Is the data required to meet the study objectives reliably documented in the patient's charts?
    - Is the data from the study cohort available for the planned data collection periods?
- When you are using patient information to recruit patients who don't have a pre-existing treating relationship with the PI/practice
  - Reviewing surgery schedules, ED lists to identify potential subjects
  - Recruiting patients from other clinics
- When you don't have another HIPAA path (authorization, waiver of HIPAA authorization, treating relationship with the patient), **AND** when the data will not be disclosed

Submission of the Reviews Preparatory to Research Form



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[2] *If you are a member of the UVMMC/UVMHN workforce, you may use the preparatory to research exception to access p… information for the purposes of recruiting subjects for your research. If you are not a member of the UVMMC/UVMHN w… patient information needs to be removed from the UVMHN environment, you will need to obtain a Partial Waiver of HIP… from the IRB to access patient information for the purposes of subject recruitment.*

- ❑ The Preparatory to Research form can be found on the UVM IRB website on the 'Forms' page: UVMHN Reviews Preparatory to Research.
- ❑ The process of submission for this form is independent of the UVM IRB and is submitted to **UVMHN Data Governance** for review & approval.
- ❑ UVMHN Data Governance will confirm receipt and verify via email that the request is approved; the date of this email is the verified start date for all activities preparatory to research – be sure to consider sufficient time for processing in your study planning!

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.

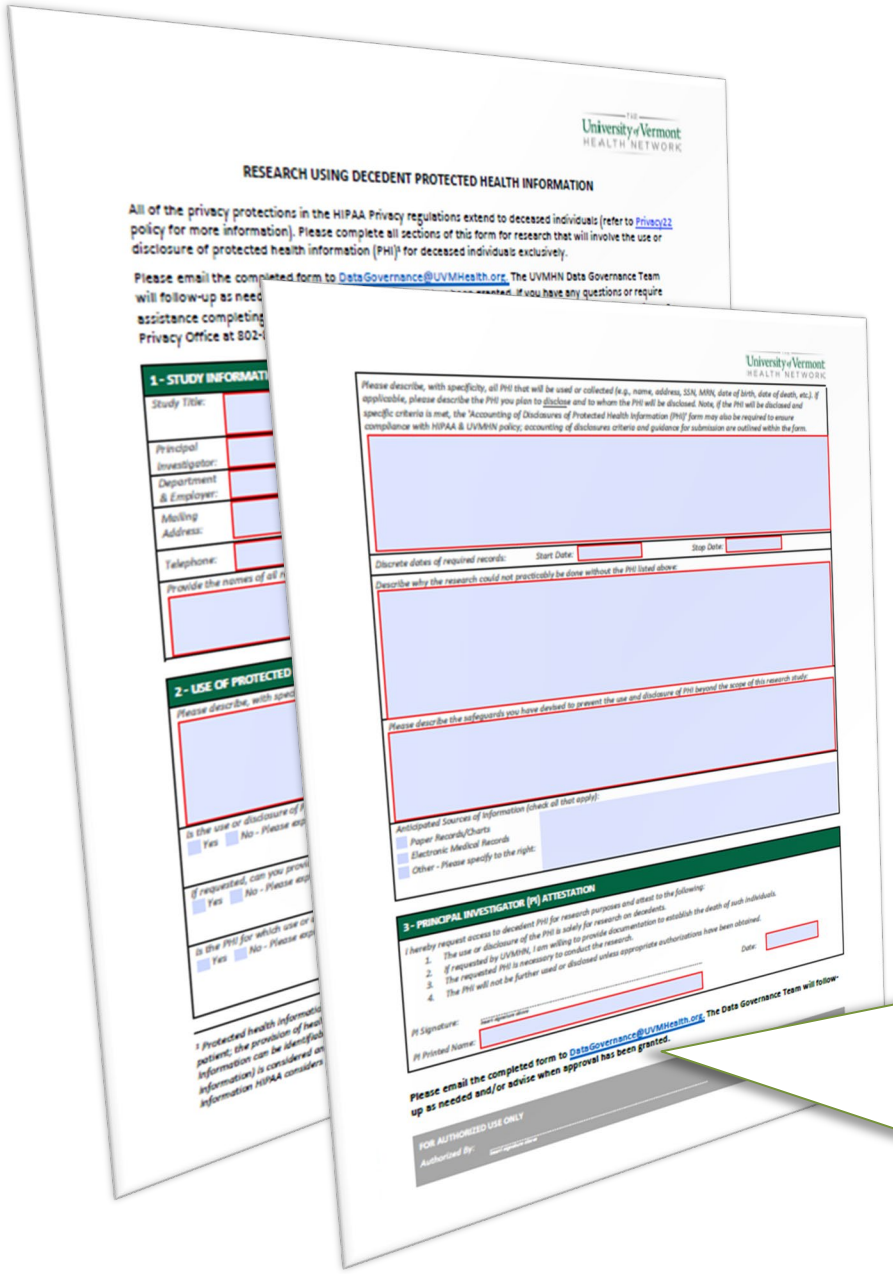
Please email this completed form to DataGovernance@UVMHealth.org. The Data Governance Team within the Data Management Office will follow-up as needed and/or advise when the request is approved.

Examples of When I Might Need a Decedent Research Form?

Anytime all the subjects in your study are deceased!

- A study that is chart review of 25 patients who died of COVID
- A study reviewing records for patients who died of congestive heart failure

Submission of the Research Using Decedent PHI Form



- ❑ The required form can be found on the UVM IRB website on the 'Forms' page: UVMHN Research Using Decedent PHI.
- ❑ Provide sufficient to describe all study activities as requested; may require additional detail/clarification before approval can be granted by **HN Data Governance Team.**
- ❑ HN Data Governance will provide an approved, signed version of the form; the date of this final authorization is the approved start date for all research activities – be sure to consider sufficient time for processing in your study planning!
- ❑ NOTE, if data will be disclosed you may be required to account for the disclosure!

3 - PRINCIPAL INVESTIGATOR (PI) ATTESTATION

I hereby request access to decedent PHI for research purposes and attest to the following:

1. *The use or disclosure of the PHI is solely for research on decedents.*
2. *If requested by UVMHN, I am willing to provide documentation to establish the death of such individuals.*
3. *The requested PHI is necessary to conduct the research.*
4. *The PHI will not be further used or disclosed unless appropriate authorizations have been obtained.*

PI Signature: ..... *Date:*

Insert signature above

PI Printed Name:

Please email the completed form to DataGovernance@UVMHealth.org. The Data Governance Team will follow-up as needed and/or advise when approval has been granted.

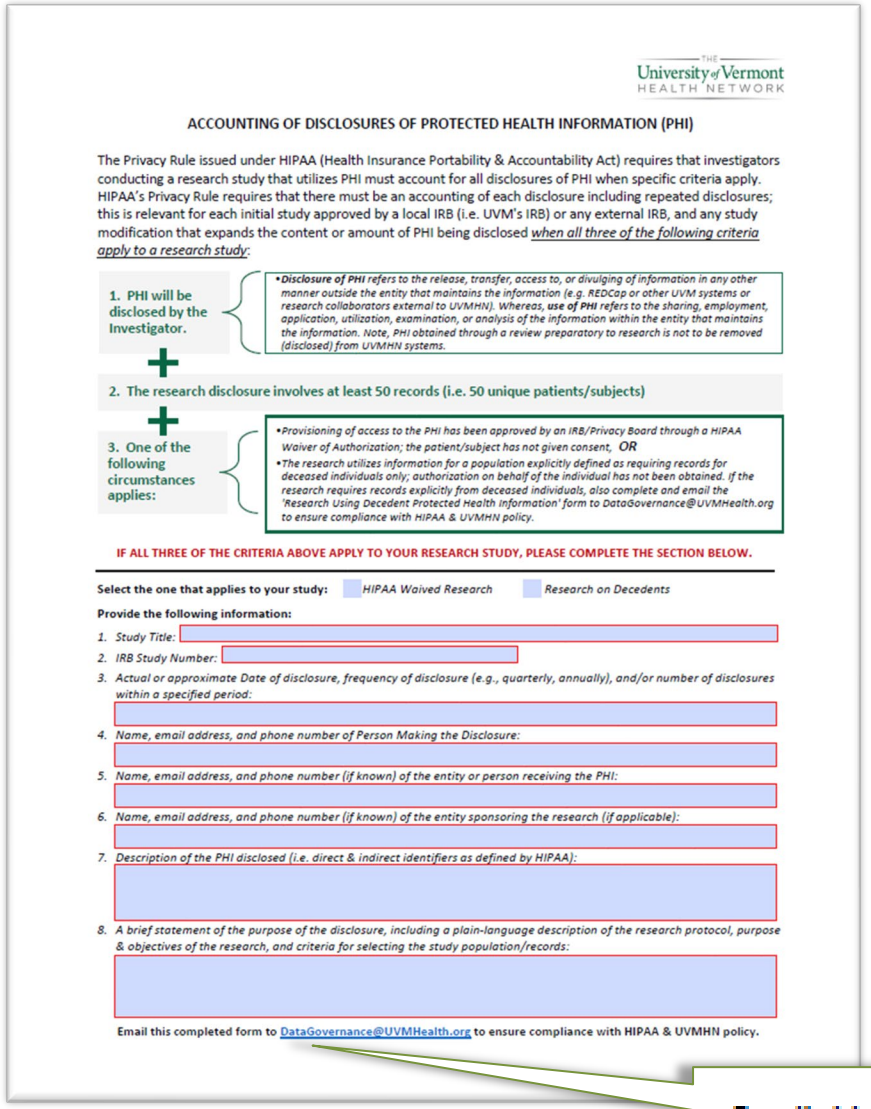
FOR AUTHORIZED USE ONLY

Authorized By: ..... *Date:*

Insert signature above

When do I need an Accounting of Disclosures Form

- When you receive patient information (for 50+ patients) for chart review via a waiver of HIPAA authorization (not patient consent) and store data with direct identifiers on REDCap
- When you are collaborating with researchers at another university and need to send patient information (with direct identifiers) (for 50+ patients) to the other university for the research
- Anytime direct identifiers for 50+ patients are leaving UVMHN for research and you don't have patient consent (e.g., when you have a waiver of HIPAA authorization or are conducting research on decedents)



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+

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 the research requires records explicitly from deceased individuals, also complete and email the 'Research Using Decedent Protected Health Information' form to DataGovernance@UVMHealth.org to ensure compliance with HIPAA & UVMHN policy.*

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 receiving the PHI:*
6. *Name, email address, and phone number (if known) of the entity sponsoring 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:*

Email this completed form to DataGovernance@UVMHealth.org to ensure compliance with HIPAA & UVMHN policy.

Submission of the Accounting of Disclosures of PHI Form

- ❑ Required information:
  - General study details
  - Person disclosing & receiving the PHI
  - Purpose for disclosure & description of PHI to be disclosed
- ❑ The form can be found on the UVM IRB website on the 'Forms' page: UVMHN Accounting of Disclosures of PHI.
- ❑ The process of submission for this form is independent of the UVM IRB and is submitted to **UVM HN Data Governance** for review & approval.
- ❑ HN Data Governance will confirm receipt and verify that the request is approved via email; no additional steps are required.
- ❑ NOTE, when the population is explicitly defined as requiring records from deceased individuals, the 'UVMHN Research Using Decedent PHI' form is required!

Email this completed form to DataGovernance@UVMHealth.org to ensure compliance with HIPAA & UVMHN policy.

Definitions

Covered Entity

Health plans, health care clearing houses, and health care providers who transmit electronic health information. A covered entity that complies with HIPAA must protect the privacy & security of health information.

HIPAA Privacy Rule

The HIPAA Privacy Rule for the conduct of research (45 CFR 164.501) establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.

De-Identified Health Information

Health information that has been stripped of all 18 identifiers, related to the patient and the patient's relatives, employers, and household members, as defined by HIPAA, the releasing entity has no actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information. Data sets may also be de-identified within the meaning of HIPAA using an "expert determination".

Indirect Identifiers

An identifier that does not link to one specific person but can be used in combination with other information to identify a person (e.g., dates including dates of birth, dates of death, zip codes, cities, counties).

Direct identifiers

An identifier that links to one specific person, can be used by itself to identify the person (e.g., name, social security number, medical record number, medical device number, email address).

Protected Health Information (PHI)

Individually identifiable health information, regardless of format, that is collected by a covered entity and relates to the past, present, or future physical or mental condition of a patient, the provision of healthcare or past, present, or future payment for the provision of healthcare, or any other information that could be used to identify the patient or members of the patient's family, employer and others who live in the patient's household.

Disclosure of PHI

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, research collaborators external to UVMHN).

Use of PHI

Use of PHI refers to sharing, employment, application, utilization, examination, or analysis of the information within the entity that maintains the information.

Resources

- UVM Research Protections Office: Melanie.Locher@UVM.edu
- Institutional Review Board: Human Subjects Research: https://www.uvm.edu/rpo/institutional-review-board-human-subjects-research
- UVM Research Protections Office, UVMClick IRB Forms Library: https://www.uvm.edu/rpo/uvmclick-irb-forms-library > scroll to 'UVM Health Network Documents and Resources'
- UVM Health Network Data Governance Team: DataGovernance@uvmhealth.org
- UVM Health Network Compliance and Privacy Office: Compliance@uvmhealth.org