

# - INSTRUCTIONS -

## Authorization Cover Form

### Header Information:

**CHRMS #:** You may or may not know the assigned number. Leave it blank if not known.

**Principal Investigator:** The name of the local Principal Investigator.

**Protocol/Project Title:** The title should reflect the title on the research protocol.

### Covered Entities:

A covered entity is a health plan, health care clearinghouse, or healthcare provider that transmits any health care information to carry out financial or administrative activities related to health care.

Fletcher Allen Health Care (FAHC) is a covered entity.

The University of Vermont is classified as a hybrid entity as some of its units, for example Student Health Services, are viewed as a covered entity (which is termed a “covered health care component”).

If you are collaborating with other covered entities and disclosing our local subjects’ PHI, those covered entities should be listed here as well as in your authorization.

### 1. Protected Health Information:

#### **A. Indicate what protected health information will be collected or used:**

Individually identifiable information received from a covered entity is referred to as protected health information or PHI. Check all sources of PHI here.

#### **B. Indicate how the research team will receive health information:**

**With identifiers:** The researcher needs access to PHI from the covered entity.

**With limited identifiers:** The research is mostly anonymous and only records such PHI as ZIP codes, geocodes, and dates. This would be considered a Limited Data Set. Researchers who wish access to a Limited Data Set must contact FAHC to execute a Data Use Agreement. FAHC will assist the researcher to identify a data custodian. The data custodian must be an agent of the covered entity (FAHC or other applicable covered entity) and independent of the research project. The data custodian creates the Limited Data Set before releasing to the researcher. The FAHC Privacy Officer should have a copy of the Data Use Agreement prior to release of the Limited Data Set to the researcher. Note: While the IRB needs to be aware of this information it does not assist in initiation of a limited data set nor execute the data use agreement. This occurs at the covered entity.

**Without any identifiers:** Researchers who wish access to de-identified PHI must contact the appropriate data custodian(s) (i.e., an individual who is an agent of FAHC and is independent of the research project) to de-identify the requested PHI. If there are no identifiers, as listed above in the dataset required for the research, then the research does not fall under the HIPAA regulations.

**2. PHI Sharing within the covered entity or entities, as listed under #1.**

Indicate here who may use or disclose PHI during the course of the research study.

**3. PHI Sharing outside the covered entity or entities, as listed on the first page.**

Indicate who may receive or use PHI. A few of these are part of the FAHC template and are required in the HIPAA Authorization; they are identified by a checkmark on the form. Check all others that apply.

**4. Principal Investigator's Signature and Date.**

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