

## HIPAA Introduction

The privacy regulations (The Privacy Rule) that have been promulgated by the federal Office of Civil Rights under the Health Insurance Portability and Accountability Act (HIPAA) impact research involving human subjects. These regulations define conditions where certain health information may be used or disclosed in research activities. Further, the regulations define conditions where authorization must be obtained from the patient. The full text of these regulations, is available at [www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa).

While SUNY New Paltz does not have HIPAA covered functions, faculty may wish to conduct research in agencies that are covered entities under HIPAA. In order to facilitate the research process, SUNY New Paltz IRB has designed forms covering multiple functions related to activities regulated by HIPAA.

Forms to be processed through the SUNY New Paltz IRB:

### 1) HIPAA Authorization – Instructions for Preparing Consent Documents for HIPAA Compliance

These forms are used to incorporate authorization for use of individually identifiable health information into informed consent documents. The instructions explain the use of Attachments A – E.

### 2) Application for HIPAA Waiver of Authorization

Refer to Part IV C of the SUNY New Paltz Policy and Procedure on Research Subjects' Right to Privacy for waiver criteria.

### 3) HIPAA De-Identification Certification Form

This form should be completed if all the health information required for use in your research activity is stripped of the subject identifiers listed below. If all of these identifiers are removed prior to use, then your research activity is considered exempt from the requirements of the federal privacy law (HIPAA).

### 4) Limited Data Set (LDS) Request Form

This form must be completed if you are requesting access to a Limited Data Set of health information of covered entity patients for research, public health, or healthcare operations activities. The use of a Limited Data Set of information is applicable if the health information required to carry out these activities excludes the individually identifiable data elements listed below. Note that the LDS differs from de-identified health information in that a LDS may contain a) a unique identifying number, characteristic or code (e.g., a registry or study number), b) elements of dates, and c) address information including town, city, state, zip code (BUT NOT STREET NAME OR ADDRESS).

## Model Forms for Use by Covered Entities

### 1. Model Data Use Agreement

Note: This form is required for processing of your Application for Research Proposal Review if you are using a Limited Data Set.

### 2. Model Request for Permission to Access Identifiable Health Information of Deceased Individuals (HIPAA)

Note: This form is an agreement between the covered entity and the researcher.

### 3. Model Request for Permission to Access Identifiable Health Information for Reviews Preparatory to Research (HIPAA)

Note: This form is an agreement between the covered entity and the researcher.