

If using Protected Health Information (PHI) submit a statement on HIPAA PHI protocol (see below).

Data De-identification: The HIPAA Privacy Rule allows principal investigators to conduct research with health information that has been stripped of elements that could identify the research subject. However, under HIPAA, the list of “**identifiers**” is extensive. The following data elements must be stripped for HIPAA de-identification:

- Names
- Geographic subdivisions smaller than a state (i.e., no city, no zip code), except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census, the geographic unit contains more than 20,000 people
- Any date (except year; i.e., no month or day of month)
- For subjects older than 89 years of age, specific age may not be mentioned
- Telephone number
- Fax number
- E-mail address
- Social security number
- Medical record number
- Health plan beneficiary number
- Any other account numbers
- Certificate or license numbers
- Vehicle identification number
- Medical device identification or serial number
- Personal website URL
- Internet protocol (IP) address
- Fingerprint, voiceprint, or other biometric identifiers
- Full-face photographic images
- Any other unique identifying number, characteristic, or code

Principal investigators who wish to collect data that involve personal identifiers must go through the covered entity’s HIPAA rules to obtain data, including Authorizations, Waiver of Authorization, Data De-identification or Limited Data Sets. Please consult with each research site and include the necessary forms and/or permissions required with your SVSU IRB application.

Authorization: If the principal investigator will be using or collecting health information and personal identifiers from his or her research subjects, then he or she will be obtaining informed consent from them as well. An authorization form is required in addition to informed consent.

Waiver of Authorization: Principal Investigators may apply for a full waiver of authorization when a signed authorization cannot be reasonably obtained, such as for emergency medical records research, or when the principal investigator (PI) of the research study has legitimate access to the desired medical information insofar as he or she is a staff member and/or has been granted privileges and provides related care (i.e., related to the information desired) to the patients, or is in the position to provide related care (including treatment, and/or diagnostic services) to the patients.