HIPAA Research Policy No. 6: Guidance on Research at Non-NSU Entities

1. Overview:

The purpose of this policy is to address which entity’s policies and forms should be followed or utilized when research is conducted at Non-NSU entities, i.e., outside entities. Questions regarding this policy should be directed to the NSU Privacy Officer.

2. Definitions:

For purposes of this policy, the following terms shall have the following meanings:

**Covered Entity:** A covered entity includes a health plan, a healthcare clearinghouse or a health care provider who submits standard transactions (such as claims submission) electronically.

Health care providers are covered entities if they submit bills electronically to insurance or other payors.

If there is any question as to whether an entity is a “Covered Entity”, the Non-NSU entity should be asked to make that determination.

Regardless of whether a Non-NSU entity is covered or non-covered, the Non-NSU entity should always be informed of and approve of any research activities that will be taking place at the entity or with the entity’s protected health information.

**Non-Covered Entity:** For purposes of this policy, the term “non-covered entity” refers to an entity that is not considered a “Covered Entity” pursuant to the definition set forth above.

3. Research at a Non-NSU Non-Covered Entity:

**Non-NSU Non-Covered Entity:** A Non-NSU Non-Covered Entity is an entity that is not a part of or affiliated with NSU and is not a covered entity per the above referenced definition. Examples of Non-NSU Non-Covered entities include: health care clinics that accept payment on a cash-only basis or accept no payment; free clinics that are not operated by a covered entity; health fairs that are not operated by a covered entity; churches, homeless shelters or other civic organizations.
A. Research by NSU Students Who are Doing a Rotation and Conducting Research at a Non-NSU Non-Covered Entity:

The Non-NSU Non-Covered Entity may require certain forms or procedures. The NSU HIPAA Research Authorization and policies are not necessary.

B. Research by NSU Faculty Members Who are Conducting Research at an Non-NSU Non-Covered Entity:

The Non-NSU Non-Covered Entity may require certain forms or procedures. The NSU HIPAA Research Authorization and policies are not necessary.

4. Research at a Non-NSU Covered Entity:

**Non-NSU Covered Entity:** For purposes of this policy, the term “Non-NSU Covered Entity” shall include a health care entity that is a HIPAA covered entity, but is not part of NSU. Examples of Non-NSU Covered Entities may include: physician offices, hospitals, clinics, etc. that are outside of the NSU system.

A. NSU Students Rotating and Conducting Research at a Non-NSU Covered Entity

If PHI is created, accessed or collected at a Non-NSU Covered Entity, the Non-NSU Covered Entity’s policies should always be followed and the Non-NSU Covered Entity’s forms should always be utilized. NSU forms should not be used when information is being gathered or accessed at a Non-NSU Covered Entity. If the entity does not have forms specific to research, the Non-NSU Covered Entity should be asked to modify its existing authorization form or draft a new authorization form to authorize NSU researchers and NSU in general to use and/or disclose the protected health information.

B. NSU Faculty/Researchers Conducting Research at a Non-NSU Covered Entity

If PHI is created, accessed or collected at a Non-NSU Covered Entity, the Non-NSU Covered Entity’s policies should always be followed and the Non-NSU Covered Entity’s forms should always be utilized. NSU forms should not be used when information is being gathered or accessed at a Non-NSU Covered entity. If the entity does not have forms specific to research, the Non-NSU Covered Entity should be asked to modify its existing authorization form or draft a new authorization form to authorize NSU researchers and NSU in general to use and/or disclose the protected health information.