

INSTRUCTIONS FOR PREPARING
THE AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED
HEALTH INFORMATION IN RESEARCH FORM

IMPORTANT: Do not include these instructions as part of the completed Authorization form.

To Prepare the Form:

1. General Preparation Instructions:
 - Fill in the blanks on the Authorization for Use and Disclosure of Protected Health Information in Research Form (“Authorization Form”) as appropriate
 - **Delete all bold instructions in brackets – they are only for your guidance**
 - Delete any inapplicable bulleted sections as appropriate (as set forth in these instructions)
 - The Authorization Form only needs to be prepared once per Study.
 - An identical Authorization Form (except for Participant Name) will be used for all Participants enrolled in the Study.

1. Section I: Specify the Sponsor of the Study, Title of the Study, the Study/Protocol number, and PI name. The name of the Participant will be added at the time the Authorization Form is signed.

2. General Information: Determine whether the study is blind or non-blind. Check the appropriate box regarding participant access to health information, as indicated.

3. Section II, A: (*Note: categories of information must be indicated for use or disclosure*)
 - Check the appropriate box to designate the covered health care component of NSU or other specified entity.
 - Check the applicable types of health information which may be used and/or disclosed; add any additional information which may be obtained for use and/or disclosure.

4. Section II, C: (*Note: if a class of person(s) or organization is not listed on the form, it may not create, disclose, receive or use Protected Health Information (“PHI”) in connection with the study.*)
 - Delete the classes of people or organizations that will not be provided PHI in connection with the Study.
 - Insert those people or organizations not covered in the listing who/which may be provided PHI in connection with the Study.
 - If information will not be disclosed outside of Nova Southeastern University, delete all bullets and insert “None”.

To Present the Form:

1. The Authorization must be presented to all newly enrolled or “re-consented” subjects in IRB-approved research at the time the IRB-approved consent form is signed. The participant or his/her legally authorized representative must be provided with a copy of the Authorization Form after it has been signed. The original, signed copy must be retained in the research file for a period of six years from the date the Authorization Form was signed (or longer, according to NSU/Sponsor requirements). Prior IRB approval of the Authorization Form is not required; however, audits of the Authorization may be conducted to ensure completeness.

2. “Notice of Privacy Practices”

- a. Each participant who receives health care services at NSU should receive a copy of a NSU HIPAA Notice of Privacy Practices (NPP) and sign a NSU Acknowledgement of Receipt of HIPAA Notice of Privacy Practices (NPP Acknowledgement form) that he/she received the NPP.
- b. If the research involves the use of health and/or medical records from NSU and the subject has not received a copy of NSU’s NPP, please provide the subject with a copy of the NPP. The subject should sign a copy of NSU’s NPP Acknowledgement form. The original, signed copy of the NPP Acknowledgement form must be retained in the research file for a period of six years from the date the NPP Acknowledgement was signed (or longer, according to NSU/Sponsor requirements).
- c. If the research involves the use of health records at a non-NSU facility(s), please contact the applicable health center, school, clinic or practice group to obtain a copy of the non-NSU facility’s authorization form for release of protected health information, obtain necessary signatures from the patient, and return to the non-NSU facility. In the alternative, the patient may supply requested copies of medical records by contacting the non-NSU facility and completing any required authorizations for release or protected health information forms. If NSU assists the patient with the process of obtaining the authorization from the non-NSU facility, a copy of the signed authorization for release for protected health information should be retained in the research file for a period of six years from the date of signature (or longer, according to NSU/Sponsor requirements).