

INSTRUCTIONS FOR PREPARING RESEARCH AUTHORIZATION FORM

The Health Insurance and Portability and Accountability Act of 1996 and implementing regulations ("HIPAA") requires that each subject in an interventional clinical research study must sign a completed Research Authorization form. Attached is the Research Authorization form for use at **New York Eye And Ear Infirmary**. This form authorizes the use and disclosure of the subject's protected health information which includes all of the types of information listed on the attached sheet. Permissible uses of protected health information are limited to those listed in the Research authorization form. It is the responsibility of the Principal Investigator to ensure that the Research Authorization form covers all of the uses and disclosures necessary for the research study. The Principal Investigator must complete the form and submit it to the IRB along with the protocol and informed consent for the study for approval. After approval, the Principal Investigator must have each subject or his or her personal representative sign the form and a copy of the form must be kept on file for six years. The subject or his or her personal representative must be given a copy of the form after it has been signed.

Under the heading "Who will disclose, receive, and/or use the information?" on page one of the Research Authorization form, Part A lists persons and entities that are likely to disclose, receive and or use the protected health information in all research studies at the Hospital Center. The Principal Investigator must fill in the blanks, identifying the principal investigator, the study coordinator, and all of the members of the research team. In Part B, the Principal Investigator should put a check in the box in front of all of the listed persons and entities that will disclose, receive and/or use the protected health information from the study and should fill in the blanks to identify the research sponsor and/or the contract research organization, if applicable. Please use the "Other" category for any person or entity not listed on the form that will receive, disclose and/or use information from the study.

Under the heading "What information will be used or disclosed?", the Principal Investigator must check the appropriate box(es) identifying the information to be used or disclosed. The box in front of "HIV-related information..." should be checked if such information will be received used or disclosed even if the first box (indicating the entire medical record) has been checked.

This is a separate document and pages should be numbered as such

If you have any questions, please contact Robert Jordan at 212-979-4447