EAST CAROLINA UNIVERSITY ACCOUNTING OF DISCLOSURES FOR RESEARCH INVOLVING 50 OR MORE INDIVIDUALS

Researchers who are accessing ECU medical records must account for any uses or disclosures of protected health information (PHI)¹ in the course of a research project when:

- (i) individual authorization has been waived (waiver of authorization granted by UMCIRB);
- (ii) access is preparatory to research; or
- (iii) the research involves the use of PHI of decedents.

Please complete the following information as it relates to all known uses or disclosures of ECU PHI for any of the reasons stated above.

- 1) Name, address and telephone number of the Principal Investigator:
- 2) Name of protocol/IRB#:
- 3) Timeframe during which the uses or disclosures occurred:
- 4) Plain English description of the protocol, including the purpose of the study and type of PHI used or disclosed²:
- 5) Name, address, and telephone number of the entity that sponsored the research:

¹ PHI is defined as any information (including demographic information) that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. In order for PHI to be "de-identified" all of the following must be removed: Name, all geographic subdivisions smaller than a state; all elements of dates (except year) for dates directly related to an individual, including date of birth, admission date, discharge date, date of death and all ages over 89 (except that ages over 89 may be aggregated into a simple category of age 90 or older); telephone numbers, fax numbers, e-mail addresses, social security numbers; medical record numbers, health plan beneficiary numbers; account numbers; license numbers; vehicle identifiers and serial numbers, URLs; IP address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images.

² The PHI of an individual may or may not have been disclosed for this particular protocol or research activity.

ECU ACCOUNTING OF DISCLOSURES LOG

FOR RESEARCH INVOLVING 50 OR MORE INDIVIDUALS

Name of Principal Investigator:	-
Name of Protocol/IRB #:	

Name of Individual	DOB	MRN	Description of PHI Accessed	Date PHI Accessed	Researcher who accessed PHI

Note: You must account for the following disclosures when conducting research:

- 1. If you have obtained a waiver for authorization from UMCIRB
- 2. Disclosures preparatory to research efforts
- 3. Research when using decedent information

Please maintain a copy of this document in your files also for six years following the completion of this document as required by the HIPAA privacy regulations.