Request for Review of PHI Preparatory to Human Research for Feasibility	Effective Date	7/16/2019
	Revisions Date	

1.0 Purpose: The purpose of this standard operating practice (SOP) is to provide guidance for requirements regarding preparatory work to determine feasibility of suggested research to be conducted at East Carolina University (ECU). This SOP describes the steps for using protected health information (PHI) to assess the feasibility of conducting a human research study at ECU in reference to determining if ECU has the patient population required that would meet eligibility criteria. This SOP describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within ECU's research network.

2.0 Persons Affected:

2.1 Principal investigators (PI) and research team members
2.2 University and Medical Center Institutional Review Board (UMCIRB) staff members
2.3 Privacy Board/UMCIRB members

3.0 SOP: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations allow an individual to review PHI to determine if they have the patient population to support and develop a specific type of human research protocol. The PHI can also be reviewed to determine if a site has enough of a particular type of patient population to participate. The privacy rules under HIPAA allow for disclosure of PHI in preparation for research activities without a HIPAA authorization, provided the principal investigator agrees to the representations set forth below. Activities for which PHI may be obtained in preparation for research involve (i) development of research questions; (ii) identification of study feasibility (i.e. available number and eligibility of potential research participants); (iii) development of eligibility (i.e. inclusion/exclusion) criteria; and (iv) eligibility of potential individual research participants.

4.0 Definitions:

4.1 Feasibility: An analysis and evaluation of a proposed project to determine the state or degree of being easily or conveniently completed.
4.2 Electronic Health Record (**EHR**): A digital version of a patient's paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users.
4.3 Patient: A person receiving or registered to receive medical treatment.
4.4 Preparatory: Serving as or carrying out preparation for a task or undertaking.
4.5 Protected Health Information (PHI): PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act (FERPA), as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
4.6 Accounting of disclosures: Information that describes a covered entity's disclosures

of PHI other than for treatment, payment, and health care operations; disclosures made with authorization; and other limited disclosures. For those categories of disclosures that need to be in the accounting, the accounting must include disclosures that have occurred during the six years (or a shorter time period at the request of the individual) prior to the date of the request for an accounting. However, PHI disclosures made before the compliance date for a covered entity are not part of the accounting requirement.

4.7 Minimum Necessary: Refers to the requirement that the access and release of PHI be limited to the least amount necessary to accomplish the intended purpose of the request.

5.0 Responsibilities:

5.1 Investigators/study staff/departments have the following responsibilities:

- **5.1.1** If accessing the medical record is required in order to make a determination on feasibility for a potential research study, the individual(s) requesting the data has two options:
  - **5.1.1.1** Request his or her department to run a de-identified data report based on criteria points, or
  - **5.1.1.2** Submit a Request for Preparatory to Research form completed and signed by the PI to Sandy Matos (matoss@ecu.edu) at the UMCIRB office via email for approval to complete these chart reviews.
- **5.1.2** The individual(s) making the request must agree to the following:
  - **5.1.2.1** The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.
  - **5.1.2.2** The PHI will not be removed from East Carolina University/Brody School of Medicine in the course of the review.
  - **5.1.2.3** The PHI for which use or access is requested is limited to the minimum necessary for purposes of the preparatory activities.
  - **5.1.2.4** Accounting of disclosures will be required to be completed by the investigator when entering the EHR of the patient upon approval.
  - **5.1.2.5** Patients (or their representatives) will not be contacted about the proposed study nor will the study team conduct any research until a related human subjects research study submission has been submitted and approved by the UMCIRB.
- **5.1.3** No PHI or data can be abstracted from the EHR if chart reviews are necessary. This is a view only review merely to determine population that fit eligibility criteria.

5.2 UMCIRB staff have the following responsibilities:

- **5.2.1** Review applications for accuracy and completeness, sign and date once approved and provide a copy to the requestor.
- **5.2.2** Keep a record of request forms on file.

Revision History:

Date	Change	Reference Section(s)

References:

National Institutes of Health
https://privacyruleandresearch.nih.gov/dictionary.asp

US Department of Health and Human Services
https://www.hhs.gov/

Office of Research Integrity and Compliance
https://rede.ecu.edu/hipaacompliance/