## Request for Review of Protected Health Information (PHI) in

## Preparation for Research

Please complete this form in the event you would like to access or use protected health information in preparation for research (see below for further information). **Please email** a copy of this form with original signature the following individual below **IF THIS IS FOR FEASIBILITY REVIEW ONLY AND YOU HAVE NOT SUBMITTED A STUDY TO THE IRB otherwise you would upload this form into ePIRATE in your study submission**:

*(You may choose one or both options, as applicable)*

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| --- | --- |
| [ ]  **Requesting ECU Health Medical Records*****Please send completed form to:***ECU Health Center for Research and Grantscrg.data@ecuhealth.org | [ ]  **Requesting ECU Medical Records*****Please send completed form to:***HIPAA Research Analyst, IRB Officematoss@ecu.edu |

**PLEASE COMPLETE THE FOLLOWING INFORMATION:**

Principal Investigator (PI) Name:

UMCIRB# (if applicable):

Employed by ECU or ECU Health?

PI Department:

PI Phone number:

PI Email:

The privacy rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) allow for disclosure of protected health information (PHI) in preparation for research activities without an 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 (e.g. available number and eligibility of potential research participants); (iii) development of eligibility (inclusion/exclusion) criteria; and (iv) eligibility of potential individual research participants.

It is very important to maintain accurate records of every individual whose PHI was accessed for purposes of reviews preparatory to research. In general, ECU and ECU Health are required to maintain an accurate record of each use of or access to a patient’s PHI for purposes other than treatment, payment, or health care operations and for which there was no prior written authorization from the individual. ***During your review of medical records, you must provide each institution with the list of individuals whose records were accessed as part of your review preparatory to research by completing accounting of disclosures electronically within the EHR.***

**Please Answer the Following:**

(1) Provide a brief description of your anticipated research project:

(2) Provide a brief description of the PHI that will be reviewed. (It should be limited to the “minimum necessary” to accomplish your review.):

(3) Provide a brief description as to how this PHI will be used or disclosed in preparation for the research project listed above:

**Statement of the Principal Investigator:**

**I certify that:**

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 as listed above;
2. The PHI will not be removed from the ECU or ECU Health entity in the course of the review;
3. The PHI for which use or access is requested is necessary for purposes of the research; and
4. A comprehensive listing of individuals whose PHI was accessed as part of this review shall be provided to relevant ECU or ECU Health officials as described above through completing electronic accounting of disclosures within the EHR.

Researchers should note that any preparatory research activities involving human subjects research as defined by the HHS Protection of Human Subjects Regulations, which are not otherwise exempt, must be reviewed and approved by an IRB and must satisfy the informed consent requirements of HHS regulations.

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*Signature of Principal Investigator Date*

***Protected Health Information (PHI) consists of 18 patient identifiers****-* ***1)*** *names* ***2)*** *all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code* ***3)*** *all elements of dates (except year) for dates directly related to an individual, including birthdate, admission date, discharge date, date of death and all ages over 89* ***4)*** *telephone numbers* ***5)*** *fax numbers* ***6)*** *electronic mail address* ***7)*** *social security numbers* ***8)*** *medical record numbers* ***9)*** *health plan beneficiary numbers* ***10)*** *account numbers* ***11)*** *certificate/license numbers* ***12)*** *vehicle identifiers and serial numbers, including license plate numbers* ***13)*** *device identifiers and serial numbers* ***14)*** *web universal resource locators (URLs)* ***15)*** *internet protocol (IP) address numbers* ***16)*** *biometric identifiers, including finger and voice prints* ***17)*** *full face photographic images and any comparable images; and* ***18)*** *any other unique identifying number, characteristic, or code*

This form must be completed before accessing Protected Health Information (PHI) for reviews preparatory to research.

The custodian of records must keep this form for a period of 6 years.