

University and Medical Center Institutional Review Board
Application for Alteration of Authorization for Recruiting
(For use by Research Team Members Who Are Not Health Care Component
Workforce Members from which the PHI is accessed.)

1. Select the records containing Protected Health Information (PHI) to be used for recruiting purposes:

- Billing records
Mental Health records
Physician/clinic records
Clinic schedule
Hospital census
Hospital/medical records (in and out patient)
Lab, pathology and/or radiology results
PHI previously collected for research purposes
Other:

2. Select all the identifiers (PHI) to be used or collected for recruiting purposes in the research study:

- Postal address
Account /medical record number
Certificate/license number
Name of relatives
E-mail address
Any device or vehicle identifiers and serial numbers, including license plate numbers
Date of birth, admission date, discharge date, date of death, all ages over 89 (circle applicable choices)
Any other unique identifying number, characteristic or code:
Health plan numbers
Name/initials
Name of employers
Photographic images
Finger or voice prints
Telephone number
Internet Protocol (IP) address number
Web universal resource locator (URL)
Fax number
Video images

Please note: Pursuant to North Carolina law, social security numbers are not permitted to be collected in reliance on this waiver of authorization. Unless social security numbers are required by law to be collected, the study subject must be given a written disclosure which (i) states that providing social security number is not required; and (ii) describes the purpose for which the social security number will be used. All uses of SSN must be approved by the Identify Theft Protection Committee (ITPC).

3. Select the response below on how participant's PHI is protected against improper use or disclosure:

- Research team members will sign a Confidentiality Agreement.
The information will not be shared outside the research team unless it is stripped of all 18 identifiers.

4. Explain the data management measures to protect the confidentiality of PHI (storage and access) , including (i) safeguards for storage of any identifiers listed as collected in #2 above in paper format; and (ii) safeguards for storage of any identifiers on servers, desktop computers, laptop computers, flash drives or any other portable electronic device, as applicable.

All data will be stored in ECU's redcap or ECU dept of internal medicine pirate drive , approved electronic storage for PHI

5. Data will be stripped of all identifiers upon completion of:

- subject participation
FDA approval
Other (please specify):
data analysis
specimen processing

OR

Identifiers will be retained indefinitely because:

- the study is longitudinal
of federal requirements (specify):
other (specify):

6. Provide any additional explanations on why the use/disclosure of PHI involves no more than minimal risk to participant privacy

The risk involves data breach. We will use secure approved measures for storage of the data. Other than this risk no direct involvement will take place with the participants

7. Explain why the participant's Authorization cannot be attained and, therefore, research cannot be practicably carried out without the Partial Waiver of Authorization.

We are seeking to alter the process of normal signed hipaa authorization. We plan to do a retrospective study of our patients with a full waiver and use the data collected to contact patients who are eligible to be screened for colorectal cancer and contact them via phone to collect why they chose not to be screened through a survey. If they agree to be screened, we will refer them to gastro for an appt. We will have no face to face contact with the participants and only offer options for screening and referrals if they choose this with phone consent. For this reason, obtaining signed hipaa authorization to share their contact info with the Gastro clinic for an appt is not feasible. We are asking to waive the signed consent/hipaa authorization and complete this task verbally over the phone. This project is both a QI and research project for our department. Offering referrals and different options is a service of the QI project while determining why people defer from being screened and if offered other options would improve numbers of follow-up screenings is the research portion of this study.

8. Select the response(s) or explain why research cannot practicably be conducted without the participant's PHI.
- PHI is needed to identify eligibility for the study
- PHI is needed to contact patients/recruit for the study
- Other (specify):

I certify that protected health information will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, or those uses outlined above. I will only collect the information as specified above, and limit access to that information as previously described. I am ensuring that an Accounting of Disclosures form will be completed by the research team for all participants recruited under this partial waiver, including those who decline to participate in the study.

I will destroy the identifiers at the earliest opportunity consistent with the conduct of the research as specified above.



Principal Investigator's signature

09/19/2019.

Date