Form 5

CENTRA HEALTH-- Institutional Review Board

PROTECTED HEALTH INFORMATION: WAIVER OF AUTHORIZATION

Version 5 17MAR2020

Use this form if you need to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects.

Instructions for Submitting

Include with your submission the items indicated in the list on the next page, where applicable.

Submission Instructions

This form is in Word format.

- Click into the highlighted area ( ) requesting an answer and type your answers into the form.
- Save the form.
- Send the application and all other pertinent documentation (ie protocol, informed consent, etc.) electronically as a pdf via email to irb@centrahealth.com.

Address for all Applications and Other Correspondence

irb@centrahealth.com electronically

CENTRA HEALTH Institutional Review Board
PROTECTED HEALTH INFORMATION: WAIVER OF AUTHORIZATION
Version 5 17MAR2020

Centra IRB Received (date):

Action:

Date:
Centra IRB #: IRB of Record: _____

Principal Investigator:

Email address:

Phone number:

Research Staff needing access to protected health information:
(As approved by IRB in Application Section A)

Study Title:

☐ I am requesting access to PHI without authorization for the following reason:

☐ identify potential subjects

☐ use or disclose minimum information during the course of my investigation.

Number of records needed: ☐ ≥ 50 ☐ < 50

The Centra Institutional Review Board (Federal Assurance Number _____ Exp: _____) may waive or alter the requirement to obtain authorization from research subjects in order to use or disclose their protected health information, provided that the investigator justifies, and the IRB agrees, that specific criteria have been met. Please explain how your research study meets the criteria by answering each of the following questions:

1. In this study, how does the use of disclosure of protected health information involve no more than minimal risk to privacy of the subjects?
   _____
   _____
   _____
2. What is your plan to protect identifiable health information from improper use and disclosure?
   _____
   _____
   _____
3. What is your plan to destroy the identifiers? Include how and when.
   _____
   _____
   _____
4. Why is it not practical to obtain an authorization from subjects?
   _____
   _____
   _____
5. Can the research be done without the protected health information? If not, why not?
   _____
   _____
   _____

6. Please complete the following to describe selection criteria for records required; the dates of the records required; and data fields required for the research.

    a. Selection Criteria for records required

    b. Dates of required records: from ___/___/___ through ___/___/___

    c. Data fields required (list fields required from an electronic data base, or list fields to be recorded from the paper record by the researcher)

    d. Anticipated sources of information (check all that apply)

    ☐ Paper medical records

    ☐ Electronic files

    ☐ Other _____

By submitting this form to the Centra IRB, the PI attests to the following:

I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

I agree that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)

Signature of PI: _____ Date: _____
Typing my name on the line above constitutes an electronic signature.

FOR IRB USE ONLY IRB # _____

On the date noted below, as prescribed by the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 [HIPAA], Centra IRB approved an alteration or waiver of authorization for the use and disclosure of protected health information in the above entitled study. The Centra IRB determined that the alteration or waiver, in whole or in part, of authorization satisfies the above criteria as indicated. This application was reviewed and approved under full convened board procedures at 45 CFR 46.108(b) or expedited review procedures at 45 CFR 46.110.

Full Board Review or Exempt Review (CIRCLE) Date: ____/_____/_____

Signature: _____
Typing my name on the line above constitutes an electronic signature.

Print Name: _____