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## Waiver of HIPAA Authorization for Research

- **Use this form** to request a waiver of patient authorization to use protected health information (PHI) in research.
- **Do not use this form** if the research or a demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs. Instead, contact the Office of the UAB IRB (934-3789).
- 1. IRB Protocol Title: Access to the Data in the N3C Data Enclave for [xxx]
- 2. Principal Investigator:
- 3. Request to Waive HIPAA Authorization for Research. Provide protocol-specific responses to the following items that describe why the waiver is being requested for this use of PHI in this research.
  - a. The use/disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals.
    - i. Describe the plan to protect the identifiers from improper use and disclosure: <u>Identifiers in the NIH Data Enclave are excluded except date and zip code. No individual data will be</u> <u>downloaded from the Enclave.</u>
    - ii. Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law: <u>No individual data will be downloaded from the Enclave.</u>
  - b. Describe why the research cannot practicably be conducted without the waiver or alteration of patient authorization to use PHI in research: <u>Data will be from many thousands of patients who have already been discharged or possible died, making contact</u> <u>difficult or impossible.</u>
  - c. Describe why the research cannot practicably be conducted without access to and use of the PHI:

Data will be used in part for epidemiologic studies that will require some knowledge of geographic location and dates in order to correlated findings with environmental factors, including season, weather, and weekday/weekend.

4. Non-UAB Disclosure or Use of PHI

Do you plan to use the waiver from the UAB IRB to justify disclosure or use of PHI from a non-UAB covered entity? Yes  $\Box$  No $\boxtimes$ 

If yes, complete a and b.

a. What covered entity or entities will disclose or use the PHI? \_\_\_\_\_

b. What PHI will the entity or entity disclose or use? \_\_\_\_\_

If the IRB approves this request for waiver, the PI can forward the IRB-issued waiver to the non-UAB covered entity as documentation of the waiver of authorization for the disclosure of PHI to UAB. Please note the entity may or may not accept the IRB's waiver and may request an additional review. By submitting this request for waiver of patient authorization, I certify that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.