INVESTIGATOR REPRESENTATION FOR REVIEW OF PROTECTED HEALTH INFORMATION PREPARATORY TO RESEARCH

1. Principal Investigator:

2. Protocol Title:

3. Institution Releasing Information:

4. Regulatory Criteria for Review Preparatory to Research

4.1 Describe the protected health information that you wish to use/disclose without patient authorization (e.g., type of data, X number of most recent surgical charts, all MRIs for patients with specific disease, etc.). Include if you are requesting the entire medical chart.

4.2 Briefly describe how this information is needed in preparation for your research study. Explain any uses/disclosures other than to develop a protocol proposal. (NOTE: Institutions cannot disclose the entire medical record without a simple statement explaining the need for the entire medical record.)

4.3 Briefly describe how this information will be used/disclosed preparatory to the research study.

A. Will any information be shared with any person who is not an employee of the facility releasing the information?

B. Will any information be removed from the facility releasing the information where it is currently maintained?

C. What patient-subject identifiers will be recorded? Explain.
4.4 Identify the individuals who are authorized to review health information on behalf of the principal investigator.

Please include the list of study personnel who are authorized to review health information

5. Investigator’s Representation

I certify that:

a. Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research.

b. No protected health information will be copied or removed from the facility releasing the information in the course of the review.

c. The protected health information for which use or access is sought is necessary for the research purposes

d. The protected health information that will be reviewed is the minimum necessary for the preparation of this research.

e. Identifiers will not be recorded if obtaining protected health information from another covered entity.

___________________________________________ ___________________
Signature of Principal Investigator Date

PLEASE ATTACH THIS FORM TO YOUR eIRB application.

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