Protocol # _____ **PI:** _____

Western Carolina University Institutional Review Board
Application for Waiver or Alteration of Authorization

1. Select the types Protected Health Information (PHI) to be collected:
   - [☐] Billing records
   - [☐] Mental Health records
   - [☐] Physician/clinic
   - [☐] Hospital/medical records (in and out-patient)
   - [☐] Lab, pathology and/or radiology results
   - [☐] PHI previously collected for research purposes
   - [☐] Other:

2. Select the responses below for all the identifiers to be captured in the research study:
   - [☐] Postal address
   - [☐] Account /medical record number
   - [☐] Certificate/license number
   - [☐] Name of relatives
   - [☐] E-mail address
   - [☐] Health plan numbers
   - [☐] Name
   - [☐] Name of employers
   - [☐] Photographic images
   - [☐] Finger or voice prints
   - [☐] Telephone number
   - [☐] Internet Protocol (IP) address number
   - [☐] Web universal resource locator (URL)
   - [☐] Fax number
   - [☐] 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
   - [☐] Any other unique identifying number, characteristic or code

Please note: Pursuant to North Carolina law, **social security numbers are not permitted to be collected in reliance on a 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.

3. Select the response below on how participant's Protected Health Information (PHI) is protected against improper use or disclosure:
   - [☐] Research team members will sign a Confidentiality Agreement
   - [☐] The information will not be shared unless it is stripped of all 18 identifiers
   - [☐] The information will be shared with a random code as outlined in the research protocol.

4. Explain the data management measures to protect the confidentiality of participant's data such as storage and access issues, including (i) safeguards for storage of any identifiers on computer workstations; and (ii) safeguards for storage of any identifiers on laptop computers, flash drives or any other portable electronic device, as applicable.

5. Data will be stripped of all identifiers upon completion of:
   - [☐] subject participation
   - [☐] data analysis
   - [☐] FDA approval
   - [☐] specimen processing
   - [☐] other (please specify):

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

7. Explain why the participant's written Authorization cannot be attained and, therefore, research cannot be practicably carried out without the Waiver or Alteration of Authorization. If required elements of a valid HIPAA Authorization are being omitted from the Authorization process, please list them and justify their exclusion.

8. Select the response or explain why research can not practicably be conducted without the participant's PHI.

[☐] PHI is needed to identify eligibility for the study

[☐] PHI is the focus of the study (e.g. – epidemiological studies)

[☐] Other (specify):

If there is additional information that cannot fit within the fields on this form, or ancillary documentation related to this request, please attach it to this form.

I verify that protected health information will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, per the terms of a valid HIPAA authorization or those uses outlined above. I will only collect the information as specified above, and limit access to that information to the greatest extent possible as previously described. I will destroy the identifier at the earliest opportunity consistent with the conduct of the research as specified above. Additionally, a comprehensive listing of individuals whose PHI will be accessed as part of this review shall be documented through completing electronic accounting of disclosures within the electronic health record (EHR).

Principal Investigator's signature **Date**

References: 45 CFR 160 and 164, Standards for Privacy of Individually Identifiable Health Information;
Final Rule NC Gen. Stat. Sect. 132-1.10 (Social Security Numbers and Personal Identifying Information)