Avera	**Institutional Review Board** **Checklist: Waiver (or Alteration) of Informed Consent Process And Waiver of HIPAA**
	NUMBER | HRP-410 and 441 Combined

IRB Number:	
Protocol Name:	
Investigator:	

Waiver (or Alteration) of IC Process: MUST meet ONE of the following three sets of criteria; Section 1,2, or 3

Section 1 – Waiver or Alteration of Consent Process (Check if "YES". All must be checked) (45CFR 46.116(d))

☐	The research is NOT FDA-Regulated.
☐	The research does NOT involve non-viable neonates.
☐	The research does NOT involve newborn dried blood spots.
☐	The research involves no more than Minimal Risk to the subjects.
☐	The research could NOT practicably be carried out without the waiver or alteration.
☐	The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Section 2 – Waiver or alteration of Consent Process (Check if "YES". All must be checked)

☐	The research IS FDA-regulated
☐	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects.
☐	The clinical investigation could not practicably be carried out without the waiver or alteration.
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Section 3 – Waiver or Alteration of Consent Process (Check if "YES". All must be checked) (45CFR 46.116(e))

☐	The research is NOT FDA-regulated.
☐	The research does NOT involve non-viable neonates.
☐	The research or demonstration project is to be conducted by, or subject to, the approval of state or local government officials.
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. One must be checked) ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternative to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs.
☐	The research could NOT practicably be carried out without the waiver or alteration.

Documentation of HIPAA Waiver Approval

Documentation of **HIPAA** Waiver Approval (Check if "Yes". All must be checked)

☐	The description of the PHI for which use or access is documented, and it is necessary for the research.
☐	The use of disclosure of protected health information involves *no more than a minimal risk* to the privacy of the subjects, based on at minimum the presence of the following elements: (Check if "Yes". All must be checked)
☐	An adequate plan to *protect the health information identifiers* from improper use and disclosure.
☐	An adequate plan to *destroy the identifiers* at the earliest opportunity
☐	Adequate written assurances that the *PHI will not be reused or disclosed* (share with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.
☐	The research could NOT practicably be conducted without the waiver or alteration.
☐	The research could NOT practicably be conducted without access to and use of the protected health information.

The Waiver (or Alteration) of IC and the Waiver of HIPAA Authorization is: (Please check one, sign and date)	
☐ APPROVED ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting ☐ Do Not Recommend approval at this time. List Reasons. (Convened board must agree by a vote if study is not approved.) Comments:	
Name of Reviewer	
Date Completed	