Avera	**Institutional Review Board** **Checklist: Waiver of Written Documentation of Consent**
	NUMBER | HRP-411

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the checklists: Criteria for Approval (HRP-314) when the research involves a waiver of written documentation of consent. This checklist should be used for all initial reviews and for any other review where the determination changes. Return completed form to the IRB Manager.

IRB Number:	
Protocol Name:	
Investigator:	

The research *MUST* meet *ONE* of the following three sets of criteria in Section 1, Section 2, or Section 3

Section 1 – Waiver of Written Documentation of Consent (Check if "YES". All must be checked)	21 CFR 56.109 (c)(1) & 45 CFR 46.117.(c)(1)(ii)
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in Section 7: Elements of Consent Disclosure in the checklist (HRP-314)
☐	The research presents no more than Minimal Risk of harm to the subjects.
☐	The research does NOT involve newborn dried blood spots.
☐	The research involves no procedures for which written consent is normally required outside of the research context.
Please select one of the following: (One must be checked)	
☐	Written information describing the research is to be provided to the subject or the subject's legally authorized representative (LAR).
☐	Written information describing the research does not need to be provided to the subject or the subject's LAR.

Section 2 – Waiver of Written Documentation of Consent	(45 CFR 46.117 (c)(1)(i))
☐	The research is NOT FDA-regulated
☐	The research does NOT involve newborn dried blood spots.
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in Section 7: Elements of Consent Disclosure in the checklist (HRP-314)
☐	The only record linking the subject and the research would be the consent document.
☐	The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.
Please select one of the following: (One must be checked)	
☐	Written information describing the research is to be provided to the subject or the subject's legally authorized representative (LAR).
☐	Written information describing the research does not need to be provided to the subject or the subject's LAR

Section 3 – Waiver Written Documentation of Consent Process (Check if "YES". All must be checked)	(45 CFR 46.117 (c)(1)(iii))
☐	The research is NOT FDA-regulated.
☐	The research IS subject to the 2018 Rule.
☐	The research does NOT involve newborn dried blood spots.
☐	The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in Section 7: Elements of Consent Disclosure in the checklist (HRP-314)
☐	The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm.
☐	The research presents not more than Minimal Risk of harm to the subjects.
☐	There is an appropriate alternative mechanism for documenting that informed consent was obtained.
Please select one of the following: (One must be checked)	
☐	Written information describing the research is to be provided to the subject or the subject's legally authorized representative (LAR).
☐	Written information describing the research does not need to be provided to the subject or the subject's LAR.

The waiver of Written Documentations of Consent 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) Board

☐ Do **NOT** Recommend approval at this time. (List reasons below)

Comments:

Name of Reviewer	
Date Completed	