AdventHealth Orlando

CHECKLIST: Waiver of Documentation of Consent

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This checklist is used to determine whether written documentation of the consent process can be waived for non-exempt <Human Research>

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All criteria in 1 or 2 must be met

1.		Waiver of written documentation of consent for research involving <Minimal Risk> to subjects *45 CFR §46.117(c)(2) and 21 CFR §56.109(c)*
1.1	☐	The research presents no more than <Minimal Risk> to subjects
	ⓘ	
1.2	☐	The research involves no procedures for which written consent is normally required outside of the research context
	ⓘ	
1.3	☐	The investigator will provide a written statement regarding the research that embodies the elements of consent in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)" (see Footnote 1)
1.4	☐	One of the following is true: ○ The investigator will provide subjects with that written statement ○ The investigator will not provide subjects with that written statement but will read it to the subjects
2.		Waiver of written documentation of consent for confidentiality risk *45 CFR §46.117(c)(1)*
2.1	☐	The only record linking the subject and the research will be the consent document
	ⓘ	
2.2	☐	The principal risk is potential harm resulting from a breach of confidentiality
	ⓘ	
2.3	☐	Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern (see Footnote 2)
	ⓘ	
2.4	☐	The research is not FDA-regulated
2.5	☐	The investigator will provide a written statement regarding the research that embodies the elements of consent in Section 4 of "WORKSHEET: Criteria for Approval (HRP-400)" (see Footnote 1)
2.6	☐	One of the following is true: ○ The investigator will provide subjects with that written statement ○ The investigator will not provide subjects with that written statement but will read it to the subjects
3.		Notes
4.		Footnotes
4.1		In general, this is a long form consent document without a signature block
4.2		In general, this is a notation by the research staff in the research records and does not need to be a signed consent document