WESTERN MICHIGAN UNIVERSITY — Homer Stryker M.D. SCHOOL OF MEDICINE	**CHECKLIST:** Waiver of Written Documentation of the Consent Process		
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The research must meet one of the following two sets of criteria

1 **Waiver of Written Documentation of the Consent Process** *(45 CFR §46.117(c)(1))* (All must be **"Yes"** – Records or minutes must document protocol-specific findings justifying each of the following determinations.)

☐ **Yes** ☐ **No**	The research is not FDA-regulated.
☐ **Yes** ☐ **No**	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 **WORKSHEET: Criteria for Approval and Additional Considerations.**
☐ **Yes** ☐ **No**	The only record linking the subject and the research would be the consent document.
☐ **Yes** ☐ **No**	The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.
☐ **Yes** ☐ **No**	Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Select one of the following:

☐ Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative.

☐ Written information describing the research **does not need to be provided** to the subject or the subject's legally authorized representative.

2 **Waiver of Written Documentation of the Consent Process** *(21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(2))* (All must be **"Yes"** – Records or minutes must document protocol-specific findings justifying each of the following determinations.)

☐ **Yes** ☐ **No**	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 **WORKSHEET: Criteria for Approval and Additional Considerations.**
☐ **Yes** ☐ **No**	The research presents no more than minimal risk[i] of harm to subjects.
☐ **Yes** ☐ **No**	The research involves no procedures for which written consent is normally required outside of the research context.

Select one of the following:

☐ Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative.

☐ Written information describing the research **does not need to be provided** to the subject or the subject's legally authorized representative.

3 **Waiver of Written Documentation of the Consent Process** *(45 CFR §46.117(c)(1)(iii))* (All must be **"Yes"** – Records or minutes must document protocol-specific findings justifying each of the following determinations.)	
☐ Yes ☐ No	The research is not FDA-regulated.
☐ Yes ☐ No	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 **WORKSHEET: Criteria for Approval and Additional Considerations.**
☐ Yes ☐ No	The subjects or Legally Authorized Representatives are members of a distinct cultural group or community in which signing forms is not the norm.
☐ Yes ☐ No	The research presents no more than Minimal Risk of harm to subjects.
☐ Yes ☐ No	There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select one of the following:

☐ Written information describing the research **is to be provided** to the subject or the subject's legally authorized representative.

☐ Written information describing the research **does not need to be provided** to the subject or the subject's legally authorized representative.

[i] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.