Waiver of Consent Documentation

Complete the questions below to request a waiver of consent documentation for the proposed research. DHHS regulations permit waivers of documentation of the consent & parental permission process if the research meets certain conditions. DHHS and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process. For additional guidance, see HRPP policy Documentation of the Informed Consent Process and the IRB Reviewer Reference Sheets - Appendix 2.

Is this research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)? Yes/No

Does the research (or research activities to which the waiver of documentation applies) present greater than minimal risk? Yes/No

If both responses are answered Yes, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If both responses are answered No, Does the research involve procedures for which written consent are normally required outside the research context? Yes/No

If No, Explain how the research does not present greater than minimal risk and does not normally require written consent outside the research context.

If Yes, Would the only record linking the participant and the research be the consent document? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If Yes, Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If Yes, Explain how the data will be restricted so the only linking record is the consent document and also why the principal participant risk is a breach of confidentiality.

If the first question (FDA) is Yes and the second question (greater than minimal risk) is No, Does the research involve procedures for which written consent are normally required outside the research context? Yes/No
If Yes, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If No, Explain how the research does not present greater than minimal risk and does not normally require written consent outside the research context.

If the first question (FDA) is No and the second question (greater than minimal risk) is Yes, Would the only record linking the participant and the research be the consent document? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If Yes, Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of consent documentation. Either review the answers provided and correct or remove the request for a waiver of consent documentation. Contact ORRP for more information.

If Yes, Explain how the data will be restricted so the only linking record is the consent document and also why the principal participant risk is a breach of confidentiality.
Waiver of Parental Permission Documentation

Complete the questions below to request a waiver of parental permission documentation for the proposed research. DHHS regulations permit waivers of documentation of the parental permission process if the research meets certain conditions. DHHS and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process. For additional guidance, see HRPP policy Documentation of the Informed Consent Process and the IRB Reviewer Reference Sheets - Appendix 2.

Is this research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)? Yes/No

Does the research (or research activities to which the waiver of documentation applies) present greater than minimal risk? Yes/No

*If both responses are answered Yes*, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

*If both responses are answered No*, Does the research involve procedures for which written parental permission are normally required outside the research context? Yes/No

*If No*, Explain how the research does not present greater than minimal risk and does not normally require written parental permission outside the research context.

*If Yes*, Would the only record linking the participant and the research be the parental permission document? Yes/No

*If No*, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

*If Yes*, Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? Yes/No

*If No*, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

*If Yes*, Explain how the data will be restricted so the only linking record is the parental permission document and also why the principal participant risk is a breach of confidentiality.

*If the first question (FDA) is Yes and the second question (greater than minimal risk) is No*, Does the research involve procedures for which written parental permission are normally required outside the research context? Yes/No

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*FOR REFERENCE ONLY – DO NOT SUBMIT*
If Yes, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

If No, Explain how the research does not present greater than minimal risk and does not normally require written parental permission outside the research context.

If the first question (FDA) is No and the second question (greater than minimal risk) is Yes, Would the only record linking the participant and the research be the parental permission document? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

If Yes, Would the principal risk to the participant be potential harm resulting from a breach in confidentiality? Yes/No

If No, Based on the answers provided, the research does not qualify for a waiver of parental permission documentation. Either review the answers provided and correct or remove the request for a waiver of parental permission documentation. Contact ORRP for more information.

If Yes, Explain how the data will be restricted so the only linking record is the parental permission document and also why the principal participant risk is a breach of confidentiality.