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Waiver of Documentation of Informed Consent

Use this page to make determinations when a consent form will not be signed by the participant.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB (or reviewer) finds and documents either 1 OR 2 as outlined below:

1 The following is true:	2 All of the following apply:
<p>(1) The research involves no more than minimal risk to the participants and (2) the research involves no procedures for which written consent is normally required outside of the research context. State the study specific procedure:</p> <ul style="list-style-type: none">Example: "(1) The research involves no more than minimal risk because the procedure is a single urine sample and (2) written consent is not normally required outside of the research context."Example: "(1) The research involves no more than minimal risk because the interviews do not collect sensitive information which could place participants at risk of harm and (2) outside of the research context written consent is not normally required for interviews." <div></div> <ul style="list-style-type: none">Please see the Consent Process page of the application to verify the investigator's plan and justification.	<p>A. Is the research subject to FDA regulation? <i>If the study is subject to FDA regulation, a waiver of documentation of consent cannot be granted.</i></p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p> <p>B. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality because:</p> <ul style="list-style-type: none">Example: "because the information collected is sensitive and a link to the information may potentially cause harm such as embarrassment or social stigma."Example: "because no identifying information is being kept with the tumor specimen that would otherwise be discarded by pathology." <div></div> <p>C. The Investigator has indicated that each participant will be asked whether he or she wants documentation linking the participant with the research and the participant's wishes will govern. <i>If no, this waiver cannot be granted.</i></p> <p><input type="radio"/> Yes <input type="radio"/> No Clear</p> <ul style="list-style-type: none">Please see the Consent Process page of the application to verify the investigator's plan.

Does the investigator have to provide subjects with a written statement regarding the research?

If yes and not described on the Consent Process page of the application, include as a stipulation for approval.

☐ Yes

☐ No

Clear

Specific Concerns:

If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:

Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the requirement for obtaining written documentation of informed consent waived?

☐ Yes.

☐ Yes, if the above stipulation is met.

☐ No.

Clear

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