Waiver or Alteration of Informed Consent

Use this page to make determinations when

- ***Consent will not be obtained (a waiver of consent)***
- ***Consent elements will be left out (an alteration of consent)***

Select the type of review (you may select more than one):

- [ ] Waiver of Informed Consent
- [ ] Alteration of Informed Consent

The IRB may waive or alter of informed consent provided that the IRB (or reviewer) finds and documents all of the following:

1. Is the research subject to FDA regulation?
If the study is subject to FDA regulation, a waiver or alteration of informed consent cannot be granted.

- ( ) Yes
- ( ) No

Clear

2. The research involves no more than minimal risk to the participants because:

- *Example: "because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely."*
- *Example: "because the review of subjects' medical records is for limited information and is not sensitive in nature."*
- *Example: "because the questionnaire responses could not reasonably damage the participants' reputation or employability."*

3. The waiver or alteration will not adversely affect the rights and welfare of the participants because:

- *Example: "because the information was collected for clinical care and the research will not change the care the individual received."*
- *Example: "because the information collected is not sensitive and a reasonable person who is in the participant's position would not consider the waiver as adversely affecting his/her rights."*
- *Example: "because participants will be given a questionnaire cover outlining the purpose of the research and that they may refuse to participate."*

4. The research could not practicably be carried out without the waiver or alteration because:

- *Refer to the application for the investigator's explanation of why the research could not be conducted without the waiver.*
- *Explain why the research could not be conducted.*
- *Example: "If consent were a requirement, the investigator would be unable to obtain consent for about 30% of participants because they have moved and lost to follow-up and the contact information in our database in incorrect. With a loss of 30% of participants, the investigator would be unable to answer the research question."*
- *Example: "If consent were a requirement, the investigator would have to obtain consent on about 100,000 individuals which would*

require about 10 years of time for the two person staff to accomplish assuming that the staff spend 50% of their time on obtaining consent. The degree of effort would make it not practicable to conduct the research."

5. Providing participants additional pertinent information after participation is or is not appropriate because (specify whether or not information should be provided):

- *Example: "Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals.*
- *Example: "Providing participants pertinent information after participation is appropriate because deception was used and the participants should be debriefed according to the investigator's protocol."*

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 informed consent waived or altered?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear