IRB Appendix M1 - Waiver or Alteration of Consent Process

Rev. March 2015

Complete this form to request a waiver or alteration of the consent process. DHHS regulations permit waivers (or alterations) of the consent process if the research meets certain conditions; however, FDA has no provision for waiver or alteration of consent.

Do not complete this form to request a waiver of documentation of consent, use Appendix M2.

Principal Investigator:

Protocol Short Title:

1. Indicate the type of waiver/alteration requested:
   - ☐ Waiver of Consent Process
   - ☐ Alteration of Consent Process

2. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biologic, device)?
   - ◯ Yes
   - ◯ No

If the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application, consent cannot be waived.

3. Is the research (or demonstration project) subject to the approval of state or local government officials and designed to study public benefit or service programs or procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs?
   - ◯ Yes
   - ◯ No

If **Yes** --> explain why the research could not `practicably' be carried out without the waiver or alteration. Inconvenience or expense is not an adequate response as it does not satisfy the criterion for waiver or alteration.

If the answer to questions 2 and 3 above is **No** --> complete the following to request waiver or alteration.

4. Explain how the research involves no more than minimal risk.

5. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

6. Explain why the research could not `practicably' be carried out without the waiver or alteration.

Inconvenience or expense is not an adequate response as it does not satisfy the criterion for waiver or alteration.

7. Will the participants be provided with additional pertinent information after participation?

- ◯ Yes
- ◯ No

Explain why or why not: