APPENDIX A

INFORMED CONSENT WAIVERS

For Social Behavioral Research Only
Use this form to request either a Waiver of Written Documentation of Informed Consent OR a Waiver of Informed Consent.

WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT

In some instances, the written consent of subject increases risk of exposure or embarrassment. The IRB may in some specific instances waive documentation per 45 CFR 46.117.

WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT

Potential participants, or the parents of children who are participants may be presented (either verbally or in writing) with the same information required in a written consent document, but the documentation of the process (signing of the consent forms) may be waived by the IRB. This process requires the approval of the IRB and must meet certain conditions.

This process is often used in minimal risk research involving the administration of online or mailed surveys, telephone interviews, or when anonymous sensitive information is collected and an investigator does not want any written documentation that links a participant to the research study. The IRB may waive the requirement per 45 CFR 46.117 for the investigator to obtain a signed consent form for some or all participants if it finds either:

1. An IRB may waive the requirement for written documentation of consent but still require that consent be obtained if either of the following conditions exist: (select the conditions that apply)

   - The only record linking the subject and the research would be the consent form and the principle risk of the research would be the potential harm from a breach of confidentiality. Each participant will be asked whether or not he or she wants documentation on linking him or her with the research. The participant’s wishes will govern.

   - The research involves minimal risk and includes no procedures for which written consent is normally required outside the research context.

NOTE: In cases in which documentation requirements is waived, the IRB may require the researcher to provide participants with a written statement about the research.
2. Describe process for “providing pertinent information” to subjects.
   Click here to enter text.

3. Please explain how in the absence of signed written consent forms, consent will be documented, e.g.,
   tape recordings, videos, chart notes, etc.
   Click here to enter text.

**WAIVER OF INFORMED CONSENT**

The IRB may, in some specific instances, waive the requirement for informed consent in accordance with 45
CFR 46.116(d).

**WAIVER OF INFORMED CONSENT**

A Waiver of Informed Consent may be applied in special circumstances when the IRB determines that it is not
necessary to obtain the participants’ consent to conduct the research.

The IRB may approve research where investigators leave out or alter elements of informed consent, provide
the research meets all applicable regulations.

The Health and Human Services (HHS) regulations allow the IRB to waive the requirement for obtaining
informed consent or parental permission or to approve a consent procedure that leaves out or alters some or
all of the elements of informed consent otherwise unrequired under the regulations.

**Examples:** The IRB may grant a waiver of consent for retrospective chart review studies.
On rare occasions, prospective collection of data through intervention or interaction with participants may be
granted a waiver of consent. With reason, a waiver of consent may be granted for studies where secondary
participants may be involved and it would be either prohibitive or potentially dangerous to obtain a consent.
For example, parent permission for a child to participate may be waived if consenting the parent could be
detrimental to the child.

As another example, some research designs require that participants be left unaware of the particular purpose
of the research, because the participants’ responses might be biased if they know in advance of what the
investigators are seeking. Such research designed do not preclude offering potential participants some
information about the research and giving them the opportunity to decide whether or not to participate.

1. Select the following that apply to this research:

   - [ ] The research involves no more that minimal risk to the subjects.
   - [ ] A waiver will not adversely affect the rights and welfare of the subjects.
The research could not practicably be carried out without waiver or alteration.

(All answers must be checked to qualify for a waiver)

☐ And: Where appropriate, the subject will be provided with additional pertinent information after participation.

2. The waiver will not adversely affect the rights to welfare of the subjects. Please explain:
   Click here to enter text.

3. The research could not be carried out without the waiver or alteration. Please explain:
   Click here to enter text.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Please explain:
   Click here to enter text.