



UNIVERSITY of
DENVER

RESEARCH & SPONSORED PROGRAMS

University of Denver Institutional Review Board (IRB)
Office of Research Compliance

IRBNet #:

PI:

APPENDIX A – INFORMED CONSENT WAIVERS FOR SOCIAL BEHAVIORAL RESEARCH ONLY

Waiver of 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

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: (the IRB may allow an option to sign or decline)
 - The research involves minimal risk and includes no procedures for which written consent is normally required outside the research context.

Note: The IRB may, in either case, require the researcher to provide the participant with a written statement about the research.

2. Describe process for “providing pertinent information” to subjects.

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)

1. Select the following that apply to this research:
 - The research involves no more than 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. Describe process for “providing pertinent information”: