

Blank Sample Protocol
Waiver of Informed Consent or Waiver of Documentation of Informed Consent for Adults

The attached document contains potential questions that will be asked in the Mentor IRB system if you select request a waiver of informed consent or a waiver of documentation of informed consent on the “Create IRB Protocol” page. These questions will only populate if you also select “Adults (18 years of age and older)” in the “Participant Age Group” question.

Please note:

- This sample protocol ONLY contains question relevant for the waiver of informed consent or waiver of documentation. If you want to see other potential questions, please see the “Blank Protocol” sample.

Blank Protocol - Adult Waiver Questions

Admin

Protocol ID	59
Panel	No Panel Assigned
PI	Anita Southwick
PI Type	Faculty
Department	Research, Grants & Contracts
Submitted By	Anita Southwick
Co-PI's	
External P.I.'s	
Review Type	Full Review Requested
Approval Status	New - Full Review
Date Received	
Date of Completion	
Date Approved	
Final Approval Date	
Proposed Projected Start Date	06/13/2017
Projected End Date	
Date Closed	
Participant Age Group	Adults (18 years of age and older)
IRB Review Fee	
Consent Waived	Yes - Request Waiver
Waiver of Documentation of Informed Consent	Requested

This document includes questions populated when requesting a waiver of documentation of informed consent for adults or a waiver of informed consent for adults.

Adults (18 years of age and older)

Who will obtain consent from participants? Will the Principal Investigator, other members of the NKU research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent? (Select all that apply)

Options:

Principal Investigator

Other members of the NKU research team

Collaborating researchers from other institutions (listed on this protocol)

Collaborating researchers from other institutions (not listed on this protocol)

Another third party

Electronic consent collection (Survey Monkey, Qualtrics, etc.). I have requested a waiver of documentation of informed consent.

Other

Describe:

1. The process that will be used to obtain consent, including how, when, and where consent will be discussed.
 2. If you might enroll any illiterate individuals, please explain how you will obtain consent from those individuals.
 3. If you plan to have more than one type of consent process (such as signed, written consent and use of an online "click" consent script), please explain which variations of the study will use which types of consent process.
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Waiver of Consent for Adults

Explain why the research involves no more than minimal risk to participants.

Explain why a waiver of consent would not adversely affect the rights and welfare of participants.

Explain why it is impracticable to carry out the research without a waiver of consent.

Explain how participants will be provided with additional pertinent information after participation (such as a debriefing sheet). If you do not plan to provide participants with debriefing information about the study, please explain why.

Waiver of Documentation of Informed Consent

Please explain why you are requesting to waive documentation of informed consent.

Continuing Reviews

Amendments

Adverse Events

Event / Date	Status / Comments / Files	Submitted By
No Adverse Events Found.		

Protocol Deviations

Event/Date	Status	Deviation File/Comments	Submitted By
No Protocol Deviations Found			

DSMB Reports

Report / Date	Status / Comments / Files	Submitted By
No DSMB Reports Found.		

Reviewer Comments