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.
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.

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.

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### Protocol Deviations

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No Protocol Deviations Found

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### DSMB Reports

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### Reviewer Comments