

Blank Sample Protocol
Waiver of Parental Permission and/or Minor Assent

The attached document contains potential questions that will be asked in the Mentor IRB system while completing your application if you request a waiver of parental permission and/or waiver of assent in the application section that is relevant for research with minors.

Please note:

- Applications sections will be generated based on your answers on the first page of the e-application. For example, if you select “Adults (18 years of age and older)” you will not see application sections relevant for research with minors.
- Some of the application sections contain sophisticated branching logic. For example, if you select that your study is confidential in nature, you will not see questions relating to studies that are anonymous in nature.
- The only documents to be uploaded in the Mentor IRB system are supporting documents like informed consent, data collection forms, recruitment materials, etc. All application questions are now built into the Mentor IRB system. The uploading of paper applications or protocols are not acceptable.

Blank Protocol 06-04-2017

Admin

Protocol ID 58
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 06/14/2017
Projected End Date
Date Closed
Participant Age Group This is a retrospective review of data that does not involve interacting with the participants
Adults (18 years of age and older)
Children/Minors (under age 18)
Not applicable (Delegation to external IRB)
What types of data are you collecting? Secondary Data Analysis (analysis of de-identified data that already exists)
Surveys/Questionnaire/Psychometric Testing
Interviews/Oral History/Focus Groups
Observational/Ethnographic Research
Audio/Video-Recording and/or Photographs
Deception/Incomplete Disclosure of Research Purpose or Procedure
Specimen Collection and/or Analysis, Including Genetic Analysis
Other
Is another institution requesting that NKU acts as the IRB of record? No
IRB Review Fee
Consent Waived Not Requested

This document includes questions populated when requesting a waiver of parental permission and/or waiver of informed assent for minors.

**Waiver of
Documentation of
Informed Consent
Participants**

Not Requested

- Adults over the age of 65
- Cognitively Impaired
- Inpatients
- Minorities
- Newborns
- NKU Employees
- NKU Students
- Non-English Speakers
- Not Applicable (i.e. secondary data analysis, delegation to external IRB, etc.)
- Other
- Pregnant or Lactating Women & Fetuses
- Prisoners or adults having limited civil freedom
- Wards of the State

Research Purpose and Procedures	Date Last Updated: 06/14/2017 2:32 PM EDT
--	--

Provide a brief, non-technical description of the purpose of the research study, including the research questions you hope to answer.

Answer:

Approximately, how many participants do you anticipate enrolling in this study (at all research locations/sites)?

Answer:

Inclusion Criteria - What characteristics (e.g., age, conditions, diagnosis, etc.) must participants have to be in this research? Answer for each participant group, if there are multiple groups.

Answer:

Exclusion Criteria - What characteristics would exclude participants who are otherwise eligible from this research? (Exclusion criteria are not the opposite of inclusion criteria, but rather a further limit.) Answer for each participant group, if there are multiple groups.

If not applicable, write N/A.

Answer:

In non-technical language:

1. Describe the procedures participants will be asked to complete or undergo.
2. Explain step-by-step what participants will be asked to do.
3. If your study includes multiple variations of the procedures, please make clear the procedures included in the variations.

Answer:

Please select the appropriate description of your study.

Answer:

- Anonymous
- Confidential

Data is being collected electronically. I have turned off IP capture (required for exempt studies). (If not applicable, leave blank)

Select all confidentiality/anonymity procedures you have put in place. (Select all that apply)

Answer:

- Use of pseudonyms
- Use of participant ID numbers that do not link participants to answers
- Institution at which research is conducted will not be named
- Data will be reported in aggregate/summary
- Signed consents will be stored separate from data so that they cannot be re-associated
- Data is collected without identifiers or assigned participant numbers
- Audio/visual transcription will be conducted by only you or a member of your study team
- Audio/visual transcription will be conducted by a service that is confidential
- Audio/visual recordings will be destroyed upon transcription (required for exempt applications)
- Other

Data and consent are: (Select 1)

Answer:

- Only being collected electronically (Survey Monkey, Qualtrics, etc.).
- Only being collected by paper, handwritten methods.
- Being collected by a combination of electronic and nonelectronic methods.

Recruitment

Who will be recruiting potential participants?

Options:

- PI
- 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 (please describe)
- Other (please describe)
- Departmentally used recruitment tool (i.e. SONA)

Select each item used in the recruitment of subjects.

Options:

- Advertisements
- Flyers
- Contact letters or emails
- Telephone contact protocols/scripts
- Website template or description (including SONA announcements)
- Other recruitment materials (please specify).

Provide details on your recruitment methods, including names of any publications/websites in which you will post recruitment information.

Identify the group, agency, or institution from which participants will be recruited. (Please note, if research will take place outside of NKU, a signed letter from the external organization on letterhead is required).

Describe measures that will be taken to ensure voluntary participation.

Data Collection, Protection, and Records Retention

Date Last Updated: 06/14/2017 2:33 PM EDT

Will direct participant identifiers be recorded?

(names; Social Security numbers; patient, hospital, laboratory or claim numbers; addresses; telephone numbers; email addresses; locator information; etc.)

Answer:

- Yes
- No

Which types of potentially identifiable information will be collected? (Select all that apply)

Answer:

- Names of people
 - Addresses
 - Phone number
 - Social Security Number
 - Names of employers, types of employers, job title
 - Other, please specify.
-

Why it is necessary to collect identifiable information and specifically describe the coding system you will use to protect against disclosure?

Answer:

Will a link between research code numbers and direct identifiers be retained **after** the data collection is complete?

Answer:

- Yes
- No

Why and for how long?

Answer:

How will data be protected against accidental disclosure to the public, other researchers, or non-researchers?

Answer:

-
- I agree to follow the NKU IRB and State of Kentucky record retention policy at the end of the research.

Secondary Data Analysis (analysis of data that already exists) Date Last Updated: 06/14/2017 2:34 PM EDT

Please provide a description of the study.

Answer:

Describe:

1. Which data sets you plan to analyze
2. Who is providing the data to you
3. Whether the data are in public use data sets, restricted access data sets, or another type of data set.

Answer:

Is the data provider requesting that the Northern Kentucky University enter into a data use agreement, license, or other agreement that sets forth restrictions on the use of the data?

Answer:

- Yes
 - No
-

Will you be collecting blood?

Answer:

- Yes
- No

I certify that all specimen collection, including venipuncture, will be performed by trained personnel using procedures recognized as standard practices in the United States

Will you be collecting urine?

Answer:

- Yes
- No

I certify that all specimen collection, including urine collection, will be performed by trained personnel using procedures recognized as standard practices in the United States

Will you be collecting saliva?

Answer:

- Yes
- No

Is the specimen you will be analyzing existing already (already collected at the time of this IRB submission, either as a part of another study or for clinical purposes)?

Answer:

- Yes
- No

Please describe.

Answer:

Will you be collecting any other specimens?

Answer:

- Yes, please explain.
- No

Explain where interviews/focus groups will take place (include possible online venues such as Skype, online chat rooms, etc.).

Answer:

Describe any steps you will take to protect the participant's privacy during the interview/focus group. Keep in mind that participants have less expectation of confidentiality in focus group settings, so focus groups may not always be appropriate for discussion of very sensitive topics.

Answer:

Describe the number of interviews/focus group sessions you anticipate for each participant.

Answer:

Approximately how long do you expect each interview/focus group to last?

Answer:

Observational/Ethnographic Research

Date Last Updated: 06/14/2017 2:34 PM EDT

Describe:

1. What and whom will be observed
2. In what setting/s (such as public events, religious ceremonies, household activities, work meetings, internet chat rooms and social media sites, etc.)

Answer:

Will you notify participants that they are being observed?

Answer:

- Yes
- No

Explain why you will not notify participants that they are being observed.

Answer:

Will you interact with participants during observations?

Answer:

- Yes
 - No
-

Explain how you will interact with participants. If you will be an intern or employee in an organization while doing research there, explain how you will make clear your role as a researcher.

Answer:

Will you: (Select all that apply)

Answer:

- collect any data containing information that identifies specific individuals or quote their remarks
 - take handwritten/typed notes
 - make any audio-recordings
 - take photographs
 - use another method of recording
 - make it clear to participants that you are collecting research data and how that data might be used
-

Will any of your ethnography involve online venues such as chat rooms or social media sites? (It is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.)

Answer:

- Yes
 - No
-

Describe the type/s of online venues you will use to conduct your research, and whether you will interact with participants online or passively observe online behavior and collect existing data.

Answer:

Deception/Incomplete Disclosure of Research Purpose or Procedure

Date Last Updated: 06/14/2017 2:37 PM EDT

Describe what information will be withheld from participants or what misinformation will be provided to participants.

Answer:

Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception/incomplete disclosure.

Answer:

Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

Answer:

Audio/Video-Recording and/or Photographs

Date Last Updated: 06/14/2017 2:37 PM EDT

Explain the types of data that will be recorded or photographed.

Answer:

If you are collecting sensitive data, will you use any procedures to de-identify/anonymize the recordings or photographs?

Answer:

Yes

No

Explain:

1. What will happen to the recordings/photographs at the end of your study.
2. If you plan to place the materials in an archive, please explain which archive and whether that archive is open to the public.

Answer:

Surveys/Questionnaires/Psychometric Testing

Date Last Updated: 06/14/2017 2:38 PM EDT

-
1. List the names of all surveys/questionnaires/psychometric tests to be used in this study. Include both established (i.e. instruments used in previous, published research/methodologies) and study-specific instruments (i.e. instruments created for this specific study).
 2. Provide a description of each instrument that is study-specific, study-created, or not otherwise established tools.

Answer:

-
1. How often will participants be asked to complete the surveys/questionnaires?
 2. Approximately how long will it take to complete the surveys/questionnaires?

Answer:

Will you be using any survey software such as Qualtrics or Survey Monkey?

Answer:

Yes

No

Risks and Benefits

Date Last Updated: 06/14/2017 2:35 PM EDT

What level of risk does this research study present to the dignity, rights, health, welfare, or privacy of

participants?

Answer:

No foreseeable risks to participants

Minimal risk to participants

More than minimal risk to participants

On the list below, select the potential risks to participants that could result, either from participating in your study or the inadvertent release of identifiable data.

Answer:

Criminal / legal (e.g., admitted law violations, past illegal behaviors or actions, threats to others)

Social status (e.g., public embarrassment, loss of reputation, or threat to social respect)

Physical well-being (e.g., bodily injury, pain, sickness, physical discomfort, or trauma)

Psychological / emotional (e.g., stress, anxiety, depression, anger, emotional reactions, painful memories, etc.)

Economic / employment (e.g., impact on conditions of employment, work assignments, job opportunities)

Privacy / dignity / self-respect (e.g., control of confidential information, control of public access, privacy)

Other, please explain.

Is the risk more than everyday life?

Answer:

Yes

No

Please explain the risks involved.

Answer:

Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare.

Answer:

Is it possible that you will discover a participant's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of the research procedures?

Answer:

Yes, please explain

No

Select the proposed Office of Human Research Protections (OHRP) category of permissible research with children.

Answer:

Category 1 - the risks of the research are no more than minimal

- ✓ Category 2 - More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual participant or by a monitoring procedure that is likely to contribute to the participant's well-being; -the risk is justified by the anticipated benefit to the participants; and, -the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

Category 3 - more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual participant, or by a monitoring procedure that is not likely to contribute to the well being of the child; --the risk represents a minor increase over minimal risk; -- the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; and, --the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition

Select the type of permission process you plan to use with the parents of child participants.

Answer:

Written permission form signed by parent (or guardian)

Waiver of documentation of Parental Permission (Information sheet/consent script without parent's signature (if using a verbal permission process or online permission script))

Request to alter parental permission (some elements of permission waived)

- ✓ Request to waive parental permission - permission is not being obtained

Please explain why you are requesting to waive parental permission.

Answer:

To request a waiver of parental permission, I confirm that (per OHRP regulations):

- This protocol is designed to study conditions in children for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and the following 2 additional criteria are also met:
 - an appropriate mechanism is in place to protect the children, **AND**
 - the waiver is not inconsistent with federal, state, or local law (45 CFR 46.408(c)).
The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition (45 CFR 46.408(c)).

Select the type of assent process you plan to use with the child/minor participants.

Answer:

Full assent with participant signature

Request to waive documentation of assent (signature not being collected)

Request to alter assent (some elements of assent are waived)

- ✓ Request to waive assent (assent is not being obtained)

Please select the reason for requesting waiver of assent. (Select all that apply)

Answer:

The capability of some or all of the children is so limited that they cannot reasonably be consulted

The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research

The research meets the same conditions as those for waiver or alternation of informed consent in research involving adults at either 45 CFR 46.116(c) or 45 CFR 46.116(d)

NKU Employees (faculty and staff)

Explain how you will minimize the potential for employees of NKU to feel coerced or undue influence to participate in the research.

NKU Students

Explain how you will minimize the potential for students of NKU to feel coerced or undue influence to participate in the research.

Non-English Speakers

Will you translate your consent information, recruitment materials, and any data collection instruments (such as questionnaires) into other languages?

Options:

Yes

No

Explain which languages will be used to communicate with participants and who will communicate with them in those languages (will it be members of the research team or will you use interpreters/translators?).

What language will the participants speak?

Prisoners

Please choose the applicable OHRP category of permissible research with prisoners:

Options:

Category 1 - (i) the study of the possible causes, effects, and processes of incarceration, and of criminal behavior is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the participants (45 CFR 46.306(a)(2)).

Category 2 - (ii) the study of prisons as institutional structures or of prisoners as incarcerated persons is permissible only if the study presents no more than minimal risk, and no more than inconvenience to the participants (45 CFR 46.306(a)(2)).

Category 3 - (iii) is research on conditions particularly affecting prisoners as a class; the regulations list as examples vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Research in this category may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)).

Category 4 - (iv) is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research. Such research may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research (45 CFR 46.306(a)(2)). OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison. (The possible advantages should not be of such a magnitude that the prisoner's ability to weigh the risks of the research against the value of such advantages in the prison environment is impaired.)

Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

If the prison has an internal IRB , have you received a permission letter or IRB approval from that department?

Options:

Yes

No

Not Applicable

Wards of the State

Explain:

1. How consent of legal guardian(s) of ward(s) will be obtained.
2. How will you ensure that the appropriate person grants permission for each ward to participate in the research.

Cognitively Impaired Participants

Provide a rationale for including decisionally-impaired individuals in your research.

How will you determine if decisionally-impaired individuals have the capacity to provide informed consent?

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.

Other participants

Explain which populations you plan to enroll and, if applicable, how you plan to take into account their vulnerabilities in carrying out your research procedures and consent process.

Costs, Reimbursement, Compensation and Recruitment Incentives

Date Last Updated: 06/14/2017 2:36 PM EDT

Are there costs that the subject may incur as a result of participation?

Answer:

Yes, please describe

No

Will your study offer any reimbursement, compensation, or recruitment incentives to participants?

Answer:

Yes

No

Will you be reimbursing participants for out of pocket expenses incurred as a part of research participation.

Answer:

- Yes, please explain.
- No

Will you be compensating participants for the time or burden associated with research?

Answer:

- Yes, please explain.
- No

Will you pay partial compensation for participants who do not complete all of the research procedures? If no, why not?

Answer:

- Yes
- No. Please explain why you will be offering partial compensation.

Will you be offering any recruitment incentives?

Answer:

- Yes, please explain.
- No

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