# **Mentor IRB Application Section Questions**

General Faculty, Staff and Student Researcher Questions

**\*NOTE: This document is to serve as an aid with the questions that could be asked during submittal of a new IRB protocol. Do not submit this word document to the IRB.\***

[Click here for instructions on how to submit a new IRB protocol in Mentor.](https://inside.nku.edu/content/dam/rgc/docs/ResearchCompliance/IRB/IRBSOPs/SOP%20%2312%20(IRB)%20PI%20-%20Submitting%20a%20New%20Protocol%20V2.0.pdf)

# Research Purpose and Procedures

1. Provide a brief, non-technical description of the purpose of the research study, including the research questions you hope to answer.
2. Approximately, how many participants do you anticipate enrolling in this study (at all research locations/sites)?
3. 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.
4. 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.
5. In non-technical language: Describe the procedures participants will be asked to complete or undergo.        Explain step-by-step what participants will be asked to do.                 If your study includes multiple variations of the procedures, please make clear the procedures included in the variations.
6. Please select the appropriate description of your study. - anonymous or confidential

**IF anonymous-check box and continue, IF confidential go to #11**

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

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

Options:

* 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 (If other is selected or if a transcription service is being used, please explain.)

1. Data and consent are: (Select 1)

Options:

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

1. Select the combined electronic and non-electronic storage procedures you will be utilizing.

Options:

* Data will be stored on a password protected computer
* Data will be stored in a password protected file
* Data will be stored on a password protected disk
* Data will be stored in a secure confidential online storage system (also password protected)
* Consents will be stored in a secure, confidential online storage (also password protected)
* Consents will be stored on a password protected computer
* Consents will be stored in a password protected file
* Consents will be stored on a password protected disk
* Storage will be in researcher's office
* Storage will be in mentor/chair/advisor's office
* Storage will be in researcher's home
* Consents will be stored in a locked cabinet
* Data will be stored in a locked cabinet
* Other (If other, please explain)

1. Is this a resubmission of a previously IRB approved study that has been terminated or has expired?

**IF YES go to #12, IF NO go to #14**

1. What is the previous IRB protocol number?
2. Please explain why this study is being re-submitted to the IRB?
3. Will you be collaborating with any researchers at other institutions to carry out this study?

**IF YES go to #15, IF NO go to #16**

1. List the collaborating researchers, the institution for which they are affiliated, Their role/s on this study (recruitment data collection, data analysis, etc.). If they are only involved in analyzing de-identified data, please say so.
2. Explain, where the research activities will take place (including recruitment, data collection, consenting, etc.) - be as specific as possible.
3. Will any of your research procedures occur outside of the United States?

**IF YES go to #18, IF NO go to #21**

1. In which countries will your research take place?
2. Explain your familiarity with and knowledge of the local research context, including cultural norms and local languages. If there are any local customs/cultural norms that could affect the consent process, please explain those customs/norms and how you will take those into account in the consent process.
3. Explain if there are any local laws that could impact how you carry out your research (such as laws that affect age of majority to consent to research participation, or laws that impact mandatory reporting of abuse/neglect).
4. Is this project funded?

**IF YES go to #21, IF NO end of survey**

1. Is the funding:

* Internal (NKU funded)
* External (outside agency or organization)
* Other (please explain) if other, please explain.

1. What is the grant number?

# Recruitment

1. Who will be recruiting potential participants?

* 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)

1. Select each item used in the recruitment of subjects.

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

1. Provide details on your recruitment methods, including names of any publications/websites in which you will post recruitment information.
2. 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).
3. Describe measures that will be taken to ensure voluntary participation.

# Data Collection, Protection and Records Retention

1. Will direct participant identifiers be recorded? *(names; Social Security numbers; patient, hospital, laboratory or claim numbers; addresses; telephone numbers; email addresses; locator information; etc.)*

**IF YES go to #2, IF NO go to #6**

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

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

1. Why is it necessary to collect identifiable information and specifically describe the coding system you will use to protect against disclosure?
2. Will a link between research code numbers and direct identifiers be retained **after** the data collection is complete? If, yes, explain why this is necessary and for how long you will keep this link. If appropriate, specify that any master file containing the subject identifiers to numeric codes will be stored in a separate locked file.

**If YES answer and then go to #5, IF NO go to #6**

1. Why and for how long?
2. How will data be protected against accidental disclosure to the public, other researchers, or non-researchers?

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

# Surveys/Questionnaires/Psychometric Testing

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). Provide a description of each instrument that is study-specific, study-created, or not otherwise established tools. Please remember to submit all data collection tools that are not established instruments to the IRB for review.
2. How often will participants be asked to complete the surveys/questionnaires? Approximately how long will it take to complete the surveys/questionnaires?
3. Will you be using any survey software such as Qualtrics or Survey Monkey? Yes or no If yes, which survey software will you be using?)

# Interview/Oral History/Focus Groups

1. Explain where interviews/focus groups will take place (include possible online venues such as Skype, online chat rooms, etc.).
2. 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.
3. Describe the number of interviews/focus group sessions you anticipate for each participant.
4. Approximately how long do you expect each interview/focus group to last?

# Risks and Benefits

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

* No foreseeable risks to participants
* Minimal risk to participants
* More than minimal risk to participants

**IF NO Foreseeable Risks…. (IF other two options see instructions below)**

1. 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?
2. Are there any benefits for society?  (explain how benefits outweigh risk)
3. Are there any anticipated benefits of this research for individual participants in each participant group? (Do not include compensation or incentives offered to participants as a benefit to be gained from the research).
4. Will sensitive information be obtained?

**If YES go to #6, IF NO end of survey**

1. Will a Certificate of Confidentiality (CoC) be obtained for this study? Please note, the NKU IRB may require a CoC for studies that are collecting identifiable, sensitive information.

**If YES survey over, IF NO go to #7**

1. Why will a CoC not be obtained?

**IF Minimal Risk or IF more than minimal risk to participants……**

1. 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.

* 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.

1. Is the risk more than everyday life?
2. Please explain the risks involved.
3. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare.
4. 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?

**Now start at question #3 from above section of no foreseeable risks**

# Secondary Data Analysis

1. Please provide a description of the study.
2. Describe:

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

1. 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?

**IF Yes go to #4, IF NO go to #5**

1. Please Explain.
2. What variables are contained in the data set (such as names, dates of birth, addresses, zip codes, test scores, etc.)?
3. Was the data you plan to analyze collected in a previous research study?

**IF YES go to #7, IF NO go to #8**

1. Provide the title/name of the previous research study and which institution/researcher collected the data for the previous study. If the data was collected in a previous NKU research study, provide the IRB number assigned to that study.
2. Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

**IF Yes go to #9, IF NO go to #11**

1. Is the data publicly available on the internet?

**IF YES go to #10**

1. What websites will you access to obtain the data? (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.)
2. Do you plan to access any data for use in your study that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or health insurer)?

**IF YES go to #12, IF NO go to #14**

1. Which organization(s) will provide the HIPAA PHI to you? Please be specific on which organization(s) will be providing the data.
2. How will permission to allow the use/disclosure of individuals' protected health information (PHI) be obtained?
3. Do you plan to access any student data that are held as education records by an elementary or secondary school (including student records held by Northern Kentucky University or other colleges/universities)?

**IF YES go to #15, IF NO go to #16**

1. Please explain.
2. Select all confidentiality/anonymity and security procedures you have put in place. (Select all that apply)

Options:

* Use of pseudonyms
* Use of protocol numbers that do not link participants
* No identifiers collected/provided
* Data will be reported in aggregate/summary
* Storage will be in researcher's office
* Storage will be in researcher's home
* Storage will be in mentor/chair/advisor's office
* Data will be stored in a locked cabinet
* Data will be stored on a password protected computer
* Data will be stored in a password protected file
* Data will be stored on a password protected disk
* Data will be stored in a secure and confidential online storage (also password protected)
* Other, please specify.
* Checkbox-I agree to follow the NKU IRB and State of Kentucky record retention policy at the end of the research.

# Specimen Collection and/or Analysis, including Genetic Analysis

1. Will you be collecting blood?

**IF YES go to #2, IF NO go to #3**

1. Please describe the procedure used for blood collection including the amount to be drawn and the frequency.

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

1. Will you be collecting urine?

**IF YES check box, IF NO go to #4**

* 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.

1. Will you be collecting saliva?
2. 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)?

**IF YES, please explain.**

1. Will you be collecting other specimens?

**IF YES, please explain.**

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1. Will genetic analysis/testing be done on any of the specimens?

**IF YES, go to #8, IF NO go to #9**

1. What type of genetic analysis/testing will be done, and will participants receive any information resulting from the genetic analysis/testing?
2. Will this study store any specimens for future use (specimen banking)?

**IF YES go to #10, IF NO go to #14**

1. Where will the specimens be banked and who will have oversight over the stored specimens?
2. How long will the specimens be stored and how will they be labeled (specify if they will be labeled with any identifiers)?
3. Will participants be able to request that their specimen(s) be destroyed?
4. Will cell lines or commercial products be developed from the specimens?

**IF yes, please explain and go to #14**

**IF NO, end of survey.**

1. Will specimens be shared with other people who are not on this research team (either individuals at NKU or at other institutions)?
2. Please specify.

# Interviews/Oral History/Focus Groups

1. Explain where interviews/focus groups will take place (include possible online venues such as Skype, online chat rooms, etc.).
2. 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.
3. Describe the number of interviews/focus group sessions you anticipate for each participant.
4. Approximately how long do you expect each interview/focus group to last?

# Observational/Ethnographic Research

1. Describe:

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

1. Will you notify participants that they are being observed?

**IF NO go to #3, IF YES go to #4**

1. Explain why you will not notify participants that they are being observed.
2. Will you interact with participants during observations?
3. 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.
4. Will you: (Select all that apply)

Options:

* 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

1. 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.)

**IF YES go to #8, IF NO end survey**

1. 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.

# Deception/Incomplete Disclosure of Research Purpose or Procedure

1. Describe what information will be withheld from participants or what misinformation will be provided to participants.
2. 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.
3. Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

# Audio/Video Recording and/or photos

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

1. If you are collecting sensitive data, will you use any procedures to de-identify/anonymize the recordings or photographs?
2. Explain: What will happen to the recordings/photographs at the end of your study.
3. If you plan to place the materials in an archive, please explain which archive and whether that archive is open to the public.

# Surveys/Questionnaires/Psychometric Test

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).Provide a description of each instrument that is study-specific, study-created, or not otherwise established tools. Please remember to submit all data collection tools that are not established instruments to the IRB for review.
2. How often will participants be asked to complete the surveys/questionnaires? Approximately how long will it take to complete the surveys/questionnaires?
3. Will you be using any survey software such as Qualtrics or Survey Monkey? (if yes, what survey software will you be using?)

# Photovoice

1. Will this project utilize Photovoice as a research technique?

**IF YES go to #2, if no end survey**

1. Will this project allow photographers to take pictures in non-public locations or places where people might expect privacy?

**IF Yes check both boxes and go to #3, IF NO go to #4**

* I have uploaded a permission template in Mentor IRB for individuals to sign who will be photographed in a non-public location.
* I have a method to link pictures with signed permission forms.

1. Will pictures taken during this project be displayed publicly (i.e. professional meeting or community gathering, or used in manuals or brochures or other publications)?

* I have uploaded a permission template to Mentor IRB to display the photos publicly.
* I have a method to link pictures with signed permission forms.

1. Will this project allow for pictures to be taken of minors?

* I have uploaded a parent/guardian permission template to Mentor IRB to photograph minors.
* I have a method to link pictures with signed parent/guardian permission forms.

1. Will this project allow for pictures to be taken of potentially illicit or illegal activities?

* I have or will contact NKU Legal Affairs for advice and guidance before allowing the photographing of illicit or illegal activity.

1. Will the photographer/study participant be required to provide a camera or use their phone for study purposes? IF yes, explain.
2. How will the pictures be printed and who is responsible for the cost?

# Children and Minors

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

Options:

* 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 wellbeing 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

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

Options:

* Written permission form signed by parent (or guardian)- **IF this is your response go to question #3**
* Waiver of documentation of Parental Permission (Information sheet/consent script without parent's signature (if using a verbal permission process or online permission script)) **(IF this is your response go to #11)**
* Request to alter parental permission (some elements of permission waived) **(IF this is your response go to #12)**
* Request to waive parental permission-Pursuant to 45 CFR 46.408 (a) and (b), I request that guardian permission be waived as the participants are non-high school students enrolled in a university where they are expected to be treated and conduct themselves as adults, and where their guardians have endorsed them to be enrolled and to conduct themselves as adults **(IF this is your response go to #5)**
* Request to waive parental permission - permission is not being obtained, other. **(IF this is your response go to #13)**

1. Who will obtain parental permission?

Options:

* PI
* Other members of the NKU research team
* Collaborating researchers from Other institutions (listed on this protocol) -
* Collaborating researchers (not listed on this protocol)
* Electronic system (Survey Monkey, Qualtrics, etc.)
* Another third party
* Other, please describe.

1. Describe the process that will be used to obtain parental permission, including how, when, and where the parental permission will be discussed.
2. Select the type of assent process you plan to use with the child/minor participants.

Options:

* Full assent with participant signature **(IF this is your response go to #6)**
* Request to waive documentation of assent (signature not being collected) (**IF this is your response go to #8)**
* Request to alter assent (some elements of assent are waived) **(IF this is your response go to #9)**
* Request to waive assent (assent is not being obtained**) (IF this is your response go to #10)**
* I have requested that guardian permission be waived as the participants are non-high school students enrolled in a university where they are expected to be treated and conduct themselves as adults, and where their guardians have endorsed them to be enrolled and to conduct themselves as adults, therefore, I am requesting that the participant complete a consent form instead of an assent form to ensure that the participant is fully informed. **(IF this is your response go to #6)**

1. Who will obtain assent?

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
* Other
* If other, please explain.

1. Describe the process you will use to explain this research study to children.

**END of SURVEY**

1. Please explain why you are requesting to waive documentation assent.

**Then go to #6**

1. Please explain why you are requesting to alter assent.

**Then go to #6**

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

Options:

* 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)

**END of SURVEY**

1. Please explain why you are requesting to waive documentation of parental permission?

**Then go to go #3**

1. Please explain why you are requesting to alter parental permission.

**Then go to #3**

1. Please explain why you are requesting to waive parental permission.

* Checkbox: 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)).

**Then go to #9**

# Adults (18 years and older)

1. 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)

* 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 (if other, please describe)

1. Describe:

* The process that will be used to obtain consent, including how, when, and where consent will be discussed.
* If you might enroll any illiterate individuals, please explain how you will obtain consent from those individuals.
* 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.

# Costs, Reimbursement, Compensation and Recruitment Incentive

1. Are there costs that the subject may incur as a result of participation?
2. Will your study offer any reimbursement, compensation, or recruitment incentives to participants?

**IF NO survey over, IF YES go to question 3**

1. Will you be reimbursing participants for out of pocket expenses incurred as a part of research participation?
2. Will you be compensating participants for the time or burden associated with research?

**IF NO go to #5, IF Yes go to #6**

1. Will you be offering any recruitment incentives?

**IF Yes go to #6, If NO survey over**

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

**YES or NO go back to question 5**

# NKU Employees (faculty and staff)

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

# NKU Students

1. 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

1. Will you translate your consent information, recruitment materials, and any data collection instruments (such as questionnaires) into other languages?  (if no, explain why)
2. 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?).
3. What language will the participants speak?

# Prisoners

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

* 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.

1. 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.).
2. Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.
3. If the prison has an internal IRB, have you received a permission letter or IRB approval from that department?

# 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

1. Provide a rationale for including decisional-impaired individuals in your research.
2. How will you determine if decisional-impaired individuals have the capacity to provide informed consent?

# Other Participants

1. 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.