| | |
|---|---|
| | **Becker College Institutional Review Board**<br>**Full Board Review Form** |
| **Full Board Review:** Full Board reviews are conducted by all members of IRB. Full Board Review is required when the procedures of the research present more than minimal risk to the subject, or where the proposed research involves one of the specific categories set forth by the IRB as needing full review. Please see the Full Review Checklist for a specific description of categories needing full review. | |
| | |
| **Part 1: Research Proposal** | |
| **Introduction and Background (literature review):**<br><br>Does the proposal contain an introduction to the study and sufficient background information to justify conducting the study? | ○ Yes<br>○ No |
| **Specific Aims/Study Objectives:**<br><br>Are the specific aims of the study clearly stated and achievable based on the proposed study methodology? | ○ Yes<br>○ No |
| **Materials, Methods and Analysis (quantitative and qualitative):**<br><br>Is the study population appropriate for the goals of the study? (consider both the nature and size of the sample) | ○ Yes<br>○ No |
| Does the proposal outline data collection methods? | ○ Yes<br>○ No |
| If the proposal includes questionnaires or interviews, are the questions attached? | ○ Yes<br>○ No<br>○ N/A |
| Are the timeline of the procedures and how long each procedure will last clearly stated? | ○ Yes<br>○ No |
| Does the proposal describes the analysis type and procedures including statistics and scientific or scholarly justification for the use of these analyses? | ○ Yes<br>○ No |
| **Research Population & Recruitment Methods:**<br><br>Are the criteria for inclusion of subjects clearly stated and appropriate? | ○ Yes<br>○ No |
| Are the criteria for exclusion of subjects clearly stated and appropriate? | ○ Yes<br>○ No |
| Are methods of subject recruitment legal, ethical and free from coercion or undue influence? | ○ Yes<br>○ No |
| Is there a statistical justification for the sample size? | ○ Yes<br>○ No |
| Is the proposed statistical treatment of the data appropriate for the design of the study? | ○ Yes<br>○ No |
| If special populations (children, prisoners, pregnant women, or decisionally impaired subjects) are being enrolled into the study, did the investigator include the appropriate justification for inclusion? | ○ Yes<br>○ No |

| | |
|---|---|
| **Potential Research Risks or Discomforts to Participants:**<br><br>Does the research design carry enough likelihood of yielding data sufficient to warrant the risks to the subject? | ○ Yes<br>○ No |
| Are the risks (including known incidence) clearly described? | ○ Yes<br>○ No |
| Have adequate safeguards been adopted to reduce risk exposure as much as possible? | ○ Yes<br>○ No |
| Is there description of study design safeguards (e.g., data and safety oversight committee) such that if the research proposal needs to be modified, or changes in the risk level occur, they will be appropriately and timely brought to the attention of the IRB for review and approval? | ○ Yes<br>○ No |
| **Confidentiality and Anonymity:**<br><br>Does the proposal outline specific steps that will be taken (i.e., during study participation, after study participation, and with the publication of study results) to ensure that the subject's participation in the research study and respective data will be confidential or anonymous? | ○ Yes<br>○ No |
| If data collected is confidential, does the proposal outline if participants' identities will be coded and where the codes will be stored? | ○ Yes<br>○ No |
| Does the proposal outline where the data will be stored and who will have access to the data and the area where the data is stored? | ○ Yes<br>○ No |
| Does the proposal contain information on how and in what format the data will be stored? | ○ Yes<br>○ No |
| **Potential Research Benefits to Participants:**<br><br>Are the potential benefits to the subject (if any) clearly described? | ○ Yes<br>○ No |
| Do the potential benefits to the subject and/or society outweigh the risks being incurred? | ○ Yes<br>○ No |
| If an incentive for participation is offered to potential subjects, is it reasonable based on the complexities and inconvenience of the study? | ○ Yes<br>○ No |
| **Part 2: Consent Form** | |
| Is the study title identical to that listed on the proposal? If no, has justification been provided for the use of a different title? | ○ Yes<br>○ No |
| Is the name, address, and phone number of each investigator listed? | ○ Yes<br>○ No |
| Is the source of financial support for the study listed and consistent with the cover sheet? | ○ Yes<br>○ No |
| Is there a clear statement of the purpose of the study? | ○ Yes<br>○ No |
| Is there a clear explanation of the reason a particular subject was invited to participate? | ○ Yes<br>○ No |
| Is it clearly stated that the subject is participating in a research study? | ○ Yes<br>○ No |
| Is the duration and length of each subject's participation included? | ○ Yes<br>○ No |
| Are the risks and benefits associated with participation in the study clearly described? | ○ Yes<br>○ No |
| If the study involves the use of a questionnaire, is there a description of the general content and time required to complete them? | ○ Yes<br>○ No |

| | |
|---|---|
| Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy? | ○ Yes<br>○ No |
| Is the assurance of confidentiality or anonymity clear and complete? | ○ Yes<br>○ No |
| Is the section regarding the subject's right to withdraw from the study at any time clearly worded and non-coercive? | ○ Yes<br>○ No |
| Is there an offer by the investigator(s) to answer questions with contact information provided? | ○ Yes<br>○ No |
| Is the statement regarding the availability of the IRB Office, to answer questions and contact information included? | ○ Yes<br>○ No |
| Does the Consent form contain the statement indicating that the participant will receive a copy of the document and a signed copy will be kept with the investigator? | ○ Yes<br>○ No |
| Are there appropriate lines for the date and signatures of the subject, surrogate/proxy, and witness? | ○ Yes<br>○ No |

**Decision of Reviewer with Rationale:**

- Approved: No further action is required from the investigator prior to initiating the study.
- Approved if designated revisions are made: The investigator may initiate the study after requested changes are made, and the IRB receives these revisions and notifies the investigator that he or she may proceed.
- Revise and resubmit: More extensive changes are required before the study may begin. Additional information must be submitted to the IRB prior to approval.
- Denied: The proposed research, because of the level of risk involved, cannot be initiated.

Rationale:

| | |
|---|---|
| Signature of IRB Chair: | Date: |