# State University of New York at DelhiInstitutional Review Board

Request for IRB Review Checklist
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| Principal Investigator: IRB #: |
| Request for IRB Review SUBMISSION REQUIREMENTS |
| [ ]  Exempt Review Requested (complete through #5 on p. 2, and sign on p. 7)[ ]  Expedited Review Requested (complete entire form)[ ]  Full Review Requested (complete entire form) |
| REQUIRED ITEMS |
| [ ]  | Complete *Request for IRB Review Form* **with all required** **ORIGINAL Signatures** |
| [ ]  | Investigators, faculty advisors and key study personnel must be in compliance with all training requirements  |
| OTHER ITEMS - DEPENDENT ON TYPE OF RESEARCH  |
| [ ]  | Clean copy of Informed Consent Form  |
| [ ]  | Child assent form |
| [ ]  | Participant recruitment materials (script, flyers, letters, etc.) |
| [ ]  | Questionnaire/survey |
| [ ]  | Standard Measures |
| [ ]  | Interview questions /script |
| [ ]  | Participant Referral Services Contact Information |
| [ ]  | Approval/permission letters from organizations, institutions, schools, secondary data set/existing data set  |
| [ ]  | Individual investigator agreement (for investigators that are not affiliated with SUNY Delhi) |
| [ ]  | Certificate of Confidentiality |
| [ ]  | Debriefing Information (if deception is used) |
| [ ]  | **2** copies of each Grant and/or Funding Application (with relevant sections identified). ***If the grant is written in highly technical terms you are required to provide a summary in layperson’s terms.*** |
| [ ]  | International Studies: Local Contact /Expert or IRB approval of proposal |
| [ ]  | Other materials to be used with participants (all materials to be used with the participants must be submitted for review).  |
| [ ]  | Other materials. Please explain:  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **IRB COVER SHEET** | **Yes** | **No** | **N/A** |
|  | Is all appropriate information provided? | [ ]  | [ ]  | [ ]  |
|  | Is risk level noted by investigators consistent with risks the study poses to subjects? | [ ]  | [ ]  | [ ]  |
|  | **IRB PROTOCOL** |  |  |  |
|  | **Significance** | **Yes** | **No** | **N/A** |
|  | Research Design and Methods | **Yes** | **No** | **N/A** |
|  | Are the study procedures and study visits clearly outlined and described? (Questions 1, 2 on request form) | [ ]  | [ ]  | [ ]  |
|  | Data Collection and Statistical Considerations | **Yes** | **No** | **N/A** |
|  | Is the study population appropriate for the goals of the study? (consider both the nature and size of the sample) (Question 4 on request form) | [ ]  | [ ]  | [ ]  |
|  | Human Subjects (these are addressed in questions 4 and 15 on request form) | **Yes** | **No** | **N/A** |
|  | Are the criteria for inclusion and/or exclusion of subjects clear? | [ ]  | [ ]  | [ ]  |
|  | If children are being enrolled into the study, did the investigator include the appropriate justification for inclusion of children information? | [ ]  | [ ]  | [ ]  |
|  | If prisoners are being enrolled into the study, did the investigator include the appropriate information for inclusion of prisoners in research?  | [ ]  | [ ]  | [ ]  |
|  | If the study involves the recruitment and/or study of decisionally impaired subjects, has the investigator included all elements required?  | [ ]  | [ ]  | [ ]  |
|  | If the study involves the recruitment and/or study of pregnant women, has the investigator provided appropriate justification?  | [ ]  | [ ]  | [ ]  |
|  | Recruitment Procedures | **Yes** | **No** | **N/A** |
|  | Are methods of subject recruitment legal, ethical and free from coercion or undue influence? Has cold-calling been avoided? (Questions 4, 5, 8 on request form) | [ ]  | [ ]  | [ ]  |
|  | Risks/Benefit Ratio (these are addressed in questions 6,7, 10, 11, 12 on request form) | **Yes** | **No** | **N/A** |
|  | Are risks and benefits in the protocol consistent with risks/benefits in the consent?  | [ ]  | [ ]  | [ ]  |
|  | Are all the risks (including known incidence) clearly described?  | [ ]  | [ ]  | [ ]  |
|  | Have adequate safeguards been adopted to reduce risk exposure as much as possible? | [ ]  | [ ]  | [ ]  |
|  | Does the protocol 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?  | [ ]  | [ ]  | [ ]  |
|  | Are the potential benefits to the subject (if any) clearly described?  | [ ]  | [ ]  | [ ]  |
|  | Do the potential benefits to the subject and/or society outweigh the risks being incurred?  | [ ]  | [ ]  | [ ]  |
|  | Does the research design carry enough likelihood of yielding data sufficient to warrant risks to subjects? | [ ]  | [ ]  | [ ]  |
|  | Costs and Payments | **Yes** | **No** | **N/A** |
|  | Do any payments seem sufficient yet not large enough to be coercive? (Question 5 on request form)  | [ ]  | [ ]  | [ ]  |
|  | Bibliography/References | **Yes** | **No** | **N/A** |
|  | Were appropriate references cited in the research protocol to support the research design and the risks and benefits of the study? (Questions 1, 2 on request form)  | [ ]  | [ ]  | [ ]  |
|  | **CONSENT FORM**  |  |  |  |
|  | **General Considerations** | **Yes** | **No** | **N/A** |
|  | If a waiver of written consent is being requested, has the investigator addressed the required criteria? | [ ]  | [ ]  | [ ]  |
|  | Is title and names of researchers included? | [ ]  | [ ]  | [ ]  |
|  | Is the length of the form appropriate for the complexity of the study? | [ ]  | [ ]  | [ ]  |
|  | Is clear, concise, non-technical language used throughout? | [ ]  | [ ]  | [ ]  |
|  | Are appropriate subheadings and sequence used throughout?  | [ ]  | [ ]  | [ ]  |
|  | Is the first page printed on departmental/institutional letterhead? | [ ]  | [ ]  | [ ]  |
|  | Is a blank line for subject initials included in the lower right corner of each page (except the signature page)? | [ ]  | [ ]  | [ ]  |
|  | Are all pages numbered sequentially? | [ ]  | [ ]  | [ ]  |
|  | Investigators | **Yes** | **No** | **N/A** |
|  | Is the name, address, and phone number of each investigator listed? | [ ]  | [ ]  | [ ]  |
|  | Study Description | **Yes** | **No** | **N/A** |
|  | Is there a clear statement of the purpose of the study? | [ ]  | [ ]  | [ ]  |
|  | Is the approximate number of subjects to be studied noted (including gender and age range)? | [ ]  | [ ]  | [ ]  |
|  | Is the duration and length of each subject’s participation included? | [ ]  | [ ]  | [ ]  |
|  | If the study involves the use of questionnaires, is there a description of the general content and time required to complete them? | [ ]  | [ ]  | [ ]  |
|  | Risks and benefits  | **Yes** | **No** | **N/A** |
|  | Does the research design carry enough likelihood of yielding data sufficient to warrant risks to subjects | [ ]  | [ ]  | [ ]  |
|  |  Are the risks and benefits consistent with the risks/benefits of the protocol? | [ ]  | [ ]  | [ ]  |
|  | Is there a complete and clear description of the potential risks (i.e., is quantitative information on the expected frequency of the listed side effects provided)?  | [ ]  | [ ]  | [ ]  |
|  | Is there a clear description of the precautions taken to minimize risks? | [ ]  | [ ]  | [ ]  |
|  | Are the potential benefits to the subjects (if any) clearly described? If there are no benefits is this clearly stated? | [ ]  | [ ]  | [ ]  |
|  | Costs and Payment | **Yes** | **No** | **N/A** |
|  | Do any payments seem sufficient yet not large enough to be coercive? (question 5) | [ ]  | [ ]  | [ ]  |
|  | Confidentiality | **Yes** | **No** | **N/A** |
|  | Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy? | [ ]  | [ ]  | [ ]  |
|  | Does the section sufficiently state who will have access to subject records? | [ ]  | [ ]  | [ ]  |
|  | Right to Withdraw | **Yes** | **No** | **N/A** |
|  | Is this section clearly worded and non-coercive? | [ ]  | [ ]  | [ ]  |
|  | Are reasons why a subject might be withdrawn from the study by investigators clearly defined? | [ ]  | [ ]  | [ ]  |
|  | Compensation for Injury | **Yes** | **No** | **N/A** |
|  | Is the standard statement or other satisfactory wording included? | [ ]  | [ ]  | [ ]  |
|  | Voluntary Consent | **Yes** | **No** | **N/A** |
|  | Is there an offer by the investigator(s) to answer questions? | [ ]  | [ ]  | [ ]  |
|  | Is the statement regarding the availability of the Human Subject Protection Advocate, IRB Chair, to answer questions and the phone number (1-607-746-4138) included? | [ ]  | [ ]  | [ ]  |
|  | Is there an appropriate line for the date and signature of the subject? | [ ]  | [ ]  | [ ]  |
|  | Are there appropriate signature spaces included if children 14-17 are included in the study? | [ ]  | [ ]  | [ ]  |
|  | Certification of Informed Consent | **Yes** | **No** | **N/A** |
|  | Has this section been appropriately included? | [ ]  | [ ]  | [ ]  |

#### Version 2008.0508