Office Use Only Protocol Number:

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
INSTITUTIONAL REVIEW BOARD
RESEARCHER'S CHECK LIST

INSTRUCTIONS

1. This checklist shall be completed and attached to the study proposal in the order listed on the last page (with item appearing at the beginning).
2. The applicant shall submit Nine (9) bound copies of all the study documents.

Title of Study Proposal:

Back ground Information	***Yes***	***No***	***N/A***
Has the application letter been signed by the PI who is directly responsible for the ethical and scientific conduct of the research?			
Are there collaborating institutions on the study?			
If YES, are all the collaborating letters attached?			
Are the study investigators NMIMR staff?			
If YES, has the protocol been reviewed by the NMIMR Scientific and Technical Committee (STC)?			
If YES, has the STC number and approval date been stated?			
Has or will this research be submitted to a research ethics committee other than the NMIMR-IRB?			
If YES, have the details been provided?			
Are the study investigators affiliated with a foreign institution?			
If YES, has a local investigator been identified and documented?			
Student Applicant	***Yes***	***No***	***N/A***
Is the applicant a student?			
Has the student's work been reviewed and approved by the Faculty, Department or School?			
If YES, has the approval letter been attached?			
Are the CVs of the student and student's supervisor(s) attached?			
If the student is from a foreign institution, has a local supervisor's letter of support and CV been attached?			
Has the source of funding been stated?			
Research Proposal Outline	***Yes***	***No***	***N/A***

Is there an abstract/ executive summary?			
Is there a write up on the introduction/ study rationale with the appropriate references?			
Is the justification for studying this population adequate?			
Have the study aim and objectives been stated?			
Does the study methodology explain how the study would be carried out?			
Is the study design scientifically sound?			
Have the inclusion and exclusion criteria been stated?			
Has the study population been adequately described?			
Have all the ethical issues such as consent procedures, confidentiality, privacy, risks and benefits, etc. been described under ethical considerations?			
Is the statistical basis for the study design appropriate and is the plan for analysis of the data appropriate?			
Are the dates on the work plan current?			
Has the budget been justified?			
Are the procedures for participant recruitment, admission, follow up and completion appropriate?			
Has the references been cited properly?			
Has the signatory page been signed?			
Clinical Trials	**Yes**	**No**	**N/A**
If the study is a clinical trial study, have the profiles on previous study i.e. Phase 1 & Phase II studies been stated?			
Is the investigational product brochure for the study attached?			
If No, why not?			
Are the Data Safety Monitoring Board (DSMB) membership,Charter of Work and current CV of members attached?			
If No, why not?			
Will insurance cover be provided for study participants?			
If No, why not?			
Is the Food and Drugs Authority approval letter for use of the Investigational Product/ Devices attached? (This should be submitted if FDA approval is granted).			
If No, why not?			
Consent Forms	**Yes**	**No**	**N/A**
Have all the technical terms been simplified or written in laypersons' language? *Is the consent form easily understandable?*			
Are the research participants below 18 years?			
If YES, has a parental consent form been attached?			

Has the parental consent form been written with reference to the child? E.g. Your ward has been invited to participate in this study because your ward…)			
If the participants are 12 to 17 years, has a child assent form been provided?			
Does the general information explain the purpose of the study, role of participants?			
Will blood or tissue samples be obtained from participants?			
If YES, has it been quantified in lay terms such as teaspoonful, tablespoonful?			
Have all the sections which are not applicable to the study been deleted? (Except general information about the study, possible benefits, risks and discomforts, confidentiality, compensation voluntary participation and right to leave the research contacts for additional information which are mandatory)			
Has the consent form been written in to directly address the participant? (E.g. You have been invited to participate in this study because you are...)			
Sample Storage and Usage	**Yes**	**No**	**N/A**
Is there a caption on the consent form titled "sample storage and usage"?			
Has participants been informed that their samples will be stored for future use?			
Has it been stated on the consent form that permission will be sought from an ethics committee before using the samples in the future?			
Specimen / sample transfer			
Has the Material Transfer form been filled?			
Data collection instruments	**Yes**	**No**	**N/A**
Have all the data collection instruments such as interview guide, questionnaire, etc. been attached?			

STUDY DOCUMENTS

1. Researchers Checklist
2. Letters (Application Letter, Letters from Collaborating institutions)
3. Study proposal *(Abstract/Executive Summary, Introduction/Rationale, Literature Review, General Aim and Specific Objectives, Methodology, Ethical Considerations, Expected Outcome/Results, References, Work Plan, Budget and Budget Justification*
4. Consent Form, Assent Form, Parental Consent Form (where applicable)
5. Data Collection Instruments (i.e. Interview Guide, Questionnaire, etc.)
6. Curriculum Vitae of Study Investigators / Supervisors
7. Any other documents that support the application

NB: THE ABOVE DOCUMENTS SHOULD BE PAGED SEPARATELY.

Please note that you are required to pay for the ethics review at the NMIMR Accounts Office and the receipt should be submitted to the NMIMR-IRB Office before the protocol would be reviewed.