D. CHECKLIST

Name of Principal Investigator:……Marigold Cobbina……..

Proposal ID (To be given by the Secretariat)……..

Title of Proposal:		PI TO COMPLETE		
		Yes	**No**	**N/A**
Vulnerable/High Risk Group				
1	Is a vulnerable population being studied?	✓	☐	☐
If yes, tick the vulnerable population being studied?				
☐ Pregnant women ✓ **Adolescents / Children** ☐ Incarcerated / Prisoners	☐Elderly (above 60yrs) ☐Refugees ☐Those who cannot give consent (unconscious)	✓ **Persons with mental or Behavioural disorders** ☐ Others		
2	Is the justification for studying this vulnerable population adequate?	✓	☐	☐
3.	Have adequate provisions been made to ensure that the vulnerable population is not being exploited?	✓	☐	☐
Comment(s) of chair of faculty/school/organisation review committee:				
Scientific and Technical Issues				
1.	Is the rational for the study clearly stated in the context of present knowledge?	✓	☐	☐
2.	Is the hypothesis to be tested fully explained?	✓	☐	☐
3.	Is the project design scientifically sound?	✓	☐	☐
4.	Where present, is the control arm adequate?	✓	☐	☐
5.	Are the inclusion and exclusion criteria complete and appropriate?	✓	☐	☐
6.	Are the types and methods for participant allocation appropriate?	✓	☐	☐
7.	Are the procedures for participant recruitment, admission, follow up and completion appropriate?	☐	☐	✓
8.	Are the drugs and/or devices to be used fully described?	☐	☐	✓
9.	Does the project design include appropriate criteria for stopping and discontinuing the research?	☐	☐	✓
10.	Are the clinical procedures to be carried out fully described and appropriate?	☐	☐	✓
11.	Are the laboratory tests and other diagnostic procedures fully described and appropriate?	☐	☐	✓
12	Is the Statistical basis for the study design appropriate and is the plan for analysis of the data appropriate?	☐	☐	✓
Proposal ID (To be given by the Secretariat)……..				

.		Yes	No	N/A
Informed Consent, Decision-making & Confidentiality				
1.	Is the information sheet free of technical terms, written in laypersons' language, easily understandable, complete & adequate?	☑	☐	☐
2.	Does it make it clear that the proposed study is a research?	☑	☐	☐
3.	Does it explain why the study is being done and why the participant is being asked to participate	☑	☐	☐
4.	Does it clearly state the duration of the research**?**	☑	☐	☐
5.	Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out?	☑	☐	☐
6.	Does it explain the nature and likelihood of anticipated discomfort or adverse effects, including psychological and social risks, if any-and what has been done to minimize these risks, and the action to be taken if they occur?	☑	☐	☐
7.	Does it outline the possible benefits, if any, to the research participants	☑	☐	☐
8.	Does it outline the possible benefits, if any, to the community or to society?	☑	☐	☐
9	If confidentiality is not possible due to the research design, has this been conveyed to all relevant persons?	☑	☐	☐
10	Does it inform the research participants that their participation is **voluntary** and refusal to participate (or discontinue participation) will involve no penalty or loss of medical benefits to which the participant was otherwise entitled?	☑	☐	☐
11.	Does it describe the nature of any compensation or reimbursement to be provided?	☐	☐	☑
12	Does it provide the alternatives to participation?	☐	☐	☑
13.	Does it provide the name and contact information of a person who can provide more information about the research project at any time?	☑	☐	☐
14.	Has provision been made for participants incapable of reading and signing the written consent form (e.g. illiterate patients)? (Please attach)	☐	☐	☑
15	Does it conclude with a statement such as ''I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any question I have asked have been answered to my satisfaction. I consent voluntarily to participate as a respondents in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care''	☑	☐	☐
16.	Does it provide information to the research participants on the costs to the participants involved in terms or time, travel, man-days lost from work, etc. and reimbursements, if any?	☐	☐	☑
17.	Has provision been made for respondents incapable of giving personal consent (e.g. for cultural reasons, children or adolescents	☑	☐	☐

	less than the legal age for consent in the country in which research is taking place, respondents with mental illness, etc)? (Please attach).			
18.	Does it outline the procedure that will be followed to keep participants informed of the progress and outcome of the research?	☐ ✓	☐	☐
Comment(s) of chair of faculty/school/organisation review committee:				
Other materials, documents and study instruments (Patient recruitment material, Questionnaires)			**Yes** ✓	**No**
N/A				
1	Is the Participant Recruitment Material (e.g. advertisements, notices, media articles, transcripts of radio messages) provided both in English and in the local language?	☐		☐ ✓
2.	Do these materials make claims that may not be true?	☐	☐	☐ ✓
3.	Do they make promises that may be inappropriate in the research setting (e.g. provide undue incentives or emphasize remuneration?)	☐	☐ ✓	☐
4.	Does the study involve questionnaires, diaries, study instrument?	☐ ✓	☐	☐
5.	Are these attached to the proposal (In English and local language)?	☐ ✓	☐	☐
6.	Are the questionnaires written in lay language and easily understood?	☐ ✓	☐	☐
7.	Are the questionnaires relevant to answer the research question?	☐ ✓	☐	☐
8.	Are the questionnaires worded sensitively?	☐ ✓	☐	☐
9.	Does the consent information and form describe the nature and purpose of the questions to be asked?	☐ ✓	☐	☐
10.	If applicable, does the consent information and form make it clear that some of the questions may prove embarrassing for the participant?	☐	☐	☐ ✓
11.	Does the proposal describe how confidentiality of the questionnaires will be maintained (i.e. will they be coded or anonymised)?	☐ ✓	☐	☐
12.	Does the consent information and form state that the participant is free to not answer any question?	☐ ✓	☐	☐
13.	Where applicable, does the informed consent form make it clear that the in-depth interview or focus group discussion is likely to be audio or video taped?	☐ ✓	☐	☐
14.	Where applicable, does the consent form mention how and for how long these tapes are going to be stored?	☐ ✓	☐	☐
Comment(s) of chair of faculty/school/organisation review committee:				
Yes			**No**	**N/A** ✓
Clinical Trials				
1.	Is this a new drug or vaccine trial?	☐	☐	☐ ✓
2.	If applicable, is clearance from the national drug regulatory authority attached?	☐	☐	☐ ✓

3.	Is the Investigator's Brochure (including safety information) attached?	☐	☐	☑
4.	Is the Adverse Drug Reaction/Adverse Event Reporting form attached?	☐	☐	☑
5.	Has a Data Safety Monitoring Board been established?	☐	☐	☑
6.	Are the names of the chairperson and members of the DSMB available for the records?	☐	☐	☑
Comment(s) of chair of faculty/school/organisation review committee:				
Human Biological Materials N/A ☑			**YES**	**NO**
1,	Will human biological materials (tissues, cells, fluids, genetic material or genetic information) be collected as part of the research?	☐	☐	☑
2.	Does the consent information and form fully describe the nature, number and volume of the samples to be obtained and the procedures to be used for obtaining them?	☐	☐	☑
3.	Does the consent information and form indicate if the procedures for obtaining these materials are routine or experimental and if routine, are more invasive than usual?	☐	☐	☑
4.	Does the consent information and form clearly describe the use to which these samples will be put?	☐	☐	☑
5.	Does the consent information and form include the provision for the respondents to decide on the use of left-over specimens in future research of a restricted, specified or unspecified nature?	☐	☐	☑
6.	Does the consent information and form cover for how long such specimens can be kept and how they will be finally destroyed?	☐	☐	☑
7.	Does the proposal describe how specimens will be coded or anonymised?	☐	☐	☑
8.	Where applicable, does the consent form mention that genetic testing/genomic analysis will be carried out on the human biologic materials?	☐	☐	☑
Comment(s) of chair of faculty/school/organisation review committee:				