REVIEWER'S EVALUATION FORM

REC Form 106

Study Title:

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Reviewed by _____Date:_____

Table 1: PROTOCOL REVIEW

Check each of the categories and provide additional information where necessary.)

UCI REC Protocol #:	Yes	No	Comment
Is there a scientific basis for initiating this study			
Research is relevant to the health needs of the community under study.			
Research includes special or vulnerable subjects in the study population (eg minors, prisoners, mentally handicapped, fetuses etc)			
If yes, is it possible to exclude them and still answer the same study questions?			
If yes, does the proposal include adequate measures to ensure that the populations are well protected?			
The study presents : ▪ no risk ☐ ▪ minimal risk ☐ ▪ more than min. risk ☐ ▪ high risk. ☐	Briefly Comment : _____ _____ _____ _____		

	N/A	Satisfactory	Requires clarification	Incomplete/ missing	Unsatisfactory	**COMMENT**
Objectives clear & achievable						
Literature reviewed/Rationale						

	N/A	Satisfactory	Requires clarification	Incomplete/ missing	Unsatisfactory	**COMMENT**
Appropriateness of study design						
Methods/Procedures Materials appropriateness						
Statistical considerations						
Study Population appropriateness						
Selection & recruitment procedures (fairness)						
Incentives to participate (appropriate & non coercive)						
Consent form/statement						
Process for assuring that consent/assent is voluntary.						
Privacy and confidentiality						
Research instrument(s)						
Risks/benefits						

Table 2: CONSENT FORM/STATEMENT

Check each of the categories and provide additional information where necessary. For studies with multiple consent evaluate each separately.

Elements of the informed consent	**Yes**	**No**	**N/A**	**Comment**
(i) A statement that reflects that it's a research.				
(ii) An explanation of the purposes of the research				
	Yes	**No**	**N/A**	**Comment**

(iii) The expected duration of the subject's participation				
(iv) .A description of the procedures to be followed				
(v) Identification of any procedures which are experimental				
(vi) A description of any reasonably foreseeable risks or discomforts to the subject				
(vii) A description of any benefits to the subject or to others which may reasonably be expected from the research				
(viii) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject				
(ix) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained				
(x) For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained				
(xi) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to				
Additional Information to be included (where appropriate)				
	Yes	**No**	**N/A**	**Comment**

a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable				
b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent				
c) Any additional costs to the subject that may result from participation in the research d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject				
e) A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject				
f) The approximate number of subjects involved in the study				
g) A statement entailing the acknowledgement that the subject has read/got explanation about the details about the study documented in the consent form and voluntarily accepted to take part in the study. (***Below this statement the investigator should include the space for print name of participant, signature/ thumb-print and date. Consent should also have lines for witness and consenter documentation of name as appropriate).***				
Are the submitted consents in appropriate language (Reference to target population and study area).				
	Yes	**No**	**N/A**	**Comment**

Are all required consents/Assent with reference to study subject categories submitted for review (Only applicable to studies with different categories of participants, or conducted in phases or with multiple components/sub A studies or involving minors or sample storage). **Note**: separate consent must be submitted for each study with intent of storage for future use).				
Are all other consenting materials mentioned in the protocol or consent document submitted for approval?				

FOR ADDITIONAL CONCERNS/REQUIREMENTS; *Use the space below and additional pages as necessary.*

ADDITIONAL CONCERNS/REQUIREMENTS

_____

_____

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RECOMMENDATIONS:

Check one only

1. ☐ Approve research proposal as submitted
2. ☐ Approve research proposal with minor modifications
   (P***lease specify modification to be made in the space below)***.
3. ☐ Major Changes suggested but the proposal shouldn't be resubmitted.
4. ☐ Major changes Suggested; the proposal has to be resubmitted.
5. ☐ Disapproved the research proposal.
   (***Please explain the reason and action to be taken by the investigator in the space provided below).***

COMMENTS _____

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_____ _____

Signature of reviewer Date