**FORM No. 2: Ethics Review Evaluation Form**

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| **Application No.** |  |
| **Study Title** |  |

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|  | **Yes** | **No** | **NA** | **Comments** |
| **Is all the documentation provided?** |  |  |  |  |
| **INTRODUCTION, SPECIFIC AIMS, AND BACKGROUND** |
| Are the specific aims clearly specified? |  |  |  |  |
| Are there adequate preliminary data to justify the research? |  |  |  |  |
| Is there appropriate justification for this research proposal? |  |  |  |  |
| **SCIENTIFIC DESIGN** |
| Is the scientific design adequate to answer the questions? |  |  |  |  |
| Are objectives likely to be achieved within a given time period |  |  |  |  |
| Is the scientific design described and adequately justified? |  |  |  |  |
| **INCLUSION AND EXCLUSION CRITERIA FOR PARTICIPANTS** |
| Are inclusion and exclusion criteria clearly specified and appropriate? |  |  |  |  |
| If women, minorities, or children are included or excluded, is this justified? |  |  |  |  |
| Is the choice of participants appropriate for the question being asked? |  |  |  |  |
| Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol? Is participant selection equitable? |  |  |  |  |
| **RECRUITMENT OF PARTICIPANTS** |
| Are the methods for recruiting potential participants well defined? |  |  |  |  |
| Are the location and timing of the recruitment process acceptable? |  |  |  |  |
| Is the individual performing the recruitment appropriate for the process? |  |  |  |  |
| Are all recruitment materials submitted and appropriate? |  |  |  |  |
| Are there acceptable methods for screening participants before recruitment?  |  |  |  |  |
| **RESEARCH PROCEDURES** |
| Are the rationale and details of the research procedures accurately described and acceptable? |  |  |  |  |
| Is there a clear differentiation between research procedures and standard care? |  |  |  |  |
| Are the individuals performing the procedures appropriately educated? |  |  |  |  |
| Is the location of where the procedure will be performed acceptable? |  |  |  |  |
| Are there adequate plans to inform participants about specific research results if necessary?  |  |  |  |  |
| **POTENTIAL RISKS, DISCOMFORTS, AND BENEFITS FOR PARTICIPANTS** |
| Are the risks and benefits adequately identified, evaluated, and described? |  |  |  |  |
| Are the potential risks minimized and likelihood of benefits maximized? |  |  |  |  |
| Is the risk/benefit ratio acceptable for proceeding with the research? |  |  |  |  |
| Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?  |  |  |  |  |
| Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified? |  |  |  |  |
| Is the standard of care the best available locally? |  |  |  |  |
| Is the medical and psychological support for the participants adequate? |  |  |  |  |
| Is the site including support staff, facilities and emergency procedures adequate? |  |  |  |  |
| Is there provision for compensation for participants who sustain injuries? |  |  |  |  |
| Have adequate provisions been made for dealing with and reporting adverse effects? |  |  |  |  |
|  Have adequate provisions been made for safety monitoring and termination of the research project? |  |  |  |  |
| Is there a possibility of an intervention being available to the population if found effective? |  |  |  |  |
| **DRUGS, BIOLOGICS, AND DEVICES** |
| Is the status of the drug described and appropriate?  |  |  |  |  |
| Are the drugs dosage and route of administration appropriate? |  |  |  |  |
| Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing? |  |  |  |  |
| Is the significant risk or non-significant risk status of the device described and appropriate? |  |  |  |  |
| **DATA ANALYSIS AND STATISTICAL ANALYSIS** |
| Is the rationale for the proposed number of participants reasonable? |  |  |  |  |
| Are the plans for data and statistical analysis defined and justified, including the use of stopping rules and endpoints? |  |  |  |  |
| Are there adequate provisions for monitoring data (DSMB)? |  |  |  |  |
| **COMPENSATION AND COSTS FOR PARTICIPANTS** |
| Is the amount or type of compensation or reimbursement reasonable? |  |  |  |  |
| Are there adequate provisions to avoid out-of-pocket expenses by the research participant, or is there sufficient justification to allow participants to pay?  |  |  |  |  |
| If children or adolescents are involved, who receives the compensation, and is this appropriate? |  |  |  |  |
| **PRIVACY AND CONFIDENTIALITY** |
| Are there adequate provisions to protect the privacy and ensure the confidentiality of the research participants? |  |  |  |  |
| Are there adequate plans to score and code the data? |  |  |  |  |
| Is the use of identifiers or links to identifiers necessary, and how is this information protected? |  |  |  |  |
| **INFORMED CONSENT/ ASSENT** |
| Are all elements of informed consent contained in the consent document? |  |  |  |  |
| Is the process of obtaining consent adequately described and adequate? |  |  |  |  |
| Is assent required? If yes, have measures been incorporated to obtain it? |  |  |  |  |
| Is waiver or modification of consent possible? |  |  |  |  |
| Are the participants competent? |  |  |  |  |
| Is the justification for the intention to include individuals who cannot consent adequate? |  |  |  |  |
| Are the arrangements for obtaining proxy consent for such individuals appropriate? |  |  |  |  |
| Will dissent be respected? |  |  |  |  |
| Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable? |  |  |  |  |
| Do you approve the incentives offered? |  |  |  |  |
| Is the consent given voluntarily and not due to deception, intimidation or inducement? |  |  |  |  |
| Will fresh informed consent be obtained if the procedures are changed during the research? |  |  |  |  |
| Is there an opportunity for the participant to ask questions regarding the research? |  |  |  |  |
| **EXTERNALLY SPONSORED RESEARCH** |
| Is there a local collaborator/ PI? |  |  |  |  |
| Has the research project been approved by aERC/ IRB in the sponsoring country? |  |  |  |  |
| Is the justification for the research to be carried out in Cameroon and not in the sponsoring country adequate? |  |  |  |  |
| Is the research relevant to Cameroon? |  |  |  |  |
| Are the post-research benefits to the country acceptable? |  |  |  |  |
| Are relevant local laws/ regulations/ guidelines of each country adhered to? |  |  |  |  |
| Is the research responsive to cultural/social differences? |  |  |  |  |
| Are participants receiving the best current treatment as part of the protocol? |  |  |  |  |
| Is the ancillary care provided adequate? |  |  |  |  |
| Are the provisions for continuity of care adequate? |  |  |  |  |
| Are the provisions for intellectual property sharing fair? |  |  |  |  |
| If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the participantss and protect intellectual property rights? |  |  |  |  |
| Is an acceptable Material Transfer Agreement attached? |  |  |  |  |
| Is an acceptable Data Sharing Agreement attached? |  |  |  |  |
| Is there provision for results of research to be conveyed to relevant authorities in Cameroon? |  |  |  |  |
| Are any conflicts of interest resolved? |  |  |  |  |
| **Additional Comments:** |

**Recommendation of Reviewer**:

[ ]  Approve

[ ]  Reject

[ ]  Conditional Approval (please state the conditions):

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| **Name of Reviewer** |  |
| **Signature** |  |
| **Date** |  |