**UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

**RESEARCH ETHICS COMMITTEE (UHAS-REC**)

**PROTOCOL SUBMISSION CHECKLIST**

Applicants should ensure that they have submitted all of the underlisted for ethical review of their proposed research in a single pdf file emailed to rec@uhas.edu.gh and 16 hard copies printed and submitted at the Institute of Health Research.

**All protocols must be arranged in the order in which they appear in this checklist.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section** | **Description**  | **YES** | **NO** | **Not Applicable** |
| ***A*** | ***Requirements for all Research Protocols*** |  |  |  |
| 1 | Signed Cover letter from the PI addressed to the REC Chairperson | [ ]  | [ ]  | [ ]  |
| 2 | Completed and signed UHAS-REC initial Submission form | [ ]  | [ ]  | [ ]  |
| 3 | Full Protocol with structured summary, Budget and time line for the study | [ ]  | [ ]  | [ ]  |
| 4 | Written Informed Consent form (with dates and version number) and translations into the local language *(where necessary)* | [ ]  | [ ]  | [ ]  |
| 5 | Written Parental Consent form & Assent form *(where applicable)* | [ ]  | [ ]  | [ ]  |
| 6 | Data collection tools - Questionnaires, Interview guide, data capturing sheet(s), Case report form(s), referral forms, etc. | [ ]  | [ ]  | [ ]  |
| 7 | Permission letter sent to the site/facility where the study will be conducted (Written approval from the site may be submitted to the REC later) | [ ]  | [ ]  | [ ]  |
| 8 | Material Transfer Agreement (MTA) for shipment of specimen/biological materials outside of Ghana *(where applicable).*  | [ ]  | [ ]  | [ ]  |
| 9 | Data Sharing Agreement *(where applicable)*.  | [ ]  | [ ]  | [ ]  |
| 10 | Approval certificate from any other Ethics Review Board | [ ]  | [ ]  | [ ]  |
| 11 | Current CV(s) of PI & Co-Investigator(s) (Max of 3 pages each) | [ ]  | [ ]  | [ ]  |
| 12 | Any other information deemed necessary to facilitate the review process (Specify) | [ ]  | [ ]  | [ ]  |
| 13 | Proof of Payment of REC Administrative Charges | [ ]  | [ ]  | [ ]  |
| 14 | Have all documents been version and date controlled?  | [ ]  | [ ]  | [ ]  |
| B | ***Additional Requirements for Undergraduates, Masters, Postgraduate, and Fellowship Students*** |
| 1 | Abridged CV of Supervisor *(only for Non-UHAS supervisors)* | [ ]  | [ ]  | [ ]  |
| 2 | Cover letter from School | [ ]  | [ ]  | [ ]  |
| **C** | ***Additional Requirements for Clinical Trials*** |
| 1 | Confirmation letter from participating/collaborative institution involved in the study | [ ]  | [ ]  | [ ]  |
| 2 | Profile on previous study i.e. Phase 1 & Phase II studies *(where applicable)* | [ ]  | [ ]  | [ ]  |
| 3 | Investigator Agreement (PI’s responsibility), Page duly signed, with name and date. | [ ]  | [ ]  | [ ]  |
| 4 | Clinical Trial Agreement | [ ]  | [ ]  | [ ]  |
| 5 | Financial Disclosure Agreement | [ ]  | [ ]  | [ ]  |
| 6 | Current Certificate of Training in Good Clinical Practice (GCP) for PI(s) | [ ]  | [ ]  | [ ]  |
| 7 | Investigational Product Brochure for the study | [ ]  | [ ]  | [ ]  |
| 8 |  Data Safety Monitoring Board (DSMB) membership, Charter of Work and Current CV of members | [ ]  | [ ]  | [ ]  |
| 9 |  Insurance cover for study participants | [ ]  | [ ]  | [ ]  |
| 10 | Data Sharing Agreement *(where applicable)* | [ ]  | [ ]  | [ ]  |
| 11 | Food and Drugs Authority approval *(May be submitted after REC approval where applicable).*  | [ ]  | [ ]  | [ ]  |
| 12 | Current CV(s) of PI & Co-Investigator(s). *REC requires that at least one member of the team of investigators be a Ghanaian at a professional rank of no less than the grade of a Senior Lecturer* | [ ]  | [ ]  | [ ]  |