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| *This form should be filled and signed by applicant for substantial amendment for an already approved clinical trial* | | | | |
| 1. **DETAILS OF THE APPROVED ORIGINAL PROTOCOL** | | | | |
| Reference Number of the approved Clinical Trial | |  | | |
| Date of approval of original protocol (dd/mm/yyyy) | |  | | |
| Clinical Trial Title | |  | | |
| Principal Investigator approved for the clinical trial | |  | | |
| Number of sites approved for the clinical trial | |  | | |
| Number of subjects approved for the clinical trial | |  | | |
| Applicant of the current amendment (Sponsor or principal investigator) | |  | | |
| Contact person responsible for this application | | First name:  Surname name:  E-mail:  Tel: | | |
| 1. **SUMMARY OF PROPOSED CHANGES** | | | | |
| **Amendment title, number and natures supporting documentation:** *List of all types of supporting documents that you will submit* | | | | |
| **Summary of current** | | **Proposed change details:** | | |
|  | |  | | |
| **Reason/rationale for change(s):**  *Please provide the rationale for each change if more than one*. | |  | | |
| **Multi-centre trials:**  *Will this amendment apply to all approved site(s)?* | | ☐ **YES** ☐ **NO** | | |
| *If No: Specify the sites for which the amendment will apply* | |  | | |
| 1. **DOCUMENTATION CHECKLIST** | | | | |
| Valid ethical approval of the proposed change(s) | | | | ☐ **YES** ☐ **NO** |
| Proof of payment of amendment fees as per Rwanda FDA regulations | | | | ☐ **YES** ☐ **NO** |
| Revised Protocol with version number (if applicable) | | | | ☐ **YES** ☐ **NO** |
| Other relevant supporting documentation in line with the amendment | | | | ☐ **YES** ☐ **NO** |
| Valid ethical approval of the proposed change(s) | | | | ☐ **YES** ☐ **NO** |
| 1. **DECLARATION (by applicant)** | | | | |
| I, (*Insert the Sponsor or PI*) the undersigned, hereby declare that I have submitted all required documentations, and have disclosed all information which may influence the approval of this application  ☐ There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.  ☐ The information submitted is true and correct. | | | | |
| **Names:** | **Signature:** | | **Date:** | |
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