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| --- | --- | --- | --- | --- |
| 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:** | |
|  |  | |  | |