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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**
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| **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**
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| 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)**
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| 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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