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| **Protocol Amendment Checklist for Clinical Trials** | | |  | | | |
| **Principal Investigator** | |  | | | | |
| **CRF Study Number** | |  | | | | |
| **Protocol Number/ Short Protocol Title** | |  | | | | |
| **Type of Document amended** | | Protocol  IB  Others …………………. | | | | |
| **Amendment Version** | |  | | | | |
| **Initial Notification date of the amendment to the site** | |  | | | | |
| **Amendment site implementation date** | |  | | | | |
|  |  | | | | |  |
| 1. **Regulatory** | | | | **Yes** | **No** | **N/A** |
| 1. Central EU approval in place through CTIS for new clinical trials registered after 31 January 2023? | | | |  |  |  |
| 1. Ethics Approval in place for new amendment (NREC) for trials not submitted under new Clinical Trial Regulation through CTIS | | | |  |  |  |
| 1. HPRA Approval in place for new amendment trials not submitted under new Clinical Trial Regulation through CTIS | | | |  |  |  |
| 1. Has the IB been updated | | | |  |  |  |
| 1. Has the PIL been updated? | | | |  |  |  |
| 1. If YES does the patient need to be reconsented | | | |  |  |  |
| 1. Does DPIA need to be updated?   Note: This is required only if there are updates to Data handling, storage, Data Transfer, or any other updates impacting data integrity | | | |  |  |  |
| 1. If yes, has the DPO been informed of the amendment and has the DPIA been approved? | | | |  |  |  |
| 1. Has the site received greenlight from the sponsor to implement the amendment? | | | |  |  |  |
| 1. If you have answered “NO” to “a” “b” “c” “g” or “h” for the above, please do not proceed. | | | |  |  |  |
| Has the study team (all on delegation log) been retrained on new protocol Amendment (documented on training log) etc | | | |  |  |  |
| PI and Sub-Investigators | | | |  |  |  |
| Nursing | | | |  |  |  |
| Pharmacy | | | |  |  |  |
| Laboratory | | | |  |  |  |
| Study Co-ordinators | | | |  |  |  |
| Other roles as per delegation log and individual trial requirements | | | |  |  |  |
| If all Staffs mentioned above could not be trained prior to implementation of updated protocol, where all staffs in the delegation log as mentioned above been trained before performing any trial tasks related to the updates. | | | |  |  |  |
| 1. **Protocol Changes** | | | | **Yes** | **No** | **N/A** |
| 1. Has the Protocol been updated | | | |  |  |  |
| 1. Has the Protocol Schedule of Events changed? | | | |  |  |  |
| 1. If YES has there been an increase in study visits? | | | |  |  |  |
| 1. Is there a new Budget or CTA to be reviewed? | | | |  |  |  |
| 1. Does CRF manager form need to be updated to reflect new study visits? Or Conditional Procedures? | | | |  |  |  |
| 1. Does the Agreement letter need to be updated? | | | |  |  |  |
| 1. Does the Risk Assessment need to be updated? | | | |  |  |  |
| 1. Have R&I been informed of Amendment by email? | | | |  |  |  |
| 1. If yes, has the approval letter been sent to R and I? | | | |  |  |  |
| 1. Is there an Up-dated IB? Has PI signed for Acknowledgement Log? | | | |  |  |  |
| 1. **Documentation** | | | | **Yes** | **No** | **N/A** |
| a. Has older version of protocol been superseded? | | | |  |  |  |
| b. Has new protocol been filed on both shared drive and site file? | | | |  |  |  |
| c. Have older protocol versions been removed from circulation? | | | |  |  |  |
| d. If PIL has been updated, have older versions been superseded and taken out of  circulation? | | | |  |  |  |
| e. Has the site file and shared drive been updated with the PIL? | | | |  |  |  |
| f. Has the PI signed the new updated version of the protocol under protocol signature  page? | | | |  |  |  |
| g. If there are any worksheets in place for the stud do they require any update? | | | |  |  |  |
| h. If there are study specific procedures SSPs in place, do they require any update? | | | |  |  |  |
| 1. **Finances and Contract** | | | | **Yes** | **No** | **N/A** |
| a. If there are additional visits – have these been costed and approved? | | | |  |  |  |
| b. Is there a new Clinical Trial Agreement CTA in place? | | | |  |  |  |
| 1. **Pharmacy – completed by pharmacist** | | | | **Yes** | **No** | **N/A** |
| a. Has the required training been completed and documented accordingly? | | | |  |  |  |
| b. Does Amendment require a change to pharmacy procedures for drug handling,  storage, dispensing, preparations, returns etc? | | | |  |  |  |
| IF YES: | | | |  |  |  |
| c. Has the Trial Summary/Prescribing & Dispensing Guide been updated if required? | | | |  |  |  |
| d. Has Trial summary/ Prescribing and Dispensing Guide been uploaded, and old version  removed and superseded? | | | |  |  |  |
| e. Have all superseded paper copies of the Trial Summary/Prescribing and Dispensing  Guide been removed and new versions filed? | | | |  |  |  |
| f. Has the new Amendment been filed in the Pharmacy Site File and the old version  superseded? | | | |  |  |  |
| g. Are there any additional pharmacy costs to be considered? | | | |  |  |  |
| h. Are there any changes required to the pharmacy section of the Risk Assessment  (CRF only)? | | | |  |  |  |
| **6. Laboratory** | | | | **Yes** | **No** | **N/A** |
| a. Has the lab manual been updated? | | | |  |  |  |
| b. Is there any change in the processing of lab samples? | | | |  |  |  |

**Checklist Reviewed by:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Reviewed by | Clinical Trial Coordinator/ Study Start-Up specialist | Lead Nurse  (Includes CCTU) | Trial/Study Pharmacist | Laboratory Manager/Coordinator | Quality and Regulatory Affairs Manager | Programme Manager |
| Initials and Date |  |  |  |  |  |  |

**Checklist completed by:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name:** |  | | |
| **Signature:** |  | **Date:** |  |