\* indicates involvement/assisting the main responsible role

All entries in columns are examples only. Please adapt with trial specific details. If a row is not relevant to a particular trial, please format the text to ‘strikethrough’.

This text in blue is for guidance only and should be deleted prior to signing this form.

| **[TRIAL NAME] Responsibilities Record** |
| --- |
| **Responsibility** | **Co-Sponsors** | **Chief Investigator** | **ECTU** | **Other** |
| **TRIAL Registration** |
| Register with an acceptable clinical trial registration scheme e.g. ISRCTN if not automatically registered by HRA |  | **CI\*** | **X** |  |
| **PROTOCOL DEVELOPMENT, PREPARATION AND MAINTENANCE OF TRIAL DOCUMENTATION** |
| Write draft Protocol, prepare Participant Information Sheet, Consent Form, GP letter and other study specific documents e.g. questionnaires, diaries (using correct templates) |  | **CI** | **X\*** |  |
| Coordinate multidisciplinary input to draft Protocol (external and internal) |  | **CI\*** | **X** |  |
| Ensure ECTU and Sponsor contribute to the relevant sections of the protocol |  |  | **X** |  |
| Manage the Protocol review process |  | **CI\*** | **X** |  |
| Ensure the Protocol has undergone scientific and statistical review |  | **CI** |  |  |
| Where applicable, ensure the protocol complies with NHS Lothian IT Security Policies and UoE IG policy | **Facilitator** |  |  |  |
| Prepare Investigator’s Brochure (IB) or Investigational Medicinal Product Dossier (IMPD)  |  | **CI\*** | **X** |  |
| Circulate final Protocol and related documents to participating Sites |  |  | **X** |  |
| Prepare Amendments as required |  | **CI\*** | **X** |  |
| Ensure Sites are informed of all Amendments, including the date on which the amendment should be implemented |  |  | **X** |  |
| Manage version controlled documents to Sites |  |  | **X** |  |
| **APPROVALS** |
| Create and control IRAS form |  |  | **X** |  |
| Review and approve document set prior to submission |  | **CI\*** | **X** |  |
| Prepare and submit documentation for REC favourable opinion/Competent Authority approval of Protocol and Amendments (via Combined Review where appropriate) |  | **CI\*** | **X** |  |
| Prepare and submit documentation for R&D/HRA approval of Protocol and Amendments |  | **CI\*** | **X** |  |
| Prepare and submit documentation for any other approvals as required e.g. ARSAC, HFEA, Phase I Committee and Amendments |  | **CI\*** | **X** |  |
| **IMP [delete if not relevant]** |
| Ensure initial and continuing supply of Investigational Medicinal Product (IMP) [and placebo] at site |  |  | **X** | **Insert organisation** |
| Manufacture and distribution of IMP |  |  |  | **Insert organisation** |
| Design IMP label | **Facilitator\*** |  | **X** |  |
| IMP [and placebo] labelling |  |  |  | **Insert organisation** |
| Qualified Person (QP) release |  |  |  | **Insert organisation** |
| **Risk assessment, monitoring and QA** |
| Prepare, circulate and sign Site feasibility questionnaires | **Facilitator\*** | **CI\*** | **X** |  |
| Share common Risk Assessment findings with CI |  | **CI\*** | **X** |  |
| Contribute to risk assessment e.g. identify / mitigate risks |  | **CI\*** | **X** |  |
| Perform monitoring activities as outlined in the Monitoring Plan | **Monitors** |  | **X\*** |  |
| Request and follow up with Sites to report Protocol deviations and violations to Co-Sponsors at agreed frequency |  | **CI\*** | **X** | **Site\*** |
| **pharmacovigilance [delete if not relevant]** |
| Ensure that all Sites are in possession of the current relevant safety information for the IMP |  |  | **X** |  |
| Notify updates to Reference Safety Item (RSI) to Sites |  |  | **X** |  |
| Report SUSARs to REC and MHRA within timeframes | **PhV** |  |  |  |
| Notify Sites of potential SUSARs |  |  | **X** |  |
| Notify Sites of USMs |  |  | **X** |  |
| Prepare substantial amendment to report USMs to MHRA and REC within timeframes |  | **CI\*** | **X** |  |
| **Filing systems** |
| Compile and maintain Trial Master File (TMF) |  |  | **X** |  |
| Provide Investigator Site File (ISF) Index to Sites |  |  | **X** |  |
| **Trial oversight and management** |
| Kick off Meeting | **ERO** | **CI\*** | **X\*** |  |
| Establish Project Management Group |  | **CI** | **X\*** |  |
| Establish Trial Steering Committee (TSC) |  | **CI** | **X\*** |  |
| Prepare TSC Charter |  | **CI** | **X\*** |  |
| Establish Data Monitoring Committee (DMC) |  | **CI** | **X\*** |  |
| Prepare DMC Charter |  | **CI** | **X\*** |  |
| Generate reports to DMC |  |  | **X** |  |
| Arrange meetings |  | **CI\*** | **X** |  |
| **Database and data collection** |
| Identify data fields required from Protocol as per DM procedures |  |  | **X** |  |
| Design Case Report Form (CRF).  |  | **CI\*** | **X** |  |
| Review and approve CRF | **Monitors** |  | **X\*** |  |
| Specification of randomisation procedures |  |  | **X** |  |
| Design randomisation procedures |  |  | **X** |  |
| Validate randomisation system |  |  | **X** |  |
| Specify data capture system |  |  | **X** |  |
| Design data capture system |  |  | **X** |  |
| Validate data capture system |  |  | **X** |  |
| Provide facility for unblinding |  |  | **X** |  |
| Ensure database security |  |  | **X** |  |
| Provide system release (for initial specification and corresponding amendments) |  |  | **X** |  |
| **DATA MANAGEMENT** |
| Draft and approve Data Management Plan | **Monitor\*** |  | **X** |  |
| Data entry to CRF / patient diaries |  | **CI\***  | **X\*** | **Site** |
| Housekeeping system, adjudication, follow up |  |  | **X** |  |
| Data query system, manage/follow up with sites |  |  | **X** |  |
| QC check of data |  |  | **X** |  |
| Database lock |  |  | **X** |  |
| **Statistical MANAGEMENT** |
| Sample size calculation and validation |  |  | **X** |  |
| Draft and approve Statistical Analysis Plan (SAP) |  |  | **X** |  |
| Interim analysis |  |  | **X** |  |
| Final analysis and validation |  |  | **X** |  |
| Statistical Reporting |  |  | **X** |  |
| **BUDGET** |
| ECTU specific costing |  | **CI** | **X\*** |  |
| Management of ECTU budget |  | **CI** | **X\*** |  |
| Management of ECTU invoices |  | **CI** | **X\*** |  |
| Organise participant payments if delegated to ECTU |  | **CI** | **X\*** |  |
| Organise supplies within ECTU budget |  | **CI** | **X\*** |  |
| **CONTRACTS** |
| Coordination of agreements | **ERO\*** |  | **X** |  |
| Ensure appropriate agreements are in place for the trial | **ERO** |  | **X\*** |  |
| **END OF TRIAL** |
| Prepare TMF for archiving |  |  | **X** |  |
| Prepare project closure and handover (to CI) plan |  |  | **X** |  |
| Archive TMF [using NHS Lothian R&D Archiving Services] in a secure location |  |  | **X** |  |
| Archive Investigator Site File and source documentation in a secure location |  | **CI** | **X\*** | **Site** |
| Archive database |  |  | **X** |  |
| Notify Sites of the end of the trial |  |  | **X** |  |
| Prepare and submit end of trial notification to REC, MHRA, R&D within timeframe |  | **CI** | **X\*** |  |
| **Reports and results** |
| Management of report deadlines/reminders |  |  | **X** |  |
| Ensure all contributors are appropriately included in dissemination plans |  | **CI** |  |  |
| Prepare and submit Funder progress reports as required |  | **CI\*** | **X** |  |
| Prepare and submit REC Annual Progress Report (APR) within timeframe |  | **CI\*** | **X** |  |
| Prepare annual Data Safety Update Report (DSUR) and supply to Co-Sponsors for review | **PhV\*** | **CI** | **X\*** |  |
| Prepare a participant dissemination plan |  | **CI** |  |  |
| Prepare and submit End of Trial Report to REC, Funder and Co-Sponsors within timeframe |  | **CI** | **X\*** |  |
| Review End of Trial Report | **QA\*** | **CI** | **X\*** |  |
| Prepare and submit primary journal publication |  | **CI** | **X\*** |  |
| Review journal publication |  | **CI** | **X** |  |
| Prepare and upload end of trial summary results to trial registry within timeframe |  | **CI** | **X** |  |
| Enter R&D accruals |  |  | **X** |  |
| Coordinate dissemination of trial results |  |  | **X** |  |
| **Communication strategies** |
| Facilitating design of trial logo |  | **CI** | **X\*** |  |
| Advertising campaign, poster/leaflet distribution |  | **CI** | **X\*** |  |
| Develop instructional video script for sites (if multicentre trial) |  | **CI** | **X\*** |  |
| Coordination of PPI activity |  | **CI** | **X\*** |  |
| Keep investigators up to date with trial progress  |  | **CI** | **X\*** |  |
| Maintain trial details on ECTU website  |  | **CI** | **X\*** |  |
| Support Investigator meetings |  |  | **X** |  |
| Deal with requests for data sharing  |  |  | **X** |  |

|  |  |
| --- | --- |
| **Sign** | **Date** |
| ECTU Representative  |  |
| Co-Sponsor Representative |  |
| Chief Investigator |  |