**Example Checklist for Inclusion with Research Project Files**

|  |  |
| --- | --- |
| **Title of Research Project:** | |
| **RGIT Ref:** | |
| **Chief Investigator:** | **Lead Centre:** |
| **Other Members of the Research Team:**  **1.**  **2.**  **3.**  **4.** | **5.**  **6.**  **7.**  **8.** |
| **ISRCTN Ref (if appropriate):**  **ClinicalTrials.gov ID (if appropriate):** | **EudraCT Ref (if appropriate):**  **Other Ref(s):** |

**PLEASE NOTE:** Those documents marked with an asterisk (\*) may not be required for all projects.

|  |  |
| --- | --- |
| **1. Protocol** |  |
| Final, signed research protocol and amended protocols, with version numbers | □ |
| Confirmation of peer review | □ |
| Example of Informed Consent Form and any amendments | □ |
| Examples of any other written information provided to subjects and any updates \* | □ |
| Copy of advertisement for subject recruitment and any amendments \* | □ |
| Copy of any letter/information for a patient’s GP or Consultant \* | □ |
| Investigator’s Brochure and updates \* | □ |
| **2. Ethics** |  |
| HRA approval and HRA approval for all amendments  Final Ethics application and any amendments | □□ |
| Ethics approval letter(s) | □ |
| Ethics Committee composition where study was approved | □ |
| Any Ethics and HRA Correspondence | □ |
| Ethics Reports | □ |
| **3. Research and Development** |  |
| Confirmation of Capacity and Capability | □ |
| Copy of financial information relating to the study (funding application/award letter/costings) | □ |
| Insurance Statement (copy of any certificate/letter/agreement) | □ |
| Copy of Sponsor agreement and allocation of responsibilities | □ |
| Copy of any signed agreement(s) between involved parties | □ |
| **4. Regulatory** |  |
| Regulatory Application Form(s) (if applicable) \* | □ |
| Regulatory Approval(s) (if applicable) \* | □ |
| **5. Correspondence (except Regulatory and Ethics/HRA)** |  |
| Relevant written correspondence | □ |
| **6. Research Team – Staff and Training** |  |
| Signed/dated CVs evidencing the qualifications of CI/research team (or other relevant documents) | □ |
| Delegation of duty log | □ |
| Staff training records | □ |
| Signature log | □ |
| Honorary Contracts or Licence To Attend or Letter of Access | □ |
| **7. Participant Information** |  |
| Copies of original informed consent forms signed by each project participant | □ |
| Master randomisation list | □ |
| Subject screening log | □ |
| Subject ID code list | □ |
| Subject enrolment log | □ |
| **8. Data Collection** |  |
| Sample Case Report Form and completion guidance | □ |
| Record of retained body fluids/tissue samples (if any) \* | □ |
| Normal laboratory reference ranges for any tests used or medical/technical procedures included in protocol (includes central labs) \* | □ |
| Lab/technical procedures/tests certification or accreditation \* | □ |
| Copies of calibration records for technical equipment \* | □ |
| **9. Serious Adverse Events \*** |  |
| Sample SAE form and copy of reporting procedures \* | □ |
| Completed SAE forms (if not included in the Case Report Forms) \* | □ |
| Copies of correspondence from CI to Sponsor/Regulatory Authority(ies) reporting SAEs \* | □ |
| Safety reports \* | □ |
| **10. Pharmacy/Product-Related \*** |  |
| Instructions for handling of IMP(s)/trial related material(s) (if not in the protocol) \* | □ |
| Sample label for IMP(s) \* | □ |
| Shipping records for IMP(s) \* | □ |
| Certificate(s) of analysis of IMP(s) shipped \* | □ |
| Decoding procedures for blinded trials \* | □ |
| IMP accountability at site \* | □ |
| IMP(s) destruction record(s) \* | □ |
| **11. Monitoring and Audit** |  |
| Record(s) of all monitoring reports | □ |
| Final close-out monitoring report | □ |
| Audit certificate (if available) \* | □ |
| Clinical trial report \* | □ |