**QUEEN’S UNIVERSITY BELFAST**

**Research File Content Checklist\***

\*Note this checklist is for guidance only and may be adapted. Documents required will vary according to the type of research.

|  |  |
| --- | --- |
| **Research Title:** | |
| **Chief Investigator:** | |
| **Members of Research Team** | |
| **Staff:** | **Students:** |
| **Reference Numbers (as applicable)** | |
| **QUB Ref:** | **Ethics Ref:** |
| **NHS/HSC Trust Ref:** | **Other Ref:** |

|  |  |
| --- | --- |
| **Title of Document** | **Tick if Included** |
| **1. Protocol and Consent** | |
| Final 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 patients GP or consultant |  |
| **2. Ethics** | |
| Final Ethics Application and any amendments |  |
| Ethics favourable opinion letter(s) |  |
| Ethics Reports |  |
| Any Ethics Correspondence |  |
| **3. Research and Development** | |
| Trust and R&D application form and approval letter |  |
| Copy of Trust Permissions |  |
| Copy of financial information relating to the study (funding application/award letter/costings) |  |
| Insurance Statement (copy of certificate/letter/agreement) |  |
| Copy of sponsor agreement and allocation of responsibilities |  |
| Copy of any signed agreement(s)/contracts between involved parties |  |
| **4. Regulatory** | |
| Copy of any correspondence with Regulatory Authority |  |
| **5. Correspondence (except Trust and Ethics)** | |
| Relevant written correspondence |  |
| **6. Research Team** | |
| CVs for Chief Investigator/research team (or other relevant documents) |  |
| Delegation of duty log/study management structure |  |
| Training records |  |
| Honorary Contracts for non-NHS Trust staff |  |
| **7. Participant Information** | |
| Copies of original informed consent forms signed by each project participant |  |
| Subject ID code list |  |
| Master randomisation list (if applicable) |  |
| Subject screening log (if applicable) |  |
| Subject enrolment log (if applicable) |  |
| **8. Data/Sample Collection** | |
| Records of human tissue samples (if any) |  |
| Transport/transfer records for human tissue samples |  |
| Samples of forms used for the study and completion guidance |  |
| Document of data storage |  |
| Standard Operating Procedures |  |
| Risk assessments |  |
| **9. Adverse Events** | |
| Completed Adverse Event report form(s) if applicable |  |
| **10. Intervention Product Related** | |
| Details of product to be used and the supplier |  |
| Instructions for usage, storage and disposal of any product to be used |  |
| Shipping records for the product |  |
| Certificate(s) of analysis |  |
| **11. Audit** | |
| Record(s) of all audit reports |  |