**Approval to begin study at UCLH**

**Applications to the Joint Research Office (Version 2: April 2022)**

All submissions for approval to begin at UCLH should be sent to uclh.randd@nhs.net

This checklist should be competed in all cases and provided with all the relevant documents to the JRO. A review cannot commence until all applicable documents are provided. Incomplete document sets will be returned for completion. Where a document is not deemed applicable to the study, this should be indicated under N/A.

**Table A: Complete in all cases**

|  |  |
| --- | --- |
| **1. Study Title** |  |
| **2. Lead Researcher (PI) name and email** |  |
| **3. Point of Contract name and email (if different from Lead Researcher):** |  |
| **4: Sponsor Name and point of contact** |  |
| **5: IRAS Reference** |  |
| **6: Is the study adopted onto the NIHR portfolio (yes/no)** |  |
| **7: Type of Study (Clinical Trial of Medicinal Product or Other)** |  |
| **8: Service departments and other groups at UCLH required to deliver the study (tick)** | **Pharmacy****Imaging (UCLH)****Imaging (NHNN)****Nuclear Medicine****Pathology****Beacon Build****Other**  |
| **9: Services and contractors external to UCLH required to deliver the study (list each including their name, point of contact, and nature of involvement)** |  |
| **10. List any letters of access/research passports which may be required for staff to work at UCLH** |  |

**Continued below**

**Table B: Complete in all cases**

Please indicate (tick) the documents which have been provided as part of the minimum document set (state N/A where the document is not applicable for the study)

|  |  |  |
| --- | --- | --- |
| **a.** **Document** | **b.** **Confirmation documents have been provided (tick) or N/A**  | **c.** **For those sections marked as N/A in column C (only) provide a brief description for why the document is considered N/A** |
| Copy of IRAS Form (combined REC and R&D form) as submitted for HRA ApprovalFor CWOW studies (only) a copy of the CWOW Ethical consideration form plus a copy of the IRAS Part B section 3 |  |  |
| Protocol |  |  |
| Any substantial or non-substantial amendments |  |  |
| Localised documents (including the Participant information and consent documents) |  |  |
| Statement of Activities/OID relevant to the participating NHS organisation (non­ commercially sponsored only) or delegation log (commercially sponsored only) |  |  |
| Relevant template contract/model agreement (in addition to the SOECAT) |  |  |
| Costing template (commercially sponsored only) or Schedule of Events/SOECAT (non­ commercially sponsored only) |  |  |
| Other documents the sponsor requires for the site to support the set-up of the study  |  |  |
| Copy of HRA Initial Assessment letter (or HRA Approval letter in cases where it has been issued) |  |  |
| UCLH [Pathology request form](https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=22107) (where pathology services are required to deliver the study) and Lab Manual |  |  |
| Pharmacy Manual and Pharmacy request form and where applicable SMPC and IB and MHRA Approved Labels |  |  |
| Imaging Guidelines and Imaging request form and where required, HRA radiation assurance |  |  |
| ARSAC Approval ( if required for the study) |  |  |
| UCLH Research Passport/Letter of Access applications |  |  |