

Assess, Arrange and Confirm UCLH

Minimum Document Set (v2 20.04.2022 UCLH/UCL JRO)

The following documents should be provided by the Sponsor and submitted to the JRO to initiate the Assess, Arrange and Confirm (AAC) approval at UCLH. The documents should be provided with the UCLH checklist for AAC (refer to [Assess, arrange and confirm | Joint Research Office - UCL – University College London](#)).

Minimum Document Set:

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA
- For CWOW studies (only) a copy of the CWOW Ethical consideration form plus a copy of the IRAS Part B section 2
- Approved Protocol
- Any substantial or non-substantial amendments
- Localised Organisation information documents (including Participant information and consent documents)
- Organisational Information Document (OID relevant to the participating NHS organisation (non-commercially sponsored only) or delegation log (commercially sponsored only)
- Relevant template contract/model agreement (if required in addition to the OID Model non-commercial agreement ([mNCA](#)) or model commercial trial agreement ([mCTA](#)).
- Commercial costing template /access to interactive [costing tool](#) (commercially sponsored only) or Schedule of Events (SoE) / Schedule of Cost Attribution Template [SoECAT](#) (non-commercially sponsored only)
- Delegation Log (for Clinical Trials)
- Any other documents the sponsor requests to be provided by the Sponsor
- Copy of HRA Initial Assessment letter (or HRA Approval letter in cases where no initial assessment letter is issued)
- Signed [PI responsibilities document](#)
- Confirmation of Epic access and Training in the Epic Research Module at UCLH (if not previously provided)

The following documents should also be included (where relevant to the study requirements):

- UCLH [Imaging and nuclear medicine request form](#) and Imaging Manual/Guidelines (where imaging at UCLH is required to deliver the study) and UCLH [NHNN Imaging request forms for imaging at NHNN](#) (also refer to the [proforma guidance](#)). The form available to download from UCLH intranet and accessible by UCLH PI / study co-ordinator. UCLH PI / study co-ordinator should complete the forms.
- HRA Radiation Assurance form
- UCLH [Pathology request form](#) (where pathology services are required to deliver the study) and Lab Manual.). The form available to download from UCLH intranet and accessible by UCLH PI / study co-ordinator. UCLH PI / study co-ordinator should complete the forms.
- UCLH [Pharmacy request form](#) and the Pharmacy Manual, SMPC, IB and MHRA approved labels (where pharmacy at UCLH is required to deliver the study).). The form available to download from UCLH intranet and accessible by UCLH PI / study co-ordinator. UCLH PI / study co-ordinator should complete the forms.
- ARSAC Approval
- Research passport/Letter of Access [application](#)