# UCL/UCLH Joint Research Office checklist

[Starting a new study](https://www.ucl.ac.uk/joint-research-office/starting-new-study)  
There are typically three stages of approval that must be considered before conducting clinical research:

* [Sponsorship and funding](https://www.ucl.ac.uk/joint-research-office/conduct-study/sponsorship-and-funding)
  + Evidence of peer review
    - [Flow diagram](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/guidance_for_researchers_-_jro_peer_review_requirements_v2.0_06.04.2020.pdf)
    - [SOP](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/jro_sop_15_peer_review_for_studies_sponsored_by_ucl_and_uclh_v2_06042020_final.pdf)
  + Draft protocol for an [observational study on a JRO template](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/JRO_UCLUCLH_Observational_Protocol_Template_-_version_1_17-08-2015.docx)
  + [Draft IRAS form](https://www.myresearchproject.org.uk/)
  + Applicable draft participant documents (where patients are being consented)
    - Participant Information Sheet
    - Consent forms
    - GP letters
  + [Details of any statistical engagement](https://www.ucl.ac.uk/joint-research-office/new-studies/biostatistics-group)
  + CV of the Chief Investigator ([HRA template](https://www.hra.nhs.uk/documents/1010/guidance_on_submission_of_cv1_3sIWGet.doc))
  + Draft [Organisation Information Document](https://myresearchproject.org.uk/help/help%20documents/Organisation_Information_Document__Data-Processing_v1-1.docx) and [Schedule Of Events](https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/excess-treatment-costs.htm)
  + Evidence of funding (where applicable)
  + Details of any collaborations with external parties, including commercial entities and suppliers
  + Any conflicts of interest
* [Regulatory Approvals](https://www.ucl.ac.uk/joint-research-office/conduct-study/regulatory-approvals-)
  + Research Ethics
  + GDPR
    - [HRA guidance](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-you-need-do/transparency/)
    - [UCLH transparency checklist](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/transparency_checklist.docx)
  + HRA
    - Complete a research application form on the [Integrated Research Application System (IRAS)](http://www.myresearchproject.org.uk/)
    - [Prepare your study documents](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/)
    - Book your application in through the [Online Booking Service](https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/)
    - E-submit your [applications in IRAS.](https://www.myresearchproject.org.uk/)
* UCLH feasibility (aka [NHS Site Assess, Arrange and Confirm](https://www.ucl.ac.uk/joint-research-office/new-studies/assess-arrange-and-confirm))
  + Checks
    - [General feasibility assessment](http://www.hra.nhs.uk/resources/hra-approval-nhs-organisation-guidance/#NHS) as required by the HRA
    - Clinical director authorisation
    - Finance review to ensure costs are identified and covered
    - Where required, a Contract review and negotiation
    - [Honorary research contracts or Letters of Access](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/jro_sop_7_-_jro_administration_of_research_passports_v4_13.11.2019_clean.pdf) where required for non-UCLH researchers to carry out research activity on site.   
      Please contact the JRO on [uclh.jro-communications@nhs.net](mailto:uclh.jro-communications@nhs.net)
  + Core documents
    - Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval Protocol
    - Any substantial or non-substantial amendments
    - Participant information and consent documents
    - Statement of Activities relevant to the participating NHS organisation (non-commercially sponsored only) or delegation log (commercially sponsored only)
    - Relevant template contract/model agreement (if needed in addition to the Statement of Activities)
    - Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
    - Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
    - Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter, and final versions of study documents.

Links

* [UCL/UCLH JRO](https://www.ucl.ac.uk/joint-research-office/)
* [Approach the JRO](https://www.ucl.ac.uk/joint-research-office/contact-us)