

CAHSS Sponsorship Review – Before, During and After

Documents to submit for Sponsorship review:

- Protocol / Study outline
- School ethics application form / IRAS form, if applying for NHS approvals
- Participant Information Sheet and Consent Form (CAHSS templates for non-CTIMP research are available by emailing Cahss.res.ethics@ed.ac.uk)
- Questionnaires and / or outline of interview questions
- Flyer / Advert / Poster to be used for recruitment purposes
- Any other documentation that will be seen by potential participants
- A completed Risk Assessment form, if relevant
- CVs for PI and CI, if applying for NHS approvals

Before you send your documents for Sponsorship review, please:

- include a header on all documents with short Study Title, version and date of document and relevant logos e.g. UoE. (Use date format ddmmmyyyy to avoid any ambiguity.)
- include a footer on all documents with Page XofX numbering
- please use this file name format: 'study document type DRAFT V1 DDMMYYYY' e.g. Participant Information Sheet DRAFT V1 01 Jan 2021
- check page numbering on all documents
- ensure consistency of information across all documents e.g. study title needs to be the same on every document

Sending your application for review:

- please email all study documentation (preferably in Word version) to Cahss.res.ethics@ed.ac.uk for review. We will aim to review and send you comments within 5 working days

Following Sponsorship review comments, please:

- accept suggested Track Changes and address comments, as appropriate
- update your documents in Track Changes, so we can see what has been changed in response to our comments. If you are making any other changes to your study, please also do this in Track Changes so that it clearly stands out when we are reviewing your updates
- change the date in the file name of any updated document, so it is clear which is the new version

Once your project is ongoing, please:

- ensure you send ethics approval letter (and R&D approval letter, if relevant) to CAhss.res.ethics@ed.ac.uk before you start your study
- remember to send any proposed changes / amendments for our review before seeking ethical approval and implementing any changes
- If your study involves the NHS remember to submit yearly Annual Progress Reports and the End of Trial declaration form to the REC c.c. CAhss.res.ethics@ed.ac.uk