Research ethics: changes due to COVID-19

This is a summary of research ethics processes to-date April 2020.

Currently, no face-to-face research interviews are permitted, and flexibility is key for current or planned research i.e. conducting video or telephone interviews wherever possible with participants.

For projects with current ethical approvals

If you have NHSREC and / or HRA approval for your current project but DON’T have provision for collecting data remotely e.g. to conduct video or telephone interviews, this is classed as a non-substantial change, see 3.1.2 (a) page 3 below. In this case, all you will need to do is inform the sponsor (the university) of the change using a non-substantial amendment form. You must not make any changes that would create additional burden to NHS staff or resources.

If you are in this situation but have approval from University ethics (FHMREC) then you will need to submit an amendment to that ethics committee.

For projects that do not yet have ethics approval

i. University ethics processes

The Faculty of Health and Medicine research ethics committee (FHMREC) is operating as usual for amendments and submissions for ethics review and University Sponsorship, web link

https://www.lancaster.ac.uk/health-and-medicine/research/ethics/

ii. NHS / HRA approval processes

A number of NHS Trusts have halted any current or future research with service users, patients or NHS staff until the pressures of COVID-19 have resolved. Please contact the relevant R&D office of the NHS Trust(s) that has agreed (or will agree) that the study can proceed within their organisation for guidance, and copy supervisors into communications with R&D offices. See a summary of the NHS / HRA guidance below. Please make time to access the web links and check back regularly because information will continue to be updated.

a. Guidance of student projects:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/
Excerpt from this guidance:

“Applications for the following types of educational projects will continue to be accepted as normal:

- PhD student projects [This will also apply to DClinPsy projects]

Applicants should include with their application assurance in principle from the relevant NHS/HSC R&D offices or clinical research network that their study is able to proceed. Even if projects are approved, it cannot be guaranteed that NHS/HSC organisations will be able to support such studies, even if in-principle agreement was given prior to submission.

Chief investigators of research projects for doctoral studies may still apply for REC or R&D study-wide review. We ask that you consider the timing of both your submission and the start of your research. If it is possible to delay either and reduce the immediate pressure on the approval service or health and/or social care system, we ask you to do so.

Exemptions

For educational studies taking place at a single NHS site in England and which do not require REC review [i.e. studies involving only NHS staff as participants rather than service users], the NHS organisation and the university sponsoring the research will usually have an existing understanding about how these types of studies are handled.

For these studies, there are two options depending on existing local arrangements:

1. Where universities and NHS organisations currently do not require an IRAS form to be submitted to the NHS R&D office but have alternative arrangements in place, these may continue.

2. Where universities and NHS organisations currently do require an IRAS form to be submitted to the R&D office, then an application for HRA Approval should be made. An outline Organisational Information Document and Schedule of Events template will not be needed as there is not likely to be the need to attribute funding. Such student studies will be reviewed against the same HRA assessment standards and criteria as other studies. It is expected that the sponsor will provide any advice and support to students using this process.

Please contact the R&D department of the NHS trust in which you wish to undertake your research for guidance on what arrangements are in place.”

b. Guidance about COVID-19 for sponsors, sites and researchers


This guidance relates to Research Ethics Committee (REC) and NHS arrangements. This is rapidly evolving and guidance will be updated in response to feedback. Please check this link regularly for updates.