Guidance for NHS/IRAS/Sponsorship applications

Research requiring the collaboration of the NHS must have an individual or organisation willing and able to take on the responsibilities of the research sponsor* under the ‘Research Governance Framework for Health and Social Care’. Full details of this Framework are available on the NHS HRA UK website. (*To note, in this context, the sponsor is the individual, company, institution or organisation which takes on ultimate responsibility for the management of the research.)

If you wish to name Lancaster as your sponsor on your NHS (IRAS) application form please follow the guidance below to apply for ‘sponsorship’:

1. Complete an IRAS application form using the Integrated Research Application System (IRAS). Please note if you have any technical difficulties in IRAS you can contact the IRAS helpdesk.

Notes on completing the IRAS form:

- **Clinical trials/investigations** – please bear in mind that this has a very specific meaning within the NHS. If you are unsure whether your study may be a clinical trial or investigation please email the ethics team.
- **Sections A4 & A64** The contact on behalf of the sponsor is Becky Gordon, Research Support and Systems Manager, Research Services, Lancaster University, Tel: +44 (0) 1524 592981, email ethics@lancaster.ac.uk
- **Section A51** – it is important that you tick all reports and dissemination methods that apply
- **Section A76 – 1,2,3** Please read the notes in the insurance section(s) on the IRAS form: if Lancaster University’s insurance cover applies insert the phrase ‘Lancaster University legal liability cover will apply’ in the insurance section(s) as appropriate and ensure that you append the Lancaster University insurance documents to your application.
- **Section A78** Please answer ‘yes’ to this question: one can usually expect to generate intellectual property in research.
- **Section D2** Please do not complete the ‘declaration by the sponsor’s representative’ section (this must be completed by the University).

2. Create a single pdf containing all the documents in the order that you will use them (including, but not limited to, IRAS form, participant information sheet, consent form, interview schedule, questionnaires).

3. Attach to an email the single pdf (as described at 2 above) and send the email to the secretary of the Faculty Research Ethics Committee [ethics@lancaster.ac.uk]

4. HRA Statement of Activities (SoA) form and Schedule of Events (SoE).
You are required to complete these two documents as part of the HRA review process. Templates can be found on the NHS HRA website.

4.1 In completing SoA, Schedule 2 (Material Transfer Provisions), consider whether your study involves the transfer of material to or from the Participating Organisation(s):
- If you are not exchanging any materials with the Participating Organisation(s), please tick the first box;
- If you are exchanging any materials with the Participating Organisation(s), please tick the second box and contact the Contracts Team (rso-contracts@lancaster.ac.uk) with full details of the project, so that they can put a suitable Material Transfer Agreement in place for the project.

4.2 IMPORTANT: in completing SoA Schedule 3 (Confidentiality, Data Protection and Freedom of Information), consider whether your study involves the transfer of Personal Data AND/OR confidential information from/to the Participating Organisation(s):
- If you are not exchanging any Personal Data or confidential information with the Participating Organisation(s) then please tick the first box; or
- If you are exchanging Personal Data or confidential information with the Participating Organisation(s) please tick the second box and append the document here to your application. (Please ensure that you have read the additional document and comply with the terms in the course of your study).
- **Under no circumstances should the third box of Schedule 3 be ticked.**

Please email the SoA and SoE as separate documents (at the same time as your application documents) to ethics@lancaster.ac.uk

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5. Route for Review

(i) If your application needs to be reviewed by NHS REC (for example projects involving patients) it will be considered first by the Chair of the Faculty Research Ethics Committee, who decides whether the University can act as sponsor for your research. Shortly after submitting your application you will receive an email to let you know whether the University can act as the sponsor for your project. At that stage you may be asked to make some amendments to your application before it can be signed off electronically in the IRAS system. You will also receive an email outlining the next steps in the process.

(ii) If your application does not require review by a NHS REC (for example projects which involve NHS staff only) it will need to be reviewed by the Faculty Research Ethics Committee. The application will be reviewed by the FREC and considered for sponsorship at the same time. Please see the FREC webpages for more information about the review process and dates of committee meetings:

FHMREC
FSTREC
FASS/LUMS

6. When the application is ready to be signed off, you will be notified by email, and will be sent the letter confirming Lancaster University sponsorship and a copy of the University's insurance documents.

7. Please remember that you must provide the NHS with annual reports, progress reports and end of study reports. This is a condition laid down by the NHS and it is also a condition of University sponsorship.

8. Please note that, if your project is externally funded, it will need to be referred to the Contracts Team, by Research Services, so that, once financial approvals are in place, the Contracts Team can negotiate an appropriate research contract with the funder and collaborators/sub-contractors. If your project is funded, please contact the Research Development Officer in pre-award dealing with your project as soon as possible regarding a referral to the Contracts Team.
Research student or non-externally funded research

Academic submits project on IRAS

Student works with supervisor to submit project on IRAS

PI submits project on IRAS

PI sends full application to ethics@lancaster.ac.uk

PI contacts Contracts Team

Contracts team negotiates collaboration agreement

Collaboration agreement signed

Once all confirmed research project starts

Externally funded research

Proposal submitted with RSO

Awarded notification to PI

PI submits project on IRAS

R&D Review (no HRA ethical review)

FREC review with all changes resubmitted and approved by lead reviewer

FREC Chair check and sign off

IRAS signed-off by Becky Gordon (or other LU authorised signatory)

HRA approval

Academic submits project on IRAS

Student works with supervisor to submit project on IRAS

Ethics team check application, SOA and SOE

Full HRA ethical review required

FREC review with all changes resubmitted and approved by lead reviewer

FREC Chair check and sign off

IRAS signed-off by Becky Gordon (or other LU authorised signatory)

HRA approval

Once all confirmed research project starts