Guidance for NHS/IRAS/Sponsorship applications and amendments

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 UK Framework for Health and Social Care Research. (*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.)

The Health Research Authority (HRA) has some useful guidance including two useful decision tools to help you to decide whether your work will be defined as research, and then what (if any) level of approval will be needed from the HRA here. To note, if the tools indicate that your project is not defined as ‘research’ for NHS purposes and/or if they indicate it does not need NHS REC review it is likely that your project will need to be submitted to one of the University’s Faculty Research Ethics Committees for review. If in doubt, please contact the ethics team.

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

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 Technical Helpdesk on 0207 043 0734 or email them at helpdesk@myresearchproject.org.uk. For other queries, contact the HRA queries line

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

- **Student applicants**: Please answer ‘yes’ to question 9, ‘Is the study or any part of it being undertaken as an educational project?’

- **Student applicants: Sections A2-2 & A3-1.** HRA guidance notes that students should not normally take the role of chief investigator. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship. Please discuss this with your supervisor before completing these sections.

- **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 A22** – it is appropriate to mention the process for participants withdrawing from the research in this section.

- **Section A26** - Include details here of the Lone Worker Policy or Guidance you are following (from which agency or source), outlining the main elements of it that apply to you. You may wish to use the University’s Lone Worker Guidance (field work) as the basis of this section: [http://www.lancs.ac.uk/depts/safety/files/fieldguidance.pdf](http://www.lancs.ac.uk/depts/safety/files/fieldguidance.pdf)

- **Section A37** - State that data on portable devices will be encrypted; if it cannot be encrypted, confirm that any identifiable data (including recordings of participants’ voices) will be deleted from the recorder as quickly as possible (eg when it has been transferred to a secure medium, such as a password protected PC) and in the meantime the recorder will be stored securely.

- **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).

- **No questions are to be left blank, instead please indicate the question is not applicable by adding ’n/a’. Leaving questions blank will invalidate the sponsor signature and could cause delays for your project.

- The HRA require specific wording to be given on your Participant Information Sheet, as well as project specific information on who will have access to personal data, where this data is held and

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how long for. Please include this information, as well as the text below:

“Lancaster University will be the data controller for any personal information collected as part of this study.

Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection"

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). Please ensure that the LU logo is present on all participant materials, and please include version numbers (starting at 0.1) and the date in full (dd/mm/yyyy) on these materials.

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. Student applicants should refer to the HRA guidance here: student research. Please note that Lancaster University processes require that students who need R&D approval for one site only need to submit an IRAS form, following the guidance laid out here.

5. HRA Statement of Activities (SoA) form and Schedule of Events (SoE).
You are normally required to complete these two documents as part of the HRA review process. Templates can be found on the NHS HRA website. Please note that student projects (educational studies) that are taking place at a single NHS site in England AND which do not require review by an NHS REC are not required to submit these documents.

5.1 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.

5.2 In completing SoA, Schedule 3 (Data Processing), consider whether your study involves the processing of Personal Data by the Participating Organisation(s) on behalf of the Sponsor:
• If your study does not involve processing of Personal Data by the Participating Organisation on behalf of the Sponsor, please tick the first box;
• If your study does involve processing of Personal Data by the Participating Organisation on behalf of the Sponsor, and the Sponsor will be providing separately a GDPR compliant Data Processing Agreement, 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 Data Processing Agreement in place for the project. OR:
• If your study does involve processing of Personal Data by the Participating Organisation on behalf of the Sponsor and the provisions of existing Schedule 3 (Data Processing) will apply, please tick the third box.

5.2 In completing SoA Schedule 4 (Data Sharing), consider whether your study involves the transfer of Personal Data AND/OR confidential information from/to the Participating Organisation(s):
• If you are not transferring any Personal Data or confidential information with the Participating Organisation(s) then please tick the first box; or
• If you are transferring 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) OR:
• If you are transferring Personal Data or confidential information with the Participating Organisation(s) and the provisions of existing Schedule 4 (Data Sharing) will apply, please tick the third box.
Please email the SoA and SoE as separate documents (at the same time as your application documents) to ethics@lancaster.ac.uk

6. 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

7. 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.

8. 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.

9. 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.

Please note: any changes made to your application form in the IRAS system after it has been signed electronically will invalidate the signature, and therefore sponsorship approval. If further changes are needed to your IRAS form following sign off, please contact ethics@lancaster.ac.uk with details before proceeding.

Amendments

The HRA have two categories for amendments – substantial, and non-substantial. Examples of each are listed here.

For substantial amendments:
1) Complete the ‘Notice of Substantial Amendment’ form in IRAS, and send this (along with any other modified documents, such as participant information sheet and consent form) to ethics@lancaster.ac.uk. Please highlight changes on the documents so that the changes can be clearly seen. It is helpful to include in your e-mail a brief summary of the changes you are making.
2) The Faculty REC Chair will consider the amendment for sponsorship.
3) When the amendment form is ready to be signed off, you will be notified by e-mail. You should request the sponsor signature in IRAS, using the same sponsor details as given in the guidance notes above.

For non-substantial amendments:
1) Complete the template document on this page (approximately half way down the page), and send this (along with any other modified documents, such as participant information sheet and consent form) to ethics@lancaster.ac.uk. Please highlight changes on the documents so that the changes can be clearly seen. It is helpful to include in your e-mail a brief summary of the changes you are making.
2) The Faculty REC Chair will consider the amendment for sponsorship.
3) When the amendment is approved, you will receive an e-mail from ethics@lancaster.ac.uk confirming
that this is ready to be submitted to the HRA at hra.amendments@nhs.net. Please note that we do not sign the notification of non-substantial amendment form.

**Under no circumstances must any amendment be submitted to the HRA without sponsor approval – the only authorised sponsor signatory for Lancaster University is obtained via ethics@lancaster.ac.uk.**