

Guidance for Non –Educational Research involving Patients or their non-anonymised data/samples

For research that is not being undertaken as part of an educational qualification the process, adopted by the Trust, in order to conduct research within the NHS that involves patients or their non-anonymised data/samples would be as per national guidelines as follows:

1. Refer to the attached leaflet and use the HRA tools (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>) to determine if you are doing research
2. If you are doing research then you will need HRA approval (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/>)
3. As a part of the HRA approval process if your project involves patients or their non-anonymised data/samples it needs to be submitted for a Research Ethics Committee (REC) approval (<http://www.hra-decisiontools.org.uk/ethics/>)
4. The process of HRA and REC approval is all done from one system (<https://www.myresearchproject.org.uk/help/hlphraapproval.aspx>)
5. Set up an IRAS account (<https://www.myresearchproject.org.uk/Help/HelpPage.aspx>) to complete the HRA/REC documentation .
6. Your research may need to obtain Consent from participants (<http://www.hra-decisiontools.org.uk/consent/>)
7. Prepare the relevant documents that are needed for the submission (<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>)
8. Complete the relevant forms within IRAS and before submission we would ask you to transfer your application form for us to check the content (this may save you time in it being validated by HRA and reduce any unnecessary delays).
9. Once your application is made through IRAS you may need to attend an Ethics mtg. - if you are invited to attend then you should as this is an excellent opportunity to put your project across and answer questions on the day (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/applying-research-ethics-committee/>).
10. Once you receive a favourable opinion (approval) from the HRA and Ethics you should forward this to us in the Research Department along with the local document pack whereupon we will review the Organisational Information Document (OID), Schedule of Events (SoE)/Schedule of Events Cost Attribution Tool (SoECAT) and complete as necessary to confirm capacity and capability (where applicable).
11. Following the Trust issuing confirmation of capacity and capability you will be able to proceed with the recruitment of participants to the study.

I hope the above explains the process for conducting NHS research within EPUT and I can confirm that the EPUT Research department is here to provide support, guidance and a certain amount of assistance in completing any of the above.

Should you need to discuss the process or require any further information then please feel free to contact the research department via e-mail to epunft.research@nhs.net