Navigating Research and Development Approvals

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Academic and Clinical Central Office for Research and Development

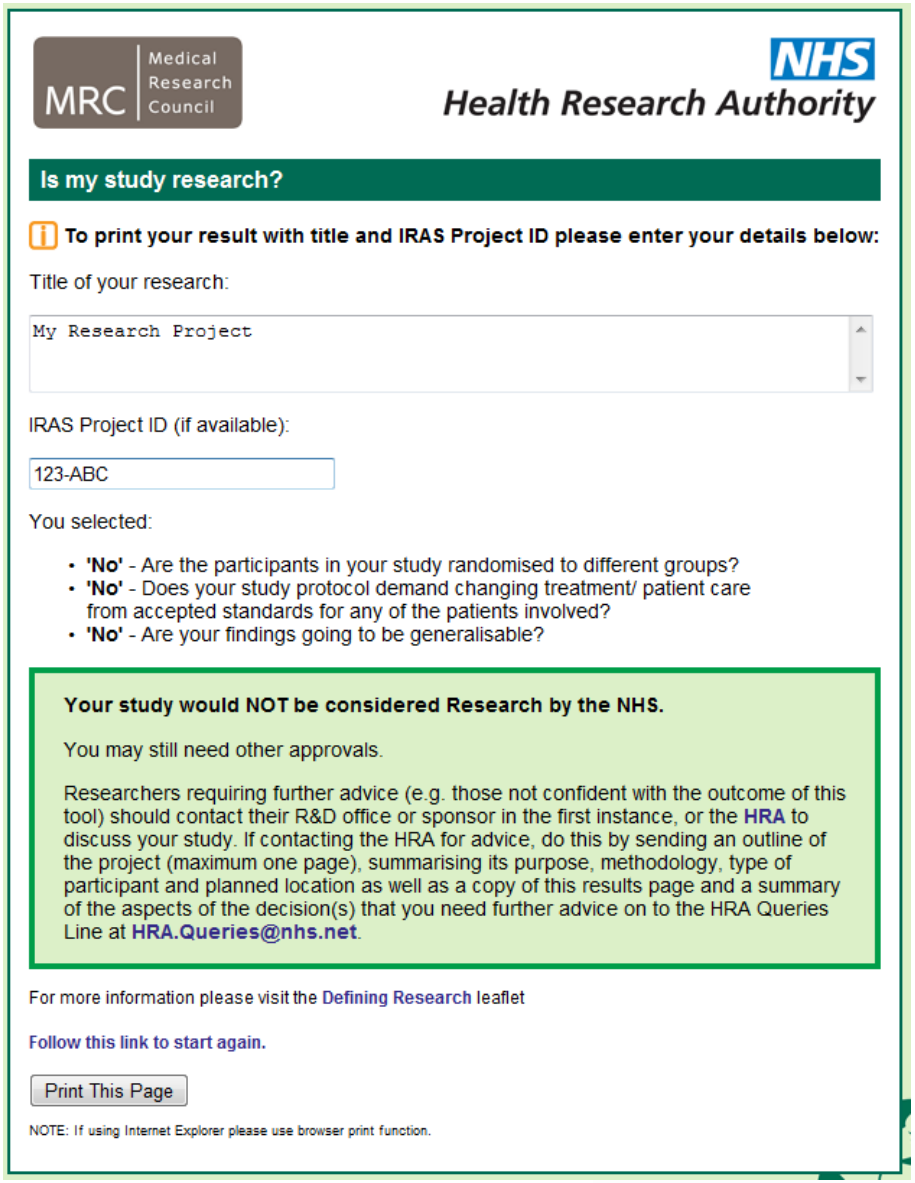
Is this Research?

Different types of projects

- Audit
- Service Development
- Service Evaluation
- Public Health Surveillance
- Case Study
- **Research**

HRA Decision Tool: NRES guidance ‘Defining Research’

http://www.hra-decisiontools.org.uk/research/



MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

My Research Project

IRAS Project ID (if available):

123-ABC

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **HRA.Queries@nhs.net**.

For more information please visit the Defining Research leaflet

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

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NHS Lothian

When is R&D approval required?

Research studies involving NHS patients, their tissues, their data, or NHS resources

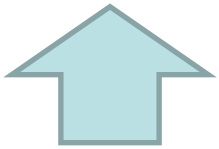
or

Research studies involving NHS staff participating by virtue of their profession

- ensures the legal obligations of the Board are met
- provides insurance/indemnity for research studies under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS)
- is a condition of a favourable ethical opinion

When is R&D approval required?

(R&D) Management Approval



Associated ‘approvals’

- Research Ethics Committee - govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants
- Medicines and Healthcare products Regulatory Agency - all studies falling into the category of Clinical Trials will require authorisation by the MHRA
- Caldicott - for ensuring patient-identifiable information is shared in an appropriate and secure manner
- Research Passports - mechanism for non-NHS staff to obtain an Honorary Research Contract or Letter of Access (LOA) when they propose to carry out research in the NHS

When is R&D approval required?

Study types:

- Regulated (Sponsor; R&D; REC; MHRA)
- Non-regulated (Sponsor; R&D; REC) … but …
  - Staff only (Sponsor; R&D)
  - Data (Sponsor; R&D; Caldicott)
  - Tissue banks/Databases (REC)
- Commercial vs Non-Commercial (Sponsor; R&D; REC; MHRA?)

Site types:

- Research
- Participant Identification Centre (PIC)

How to apply for approvals

IRAS

- web-based application system(s!)
- enables you to enter information once about your intended research project - generating all your necessary research approvals
- the only way to apply for approvals (and changes to ongoing studies) in the UK
- https://www.myresearchproject.org.uk/Help/HelpPage.aspx

Anything else to consider?

- current (short) CV
- GCP certification
- research passports

NHS R&D and NRSPCC

NHS Research Scotland Permissions Coordinating Centre (NRSPCC) coordinates the R&D NHS Management approval process and liaises with NHS Board R&D Offices to streamline the process

http://www.nhsresearchscotland.org.uk

Generic review – 10 days

(Where a project also involves NHS organisations elsewhere in the UK the study will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances from national coordinating functions)

Local review – 15 days

Combined review (CTIMP) studies) – 60 days (30+14+16)

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Common pitfalls

Budget & Contract Negotiation

Capacity to Review

Capacity to take part – who is involved?

Sign Offs

IG/IT Security

Caldicott

Local policies – Priorities; Amendments

How to avoid pitfalls

Feasibility:

- Sponsor
- Your own local checks

Paperwork:

- LIP
- Contract or OID?
- Site types?
- GCP/CVs

Oral and Dental Early Career Research Network!

R&D Permission – What Next?

Amendments

Reporting requirements (recruitment)

End of study

Help!

Lothian

- Ask ACCORD if you are not sure accord@nhslothian.scot.nhs.uk
- **It is never too early to talk to us!**

Ethics

- www.hra.nhs.uk
- (SESRES) sesres@nhslothian.scot.nhs.uk

IRAS

- Use the information buttons! Get a project from someone else
- helpdesk@myresearchproject.org.uk

NRS

- https://www.nhsresearchscotland.org.uk/