accord

Academic and Clinical Central Office for Research and Development

WHAT APPROVALS DO I NEED?

Before a research study can commence, all necessary approvals must be in place. The type of approvals needed will depend on what your research involves.

DO I NEED A SPONSOR?

- All health and social care-related research needs a Sponsor, except systematic reviews and meta-analysis of publicly available data.
- If your study is a service evaluation or clinical audit, other approvals may be needed instead e.g. in NHS Lothian, we recommend you contact the Quality Improvement Team.
- To determine if your project is research or service evaluation/audit, use this tool.
- If you are using data or samples from a research database or tissue bank, a Sponsor may still be needed, even if you have ethics approval already.

DO I NEED ETHICS APPROVAL?

- Nearly every research study needs to be reviewed by a Research Ethics Committee (REC) to obtain a favourable opinion.
- If your research study involves NHS patients, data, tissue, facilities or carers, an NHS REC opinion is needed.
- If there is no NHS involvement, you may still need review by a University REC. Within the Edinburgh Medical School, the Edinburgh Medical Research Ethics Committee (EMREC) may review or will advise on another appropriate committee.
- There are other scenarios where an NHS REC opinion may be necessary, even though there is no direct NHS involvement e.g. research involving Adults with Incapacity. Your Sponsor Representative will advise.
- Students should also check with their academic supervisor/programme lead about any other approvals required for their projects.

OTHER APPROVALS?

- If your research involves NHS patients, data, tissue, staff, facilities or carers, NHS R&D Management Approval is needed (also known as R&D approval).
- If your research involves the administration of radioactive substances, ARSAC approval will be needed.
- Caldicott Guardian (for single-site projects) or Public Benefit and Privacy Panel (PBPP, for multi-site projects) approval is needed to access unconsented data in Scotland, and Confidentiality Advisory Group (CAG) approval is needed in England and Wales to access identifiable, unconsented data.
- This list is not exhaustive. Speak to your Sponsor Representative for guidance on the relevant research approvals for your study.

APPLY FOR SPONSORSHIP

- Draft ethics form
- Draft protocol
- Participant Information Sheet
- Consent Form
- GP Letter
- Any other documentation e.g. poster, advert
- Brief CV for the Chief Investigator (and student if applicable)
- If NHS staff or resources are involved, a Local Information Pack
- (useful templates can be found here, CR007 Study Documents).

- Seek sponsorship in the early stages of study planning. You need Sponsor authorisation before seeking REC and NHS R&D Management Approval.
- If your study needs NHS REC/R&D approval, submit an IRAS form with study documents to the Research Governance team. You will need to create an IRAS account if you don't already have one.
- If your study needs EMREC approval, visit the EMREC SharePoint site for the most up to date form.

If you have any questions or want to seek advice before requesting sponsorship, please contact us by emailing resgov@accord.scot

Read more at www.accord.scot

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