Academic and Clinical Central Office for Research and Development

Sponsorship

Paul Dearie

Clinical Research Facilitation Manager

Sponsorship

- The UK Framework Policy for Health and Social Care sets out principles of good practice in the management and conduct of health and social care research.

- All health research involving humans, their tissue or data requires a Sponsor. This is defined in the UK Framework Policy for Health and Social Care Policy.

- Although the Policy specifically relates to the UK, at the University we apply these standards to all health related research.

What is a Sponsor?

- A Sponsor is the institution that takes responsibility for the overall management and conduct of a study.

- The Sponsor has a number of responsibilities. Some examples include:

❑ Ensuring the project is ethical, legal, feasible and safe

❑ To provide insurance and indemnity for research projects

❑ Ensuring that correct approvals are in place

❑ Ensuring that sufficient funds have been secured

Who is the Sponsor?

- Students – the Sponsor is usually the awarding institution (UoE).
- Staff – the Sponsor is usually the substantive employer.
- As it is the responsibility of the awarding institution to provide sponsorship, UoE would be Sponsor for projects even though they are not taking place in Lothian or indeed the UK.
- Currently around 500 active studies.
- In 2021 we Sponsor reviewed 185 new studies.

Research Governance Team – Sponsor Representatives

- Jo-Anne Robertson – non regulated
- Chris Coner – non regulated
- Tiago Santos – all except GH
- Fiach O'Mahony – regulated
- Paul Dearie – regulated
- Ellie McMaster – Global Health

How to get Sponsor approval?

- A protocol and all study related documents should be sent to resgov@accord.scot
- A brief CV for the Chief Investigator of the study.
- The expectation is that the academic supervisor is the CI for the study (not the student).
- ACCORD has a variety of templates that can be used for protocols, information sheets etc, found on the 'Researcher Access – Important Documents for Researchers' section of the ACCORD website (www.accord.scot).
- ACCORD also has a number of 'leaflets' covering FAQs and other important sponsorship considerations, found on the 'Training' section of the ACCORD website.

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When to seek sponsorship?

- You should seek sponsorship in the early stages of study planning.
- If unsure send a dissertation proposal to resgov@accord.scot and we will advise.
- You will need Sponsor authorisation for your research study **prior** to seeking ethics and any other approvals.

What happens next?

- The Sponsor Reviewer will assess documentation and provide a review document of comments relating to the study.
- The review can take approximately 10 working days.
- Once all comments have been addressed, the research study can be authorised for ethics submission and R&D submission or Combined Review for.
- Feedback from the aforementioned submissions should be discussed with your Sponsor Reviewer. Risk-assessed studies will also require separate authorisation to open from the Sponsor.

Regulated Studies

- Usually more documents required, e.g. IB, SPC, IMPD, labels, feasibility questionnaire.
- Risk assessment process is initiated once documents are received and the risk assessment involves multiple departments.
- Once the risk assessment has been completed, the research study can be authorised for regulatory/ethics/R&D submissions.
- Combined Review is mandatory for CTIMPs and IMP-device combinations. It is expected to be mandatory for device investigations in future.

Amendments

- Documents (amended documents, amendment tool and any other relevant documents) resgov@accord.scot
- Classification by the Sponsor Reviewer
- Sponsor Reviewer will sign the amendment tool electronically before submission to the REC/R&D/MHRA
- Authorisation required form the Sponsor Reviewer to implement substantial amendments from risk-assessed studies.

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Useful links

- ACCORD website: www.accord.scot - sign up to our updates
- Twitter: **@EdinburghACCORD**
- HRA website: https://www.hra.nhs.uk/
- Any insurance questions contact: insurance@ed.ac.uk
- Is it research, audit or service evaluation: http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf