

Research Studies requiring sponsorship within CAHSS,
in line with the UK policy framework for health and social care research

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/>

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All health and social care research should have a sponsor.

What is a research sponsor?

An individual, company, institution or organisation who:

- Takes on legal responsibility for putting and keeping in place arrangements to initiate and manage research projects including ensuring insurance and indemnity are in place
- Satisfies itself that the research protocol, research team and research environment meet appropriate standards
- Satisfies itself that the research project has ethical approval before it begins (School or NHS)
- Satisfies itself that arrangements are kept in place for monitoring the conducting and reporting of the research project.

The University of Edinburgh will usually act as the Sponsor for research projects where the Chief Investigator is a university employee / student and has designed the study.

Do I need a sponsor for my research?

If you are a member of University staff, or a student, undertaking funded or unfunded research that meets the criteria set by the UK Policy Framework for Health & Social Care Research [available here](#), you must request sponsorship from the University.

The UK Policy Framework states that studies must meet two criteria to require sponsorship:

1. Research

Your project must be research (rather than a service evaluation or audit). There is a useful tool www.hra-decisiontools.org.uk/research to help guide you with this.

2. Healthcare and/or social care related

Your project must be healthcare and/or social care related. This includes research within the NHS but is much broader including research within the community and can cover topics such as physical health, mental health, lifestyle changes and fitness tracking.

Please see the following sections for examples of studies that would require sponsorship.

Research studies requiring sponsorship within CAHSS

NHS involvement

Research involving NHS patients or carers, their data, or tissue MUST HAVE A SPONSOR and will require NHS ethics and/or R&D approval, through a system called IRAS – please contact Research Governance Coordinator for guidance.

Research involving NHS healthcare professionals or NHS facilities may require R&D approval and, if so, would require a sponsor - please contact Research Governance Coordinator for guidance

Examples

Research carried out recruiting patients from an NHS clinic Requires a sponsor, NHS ethics and R&D approval.

Research carried out interviewing NHS professionals Requires a sponsor and R&D approval. No NHS ethics required (only School ethics approval)

Research using tissue samples from recently deceased patients Requires a sponsor and NHS ethics

Participants to be recruited through a charity that is part funded by the NHS Requires a sponsor and NHS ethics (as the participants are being identified by the use of an NHS service)

There is a useful online tool that can help determine if your study requires NHS ethics

<http://www.hra-decisiontools.org.uk/ethics/>

Storage of data on NHS property only

MAY REQUIRE R&D approval as it is using NHS facilities and therefore will require a sponsor – please contact the Research Governance Coordinator for further guidance.

Examples

Research carried out in a primary school looking at internet use. Signed consent forms and questionnaires to be stored in a locked filing cabinet in a NHS hospital Requires a sponsor and R&D approval as it is utilising NHS resources

Research carried out in a primary school looking at internet use. Signed consent forms and questionnaires to be stored in a locked filing cabinet on University of Edinburgh property

Does not require R&D approval as this does not involve NHS property and also DOES NOT require a sponsor as it not health care related

Out with the NHS environment – Healthcare research

All healthcare-related research requires a sponsor. The UK Policy Framework for Health & Social Care Research covers:

research concerned with the protection and promotion of public health

any research undertaken within the health and social care systems that might have an impact on the quality of those services

Possible Scenarios

Research involving Marie Curie staff, looking at how staff deal with stress and difficult situations

This is within the health and community care system and therefore requires a sponsor and permission from Marie Curie research governance.

Research looking at dietary change in low income areas, which takes place in community centres. The objectives are looking at impact of changing diet on family's health

This is research within the community care system, which could impact on the quality of services, therefore requires a sponsor.

Research involving office staff, looking at physical activity levels via a fitness tracking devices

This is healthcare related research within the community and therefore requires a sponsor.

Research looking at increasing physical activity in elderly populations, recruited via nursing home, and the impact on physical and mental health.

This is healthcare related research within the community care system and therefore requires a sponsor (N.B if any of the nursing homes are NHS facilities, it would also require NHS REC approval – as the participants would be NHS patients - and R&D approval).

Research looking at improving mental health in homeless populations via an intervention

This is healthcare related research within the community care system and therefore requires a sponsor.

Research involving prisoners

In Scotland, healthcare-related research will require a sponsor, NHS ethics and R&D approval as well as approval from the Scottish Prison Service. In the rest of the UK, approval for healthcare-related research in prison is obtained through His Majesty's Prison and Probation Service (HMPPS)

Examples

Research looking at drug use within prisons in Scotland and England

Requires a sponsor, NHS ethics and R&D approval. In addition will require approval from the Scottish Prison service in Scotland and HMPPS approval for English sites

Research looking at bullying within prisons in Scotland and England

Requires approval from the Scottish Prison service and HMPPS, but would not require sponsorship, as not healthcare-related

Adults with Incapacity (AWI)

All research involving adults (aged 16 or over) who lack capacity to consent for themselves requires a sponsor and NHS ethics approval. In England and Wales only, this includes participants retained in the study following loss of capacity

Examples

Research looking at people with dementia and their response to musical therapy

Requires a sponsor and NHS ethics review. It may also require R&D approval if NHS facilities are to be used.

Research looking at psychological adjustment in people who have suffered a traumatic brain injury (including those who do not have the capacity to consent)

Requires a sponsor and NHS ethics review. It may also require R&D approval if NHS facilities are to be used.

These are just a few examples of studies that would require sponsorship. If you are unsure about whether your study requires a sponsor or have any questions please contact cahss.res.ethics@ed.ac.uk. If you are emailing about your project it would be helpful to email your research proposal or if you do not have one yet please complete the attached pro forma.

For international studies and for students completing a qualification through distance learning who are based out with the UK – sponsorship would be considered on a case by case basis and would depend on the nature of the study. Please contact the Research Governance office for guidance

Insurance and Indemnity

Certain categories of research must be referred to the University insurance officer for individual consideration. Any studies meeting the below criteria must be referred for checking and logging on the insurer's database, to ensure they are appropriately covered.

For sponsored studies, it is the responsibility of the CAHSS Governance Team to ensure a study has insurance and indemnity in place. For non-sponsored studies, it is the responsibility of the ethics reviewer or research office (depending on the School structure). [Contact - Finance.Helpline@ed.ac.uk]

Categories can include any research involving (but not limited to) the following:

Children under 5 years old

Participants who are pregnant

Participants from outside the UK

Data from outside the UK (in particular the US)

Please note that this list has been provided by the Insurance Office on behalf of the insurers, but this can change. It is also advised that any particularly high-risk studies are sent to the Insurance Office to be checked.

**If you have any queries about sponsorship please contact:
cahss.res.ethics@ed.ac.uk**

Useful terms:

IRAS (Integrated Research Application System)

Online system for applying for approvals (e.g. NHS ethics or R&D approvals) for health and social/community care research in the UK. It is a UK wide system. There is an e-learning module available on the website: www.myresearchproject.org.uk

HMPPS (His Majesty's Prison and Probation Service)

Approval required from HMPPS for any healthcare related research to be carried out in prisons or probation trusts within the UK (excluding Scotland). This can be done through IRAS. The HMPPS approval process extends to research in Young Offenders' Institutions (YOIs), but excludes research in Secure Training Centres, Secure Children's Homes or with Youth Offending Teams. Applications to conduct research in these areas should be directed to the Youth Justice Board.

R&D (Research & Development) approval

Researchers wishing to conduct research in the NHS must obtain NHS permission for each NHS research site. If your research involves undertaking the research on NHS sites, with NHS patients or with NHS staff, then you will need to complete the IRAS form as detailed above. Please contact the Research Governance Coordinator for guidance.

NHS Research Ethics Committees (RECs)

Consists of up to 18 members, 1/3 of whom are lay people. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. There are a number of RECs across the UK. Within Scotland there are 11 RECs; 4 RECs in the West of Scotland and 2 RECs in each of the East, North and South East Scotland areas. The 11th REC is Scotland A REC which deals with complex research such as AWI studies, please see below for more information. You are encouraged to be present at the ethics committee to answer any questions they may have, every effort will be made to book you into the REC venue of your choice.

Adults with Incapacity (AWI) -NHS Research Ethics Committees

If the research is recruiting AWI participants in Scotland then Scotland A REC is the only ethics committee that can approve the study in Scotland. Scotland A REC is based in South East Scotland and meets once a month. If you are recruiting AWI from the rest of the UK then the research must be reviewed by a REC flagged for AWI (i.e. not all RECs can review these projects). If you are recruiting from both Scotland and for example England, you will require an ethical opinion from both Scotland A REC and a REC flagged for AWI in the rest of the UK.
