

Research Studies requiring sponsorship within CAHSS, in line with the Research Governance Framework

What is a research sponsor?

An individual, company, institution or organisation who:

- Takes on responsibility for putting and keeping in place arrangements to initiate, manage (and sometimes fund) 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.

Do I need a sponsor for my research?

If you are a member of University staff, or a student, undertaking research that meets the criteria set by the Scottish Executive Health Department Research Governance Framework (2006) [available here](#), i.e. research involving healthcare, you must request sponsorship from the University. You will be advised on whether additional approvals are required e.g. NHS ethic committee or R&D approval

Research studies requiring sponsorship within CAHSS

NHS involvement

Research involving NHS patients or carers, their data, or tissue, or NHS healthcare professionals 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.

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)

Research involving prisoners

In Scotland, prisoners are classed as NHS patients so must have a sponsor, NHS ethics and R&D approval as well as ethical approval from the Scottish Prison Service. In the rest of the UK NHS ethics is required if it is 'healthcare related research' and requires a sponsor and approval from the prison service, which is obtained through NOMs (National Offender Management Service).

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 NOMs approval for English sites

Research looking at bullying within prisons in Scotland and England

Requires NHS ethics, R&D approval and approval from the Scottish Prison service and a sponsor but not for the English sites as not healthcare related.

Adults with Incapacity (AWI)

Research involving adults (aged 16 or over) who lack capacity to consent for themselves. In England and Wales, this includes participants retained in the study following loss of capacity – requires a sponsor, NHS ethics and R&D approvals.

Example

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

Requires a sponsor, NHS ethics and potentially R&D approval.

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 so DOES NOT require a sponsor

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

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

Out with the NHS environment – Healthcare research

The Research Governance Framework states that ‘any research undertaken by industry, charities, research councils and **universities within the health and community care systems that might have an impact on the quality of those services**’ requires a sponsor.

Possible Scenarios

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| 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. |
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| 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. |
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| Research involving staff, to be recruited through an online register of health professionals asking about burnout and stress | This is within the health care system and therefore requires a sponsor. |
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Healthcare research studies within local authority facilities (i.e. schools and some nursing homes) are not covered by the Research Governance Framework HOWEVER if you plan to store data on NHS facilities or are utilising NHS staff for the research you may require a sponsor please contact the Research Governance Coordinator.

This is just a very small list of examples of studies that fit under the ‘healthcare’ banner. If you are unsure about whether your study requires a sponsor please contact the Research Governance Coordinator. You can either email your research proposal or if you do not have one yet please complete the attached pro forma. Please send this to the Research Governance Coordinator:

Please contact: Cahss.res.ethics@ed.ac.uk or by phone on 0131 651 1619

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.

Insurance and Indemnity

For most research, insurance and indemnity will be confirmed through sponsorship. However, certain categories of research must be referred to the University insurance officer (please contact the Research Governance Coordinator for guidance) for individual consideration before doing so. These 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)

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

NOMs (National Offender Management Service)

Approval required from NOMs 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 NOMs 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.
