What are the research governance requirements for your health or social care study? (applies to projects classed as research by the HRA)

Is it a human interventional study?
The University definition of human-interventional studies can be found here: https://www.sheffield.ac.uk/polopoly_fs/1.393607!/file/TypesOfStudy.pdf

Is NHS ethics approval required?
Please ensure you use the Health Research Authority's decision tool to establish this: http://www.hra-decisiontools.org.uk/ethics/

Does the study involve* the NHS/services provided by the UK Health Departments AND/OR social care services provided by a local authority (including organisations providing services under contract with a local authority) AND/OR prison health services?
*Involvement refers to where the service has a duty of care within the research to participants, either as patients/service users or staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

The University's Research Governance Procedure is not required; however, you may need ethics approval via the University/another approved body
For guidance see: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/index

Please note the University may require ethics approval even for studies that are not classed as research by the NHS (e.g. service evaluation), as the University’s definition of research, as set out in the Research Ethics Policy, is much broader.

Follow the University’s Research Governance Procedure:
- register the project via the online costing tool
- identify a research governance sponsor
- meet sponsor’s research governance requirements (specific requirements may vary by sponsor)

NB. Clinical trials of investigational medicinal products (CTIMPs) and medical devices have additional specific legislative and regulatory requirements. CTIMPs can include administration of nicotine and dietary supplements such as probiotics that are available over the counter. For further guidance refer to the MHRA’s website: https://www.gov.uk/topic/medicines-medical-devices-blood

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*If University ethics approval is sought, please be aware that the ethics reviewers will be asked to assess the risk of your study according to a set of criteria; if the study is flagged as medium/high risk, you will be asked to follow the University’s Research Governance Procedure, as set out below.

Follow the University’s Research Governance Procedure:
- register the project via the online costing tool
- provide confirmation of registration on a publicly accessible clinical trials register
- identify a research governance sponsor
- meet sponsor’s research governance requirements (specific requirements may vary by sponsor)

And ONLY IF THE UNIVERSITY OF SHEFFIELD IS THE RESEARCH GOVERNANCE SPONSOR,
Follow the Quality Assurance Procedure for Human Interventional Studies
- complete a risk assessment checklist to indicate the appropriate level of scrutiny for your study (see https://www.sheffield.ac.uk/rs/ethicsandintegrity/clinicaltrials/index for more details).

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