Overview of the research governance procedure for researchers to meet their obligations to the Sponsor

1. INITIAL DECISIONS STAGE:

Decide if the research governance procedure applies to your project

(consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/definition)

(NB. additional regulatory requirements apply to clinical trials of investigational medicinal products and studies involving medical devices including apps – refer to the MHRA for guidance)

Establish which organisation will be the project's research governance sponsor

(consult: https://www.sheffield.ac.uk/polopoly_fs/1.121332!/file/sponsor.pdf)

(Where the University is NOT the research governance sponsor then evidence is required from the sponsor organisation to confirm that it will take on this role)

Decide if an honorary research contract or letter of access is needed and, therefore, whether the Research Passport application form needs completing

(consult the guidance: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/passport)

2. REGISTRATION STAGE:

Always register the project via the Online Costing Tool

(consult: https://www.sheffield.ac.uk/rs/pricing/costingtool - helpline: 222 7629)

Always required - even when there are no costs or even when the University is not the project's research governance sponsor (student research projects should be registered as a student research governance project). This will ensure that your departmental research governance contact is notified of your study, and they will liaise with you to ensure the required information is obtained.

An additional step that only applies to studies that will be sponsored by the University:

Identify a Study Governance Administrator

Where the University is to be the research governance sponsor, it is the responsibility of the PI (or supervisor in the case of a student project) to identify a Study Governance Administrator to take day-to-day responsibility for ensuring that all necessary governance approvals/requirements are in place BEFORE data collection commences. More details about the role are available here: [Link to role description]. This person may be the PI themselves, a specified member of the research team, a student, or a person nominated to fulfil this role by the department. Please note where this person is not specified by the PI it will be assumed that the PI undertakes the role themselves.

3. APPLY FOR APPROVALS STAGE

(NB. send copies of all approvals when received to the relevant sponsor contact. If University sponsored, this will be your departmental research governance contact: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance):

APPLY FOR INDEPENDENT SCIENTIFIC REVIEW

Submit application to the research funder (the funder will normally peer review it)
or apply for scientific peer review within the University
(consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/science)

APPLY FOR ETHICS APPROVAL:

If your HRA approval (see below) includes review by an NHS research ethics committee you do not require additional ethics approval
Otherwise, apply for ethics review via the University's ethics review procedure
(consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/index)

If your research involves the NHS, or requires NHS ethics approval:

APPLY FOR HRA APPROVAL

(consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/approval)
All projects need to enclose a certificate of insurance with their HRA application
(consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/insurance)

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If your research involves social care services provided by a local authority (including organisations providing services under contract with a local authority) or prison health service:
APPLY FOR LOCAL AUTHORITY/HEALTH SERVICE APPROVAL:
Each local authority/prison health service defines its own process for managing the approval process; consult the relevant authority/service for details.

An additional step that only applies to studies involving medical devices (including software/apps) where the University is the sponsor:
notify the MHRA (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information) as soon as possible, and submit full details for assessment at least 60 days before starting the investigation.

An additional step that only applies to clinical trials and human-interventional studies:
Register the study on a publicly accessible register (for more details regarding available registers consult: https://www.sheffield.ac.uk/rs/ethicsandintegrity/clinicaltrials/ctt)

An additional step that only applies to human-interventional studies where the University is the research governance sponsor:
Complete and return 'Risk Assessment Checklist for University Sponsored Human-Interventional Studies' (this will be provided by your departmental governance contact).

4. THE RESEARCH GOVERNANCE SPONSOR AUTHORISES THE PROJECT TO START

NB. You must not commence any research until formal authorisation to start your project has been received from the sponsor. Aspects of the research requiring additional approvals (e.g. site approvals) must not commence until the relevant approvals have been obtained.

Where the University is the research governance sponsor then written evidence of scientific approval, ethics approval, and EITHER HRA approval OR research approval from the relevant local authority/prison health service is required before authorisation can be granted; certain types of study* will also require additional University approval before University sponsorship can be confirmed. Where the University is not the research governance sponsor then the University (via your departmental research governance contact) will require written confirmation from the organisation that has agreed to be the research governance sponsor of its agreement to be the sponsor.

If your project is sponsored by the University you will receive a letter similar to this template here:
https://www.sheffield.ac.uk/polopoly_fs/1.747339!/file/AUTHORISATIONLETTERwebtemplate.pdf

PLEASE REMEMBER: It is ultimately the responsibility of the PI to ensure that all necessary approvals are in place BEFORE starting the project.

5. MONITOR YOUR PROJECT AND CREATE AND MAINTAIN YOUR PROJECT RECORDS

It is the responsibility of the PI to inform the Sponsor, and where appropriate the HRA/ethics committee, of any changes within the project (e.g. changes to documentation, staff changes, inclusion of new sites). It is the responsibility of the PI to monitor the study in line with the responsibilities set out in the sponsor authorisation letter.

Guidance on the post-award requirements is at:
https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rg-forms
https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/archive

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6. REPORT THE RESULTS OF THE PROJECT

Report summary results in a timely fashion following the end of the trial, including on the registry in which the study was originally registered (ideally within 12 months, unless there is a valid reason for delay). Make the full findings (whether positive or negative), and wherever possible, the data, available in a timely manner after the end of the trial.

Please note studies may be audited periodically by the Sponsor or funder to ensure that all necessary documentation is in place.

***Please note that certain types of human interventional study may require additional approval by the University, before the University will agree to accept sponsorship:**

- Studies involving the administration of a substance outside the terms of its existing licence; or
- Investigating the safety/tolerability of a substance in humans; or
- Investigating a substance in order to ascertain the appropriate dose to administer in humans.

Please contact your department's research governance contact for further information: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance.