

**Changes to research governance arrangements for health and social care studies –  
Summer 2019**

The following changes have been introduced:

- **A new policy setting out transparency requirements for clinical trials and human interventional studies.** This was approved by Senate in June 2019 and requires all studies meeting the relevant definition (<https://www.sheffield.ac.uk/rs/ethicsandintegrity/clinicaltrials/index>) to meet 3 key responsibilities: recording of the study details on a public register, prompt reporting of summary results, and making all results (positive and negative) available in a timely manner. Going forward, checks will be undertaken as part of the existing annual audit of the Research Governance Procedure, to ensure that these requirements are met.

Further details can be found here:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/clinicaltrials/ctt>

- **Clarification of research governance requirements for social care studies.** Studies involving social care services provided by a local authority (including organisations providing services under contract with a local authority) or prison health services are now explicitly required to follow the University's Research Governance Procedure (including the identification of a formal research governance sponsor).

New guidance regarding the requirements for social care studies can be found here:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/social/socialcare>

- **A requirement for HRA approval (or equivalent) to be in place before the University issues a letter confirming sponsorship of a health or social care study.** Where the University is to take on the role of research governance sponsor for a health or social care study, formal research governance approval from the relevant health/social care organisation must be obtained before a letter can be issued confirming the University's sponsorship (NB. conditional sponsor letters can be provided where required, e.g. when submitting an IRAS application). This approval will normally take the form of HRA approval in the case of research involving the NHS/Department of Health, or the equivalent approval from the relevant local authority/prison health service for a social care study.

Updated guidance on the Research Governance Procedure can be found here:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rgp>

- **A new requirement for health and social care studies sponsored by the University to have an identified 'Study Governance Administrator' (SGA).** This requirement has been introduced as part of the Research Governance Procedure, to ensure that there is an identified point of contact with day-to-day responsibility for ensuring that appropriate research governance approvals, including relevant site approvals, are in place before data collection commences. This person may be the Principal Investigator, or an alternative identified by them (e.g. a specified member of the research team, a student, or a person nominated to fulfil this role by the department).

Regular information sessions for SGAs will be held to provide details of the Research Governance Procedure and the University's expectations as sponsor. Details can be found here: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/sga>.

- **Certain higher risk types of study will require specific University approval before sponsorship will be accepted.** For studies falling into one or more of the following categories an additional review process will now be undertaken as part of the [Research Governance Procedure](#) to confirm whether the University will agree to act as sponsor:
  - 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.

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