

Address

Address: [department address]

Telephone: [departmental contact no]

Email: [departmental contact email]

Project title: TITLE

6 digit Project Code: NUMBER

Dear NAME,

### LETTER TO CONFIRM THAT THE UNIVERSITY OF SHEFFIELD IS THE PROJECT'S RESEARCH GOVERNANCE SPONSOR

The University has reviewed the following documents:

1. A University approved costing record;
2. Confirmation of independent scientific approval (or the award letter if externally funded);
3. Confirmation of independent ethics approval.

All the above documents are in place. Therefore, the University can now **confirm** that it is the project's research governance sponsor and, as research governance sponsor, **authorises** the project to commence any non-NHS research activities. Please note that HRA approval will be required before the commencement of any activities which involve the NHS.

You are expected to deliver the research project in accordance with the University's policies and procedures, which includes the University's Good Research & Innovation Practices Policy: <https://www.sheffield.ac.uk/rs/ethicsandintegrity>, Ethics Policy: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/index> and Data Protection Policies: [www.shef.ac.uk/cics/records](http://www.shef.ac.uk/cics/records). More details can be found on the University's research governance website: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance>.

As the Principal Investigator you are responsible for providing up-to-date study documentation to all relevant sites, and for monitoring the project on an ongoing basis. Your Head of Department is responsible for independently monitoring the project as appropriate. The project may be audited during or after its lifetime by the University. The monitoring responsibilities are listed in **Annex 1**.

Yours sincerely

[Authorised signatory for department on behalf of the University]

cc., Head of Department/School:

## Monitoring responsibilities of the Principal Investigator ('PI'):

The primary responsibility for project monitoring lies with the PI. You agree to:

1. Establish a **site file** before the start of the project and ensure it remains up to date over the project's entire lifetime:  
<https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rg-forms>
2. Provide **progress reports/written updates** to the Head of Department at reasonable points over the project's lifetime, for example at:
  - a. three months after the project has started; and
  - b. on an annual basis (only if the project lasts for over 18 months); and
  - c. at the end of the project.
 See: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rg-forms>
3. Report **adverse events**, should they occur, to the Head of Department:  
<https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance/rg-forms>
4. Provide progress reports to the research funder (if externally-funded).
5. Establish appropriate arrangements for recording, reporting and reviewing significant developments as the research proceeds, and taking appropriate steps to address them – i.e. developments that have a significant impact in relation to one or more of the following:
  - the safety and well-being of the participants in the project;
  - the project's scientific direction;
  - the conduct or management of the project, including the suitability of the protocol.
 The Head of Department should be alerted to significant developments in advance wherever possible.
6. Establish appropriate arrangements to record, handle and, as appropriate, store all information collected for or as part of the research project in such a way that it can be accurately reported, interpreted and verified without compromising the confidentiality of individual care users.
7. Establish appropriate arrangements for making information about the findings of the research accessible (and data and tissue where appropriate, with adequate consent and privacy safeguards, in a timely manner after the research has finished)

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## Monitoring responsibilities of the Head of Department

You agree to:

1. Review the **standard monitoring progress reports**, submitted by the PI, and follow up any issues or concerns that the reports raise with the PI.
2. Verify that **adverse events**, should they occur, have been reported properly and that actions have been taken to address the impact of the adverse event(s) and/or to limit the risk of similar adverse event(s) reoccurring.
3. Verify that a project is complying with any **ethics conditions** (e.g. that the information sheet and consent form approved by ethics reviewers is being used; e.g. that informed consent has been obtained from participants).
4. Introduce a form of **correspondence** (e.g. regular email, annual meeting) with a project's PI, that is **proportionate to the project's potential level of risk**, in order to verify that a project is complying with the approved protocol and/or with any research funder conditions. Whatever correspondence is chosen the Head of Department should, as a minimum, ensure that s/he is informed sufficiently in advance about significant developments wherever possible.