

Your responsibilities for conducting research

The following are responsibilities you have signed off on when you completed your IRAS application. You are responsible for:

- Your research team's treatment of research participants, ensuring their safety, dignity, rights and wellbeing.
- Ensuring your research is carried out in accordance with legal, safety and regulatory requirements.
- Ensuring your study does not start without a favourable ethical opinion and Trust R&D approval, and if necessary, the appropriate regulatory body.
- Making all data and documentation associated with your study available at the request of the inspection and auditing authorities.
- Ensuring your research team is qualified/experienced and able to do all the tasks you have delegated to them.
- The supervision, training and support of students and new researchers in your research team.
- Ensuring you follow your research protocol at all times.
- Reporting any serious breaches of the protocol and serious adverse events, within 24 hours using the Trust incident reporting system DATIX.
- The safe, secure storage of your research data/documents during the duration of your study and up to 5 years post-study completion.
- Ensuring the Research Office is made aware if any changes or amendments to the research study and that you work with R&D to gain ethical approval for these changes.
- The quality, accuracy and integrity of your data and must promote confidentiality of data during processing and storage.
- Informing the patient's care team of their participation in your research.
- Reporting all progress and outcomes of your research on request from the Trust or regulatory bodies.

- The dissemination of your research findings to participants, the Trust and members of your division.
- Preventing, detecting and reporting of scientific misconduct.
- The management of your research funding and other resources.
- Ensuring all serious adverse events and SUSARs are reported to the Sponsor immediately.
- Ensuring responsibilities you have delegated to members of your research team are clearly documented in the delegation log which is signed and dated by the relevant individuals.