accord
Academic and Clinical Central Office for Research and Development

THE UNIVERSITY of EDINBURGH

NHS Lothian

Research Transparency

When research is carried out openly and transparently, everyone benefits:

- Patients and the public can see what research is taking place and access clear information about the results.
- Patients, service users, and carers can find out what research is relevant to them giving them the opportunity to join studies.
- Health professionals, researchers, and funders can use research findings to make informed decisions and avoid duplication of effort.

What is Transparency in Relation to Research?

- When we talk about research transparency, we mean:
- **Registration**: making it public that a study has started
- **Reporting results**: making it public what the study has found
- **Informing participants**: letting those who took part know what the study found
- **Sharing study data and tissue**: enabling further research

All research should be registered and results reported in a publicly accessible database.

The HRA have published a 'Make it public: transparency and openness in health and social care research' strategy to help make this the norm.

Should I Register my Research Project?

Registration is a condition of a favourable ethics opinion for Clinical Trials of Investigational Medicinal Products (CTIMPs) and it is good practice for all types of research.

You should register your study before the first participant is recruited and no later than six weeks after recruitment of the first participant.

Once registered, the information on the record should be continually updated through the lifecycle of the project.

Version 2. July 2024

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What Database Should I Register With?

From 1 January 2022, the HRA will automatically register CTIMPs and combined CTIMP/CIMDs with ISRCTN Registry, with no charge to the researcher (this service will be rolled out to other types of clinical trials in time).

Recognised registries for research other than CTIMPs are:

- ISRCTN: accepts registration of all clinical research studies and is the preferred partner of the Department of Health and Social Care.
- ClinicalTrials.gov: a US resource that accepts registration of medical studies in human volunteers. You should be aware that non-compliance with reporting requirements could result in substantial FDA fines.

Should I Publish My Research Results?

Regardless of the nature of the results, it is important that the results of research studies are shared publicly. This is an expectation in the UK Policy Framework for Health and Social Care Research, a regulatory requirement for CTIMPs and a key standard in the UK Research Integrity Office's Code of Research Practice.

You should upload results to the publicly accessible database that you initially registered with within 12 months of study completion. This should not be delayed by any plans to submit a manuscript to a research journal.

In an attempt to improve Research Transparency, ACCORD requests a written commitment from the Chief Investigator to upload results of regulated CTIMPs and CIMDs. Work is ongoing to extend this to other clinical research.

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Should I Inform Research Participants of the Results?

Giving participants information about the findings of a research study is an important part of good public engagement and a key aspect of research transparency. It respects participants and acknowledges their contribution.

Useful ways to communicate findings to participants and the wider public include a study newsletter or website. Remember that publishing results in a peer-reviewed journal doesn't make the findings easily accessible to the public.

You should describe your plans for informing participants in your ethics submission and Participant Information Sheet. A plain language lay summary of research findings should also be included in the final report that is required by an NHS Research Ethics Committee. The HRA publish these alongside research summaries extracted from IRAS.

If you have any questions or want to seek advice about transparency, please contact the Research Governance Team.

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