Research and Enterprise

Standard Operating Procedure

Research Governance

Title:	**Registration of Clinical Trials**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) provides guidance on the registration of Clinical Trials that are sponsored by the University.

2. Scope

This SOP applies to all Clinical Trials where the University is acting in the capacity of Sponsor/Lead Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

3. Responsibilities

3.1 Chief Investigator (CI)

The CI is responsible for completing the registration of a Clinical Trial. This would include the following:

- Completion of the initial registration record;
- Ensuring the record is maintained during the trial;
- Uploading results once trial is complete.

3.3 Sponsor

The Sponsor must ensure that Clinical Trials are appropriately registered, maintained and results submitted.

4. Procedure

4.1 What needs to be registered?

While it is considered good practice that all research should be registered on a publically accessible database, it is a condition of an NHS/HSC Research Ethics Committee (REC) Favourable Opinion that all Clinical Trials are registered on a publically accessible database.

Trials should be registered before the first participant is recruited, and no later than six weeks after. If the trial is registered before submitting for REC review, then the registration number should be included at A5-1 of the IRAS form and further details given at A50. Where registration is completed following REC review, the REC should be emailed the registration number to allow the study record to be updated.

A Clinical Trial is:

- a clinical trial of an investigational medicinal product
- a clinical investigation or other study of a medical device
- a combined trial of an investigational medicinal product and an investigational medical device
- any other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

These are the first four options of Filter Question 2 on the IRAS Form.

4.2 Acceptable Registries

In order to satisfy the condition of the REC, the Clinical Trial must be registered on a registry that is on the WHO list of primary registries or the ICMJE list of registries.

These include:

- International Standard Randomised Controlled Trial Number (ISRCTN) Registry which accepts prospective and retrospective registration of all clinical research studies. ISRCTN Registry is the preferred partner of the Department of Health and Social Care.
- ClinicalTrials.gov which accepts prospective and retrospective registration of medical studies in human volunteers.

Registration on ISRCTN requires payment of a fee. This is to cover the cost of maintaining a free to access public registry. This registration fee is considered an allowable research cost by many UK research funders. If the research is eligible for NIHR CRN support and has a component in England, then it will qualify for free ISRCTN registration.

The University has an account with ClinicalTrials.gov. Chief Investigators should contact ResearchGovernance@qub.ac.uk to request addition as a user of this account.

The Chief Investigator is the Responsible Party for the record, and that individual is responsible for creating and maintaining the record, as well as submitting study results. The Chief Investigator should respond promptly to requests from the Registry for updates to the record. Study results must be uploaded in a timely fashion.

5. References

Health Research Authority:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/ (last accessed September 2022)
ISRCTN: https://www.isrctn.com/ (last accessed September 2022)
ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home (last accessed September 2022)