Joint Research and Enterprise Services (JRES)	
Clinical Trial Transparency Policy	
Policy Number:	JRESGOVPOL0001
Version:	5.0
Authors:	Mark Cranmer / Georgia Bullock
Job Titles:	Director, Research and Innovation Services / Research Development and Governance Manager
Date:	16/06/2025
Review Date:	16/06/2026

Policy Chronology		
Version	**Date**	**Reason for Change**
V1.0	11th November 2019	Original version
V2.0	25th February 2021	Update to clinical trial registration and publication requirements from 1st January 2021
V3.0	28th January 2022	Update to incorporate HRA updates to public database registration
V4.0	12th January 2024	Update to references and external links
V5.0	16th June 2025	St George's University (SGUL) updated to City St George's (CSG) (Tooting Campus)

City St George's, University of London (CSG) (Tooting Campus) and St George's University Hospitals NHS Foundation Trust (SGHFT) fully support the moves to ensure greater transparency in clinical trials and support the use of data sharing providing it preserves and maintains patient confidentiality. These principles are important for ethical, moral, accountability, research integrity and waste reduction perspectives, to foster a relationship of confidence with patients and members of the public and to ensure compliance with our legal obligations.

Our approach will take into consideration the WHO Joint Statement on public disclosure of results from clinical trials and is consistent with our responsibilities under the current clinical trial legislation and the Health Research Authority's UK Policy Framework for Health and Social Care Research.

- **Clinical trial/research registration**

All applicable clinical trials and studies of an interventional nature sponsored by either CSG/SGHFT will be required to prospectively register on a WHO recognised clinical study/trials register prior to the start of the trial/ before the 1st patient/participant is recruited.

For clinical (drug or device) trials (ie: those requiring MHRA approval), **the International Standard Randomised Controlled Trial Number Register (ISRCTN) must be used** (as a minimum):

ISRCTN registration | NIHR

All clinical trials submitted through the HRA's Combined Review process will be automatically added to the ISRCTN by the HRA, once fully approved. Currently the Combined Review process has to be followed for all Clinical Trials of Investigational Medicinal Products (CTIMPs) and combined trials of an Investigational Medicinal Product (IMP) and a Medical Device.

Combined Review may be rolled out to other types of trial in time.

For trials which cannot be submitted through Combined Review, responsibility for timely trial registration resides with the Chief Investigator of the study; however accountability will reside with CSG/SGHFT as the sponsoring organisation. The JRES will monitor this in line with the oversight of trial set up.

CSG/SGHFT recognise the importance for our local patient and public population to be aware of the clinical trials and research occurring on either of our sites. We have created a search function on our public facing research website, linked to our R&D database, primarily for the local public to search for trials conducted on site/by us. We will be expanding this by creating a function to provide links to published results of our sponsored projects. This is an additional, local initiative to promote transparency of our research portfolio on site.

- **Publication of trial findings**

CSG/SGH acknowledges that a fundamental principle of conducting clinical research is that findings must be published/disseminated regardless of whether they are seen to be positive or negative. Publication in a Peer-Reviewed journal or platform is required for all relevant research projects. We will aim to ensure appropriate publication of research findings within an indicative timeframe of 24 months from Primary Study Completion. Where any fee is payable to ensure Open Access, this may be paid in accordance with our Open Access Policy.

It is CSG/SGHFT policy to pursue appropriate funding for its interventional research and clinical trials from external sources, ie: medical research councils, charities and government funding sources such as the NIHR. The dissemination policy of the funder will be adhered to.

Where appropriate, trial findings will be disseminated to participants and others involved in the research once results have been published and if they have consented to be kept informed (in line with the original ethics submission and participant information sheet).

Responsibility for timely publication and dissemination of findings within a Peer-Reviewed Open Access journals and or to patients/public resides with the Chief/Principal Investigator. Accountability resides with CSG/SGHFT as the sponsoring organisation. The JRES will monitor this in line with the oversight of trial closure.

- **Reporting trial findings on a clinical trials register**

It is a legal obligation that the results of all interventional clinical trials (ie: those requiring MHRA approval), sponsored by CSG or SGHFT, are published in the public register (or registers) where the trial has been registered. The timeframe for publishing results is 12 months from the end of trial date (6 months for paediatric trials).

Responsibility for timely trial registry completion resides with the Chief Investigator of the study; however accountability will reside with CSG/SGHFT as the sponsoring organisation.

For interventional (drug and device) trials, the JRES, in liaison with the Chief Investigator, will enter the clinical trial results and upload the final report on the ISRTCN, or on EudraCT for trials which were registered there prior to the 1st January 2021.

The JRES will monitor monthly outstanding clinical trials that are due to report and will remind the Chief Investigator if a trial is outstanding, and in the event of non-response will escalate the issue to senior management.

To ensure effective oversight, the JRES will provide a report each quarter to the Research Governance Committee on the number of clinical trials which are due to report which have not yet reported.

- **Sharing research data**

Research data are an important output from Clinical Trials and projects and it is expected that there is the ability for appropriate re-use of data. This is important because re-use of data increases the impact resulting from the initial financial, research infrastructure, and research participants' investments needed to collect data. Appropriately anonymised datasets from our sponsored research will be made available for further analysis wherever possible under our Research Data Management policy:

Research Data Management (sgul.ac.uk)

References

Research registration and research project identifiers - Health Research Authority (hra.nhs.uk)

Combined review is here and applicants benefit from automatic registration - Health Research Authority (hra.nhs.uk)