CLINICAL TRIAL TRANSPARENCY POLICY

V6.0

Policies superseded by this version

V1.0 11 Nov 2019 Original version

V2.0 25 Feb 2021 Update to clinical trial registration and publication requirements from 1 January 2021

V3.0 28 Jan 2022 Update to incorporate HRA updates to public database registration

V4.0 12 Jan 2024 Update to references and external links

V5.0 16 Jun 2025 St George's University (SGUL) updated to City St George's (CSG) (Tooting Campus)

Summary of changes to previous version

V6.0 Jul 2026: Policy updated to cover City St George's; JRES change to JCRO; ICH E6(R3) alignment; EU CTIS obligations added; publication target revised to 12 months primary / 24 months escalation; regulatory lay summary requirements; research misconduct linkage; annual public transparency reporting; KRI monitoring framework; patient and public involvement in transparency; post-Brexit regulatory updates

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1 Introduction

City St George's, University of London (CSG) operating through the Joint Clinical Research Office (JCRO), fully support the move to ensure greater transparency in clinical trials and research. CSG supports the use of data sharing, providing it preserves and maintains patient confidentiality. These principles are important from 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 takes 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, the Health Research Authority's UK Policy Framework for Health and Social Care Research, and ICH E6(R3) Good Clinical Practice (effective UK go-live 28 April 2026).

2 Freedom of Speech and Academic Freedom

2.1 City St George's, University of London, regards freedom of speech and academic freedom to be fundamental to delivering its mission as the University of business, practice and the professions. Its values in this respect are set out in a code of practice on freedom of speech and academic freedom, which explains how the University will uphold, secure, and promote freedom of speech within the law: https://www.citystgeorges.ac.uk/about/governance/policies/code-of-practice-on-freedom-of-speech.

2.2 Nothing in this policy should be interpreted in any way that would be inconsistent with the code of practice and – in the event of any inconsistency – the provisions of the code will prevail.

3 Equality, Diversity and Inclusion

3.1 City St George's, University of London works to advance equity, diversity and inclusion in its activities, processes, and culture, for the whole University community, including staff, students and visitors.

3.2 The University will meet its obligations under the Equality Act 2010 in its policies and seek to eliminate discrimination on the basis of age, caring responsibilities, disability, gender identity, gender reassignment, marital status, neurodiversity, pregnancy, race, religion or belief, sex, sexual orientation, and socio-economic background.

4 Definitions

Term	Definition
Clinical Trial	Any research study involving human participants that investigates the efficacy or safety of therapeutic interventions
CTIMP	Clinical Trial of an Investigational Medicinal Product –trials requiring MHRA approval
ISRCTN	International Standard Randomised Controlled Trial Number Register
JCRO	Joint Clinical Research Office – responsible for sponsorship oversight and governance
Primary Study Completion	The date when the last participant was examined or received an intervention for the purposes of the primary outcome measure
End of Trial	The last participant last visit to the trial, or the date the sponsor confirms the trial is closed to recruitment and follow-up, whichever is the later

Lay Summary	A plain-language summary of trial objectives, methods and results written for public understanding
CTIS	EU Clinical Trials Information System – EU transparency and reporting platform for clinical trials
ICH E6(R3)	International Council for Harmonisation Good Clinical Practice guidelines effective 28 April 2026
KRI	Key Risk Indicator – metric used to monitor sponsor oversight compliance

5 Policy

5.1 Purpose

To establish requirements for the transparency of clinical trials and research sponsored by CSG through mandating prospective registration, timely publication of findings, appropriate data sharing, and structured governance oversight in accordance with national legislation, ICH E6(R3) Good Clinical Practice, EU regulations where applicable, and ethical best practice.

5.2 Scope

This policy applies to all applicable clinical trials and studies of an interventional nature sponsored by CSG, including CTIMPs, combined trials of IMP and Medical Device, non-CTIMP interventional studies, and observational studies where registration is mandated by funders or target journals. The policy sets expectations for the Chief Investigator, JCRO, and all personnel involved in trial conduct and oversight. EU regulatory obligations apply where CSG acts as sponsor for trials in EU member states.

5.3 Principles

- All applicable clinical trials must be prospectively registered on a WHO-recognised register prior to first patient/participant recruitment
- Trial findings must be published/disseminated regardless of outcome (positive, negative, or inconclusive)
- Primary publication target is 12 months of Primary Study Completion; studies not published within 24 months trigger escalation
- Results must be reported on clinical trial registers within legal timeframes (12 months adult, 6 months paediatric)
- Appropriately anonymised datasets must be made available for secondary analysis in accordance with Research Data Management Policy
- Lay summaries and plain-language results summaries must be prepared for participants and public
- Patient and public involvement must be embedded in transparency activities where practicable
- Transparency compliance is a core sponsor obligation monitored via Key Risk Indicators under ICH E6(R3) quality-by-design framework
- EU CTIS obligations must be fulfilled for trials authorised under EU Clinical Trials Regulation 536/2014

5.4 Roles and responsibilities

Role	Responsibility
Chief Investigator	Responsible for timely prospective trial registration; responsible for timely publication within 12-month target; responsible for results registry completion within legal timeframes; responsible for lay summary preparation and dissemination to participants; must notify JCRO with written justification if 12-month publication target cannot be met
JCRO	Accountable for CSG as sponsoring organisation; monitors registration, publication and registry reporting compliance; conducts periodic quality audits against WHO criteria; manages structured escalation process; liaises with CI on outstanding registry submissions; uploads final reports to ISRCTN/EudraCT/CTIS; provides quarterly KRI and compliance reports to Research Governance Committee; escalates non-compliance to senior management and MHRA where required
Research Governance Committee	Receives quarterly KRI and transparency compliance reports from JCRO; reviews escalated issues and persistent non-compliance; approves public disclosure of annual transparency performance metrics; considers research misconduct referrals related to publication failure; provides governance assurance on sponsor obligations

6 Procedure

6.1 Clinical Trial / Research Registration

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

For clinical (drug or device) trials (i.e. those requiring MHRA approval), the International Standard Randomised Controlled Trial Number Register (ISRCTN) must be used as a minimum: ISRCTN Registration | NIHR – https://www.isrctn.com

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 must be followed for all CTIMPs and combined trials of an IMP and a Medical Device.

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 as the sponsoring organisation. The JCRO will monitor this in line with the oversight of trial set-up and will confirm registration prior to issuing site activation.

Registration Content

Trial registration must include as a minimum:

- Trial title, acronym and lay summary
- Eligibility criteria (inclusion and exclusion)
- Primary and secondary outcomes
- Planned sample size and recruitment period
- Funding source(s) and sponsor details
- Contact information for public and scientific enquiries

The JCRO will conduct periodic audits of registration quality against WHO criteria as part of its centralised monitoring programme under ICH E6(R3).

Non-CTIMPs and Observational Studies

For non-CTIMP interventional studies, registration on an appropriate WHO-recognised register is mandatory before first enrolment. For observational and non-interventional studies, registration is strongly encouraged and is mandatory where required by the funder or a target publication journal.

EU Clinical Trials Information System (CTIS)

For studies authorised under the EU Clinical Trials Regulation (EU CTR 536/2014), transparency obligations relating to registration, summary results reporting and publication of lay summaries shall be fulfilled through the Clinical Trials Information System (CTIS) in accordance with applicable EU regulatory requirements. This applies where CSG is acting as sponsor or co-sponsor for trials running in EU member states. The JCRO will ensure CTIS obligations are identified at study set-up and incorporated into the trial oversight plan alongside UK-specific requirements.

Public-Facing Trial Search

CSG recognises the importance for the local patient and public population to be aware of the clinical trials and research occurring on either site. A search function on the public-facing research website, linked to the JCRO R&I database, allows the local public to search for trials conducted on site. The JCRO will expand this by creating a function to provide links to published results of sponsored projects, as an additional local initiative to promote transparency.

6.2 Publication of Trial Findings

CSG acknowledge that a fundamental principle of conducting clinical research is that findings must be published and 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.

CSG will aim to ensure appropriate publication of research findings within:

- 12 months of Primary Study Completion (primary target for all sponsored studies)
- 12 months of Primary Study Completion for NIHR-funded studies (mandatory NIHR requirement)

Where the 12-month target cannot be met, the Chief Investigator must notify the JCRO with written justification. Studies not published within 24 months of Primary Study Completion will be treated as an escalation threshold and reported to the Research Governance Committee. The JCRO will document all delays and justifications as part of the trial oversight record.

Open Access

Where any fee is payable to ensure Open Access, this may be paid in accordance with the CSG Open Access Policy. CSG are committed to maximising open access publication to enhance the reach and impact of sponsored research. The JCRO will include Open Access requirements in research contracts and funding agreements at study set-up stage.

Funder Dissemination Requirements

It is CSG policy to pursue appropriate funding for interventional research and clinical trials from external sources including medical research councils, charities and government funding sources such as the NIHR. The dissemination policy of the funder will be adhered to in addition to the requirements of this policy.

Lay Summaries

For applicable CTIMPs, lay summaries will be prepared and submitted in accordance with relevant UK and EU regulatory requirements and made publicly available within required timelines. Lay summaries must be written in plain, accessible language and, where practicable, reviewed by patient and public representatives prior to submission. The Chief Investigator is responsible for preparing lay summaries; the JCRO will provide templates and guidance and will verify submission as part of trial closure oversight.

Dissemination to Participants

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. Plain-language summaries will be prepared by the CI with JCRO support, with patient and public involvement input wherever practicable. This is a legal requirement for CTIMPs.

Responsibility and Accountability

Responsibility for timely publication and dissemination of findings in peer-reviewed Open Access journals and to patients/public resides with the Chief/Principal Investigator. Accountability resides with CSG as the sponsoring organisations. The JCRO will monitor this in line with the oversight of trial closure.

6.3 Reporting Trial Findings On A Clinical Trials Register

It is a legal obligation that the results of all interventional clinical trials (i.e. those requiring MHRA approval), sponsored by CSG, 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 (adult trials)
- 6 months from the End of Trial date (paediatric trials)
- 12 months from the date of termination (terminated trials)

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

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

Monitoring and Escalation

The JCRO will monitor monthly all outstanding clinical trials that are due to report. A structured escalation process applies:

- 3 months before deadline: JCRO sends reminder to Chief Investigator
- 1 month before deadline: JCRO sends formal reminder with escalation warning
- At deadline if unreported: JCRO escalates to Director of Research & Innovation Services, where applicable, to the funder
- Persistent non-compliance: reported to Research Governance Committee and, if a legal breach is confirmed, to the MHRA

To ensure effective oversight, the JCRO 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, alongside a summary of any escalation actions taken.

6.4 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 sponsored research will be made available for further analysis wherever possible, in line with our Research Data Management Policy. https://www.sgul.ac.uk/about/governance/policies/research-data-management

Data Management and Sharing Plans

All sponsored studies must include a Data Management and Sharing Plan as part of the protocol and ethics submission. This plan must address:

- What data will be generated and in what format
- Where data will be stored and for how long, in line with UK GDPR and sponsor requirements
- How and when data will be made available for secondary use
- What access controls, data use agreements or application processes will govern secondary access
- Any restrictions on sharing, such as commercial confidentiality, patient safety, or legal constraints

Anonymisation must be conducted in accordance with ICO guidance and UK GDPR. The JCRO, in collaboration with the Data Protection team, will oversee Data Protection Impact Assessments (DPIAs) where required.

ICH E6(R3) Alignment

Under ICH E6(R3), data integrity and provenance are subject to enhanced quality requirements. Data management plans will be reviewed as part of trial set-up oversight by the JCRO and documented in the Trial Master File.

6.5 Patient and Public Involvement in Transparency

CSG are committed to meaningful patient and public involvement (PPI) in research, including transparency activities. CSG recognise that participants and the public have a right to access the findings of research they have contributed to.

- Plain-language summaries of trial results will be developed with PPI input wherever practicable
- Lay abstracts will be reviewed by patient representatives before public dissemination
- The public-facing trial search function will be developed with accessibility and health literacy in mind
- Findings will be disseminated to consenting participants in accessible formats, with consideration of digital inclusion

The JCRO will maintain records of PPI involvement in transparency activities as part of trial oversight documentation.

6.6 Monitoring, Oversight and Key Risk Indicators

Under ICH E6(R3), sponsors are required to apply a risk-based, quality-by-design approach to trial oversight. Transparency activities, including registration timeliness and results reporting, are identified as critical processes subject to Key Risk Indicators (KRIs) and quality tolerance limits. The following KRIs will be used to monitor transparency performance across the portfolio:

KRI	Amber Threshold	Red / Escalate
Trials not registered prior to first enrolment	>0	>0 (Immediate Escalation)
Results not reported within legal timeframes	>10% of portfolio	>20% or any legal breach
Publications not achieved within 12 months	>20% of portfolio	>40% of portfolio
Publications not achieved within 24 months	>0	Reported to RGC
Missing Data Management Plans before activation	>0	>0 (block activation)

Transparency compliance metrics will be reviewed quarterly by the Research Governance Committee and incorporated into sponsor oversight reporting and annual governance reviews. This ensures transparency performance is treated as a core sponsor obligation alongside safety reporting, protocol compliance and data quality, not a secondary administrative activity.

Research Misconduct Linkage

Failure to register, report or disseminate trial results without justified reason may be considered a breach of sponsor requirements and research governance expectations. In such cases, the matter may be escalated under relevant research misconduct or governance procedures applicable to CSG. This reflects the growing regulatory and ethical position that non-publication of trial results constitutes a form of research misconduct, causing harm to patients, the evidence base and public trust in research.

Public Disclosure of Sponsor Transparency Performance

The JCRO may publish annual transparency performance metrics summarising registration, results reporting and publication compliance across the sponsored portfolio. This demonstrates genuine institutional commitment to transparency and enables benchmarking against sector expectations. Publication will be agreed with the Research Governance Committee and the Director of Research & Innovation Services on an annual basis.

The JCRO will provide a quarterly report to the Research Governance Committee covering KRI status, outstanding results reporting, publication compliance, and any escalation actions taken.

7 Advice and guidance

For queries regarding trial registration, publication timelines, data sharing requirements, or compliance with transparency obligations, please contact the JCRO in the first instance:

- JCRO Governance Team: researchgovernance@sgul.ac.uk

Additional resources and guidance on transparency obligations are available from:

- Health Research Authority (hra.nhs.uk) – registration and Combined Review guidance
- ISRCTN registry – registration and results reporting (https://www.isrctn.com)
- EU Clinical Trials Information System (CTIS) – EU CTR obligations (https://euclinicaltrials.eu)
- ICO UK GDPR guidance on anonymisation (https://ico.org.uk)
- CSG Research Data Management Policy
- CSG Open Access Policy

8 Failure to comply

Failure to comply with the requirements set out in this policy may result in:

- Formal escalation to the Director of Research & Innovation Services and senior management
- Reputational harm to CSG and impact on future research accreditation
- Breach of regulatory requirements under MHRA, HRA, or EU CTR legislation
- Restrictions on future research sponsorship eligibility and funding access
- Breach of funder terms and conditions and potential funding recovery
- Classification as research misconduct under CSG research governance procedures
- Investigation by regulatory authorities (MHRA, HRA)
- Legal liability for sponsor obligations and patient safety implications
- Escalation to Research Governance Committee and external audit bodies

The JCRO will use structured escalation procedures (as detailed in Procedure section) to support timely compliance. However, persistent non-compliance may be treated as a governance or misconduct matter subject to formal investigation and disciplinary procedures where applicable.

9 Review

This policy will be reviewed by July 2027 or sooner if required by changes in legislation, regulations (including further ICH E6(R3) implementation guidance), institutional requirements, or significant governance developments.

Policy information

Should you require further information regarding this policy or access to the policy in an alternative format, then please contact JCRO Governance Team at researchgovernance@sgul.ac.uk

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Policy Title:	Clinical Trial Transparency Policy
Policy Version:	V6.0
Primary Author:	Rebecca Pararajasingam, Head of Clinical Research Services, RIS
Related Policies:	Data Protection Policy; Research Data Management Policy; Open Access Policy; ICH E6(R3) Implementation Guidance; •ICHE6(R3) Good Clinical Practice https://www.ich.org/page/efficacy-guidelines •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) •ISRCTN Registration | NIHR – https://www.isrctn.com •EU Clinical Trials Information System (CTIS) – https://euclinicaltrials.eu •EU Clinical Trials Regulation 536/2014 (EU CTR) – https://ec.europa.eu •WHO Joint Statement on public disclosure of results from clinical trials – https://www.who.int •NIHR Open Access Policy – https://www.nihr.ac.uk •Research Data Management Policy – CSG internal policy •UK GDPR and Data Protection Act 2018 – https://ico.org.uk
Accountable Authority:	Director of Research & Innovation Services, CSG
Approving Authority:	Research Governance Committee
Date of Approval:	22 July 2026
Policy effective from:	22 July 2026
Date of Review:	July 2027