	Liverpool Clinical Trials Centre Standard Operating Procedure **Trial Registration, Publication & Dissemination, & Lay Summary**		
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AUTHORED BY		
Print Name: [redacted]	**Position:** Head of QA & Regulatory Affairs	**Authorship evidenced via Q-Pulse workflows** **Date:** 19/10/2020
REVIEWED BY		
Print Name: [redacted]	**Position:** Head of Trial Management	**Review evidenced via Q-Pulse workflows** **Date:** 19/10/2020
APPROVED BY		
Print Name: [redacted]	**Position:** LCTC Director	**Approval evidenced via Q-Pulse workflows** **Date:** 20/10/2020

REVISION HISTORY		
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N/A*		

* All legacy LCTU and legacy CTRC SOPs are currently undergoing a merge. Once merged they will be processed as the first version of an LCTC SOP. For revision history of these legacy SOPs please refer to the superseded or withdrawn versions that are held in the legacy IT systems (DMS and CRUMbS).

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1 BACKGROUND & PURPOSE

This Standard Operating Procedure (SOP) applies to clinical studies (and Tissue Banks for registration processes only) managed by the Liverpool Clinical Trials Centre (LCTC). It deals with research transparency and covers the inclusion of projects on public registries, trial publication and dissemination and lay summaries.

Research transparency is essential to prevent waste in research and inform high quality research. This involves registering research projects when they begin, providing timely updates, submitting summary trial results, making this information publicly available, and onward sharing of trial data.

The requirement for studies to register onto a publicly accessible registry is stated in the Declaration of Helsinki and the UK Policy Framework for Health and Social Care Research, is a condition of ethical and regulatory approval, and for publication in ICJME journals. Registration is also a requirement of ethical approval for Tissue Banks. All LCTC projects will be registered in a World Health Organisation (WHO) approved publicly accessible registry.

A full list of registries can be found on the WHO and ICMJE websites. Projects may be registered on multiple registries. The main registries for LCTC research are:

- ISRCTN
- ClinicalTrials.gov
- UK Clinical Research Collaboration (UKCRC) Tissue Directory (for Tissue Banks only)

All LCTC trial results will be made publicly accessible, and LCTC research is intended to be publishable within high-quality academic journals where possible. The timeliness of the final publication and the public accessibility should be included in any publication plan. Authorship for papers should be referenced against International Committee of Medical Journal Editors (ICMJE) requirements.

The LCTC is committed to disseminating trial results as widely as possible and staff should read and comply with the University of Liverpool Open Access Publication Policy in addition to this SOP.

This SOP does not cover processes for the submission of End of Trial results to the Regulator and ethics (see LCTC SOP ***Clinical Study Report,*** LCTC_TM010), or processes for sharing of trial data (see SOP on ***Data Requests, Transfers & Sharing***, LCTC_GE013).

2 WHO & WHEN

This SOP should be referred to at project set-up (to register a project), during the project's life-time (when updating registry entries and publishing) and at trial closure (when publishing and disseminating trial results and issuing lay summaries). It is applicable to LCTC Trial Management and Statistics staff.

For hybrid trials, the main study contact (e.g. workstream lead) will perform the duties of the Trial Manager (or confirm that these have been performed by another member of the trial team – e.g. external Trial Manager).

The **Trial Manager (TM)** is responsible for:

- Ensuring the project is registered on applicable public registries and the LCTC website at set-up;
- Keeping project registry entries up-to-date: during the project's lifetime;
- Ensuring funder and Sponsor publication requirements are met (e.g. prior notification);
- Ensuring the project's publication and dissemination plans are adhered to.

The most **senior Trial Management representative** is responsible for:

- Keeping project registry entries up-to-date: when the End of Trial is declared and when results are submitted to regulators and ethics;
- Coordinating the production of Trial Results Lay Summaries;
- Ensuring the dissemination of Lay Summaries.

The **Lead Statistician (or delegate)** is responsible for:

- Ensuring the project's results publication is added to the LCTC website.

3 PROCEDURE

3.1 Trial Registration

The ISRCTN Registry is applicable to observational and interventional research studies. Registration must be applied for the study team and involves a fee. For studies adopted to the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio, registration is free and should be made via the Central Portfolio Management System (CPMS) platform rather than directly to ISRCTN. However, all ISRCTN registry entries require updating by study teams directly in ISRCTN.

The ClinicalTrials.gov registry is maintained by the US National Library of Medicine. It is a requirement for trials requiring US Food & Drug Administration (FDA) approval to be registered on this registry; non-FDA approved studies can also be registered. Registration is via an application to the Protocol Registration and Results System (PRS). Registry entries require updating by study teams.

The EU Clinical Trials Register is applicable to Clinical Trials of Investigational Medicinal Products (CTIMPs) only and is populated automatically as part of the initial trial application to the Regulator. It includes all CTIMPs which have sites within the EU/EEA (with the exception of Phase I volunteer trials). This register is updated when the End of Trial results are uploaded to the EU Clinical Trial Database (EudraCT). For LCTC CTIMPs which were registered prior to 01 January 2021, an entry will exist,

however CTIMPs registered post 01 January 2021 (end of BREXIT Transition Period) will only be registered here if they have a site within the EU/EEA.

The UKCRC Tissue Directory is a register of human tissue sample collections and is the public register for UK Tissue Banks. Registration must be applied for the study team via the website. Registry entries require updating by study teams.

The below process does not cover registry-specific application processes or update processes – staff should refer to the applicable trial registry websites for detailed guidance on these processes (see references section below for website addresses).

At Trial Set-up Stage

3.1.1 The Trial Manager (TM) will agree with the Sponsor and Chief Investigator (CI) which registries are applicable to the project and ensure registration. At a minimum, non-CTIMPs must be registered on ISRCTN and CTIMPs on ISRCTN and the EU Clinical Trial Register. Funder requirements for inclusion on specific registries must also be complied with where applicable.

3.1.2 The TM will ensure the project is included on the registries and additionally on the LCTC website ideally prior to greenlight checklist completion and at the latest before the first participant is entered onto the project.

3.1.2.1 If the trial is to be adopted onto the CRN Portfolio, the ISRCTN fee will be waived. In this case the application for ISRCTN should be made via CPMS, instead of directly on the ISRCTN website.

3.1.3 The TM will ensure evidence of trial registration is documented within the Trial Master File (TMF) and registry numbers included on applicable project documents (at a minimum protocol, participant information sheet and publications).

During Trial Lifetime

3.1.4 The TM will ensure that all trial registry entries (and any other publicly accessible areas such as trial/LCTC websites where the project is mentioned) are kept up-to-date. Consideration must be given to updating at the time of project amendments and whenever project timelines are changed (e.g. extension to recruitment, delays in set-up, etc.).

At End of Trial

3.1.5 Once the project's protocol-defined End of Trial (EoT) definition has been reached, the TM will ensure all trial registry entries and other publicly accessible areas (e.g. website) are updated with the trial status.

3.1.6 Once the project's EoT results have been submitted to MHRA/REC (i.e. within 12 months for adult studies and 6 months for paediatric studies), the TM will ensure this is stated in all trial registry entries, the LCTC website and other publicly accessible areas (e.g. trial website).

3.2 Trial Publication & Results Dissemination

Publication includes publishing of the study protocol, and of additional articles of interest prior to the main results paper. If the protocol is intended to be published, it should be noted that this should be done preferably prior to end of participant recruitment and at the latest last patient last visit. The timing of publication in relation to trial status will impact which journal will consider publication.

Publications may be disseminated in various ways: via social media (e.g. twitter), University of Liverpool press release, patient organisation websites, etc.

3.2.1 The TM must check the funder contract and Sponsor requirements for publications requirements, including prior notification of planned publications.

3.2.2 The TM will ensure that planned publications are notified to funder and Sponsor (and any other applicable parties) within the required timeframes.

3.2.3 The TM must also check the University of Liverpool's Open Access Policy (see References section for link). The University may be able to provided funds to cover cost of publication in open-access journal.

3.2.4 The study's Lead Statistician will ensure all publications are added to the LCTC website and also instruct the TM to ensure they are also added to the trial's applicable registries (e.g. ISRCTN require a list of publications).

3.2.5 The TM will check the study dissemination plan and ensure it is adhered to when publications are available (e.g. notification to patient organisations, press offices, etc.).

3.3 Trial Results Lay Summary

Making the findings of a research study accessible to the public in lay terms is an important part of good public engagement and a key aspect of research transparency. Making results available to participants is also an expectation of research subject to the UK Policy Framework for Health & Social Care Research.

3.3.1 The most senior Trial Management representative (or delegate) will liaise with the CI, Sponsor and TMG to produce a Trial Results Lay Summary for public dissemination. The most senior Trial Management representative (or delegate) will ensure this document:

3.3.1.1 includes all relevant trial identifiers – at a minimum these must be those included on the Participant Information Sheet.

3.3.1.2 is controlled in accordance with the LCTC SOP on version and document control.

3.3.2 Once fully approved, the most senior Trial Management representative (or delegate) will ensure the Trial Results Lay Summary is made available on the LCTC website (and trial website if applicable).

3.3.3 The most senior Trial Management representative (or delegate) will check if other means of dissemination of a lay summary (e.g. directly to participants via post/email) has been planned in the trial and if so will ensure this is actioned. Checks should include the funder requirements, trial protocol, initial IRAS application and ethics approval conditions.

3.3.4 If the Trial Results Lay Summary is available at the time of submission of results to the ethics committee (see LCTC SOP ***Clinical Study Report***, LCTC_TM010), then the most senior Trial Management representative (or delegate) will include this in the submission.

4 STUDY IMPACT ASSESSMENT

All applicable sections of this SOP must be followed in their entirety.

5 RELATED PROCEDURES & DOCUMENTS

- Health Research Authority (HRA), "Make It Public: Transparency and openness in health and social care research", July 2020, available at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/ (last accessed 12/10/2020)
- UK Policy Framework for Health and Social Care Research (V3.3, Nov 2017), available at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ (last accessed 12/10/2020)
- World Medical Association (WMA), Declaration of Helsinki, 2018, available at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (last accessed 12/10/2020)
- University of Liverpool Open Access Publication Policy (2018), available at https://libguides.liverpool.ac.uk/openaccess/OApolicies (last accessed 12/10/2020).
- ISRCTN website: https://isrctn.com (last accessed 12/10/2020)
- ClinicalTrials.gov website ("How to Register Your Study" page): https://www.clinicaltrials.gov/ct2/manage-recs/how-register (last accessed 12/10/2020)
- UKCRC Tissue Directory website: https://biobankinguk.org/ (last accessed 12/10/2020)
- EU Clinical Trials Register website: https://www.clinicaltrialsregister.eu/about.html (last accessed 12/10/2020)
- HRA website ("Research registration and research project identifiers" page): https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/ (last accessed 12/10/2020)
- MHRA website ("Registration of clinical trials for IMPs and publication of summary results from January 2021" page): https://www.gov.uk/guidance/registration-of-clinical-trials-for-investigational-medicinal-products-and-publication-of-summary-results-from-1-january-2021 (last accessed 12/10/2020)

Related LCTC documents	
Document Code	**Document Title**
LCTC_TM010	Clinical Study Report
LCTC_GE013	Data Requests, Data Transfers & Data Sharing

6 APPENDICES

None.