UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 22

Publication and Dissemination

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Revision Chronology:	**Effective date:**	**Reason for change:**
Version 4.0	29 April 2026	Biennial review: Updates to make text more concise; reduce repetition; signpost to external sources; ensure compliance with ICH GCP E6R3. Notes added regarding contractual requirements.
Version 3.0	8 March 2024	Biennial review: Minor updates to text including new NIHR requirements. Addition of data accuracy check form.
Version 2.0	19 November 2021	Biennial review: Change to new format. Addition of information on group authorship and dissemination to the public. Other minor amends to text.
Version 1.6	25 July 2019	Biennial review: Major revisions to text and inclusion of process flowchart.
Version 1.5	17 January 2017	Biennial review: Additions to text in background section, plus other minor text amends. Web links updated. Creation of publication policy template. Change to new format.
Version 1.4	21 March 2014	Addition of procedure for generation, review and approval of publications and information on Open Access publication and authorship acknowledgement.
Version 1.3	21 May 2012	Updated address to reflect new Divisions in WMS. Section 3.3.2 updated. Format changed to comply with SOP 1.
Version 1.2	21 December 2009	Updated to reflect REF.
Version 1.1	30th January 2008	Biennial review. Format change.
Version 1.0	March 2006	

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CONTENTS

1 Purpose and Scope

To describe procedures for publication and dissemination of study findings from all University of Warwick sponsored research projects involving human participants, or for externally sponsored studies where this activity has been explicitly delegated and the use of UoW SOPs agreed.

It is applicable to all staff involved in the publication and/or dissemination of trial information and results.

It is recommended that this is read in conjunction with SOP 28: Transparency in Clinical Research studies.

2 Acronyms

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CONSORT	Consolidated Standards of Reporting Trials
GCP	Good Clinical Practice
HEAP	Health Economic Analysis Plan
HRA	Health Research Authority
ICMJE	International Committee of Medical Journal Editors
IP	Intellectual Property
ISRCTN	International Standard Registered Clinical/soCial sTudy Number
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute of Health and care Research
PPI	Patient and Public Involvement
PRP	Policy Research Programme
QA	Quality Assurance
REF	Research Excellence Framework
RCT	Randomised Controlled Trial
R&IS	Research and Impact Services
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
T/SMF	Trial/Study Master File
WCTU	Warwick Clinical Trials Unit
WRAP	Warwick Research Archive Portal

3 Definitions

Publication	Publishing matter in print or electronic form.
Dissemination	Spreading information widely, usually study results.
Research Transparency	The ethical obligation to make data, analysis, methods, and interpretive choices underlying claims visible in a way that allows others to evaluate them.

4 Background

Good research is conducted to high standards and shared through clear, justified methodology and meaningful dissemination of its findings. Governments, funders, regulators, publishers, universities and individuals are all involved in improving and maintaining research integrity and transparency. Researchers have a duty to the scientific community, the public and study participants, to ensure that the results of research projects are fully reported.

The research community must foster and support a culture of research integrity, with transparency and honesty which promotes good practice, recognises relevant interests or conflicts and deals with these openly and explicitly. This applies across all research activity including study design, data management and analysis, sharing data and materials, applying for funding, publishing findings, acknowledging the contributions of others and engaging in the peer review process.

The UK Government's Science, Innovation and Technology Select Committee has raised concerns that UK higher education institutions are failing to meet required standards for transparency in clinical trial reporting:

https://committees.parliament.uk/committee/135/science-innovation-and-technology-committee/

While clinical trials must comply with all relevant legislation and regulations, these principles should be applied to other forms of research wherever possible. In relation to publication and dissemination, the following elements are important:

- Registration in advance in a publicly accessible registry*
- Publication of at least a summary of results within a set timeframe following the end of the study**
- Reporting all the study results and not just a subset or those that are statistically significant

** e.g., International Standard Randomised Controlled Trials Number (ISRCTN) (for clinical trials and other studies), PROSPERO (for systematic reviews)*

***For Clinical Trials it is expected that results are uploaded to the relevant registry record within 12 months from the end of the study.*

5 Responsibilities

Chief Investigator	• Ensure timely publication and dissemination of findings and/or results • Ensure publication fees and dissemination costs are included in the grant application • Confirm issues around who holds the IP for any dataset and/or publication • Ensure that a suitable lay-friendly final report is prepared and disseminated to study participants
Sponsor	• Ensure that clinical trial reports are prepared and provided to the regulatory agency(ies) as required

6 When

Publications may be prepared at any time point during a research project (e.g., study protocols should be published before recruitment is completed). Results and findings are usually published at the end of a funded study via papers and published funder reports.

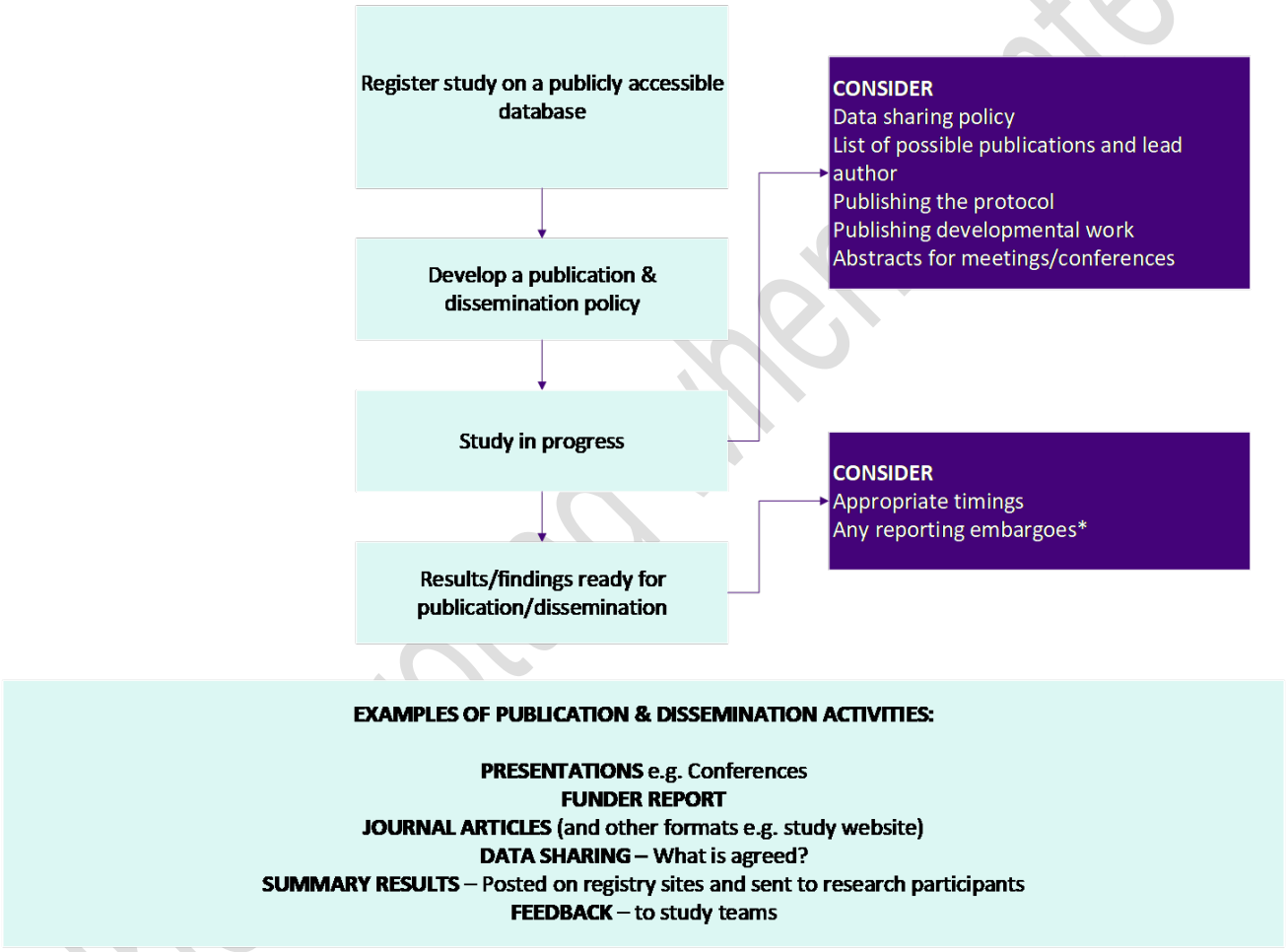
Where the main findings are also to be submitted for publication in a journal, this should be done within 12 months of study completion (as defined in the protocol), to be published through an open-access mechanism in a peer-reviewed journal.

For CTIMPs, results must be made publicly available within 12 months of primary study completion.

7 How

7.1 Overview

Publication and dissemination process:



* The ICMJE does not consider the posting of trial results in any registry as prior publication if results are limited to a brief structured abstract or tables (to include trial participants enrolled, baseline characteristics, primary and secondary outcomes, and adverse events): http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Publication of key results on publicly accessible registries e.g. ISRCTN or clinicaltrials.gov must be completed for all research, and researchers should make themselves aware of relevant funder and regulatory requirements. Researchers should make themselves aware of The University of Warwick's research code of practice and research integrity information.

The REF is a system for assessing the quality of research in UK higher education institutions. When planning and publishing research, study teams and researchers should consider how their work will contribute to this assessment exercise. More information can be found at http://www.ref.ac.uk/ and on the University web pages: http://www2.warwick.ac.uk/services/spa/researchassessment.

7.2 Generation, review and approval of publications

Early stages of the study

Study teams should agree a publication policy and plan early in the project. An example template 'Publication and Presentation Group Operating Procedure' document is available on the WCTU website alongside this SOP (**T17**).

All clinical trials and other studies if required, should be registered on publicly accessible research registers prior to recruitment of the first participant. Changes to the design, methods or outcomes during the conduct of a study should be reflected by updating the information on the registration record to ensure it matches the current protocol as well as the Statistical Analysis Plan.

Consider publication of the study protocol in the interests of transparent reporting. Ensure that trial protocols are published according to SPIRIT Statement: GUIDANCE FOR CLINICAL TRIAL PROTOCOLS.

Trial teams should consider publishing the SAP and HEAP.

If data are going to be made available for future research, consider what consents are required from study participants. Consideration should also be made regarding future data sharing processes at an early stage of the study.

On completion of the study/when results are ready for publication

Summaries for registries, reports, presentations and journal publications should be prepared as agreed by the study team, publishing within regulatory and funder timeframes.

Presentation of study materials should be approved in advance by the CI and where any data/results are being presented, this should be reviewed, where appropriate, by a statistician to ensure accuracy of the results reported using form **T68**.

See SOP 15 part 4 'Extraction of Data for Analysis and Data Lock' for information on data freeze/snapshots and locking the database to prepare for publications.

Any research output using data purchased or accessed from NHS England should include any covering statement(s) stipulated in the contract.

If a study is closed prematurely, it should still be published, giving an overview of results and conclusions as far as possible, and an explanation about why the study was closed.

Approval process:

- All draft publications should be circulated to co-authors for peer-review.
- Completion of form T68 by the statistician who has undertaken the checks to confirm accuracy of the results reported.
- File a copy of **T68** in the TMF.
- Obtain evidence of approval If approval is via email, follow guidance in **G33** 'email approval guidance'. All forms should be saved in the TMF.
- A record of publications and associated documents (including the statement on authors contributions and conflict of interest statements) should be filed in the TMF.

Where applicable, authors should also assess to what extent the trial complied with GCP and to consider if any deviations, violations and/or breaches which may have occurred during the trial could have had any impact on the results. The GCP compliance statement should be written to reflect findings of the review and included in publications, final reports and presentations as appropriate.

7.3 Reports and presentations for funders, participants and collaborators

Researchers should check and comply with funder requirements for study reports. Final reports may be publicly accessible.

A summary of the final report should be provided to the main REC within 12 months of the formal notification of the end of the study. For CTIMPs, it is a requirement to upload a summary of clinical trial results onto the registry on which it was initially registered. Both requirements must be completed within 12 months of the End of the Study (as defined in the protocol).

Participants should have, wherever possible, the opportunity to receive a report of the results. It is the responsibility of the CI to ensure that a suitable report is prepared and disseminated. The HRA have developed guidance to explain how and what information must be provided to participants, their legal representatives, consultees, relatives or close friends (where applicable), at the end of a trial. Further guidance from the HRA is available: Publication and dissemination of research findings - Health Research Authority

It is important to emphasise the message that patient data underpin research and care. The Understanding Patient Data group recommends including a 'data citation' on all publications e.g. ‘This work uses data provided by patients and collected by the NHS as part of their care and support’.

It is also important to ensure that all collaborating staff are acknowledged in outputs and final reports (where appropriate), informed of the results and thanked for their efforts.

NIHR-funded studies

Requirements for branding and statements published outputs are available here: (https://www.nihr.ac.uk/researchers/i-need-help-to-deliver-my-research/outputs-and-branding.htm#four)

Information regarding the NIHR publishing platform is available: https://www.nihr.ac.uk/news/nihr-launches-new-publishing-platform-to-expand-its-publicly-available-research-information/30872.

7.4 Publication in Journals

Reporting standards

Randomised clinical trials must conform to the CONSORT statement guidelines.

Reporting standards for other types of study are available on the EQUATOR Network website: https://www.equator-network.org/about-us/uk-equator-centre/

Authorship

ICMJE recommends how authorship credit should be determined, strongly recommends editors of publications have a contributor policy for authorship, and recommends that authorship be based on the following criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In keeping with the University's policies on Research Integrity, authorship opportunities should be offered, where appropriate, to all members of the study team.

The ICMJE guidance contains information on non-author contributors.

Group authorship

Group authorship provides a way in which a group of authors may be identified by a collective name. This may be helpful where a large number of individuals meet authorship criteria. This may be either: a list of authors writing on behalf of the collaborative group or describing all authors as the collaborative group.

Open Access

The University of Warwick has a policy on open access publishing.

Warwick Research Archive Portal (WRAP) is the University's full text, open access research content portal: University policy states that to be eligible for inclusion for the REF, journal articles and conference contributions must be deposited into a repository. University of Warwick's policy is that all outputs should be deposited in WRAP. Relevant trial materials) can be copyrighted and also held in WRAP.

Funder Requirements

Researchers should check and comply with the relevant funding bodies' requirements for notification of publications/presentations, acknowledgement of funding source, disclaimers and open access requirements.

NIHR-funded studies

NIHR open access policy makes published academic research freely, immediately and permanently available online for anyone to read, share and reuse

The NIHR will continue to require notification of newsworthy, impactful or sensitive outputs to enable them to support and amplify any communications. This notification should take place as soon as reasonably practicable and a minimum of three working days prior to any media outreach. The NIHR still asks that award holders continue to report outputs, outcomes and impacts through the normal reporting process including Researchfish: https://app.researchfish.com/user/login?destination=awards#/

NIHR will also ask new and existing award-holders to help them identify potentially newsworthy research outputs with longer notice periods, to enable more in-depth public-facing and media content to be produced.

For research funded by the NIHR Policy research Programme, researchers must notify the research programme 28 days BEFORE submission to a journal or conference.

For further information, refer to the guidance available on the NIHR website or contact the relevant NIHR programme manager or communications team with any questions.

7.5 Data sharing

There is an ethical obligation to responsibly share data generated by interventional clinical trials. Many funders and journals now mandate data sharing and require a statement to that effect within a publication. Data sharing should be considered for all types of study.

The process of data sharing is detailed in WCTU SOP 15 part 3 'Information Handling: Sharing Data'.

Clinical trials must include a data sharing plan in the trial's registration information.

Manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement indicating the following:

- Whether individual deidentified participant data (including data dictionaries) will be shared
- Which data will be shared
- Whether additional, related documents will be available (e.g. protocol, statistical analysis plan)
- When the data will become available and for how long

By what access criteria data will be shared, including with whom, for what types of analyses, and by what mechanism.

A guidance document on data sharing statements is available (**G27**).

Information and examples of data sharing statements that meet these requirements are provided: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html.

NIHR position on the sharing of research data

For studies funded by the NIHR, expectations are available: NIHR position on the sharing of research data | NIHR

7.6 Dissemination of results

Study teams should consider developing a dissemination plan early in the study and many funders require a detailed dissemination plan within the grant application. Reports and publications are part of this plan, but other modes of dissemination should be considered, as appropriate to the study. This includes the use of social media, patient organisations, patient support groups and clinical/professional networks.

Presentations, posters for academic and other audiences are also considered dissemination. Study teams should consider other opportunities for dissemination activities. University of Warwick has a public engagement group that can help advise at all stages of research including grant applications.

If required by the contract, the funder should be notified about any upcoming dissemination of publications, presentations etc. prior to issue. It is the CI's responsibility to ensure this is documented in the publication policy and is done in a timely manner.

It is also important to ensure that all collaborating staff are informed of the results and thanked for their efforts.

Dissemination to the public:

Information about research findings should be available for interested groups or communities and the general public in a format that is accessible and easy to understand. The HRA require sponsors to

include a plain language summary of the findings in the final report which will be published on the HRA website alongside the study research summaries. WCTU have also produced a guidance document on patient accessibility (**G37**). See further guidance on writing a plain language (lay) summary of your research findings.

PPI is now generally a funder requirement in research ethics applications and PPI activities are embedded in many aspects of research. Patient and public partners can be and are involved in research studies from the initial design of the study through to the dissemination of results. These patient and public partners may be willing and able to present findings from a patient perspective at conferences and forums. They can also help ensure that results are presented in a way that will be understood by a wider audience. Therefore, it is important to consider their involvement when developing a dissemination plan.

Patient and public partners can contribute towards preparing lay-friendly summaries and bulletins. It is important to look for opportunities to disseminate findings on public forums to keep the public informed of research outputs. Forums may include patient specific non-profit organisations and charities and patient support groups on social media platforms. Findings must be written in plain English and present a balanced interpretation of risks and benefits. See patient accessibility guidance (**G37**) for further details.

All dissemination activities must be approved by the funder.

Branding:

Warwick Medical School marketing and communications teams provide information on branding requirements, which should be considered as appropriate to the dissemination activity.

8 Associated Templates and Documents

T17	Publication and Presentation Group Operating Procedure Template
T68	Confirmation of Accuracy of Data Form
G27	Guidance on data sharing statements
G33	Email approval guidance
G37	Patient Accessibility Guidance