STANDARD OPERATING PROCEDURE 22

Publication and Dissemination

Version:	3.0	Effective Date:	8 March 2024
Issue Date:	23 February 2024	Review Date:	8 March 2026
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Revision Chronology:	Effective date:	Reason for change:
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	

STANDARD OPERATING PROCEDURE 22
Publication and Dissemination

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for publication and dissemination of study findings from all University of Warwick sponsored research projects involving human participants (or sponsored studies where use of University of Warwick SOPs has been agreed). For non-Warwick sponsored studies, researchers must be aware of, and comply with, their sponsor's requirements and SOPs.

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

The government, funders, regulators (e.g., the Health Research Authority (HRA), or Medicines and Healthcare products Regulatory Agency (MHRA)), publishers, universities and individual researchers all have a part to play in improving and maintaining research integrity and transparency including in reporting results and findings. Researchers therefore have a duty to the scientific community, the public and study participants, to ensure that the results of research projects are fully reported.

2. Definitions

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

3. Background

Good research is that which is not only conducted to a high standard, but that the methodology and research findings are published and disseminated in a way that justifies its existence and its relevance.

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 the whole range of research activity from study design, generating, analysing and recording (including archiving) of data, 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 and Technology Select Committee is particularly concerned that UK higher institutions are not complying with required transparency in Clinical Trials reporting (https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/1480.pdf) For clinical trials, the relevant legislation and regulations supporting them must be complied with, but they should also be applied to other types of research wherever possible. There are four pillars central to transparency (see SOP 28 'Transparency in Clinical Research Studies'), including the requirement for future sharing of data, but in relation to publication and dissemination, the following three items are relevant:

Registration of details of studies 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.*

Researchers should make themselves aware of The University of Warwick's research code of practice and research integrity information.

The Research Excellence Framework (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

4. Procedure

4.1 Responsibilities

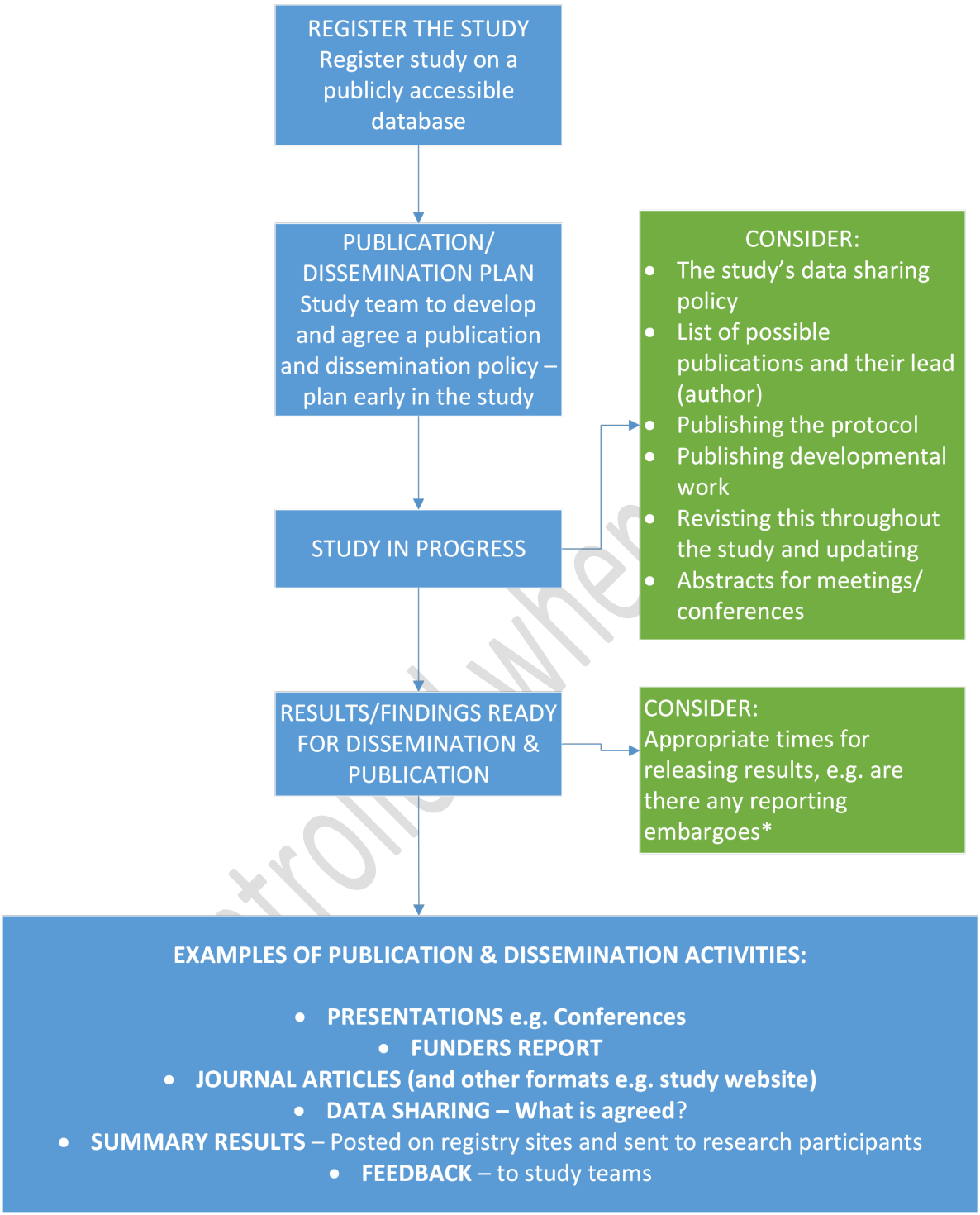
Chief Investigator	• Ensure timely publication and dissemination of research findings and/or results • Ensure publication fees and dissemination costs are included in the grant application • Confirm any issues around who holds the Intellectual Property (IP) for any dataset and/or publication • Ensure 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 by the applicable requirement(s)

4.2 When?

Publications may be prepared at any time point during the lifetime of a research project e.g., study protocols should be published at an early stage, before recruitment is completed. Results and findings are usually published at the end of a funded study in the format of papers and published funders reports. 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 appropriate to their research. See SOP 28 'Transparency in Clinical Research studies' for further details. Although timings can vary, it is generally expected that results are published within 12 months of study completion (e.g. after final data collection timepoint and after participant follow-up is completed).

4.3 How?

Flowchart, outlining publication and dissemination process:



* The International Committee of Medical Journal Editors (ICMJE) does not consider the posting of trial results in any registry as prior publication if results are limited to a brief (500 word) structured abstract or tables (to include trial participants enrolled, baseline characteristics, primary and secondary outcomes, and adverse events).

For further details see:

http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

4.3.1 Procedure for the generation, review and approval of publications

Early stages of the study

All clinical trials and other studies, if required and wherever possible, should be registered on publicly accessible research registers prior to recruitment of the first participant. Examples include the ISRCTN registry or clinicaltrials.gov for prospective registration of clinical trials. See SOP 28 'Transparency in Clinical Research studies' for further details.

Any 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 which will be ratified by the Data Monitoring Committee/Trial Steering Committee.

Consider publication of the study protocol in the interests of transparent reporting. See SOP 4 'Trial Protocol' for more information. Ensure that trial protocols are published according to SPIRIT Statement (GUIDANCE FOR CLINICAL TRIAL PROTOCOLS (spirit-statement.org).

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 (see section 4.3.4 for more details).

Study teams should develop and 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). Trial teams should consider publishing the Statistical Analysis Plan (SAP) and Health Economic Analysis Plan (HEAP); this can be added to the study website (see also SOP 21 and SOP 33).

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

All research projects' results/findings should be published to make them publicly available. For Clinical Trials of Investigational Medicinal Products (CTIMPs) this is mandatory. 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. for further details.

Any research output using data purchased or accessed from NHS England (previously NHS Digital) should include the covering statement: 'This work uses the data provided by patients & collected by the NHS as part of their care and support'.

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.

Summaries for registries, reports, presentations and journal publications should be prepared as agreed by the study team publishing within timeframes set by regulatory requirements, funders and otherwise as soon as possible.

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

Approval process:

1) All draft publications should be circulated to co-authors for peer-review.
2) Completion of form T68 by the statistician who has undertaken the checks to confirm accuracy.
3) File a copy of T68 in the Trial/Study Master File (T/SMF).
4) Obtain evidence of approval (this may be via the Q-Pulse electronic quality management system for WCTU managed studies, paper review/approval form or via email following the guidance in G33 'email approval guidance'. All emails or paper review/approval forms should be saved in the T/SMF.
5) A record of any publications and associated documents (including the statement on authors contributions and conflict of interest statements (required by journals)) should be filed in the T/SMF.

Where applicable, e.g., Randomised Controlled Trials (RCTs), authors should also assess to what extent the trial complied with Good Clinical Practice (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.

4.3.2 Study reports and presentation of findings for funders, participants and collaborating staff

- Researchers should check and comply with funder requirements for study reports. Final reports may be publicly accessible e.g., via the National Institute for Health and care Research (NIHR) Journals Library. Please also check requirements for branding and use of NIHR logo on published outputs (https://www.nihr.ac.uk/researchers/i-need-help-to-deliver-my-research/outputs-and-branding.htm#four
- From 2023, NIHR have updated requirements for final reporting of NIHR-funded studies, changing from a single comprehensive report (e.g. Health Technology Assessment monograph) to a threaded publication model. Please refer to website for further information: https://www.nihr.ac.uk/news/nihr-launches-new-publishing-platform-to-expand-its-publicly-available-research-information/30872.
- A summary of the final report should also be provided to the main Research Ethics Committee within 12 months of the formal notification of the end of the study. See SOP 5 part 3 'Communication with Approval Bodies' for further details.
- Information about research findings should be available to those who took part in the study, 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.
  See further guidance on writing a plain language (lay) summary of your research findings.
- Participants should have the opportunity to receive a report of the results. It is the responsibility of the CI to ensure that a suitable lay-friendly final report is prepared and

disseminated. Consider also publishing a lay-friendly summary on the study/trial website. The HRA provides guidance. See also SOP 28 'Transparency in Clinical Research Studies'.

- 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.

4.3.3 Publication in Journals

Reporting standards

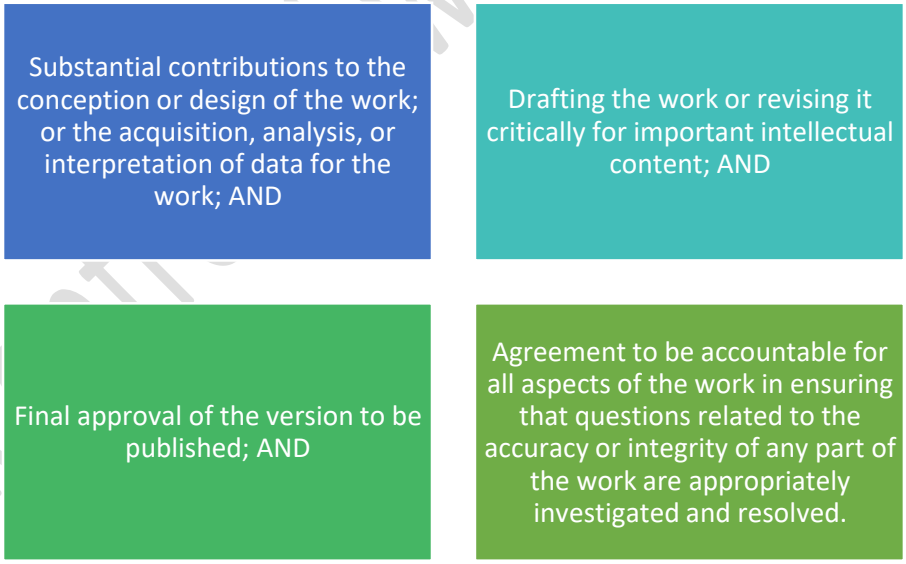
Standards for reporting research of different types are available and should be used to ensure transparency. Randomised clinical trials must conform to the CONSORT (*Con*solidated *S*tandards *o*f *R*eporting *T*rials) statement guidelines.

Reporting standards for other types of study are available on the equator network website.

Authorship

Journals always have authorship requirements. The International Committee of Medical Journal Editors (ICMJE), recommends how authorship credit should be determined and strongly recommends editors of publications have a contributor policy for authorship.

The ICMJE recommends that authorship be based on the following 4 criteria:



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 and states:

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical

editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients," "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals. Written signed consent is also required for articles containing images or photographs, whether anonymised or identifiable images (e.g. intervention development materials).

Group authorship

Group authorship provides a way in which a group of authors may be identified by a collective name. This may be particularly helpful where a very large number of individuals meet authorship criteria. This may be operationalised as either: a list of authors writing on behalf of the collaborative group (e.g. http://dx.doi.org/10.1056/NEJMoa1806842) or describing all authors as the collaborative group (e.g. https://doi.org/10.1016/S2213-2600(21)00089-8).

Open Access

The University of Warwick has a policy on open access publishing which researchers should be aware of.

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 (e.g., trial intervention manuals) 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 e.g., the NIHR open access policy.

For NIHR funded studies, the previous requirement for grant recipients to provide an output notification and final copies of research papers and press releases 14/28 days before they enter the public domain is no longer in force (from December 2020).

The NIHR will continue to require notification of newsworthy, impactful or sensitive outputs to enable them to support and amplify any communications and maximise publicity. 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.

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

Please note that these changes do NOT apply to outputs generated by the Policy Research Programme (PRP). For research funded by PRP, 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.

4.3.4 Data sharing

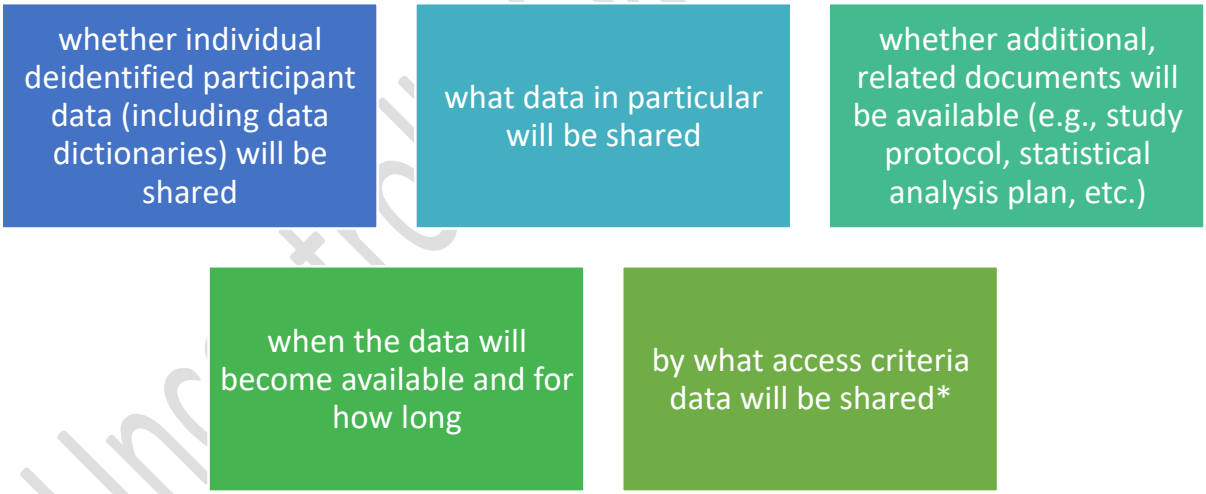
There is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have given up their time to contribute to research, and for some interventional studies, put themselves at risk. Many funders and some journals now mandate data sharing and require 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' and in SOP 28 'Transparency in Clinical Research Studies'.

Clinical trials that begin enrolling participants on or after 1 January 2019 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 as described below.

Data sharing statements must indicate the following:



*Including with whom, for what types of analyses, and by what mechanism.

WCTU have produced a guidance document on data sharing statements (G27) and more details can also be found in SOP 28 'Transparency in Clinical Research Studies'.

Further information and illustrative examples of data sharing statements that would 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 around data sharing have been published: https://www.nihr.ac.uk/about-us/who-we-are/our-policies/sharing-of-research-data.htm

4.3.5 Dissemination of results

Demonstrating the impact of research is now an important part of REF. Study teams should consider developing a dissemination plan early in the study and many funders require a detailed dissemination plan as part 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. 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.

A summary of the final report should also be provided to the main Research Ethics Committee. For CTIMPs it is also 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. See SOP 7 'Participant Information and Consent' and further guidance from the HRA.

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

Dissemination to the public:

Patient and public involvement (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.

Whilst dissemination and publication of studies is usually considered to be an academic task, publishing in scientific journals and presenting at conferences etc., consideration should also be given to how or whether findings will be disseminated to the general public. Patient and public partners can be a great help with 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 (e.g., Versus Arthritis, British Heart Foundation, Cancer Research UK etc.) and patient support groups on social

media platforms. The important thing about presenting findings to the general population is to ensure they are written in plain English and present a balanced interpretation of risks and benefits. .

As with all dissemination activities these will have to 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.

The central marketing team has information at:
https://warwick.ac.uk/services/engagementgroup/brand/

List of abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CONSORT	Consolidated Standards of Reporting Trials
EUdraCT	European Union Drug Regulating Authorities Clinical Trials Database
GCP	Good Clinical Practice
HEAP	Health Economic Analysis Plan
HRA	Health Research Authority
ICMJE	International Committee of Medical Journal Editors
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

Template Documents

T17 Publication and Presentation Group Operating Procedure Template

G33 email approval guidance

G27 Guidance on data sharing statements

T68 Confirmation of Accuracy of Data Form