

## SOP-QA-33 V6

### Title: Research project publication and dissemination

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#### Document History

Version	Description of update	Date Effective
4	Change in Author/Owner and reference to ISRCTN added Update on reporting CTIMPS through EudraCT	11-10-22
5	Update to procedure for posting results in EudraCT at 3.19	20-12-23
6	Updated requirements re dissemination of results at 3.18 Updated definitions at 4	28-04-26



### 1. Scope

- 1.1 This SOP applies to all Published Outputs from co-sponsored studies and all single sponsored interventional studies, Clinical Trials of an Investigational Medicinal Product (CTIMPs), Medical Device Clinical Investigations (MDCI), and any other studies identified by the Sponsor where the study has not already been registered on ISRCTN by the HRA.

### 2. Responsibilities

Chief Investigator (CI)	Ensure study findings are published and disseminated appropriately. An awareness of funder requirements in respect of study publications and to inform the funder of any impending publications. Complete and submit self-certification form.
All authors	Declare relevant conflicts of interest as specified by funder/journal policies.
Sponsor	Identify any issues from the self-certification form which must be reflected in the publication, ensure CI posts clinical trial summary results in EudraCT (CTIMPS which began before 2021) and/or on appropriate registered public accessible database.

### 3. Procedure

- 3.1  There is an obligation to full and open publication of research project results, regardless of findings. Research projects with null results, those which failed to recruit to target and those which were unexpectedly terminated, all need to be published. In so far as possible, CTIMPs should be reported to their planned intentions and as soon as is practicable.
- 3.2  The results of all co-sponsored studies and all single sponsored interventional studies, CTIMPs, MDCIs, and any other studies identified by the Sponsor shall be appropriately disseminated through publication in peer-reviewed scientific journals.

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- 3.3 Many funders publish a final report upon completion of the research project. The format and deadline for reports will differ depending on the funder. If a final report is required, the CI must ensure it is completed accurately and submitted within specified time frame.


#### Authorship

- 3.4 There shall be a clear statement of authorship policy included in the study protocol. This shall include all individuals who have made a substantial academic contribution according to the guidance and recommendations of the International Committee of Medical Journal Editors (ICMJE) <http://www.icmje.org/>
- 3.5 All individuals who have made a substantial contribution to the research project without fulfilling the authorship criteria should be clearly acknowledged, usually in an 'Acknowledgements' section, detailing their contributions.


#### Acknowledgement of funders and any disclaimers

- 3.6  The contributions of funders should be clearly acknowledged. Where a format for this acknowledgement has been specified by the funder(s) the CI must ensure this is followed. The CI must also ensure that any contractual obligations to the funder relating to publications are met including any requirements for prior notification of the publication of project outputs.
- 3.7 It is often necessary to include an appropriate disclaimer (eg funder's disclaimer) when reporting research findings or opinions.


#### Acknowledgement of regulatory bodies and Sponsor

- 3.8  Authors must include details of the Sponsor, any ethics committee and other approvals (eg MHRA) within the manuscript. Where applicable, all study reference numbers (eg REC, MHRA, etc) shall be stated in the publication.


#### Acknowledgement of Trial Steering Committee and Data Monitoring Committee as relevant

- 3.9  To maintain their strict independence, independent members of the Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) should not gain any academic credit by being a co-author on study publications.
- 3.10 The role of individual members of the TSC and DMC should be acknowledged and their agreement to this sought before accepting their role, unless they request otherwise.



#### Reporting standards

- 3.11 Authors are encouraged to use the relevant reporting guidelines for the research project provided by the EQUATOR (Enhancing the Quality and Transparency of health Research) Network. [www.equator-network.org](http://www.equator-network.org). These reporting guidelines will ensure that all relevant information is reported in the publication.
- 3.12  The CI must ensure that any key issues raised by the Sponsor are adequately addressed within the publication.

#### Submission of publication

- 3.13  The CI or delegate (eg lead author) must complete a **publication self-certification form** (TMP-QA-33) in relation to the publication and submit it to the Research Governance team via [researchgovernance@abdn.ac.uk](mailto:researchgovernance@abdn.ac.uk) at least **3 weeks prior** to the intended submission date.

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3.14 The Sponsor shall review the publication self-certification form to determine whether they:

- Approve submission of the publication.
- Require a full Sponsor review of the draft publication to approve submission of the publication or request changes and further review.

Please refer to Appendix 1 for the flow-chart detailing the publication self-certification process.


3.15 Following Sponsor approval the CI or delegate shall submit the publication. If the journal requests that substantial changes must be made to the manuscript in response to the journals' reviewers' comments, the CI shall notify the Sponsor.

### Dissemination


3.16  There shall be a commitment to disseminate outputs from the research project to study participants, the general public, internally within the UoA and/or NHSG, at scientific meetings and to professional and lay publications when appropriate.


### Dissemination to participants

3.17 The process for disseminating results to participants shall have been addressed at the time of ethical approval and detailed in the protocol. Any deviations from this should be discussed and agreed with Sponsor.

3.18  For CTIMPs approved after 28-04-26 it is mandatory that the summary of results is provided to participants and/or other relevant people within **twelve months** of end of trial in a way that can be understood by members of the public. The only exception is if a trial has a deferral or waiver.

### Dissemination to the public



3.19 Consideration shall be given to issuing a press release. It is advisable that research personnel contact the appropriate communication/press office teams in the UoA and/or NHSG.  If the press release contains research project results, the press release should be embargoed until the day of publication. The CI must also ensure that any contractual obligations to the funder are met including any requirements for prior approval of press releases or other media material. All relevant parties including the funder and Sponsor shall be informed in advance of any press release.

3.20  It is mandatory for the Clinical Trial summary results to be posted in EudraCT (if approved pre 2021) this is the responsibility of Sponsor and delegated staff. Clinical Trials which began on or after 01-01-21 will need to report results on the publicly accessible database that they are registered on. Reporting of results must be done within a specific period following the end of the trial (**six months** for paediatric and **twelve months** for other trials).

## 4. Abbreviations and definitions

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
ISRCTN	International Standard randomised control trial number
MDCI	Medical Devices Clinical Investigation
MHRA	Medicines and Healthcare products Regulatory Agency
REC	Research Ethics Committee

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## Definitions


Relevant persons (as defined by HRA):

- A parent, someone with parental responsibility for, or a legal representative of the participant where the participant is under 16 years of age (this should normally be the person who provided consent on behalf of the child to participate).
- The legal representative who provided consent on behalf of an adult lacking capacity.
- In cases where the participant was a child at the time of recruitment but reaches the age of 16 by the time the summary results are to be provided, both the participant and the person who originally provided consent for their involvement.
- In cases where the participant has lost the capacity to provide consent after the start of the trial or has died, someone who's engaged in caring for the participant or is interested in the participant's welfare, for example, their legal representative (if there is one) or their next of kin.

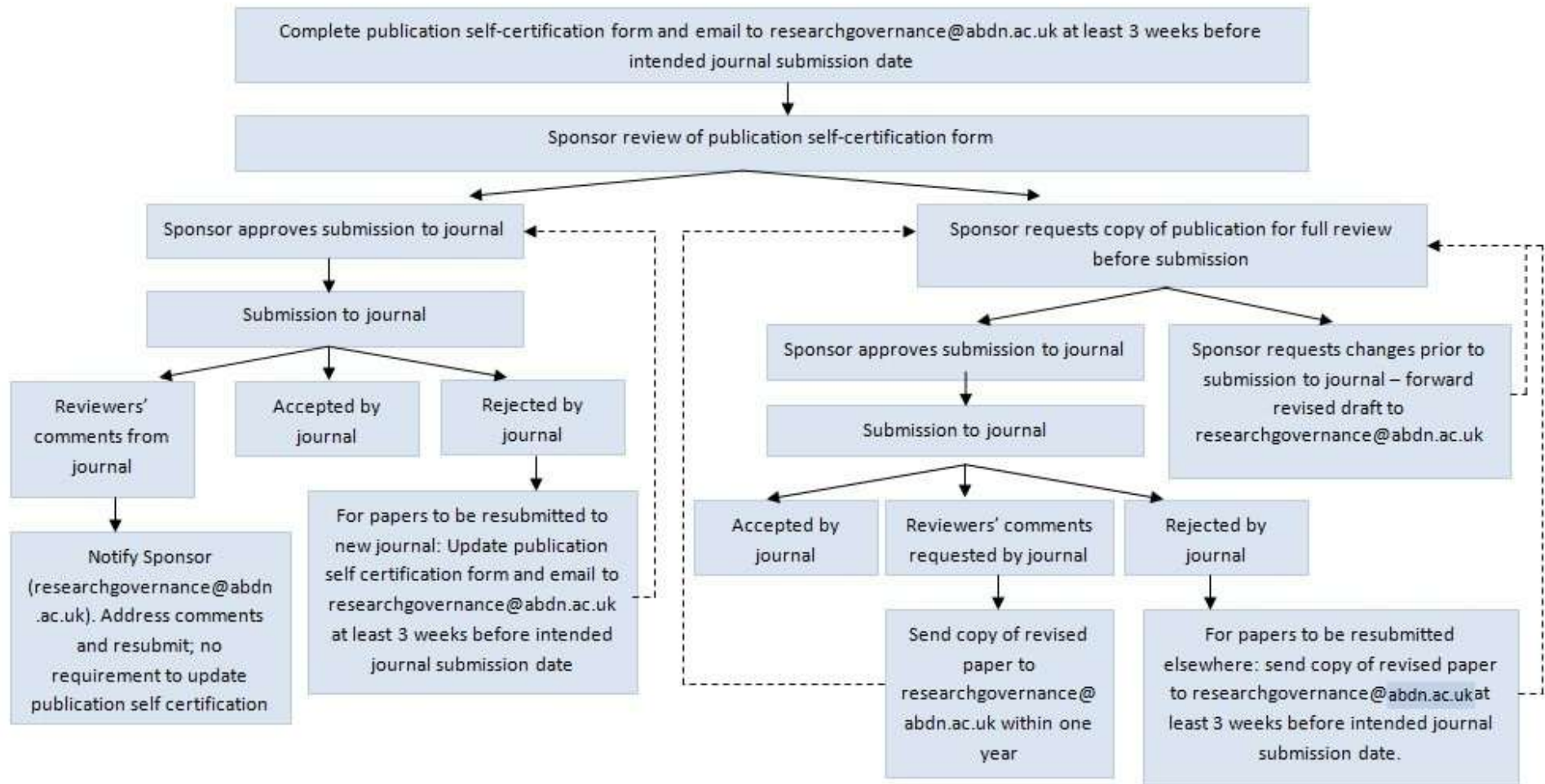
## 5. Related documentation and references

SOP-QA-17	Project committees
SOP-QA-31	Research project closure
TMP-QA-33	Self certification form

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6. SOP-QA-33 Appendix 1 Process flowchart



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