

**ENDIA Publications Policy**

Extracted from Governance Policy, v1, 30/5/2016

1. Publication Policy**1.1. Statement of principles regarding publications****1.1.1. General principles for publications**

The ENDIA Study Team shall actively disseminate findings of the Study to the scientific community in the form of publications. A publication is defined as any document submitted to a professional journal listed in MEDLINE, any popular periodical with regional or national circulation, published books and book chapter, and peer-reviewed conference papers. A single publication policy will be applied across all investigations that include ENDIA data or biological samples, as per the conditions stipulated in the sample/data access policy (Section 4).

1.1.2. General considerations

- The publication of results generated using ENDIA samples or data must conform to this policy unless agreed upon by the ENDIA Study Steering Committee in advance of the publication's submission. Non-conformance may jeopardise future sample/data access requests on behalf of the investigator(s).
- The rules contained herein should not be allowed to contravene the principles of the Australian Code for the Responsible Conduct of Research¹ nor relevant institutional and/or journal policies, as applicable.
- Authors should aim to submit ENDIA Study findings to high impact factor or high Excellence in Research for Australia (ERA) ranked journals. Combining multiple lines of investigation to increase the potential impact of a publication is encouraged.
- The status of publications in preparation will be reviewed at each ENDIA Steering Committee meeting with respect to the assigned PP number.

1.2. Publication considerations for manuscripts**1.2.1. Definitions: manuscripts**

Journal articles, books and book chapters (henceforth collectively referred to as "manuscripts") generated fully or in part using ENDIA samples and data will be assigned to one of four categories by the ENDIA Steering Committee:

1. Primary Manuscripts: These are publications that address the principal goals and objectives of the Study (i.e. where development of islet autoimmunity and/or type 1 diabetes is the focus of the investigation).
2. Secondary Manuscripts: These are publications that utilise samples/data from all, or at least many, of the participating institutions but address issues that are peripheral to the major objectives of the Study.
3. Tertiary Manuscripts: These are publications that describe only certain sub-groups from a limited number of participating institutions, or utilise significant amounts of non-ENDIA data. For example, where ENDIA samples/data may be contributing to or validating results generated by other cohorts.
4. Miscellaneous Manuscripts: It is expected that publications, mostly concerned with methodological issues, will arise within and across the Study Themes that do not deal with the ENDIA cohort or the Study directly but are prompted by discussions during development and/or

¹ <https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/r39.pdf>

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performance of ENDIA. These manuscripts should include an acknowledgement of the ENDIA Study grant support.

1.2.2. Definitions: The ENDIA Study Group

“The ENDIA Study Group” will be defined as all members of Groups 1, 2 and 3 of the ENDIA Study Team as per Figure 1 and outlined in **Appendix 1: Study Personnel**. All current members at the time of manuscript submission should be included, as well as former members as deemed appropriate by the ENDIA Steering Committee. The Committee may also elect to include Administration staff (Group 4), Students (Group 5), and Associated Investigators (Group 6) as members of the ENDIA Study Group where appropriate. External Collaborators (Group 7) would not normally be included in the Study Group. The list of “The ENDIA Study Group” members will appear as part of the manuscript, usually at the end of the manuscript if allowable, or in an electronic supplement. Group members should also be indexed individually within PubMed.

1.2.3. Proposing new manuscripts

It is expected that manuscripts will be initiated in one of two ways: (1) internally via research questions proposed within the context of a Theme that may or may not directly relate to core Study outcomes, or (2) externally via known or unknown collaborators proposing research questions that ENDIA samples/data may contribute towards. Working titles of all proposed manuscripts should be put to the ENDIA Steering Committee using the ENDIA Sample/Data Access Concept Form (ESDAC; refer to Section 4.2). When sample/data access is granted, the ENDIA Steering Committee will assign Publication Preparation (PP) numbers.

1.2.4. Authorship of manuscripts

Authorship arrangements should be discussed at the time of developing the Sample/Data Access Concept Form, although it is not a requirement for all proposed authors to be included on the form. Decisions on authorship should follow:

1. Primary Manuscripts: The Steering Committee will be responsible for establishing the named authors that will take responsibility for writing the manuscript in addition to “The ENDIA Study Group”.
2. Secondary Manuscripts: Named authorship will be determined within the Theme or Themes involved in the analyses and should be approved by the Steering Committee. “The ENDIA Study Group” should also be listed as an author.
3. Tertiary Manuscripts: If significant amounts of ENDIA data or effort are involved, authorship should be the same as for secondary manuscripts. If this is not the case, or the manuscript is being driven by a person(s) external to the study, those individuals performing the study shall determine authorship and ENDIA Investigators that have been directly involved in the acquisition, analysis, interpretation or preparation of the data/manuscript should be included. The list of ENDIA authors will be reviewed and approved by the Steering Committee prior to publication. The contribution of “The ENDIA Study Group” should be recognised in the manuscript’s acknowledgements section (refer to Section 5.2.6).
4. Miscellaneous Manuscripts: Authorship should be determined within the Theme or Themes involved in the analyses. The Steering Committee will determine whether “The ENDIA Study Group” should be included as an author. If the ENDIA Study Group is not included as an author then their contribution should be recognised in the manuscript’s acknowledgements section (refer to Section 5.2.6).

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1.2.5. Recommendations for authorship

For all publication types, lead authors will take responsibility for ensuring that named authors conform with the principles of the Australian Code for the Responsible Conduct of Research, and/or the policies of relevant institutions and journals. The University of Adelaide's Authorship Policy states that:

- Although attribution of authorship depends to some extent on the discipline involved, in line with the Code and the 'Vancouver Protocol' on Authorship and Contributorship, authorship must be based on a substantial contribution to at least two of the following three activities:
 - conception and design of the project;
 - analysis and interpretation of research data;
 - drafting significant parts of the article or critically revising it so as to contribute to the interpretation.
- Each individual author must be able to take public responsibility for the part of the work they contributed.
- Publication may not proceed, if any of the authors have legitimate reservations concerning the theory, data or its interpretation underpinning critical parts of the work.

Any author, whether named directly or included as part of "The ENDIA Study Group" has the right to remove themselves from the publication if they wish to do so. In general, the ENDIA Steering Group will aim to be more inclusive than exclusive such that publications should involve as many of the ENDIA investigators, coordinators, scientific staff and students as possible.

1.2.6. Funding declaration

All manuscripts must include the following statement to acknowledge ANZCTR registration and the funding source:

"ANZCTR registration number: ACTRN1261300794707. This research is supported by JDRF Australia, the recipient of the Australian Research Council Special Research Initiative in Type 1 Juvenile Diabetes; The Helmsley Charitable Trust; JDRF International; and the National Health and Medical Research Council."

If the option is available, the acknowledgement statement could be extended to include:

"The ENDIA Study Team would like to thank the contributions of the following lead clinical sites: Women's and Children's Hospital, Children's Hospital at Westmead, The Royal Hospital for Women, St George Hospital, The Royal Melbourne Hospital, Barwon Health, Mater Health Service and Princess Margaret Hospital; as well as the participating institutions: University of Adelaide, Walter and Eliza Hall Institute, University of NSW, University of Sydney, University of Melbourne, University of Queensland and University of WA. We also gratefully acknowledge the participants and their families who contribute to the ENDIA Study."

1.2.7. Publications review process

The lead author will take responsibility for gathering approvals for a final draft from the writing team members and completing any institutional documentation. The final draft should be submitted by e-mail to the Steering Committee via the ENDIA Project Management Team (endia@adelaide.edu.au). The Steering Committee will be responsible for securing publication approval from JDRF Australia as per Section 3.1.7.

All manuscripts will be forwarded by the ENDIA Project Management Team to all members of the ENDIA Steering Committee via email. Steering Committee members will have a three week window to lodge

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any objections to publication. During this window the Steering Committee will notify JDRF of the intention to submit for publication.

1.3. Considerations for other types of publications

1.3.1. Conference abstracts/posters

Abstract submissions for external conference presentations require approval by the ENDIA Publications Committee prior to submission. Document will be forwarded by the ENDIA Project Management Team to all members of the Publication Committee via e-mail. The Publication Committee will have a one week window to lodge any objections to publication. Authorship for conference abstracts/posters should follow that for Tertiary or Miscellaneous Manuscripts whereby The ENDIA Study Group should be listed as an author only if ENDIA samples/data contributed to a majority of the investigation.

1.3.2. Newsletters, booklets and other non-peer reviewed documents for public circulation

These types of publications should be forwarded by the ENDIA Project Management Team to all members of the Publication Committee and any other specific contributors to the document via e-mail for review prior to public release. The Publication Committee will have a two week window to lodge any objections to publication. Authorship, where recognised, should be considered on a case-by-case.

1.4. Dispute resolution

In all disagreements and disputes relating to the publication of ENDIA research materials, every effort should be made to resolve the issue among the relevant parties. If required, teleconferences can be scheduled at limited notice by the ENDIA Project Management Team. In those cases where consensus agreement cannot be reached following discussion, a written request should be forwarded to the Publications Committee for immediate review. The Publications Committee will thoroughly investigate the matter and in a timely manner produce a final decision that is binding upon all involved parties.