European Reference Network
for rare or low prevalence complex diseases

Network Transplantation in Children (ERN TRANSPLANT-CHILD)

ERN TransplantChild
SOT & HSCT Paediatric Transplantation in Children

Publication Policy. V2

Funded by the European Union

EU4Health Programme/
EU4H-2023-ERN-IBA-01
GA- 101156607

Publication date: 13 November 2024

Disclaimer

DOCUMENT HISTORY

Issue Date	Version	Changes Made / Reason for this issue
07.11.2024	02	Inclusion of formatting, review, and update of the complete document

DOCUMENT SIGNED OFF

Drafted by:	Approved by:
Position: Executive Operating Committee &Steering Committee	Position: Board of the Network
07.11. 2024	12.11.2024

DISSEMINATION LEVEL

PU	Public	✓
IN	Internal use only	☐
CO	Confidential, only for members of the consortium (including Commission Services)	☐

DOCUMENT INFORMATION

PUBLICATION POLICY

ERN Document type: Policy

Taxonomic reference: Reporting ERN Activities

ERN: TransplantChild

See SOP00 Standard Operating Procedure for TransplantChild documentation management for further information on this classification

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1. OBJECTIVE

The objective of this document is to establish the rules for approving publications that involve data from ERN TransplantChild or are made on behalf of the network.

2. SCOPE

This document applies to all the members of the Network and third parties involved in publications of ERN TransplantChild.

3. ABBREVIATIONS

EC: European Commission

EOC: Executive Operating Committee of the Coordinating centre

ERN: European Reference Network

HCP: Healthcare Provider

HSCT: Haematopoietic Stem Cell Transplantation

SOT: Solid Organ Transplantation

4. APPROVAL OF THE USE OF THE ERN DATA WITH SCIENTIFIC AIMS

The use of data obtained from the ERN TransplantChild activities in order to present an abstract to a congress or to an original publication has to be approved by the Executive Operating Committee (EOC), with the prior knowledge of the project Steering Committee.

The procedure will be as follows:

- The person who makes the proposal has to be a member of the ERN.
- Each proposal has to be accompanied by a request (Annex I) indicating:
  - Name and data of the applicant.
  - Abstract of the article.
  - Parameters that are going to be used in the publication, which are going to be sent to the applicant.
  - Approval of the competent authorities (Research Ethics Committee with Medical Products, in all cases; and regulatory Agencies, when applicable).
  - Undertaking of confidentiality (Annex II).
  - A declaration certifying that there is no conflict of interest (Annex III).
- The application will be collected by the ERN Technical Secretariat in Madrid and sent to the Steering Committee. In the event of decision, no opinion against, the proposal should be sent to the EOC for ratification.

5. AUTHORSHIP

Every publication will have:

- **Writing Committee**: This Committee will be composed by the people in charge of the writing of the manuscript, and by the people who appear as the main authors on behalf of the ERN.
- **Group Signature**: it refers to all the members of the ERN TransplantChild.

  An annex must be prepared and attached to every publication. All members of the ERN must be included in that annex, indicating their membership and position in the Network. For scientific purposes and authorship, the "ERN TransplantChild Study Group" has to be mentioned.

The Writing Committee will vary according to the type of publication:

A. **ERN-descriptive manuscript** (position paper or similar), the Writing Committee has to be proposed by the Executive Operating Committee, and the members will be the following:

   – Main researcher: responsible for the writing of the manuscript, proposed by the Executive Committee.
   – Network representatives and members.

   Should the position paper is about a specific area of the activities developed in the ERN, the members of the Writing Committee will be proposed by the Steering Committee and approved by the EoC. The members will be the following:

   – Main researcher: responsible for the writing of the manuscript, proposed by the Steering Committee.
   – Other members: leader of the WP, beneficiaries and network members according to their contribution.

B. **Clinical Practice Guidelines:** The members of the Writing Committee will be**:**

   – Main researcher: Guideline coordinator proposed by WP Clinical Practice Guidelines leader.
   – Subgroup members: all members of the subgroup that had prepared the guideline.
   – ERN representatives: ERN Coordinator and leader of the corresponding WP.
   – Guideline support group: they will appear in an annex including all the collaborators.

C. **Research studies.** The members of the Writing Committee will be:

   – Main researcher: person who has come up with the idea of this publication and has developed the working plan. He/she must be an ERN member.
   – Senior researcher: should the main researcher be a junior researcher, his/her activity has to be overseen by a senior researcher.
   – Statistical and study coordinator.
   – Other researchers, that contribute significantly to the publication.
   – Site representatives who has contributed in the recruitment of the patients in the study or in the ERN information Registry.

6. ORDER OF AUTHORS

- First author: it will be the main researcher or whoever the main researcher delegates to.
- Last author/Corresponding author: it will be the senior researcher in the case of research studies; the WP leader/coordinator in case of specific position paper and Clinical Practice Guidelines, or a BoN member in the rest of the position papers.
- The order of the rest of the authors will be discussed and decided previously by the people in charge of the manuscript according to the type of the publication. For example:
  - Clinical trials, prospective studies and retrospective depending on the number of patients included in the study.
  - Other types of manuscripts: following the criteria published in *"A.Costa. How to define authorship and order of authorship in scientific document using quantitative criteria. Universitas Scientiarum, Vol 12, No. 1, pp. 67-81"*.
  - If is not possible to follow these criteria, it will depend on the share of contribution to the manuscript, on the judgement of the researchers responsible for the manuscript.
  - If it were not possible to quantify the degree of contribution, alphabetical order will be applied.

As long as the journal allows it, the publication will be signed on behalf of the ERN TransplantChild, including the annex with all the members of the Network, indicating their membership and position in TransplantChild. The sentence *"On behalf of ERN TransplantChild Study Group"* must appear.

7. APPROVAL OF A PUBLICATION SIGNED ON BEHALF OF THE ERN

Every TransplantChild researcher can indicate their affiliation to TransplantChild in their signature. For example:

> *Clinical Pharmacology Department. La Paz University Hospital. IdiPAZ. Member of ERN TransplantChild.*

In order to publish on behalf of the ERN (abstract to Congresses included), the manuscript must be reviewed and be approved by the EOC, with the prior knowledge of the Steering Committee. The procedure will be as follows:

- The authors must send the manuscript to the Technical Secretariat for its review and approval. The technical Secretariat will forward this information to the EOC.
- The manuscript has to be accompanied by a request (Annex IV), indicating, at least, the following:
  - In abstracts, it must appear the details of the Congress.
  - In any event in which data obtained from the ERN registry, will be used.
- The request for publication must come from an ERN member.
- The request for publication must fulfill the publication policy, the order of authors and signature described in this document.
- The EOC must reply to the applicant within 2 weeks.
- The following sentence must appear below the main authors:

  On Behalf of ERN TransplantChild

8. OTHER

Unless otherwise agreed with the granting authority, communication activities of the beneficiaries related to the action dissemination activities must acknowledge EU support and display the European flag (emblem) and funding statement:

- Funding: This study has been supported by the European Reference Network on pediatric Transplantation (ERN TransplantChild), which is funded by the European Union within the framework of the Fourth Health Programme ERN. Specific Agreement Number: 101156607.
- "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them."

If data from the PETER registry are used for a report or publication, the use of data must be acknowledged along with the following statement: 'This project is part of project '947629/PETER' funded by the European Union's Health Programme (2014- 2020). PETER is also supported by the European Reference Network for Transplantation in Children (ERN- TransplantChild).

9. ANNEXES

- Annex 1: Request for the use of the ERN data with scientific aims
- Annex 2: Confidentiality
- Annex 3: Conflicts of interest disclosure
- Annex 4: Request for publication on behalf of TransplantChild

Annex I: REQUEST FOR THE USE OF THE ERN DATA WITH SCIENTIFIC AIMS

APPLICANT NAME AND SURNAME
HEATH CARE PROVIDER (member of TransplantChild)
ABSTRACT
PARAMETERS TO USE
APPROVAL OF THE COMPETENT AUTHORITIES
☐ Research Ethic Committee ☐ Regulatory Agency ☐ Other (specify):

Annex II: CONFIDENTIALITY

I, [NAME, SUNAME], as member of ERN TransplantChild, representing [NAME OF HCP], ACEPT the following:

Any information property of the ERN TransplantChild or any of its members to which you have access as a consequence of this relation, will be confidential information, and would be processed in accordance with this clause.

It is considered confidential information that whether in informatics support or in paper, is contained in papers, books, accounts, recordings, computer programmes, proceedings, or other documents.

The obligation includes the following:

- Access only to the information essential to the performance of the study.
- In the case that, in the performance of the tasks, you access to the information property of TransplantChild or any of its members, you cannot erase it nor reveal its details nor use it for own purposes.

This confidential obligation will last indefinitely, even after the conclusion of this task. In case the project for which the data has been requested finalized or stoped, you are obliged to return to TransplantChild all the confidential information you have or destroy it.

The breach of this confidential obligation can be a criminal offense, criminalized under the art. 197 of the Criminal Code, as discovery of secrets, independently of that TransplantChild (coordinator entity or other member of the ERN could claim, by legal meanings, damages.

In [CITY], [DD] of [MM] 202_

Signed:

Annex III: CONFLICT OF INTEREST DISCLOSURE

Name:

Affiliation:

I. I declare to have taken note of the European Reference Networks Conflict of Interest policy and Code of Conduct;
II. I honestly declare to have summed all relevant relationships and interests that I have;
III. I declare to immediately report any relevant changes in the reported interests, and possible conflicts of interest when they become apparent during the performance of my activities for ERN TransplantChild.

1. Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of this activity or results (including but not limited to grants, personal fees, access to facilities etc.)?

   Yes/no

   yes, please fill out the appropriate information below.

Name of third party	Type[1]	Description[2]	Conflict of interest?[3]

2. Do you have any financial relationships (regardless of amount of compensation) with entities as described in the instructions? You should report relationships that were present during the 36 months prior to publication.

   Yes/no

   If yes , use one line for each entity; add as many lines as you need by clicking the "Add +" box.

   yes, please fill out the appropriate information below.

Name of entity	Type[4]	Comments[5]	Conflict of interest?[6]

[1] Grant, personal fee, non-financial support or other
[2] Describe purpose of support. For research, indicate if it is basic, preclinical or clinical research. For clinical research, indicate whether investigator-initiated or sponsor-initiated.
[3] No, yes- possible, yes – actual, yes- perceived
[4] Grant, personal fee, non-financial support or other
[5] Describe purpose of support. For research, indicate if it is basic, preclinical or clinical research. For clinical research, indicate whether investigator-initiated or sponsor-initiated.
[6] No, yes- possible, yes – actual, yes- perceived

3. Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

Yes/ no

If yes, please fill out the appropriate information below.

Patent number or title	Licensee	Stage[7]	Royalties	Comments	Conflict of interest?[8]

4. Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, your contribution to the ERN activity or results?

Yes, the following relationships/conditions/circumstances are present (explain below):

No other relationships/conditions/circumstances that present a potential conflict of interest.

In [CITY], [DD] of [MM] 201

Signed:

[7] Pending, issued or licensed

[8] No, yes- possible, yes – actual, yes- perceived

Annex IV: REQUEST FOR PUBLICATION ON BEHALF OF TRANSPLANTCHILD

I, [NAME, SUNAME], as member of ERN TransplantChild, representing [NAME OF HCP], request authorization for publishing the document attached in:

[NAME OF THE PUBLICATION/ CONGRESS/WORKSHOP]

In this publication we include the data relating [SHORT DESCRIPTION] obtained from the ERN TransplantChild.

I declare that this publication fulfills the indications of the *Publication Policy* in place in the ERN TransplantChild.

In [CITY], [DD] of [MM] 201

Signed: