

ERACODA regulation for research proposals

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Collaborators who have supplied data for ERACODA remain owner of the supplied data.

The individual patient data cannot be disclosed to any third party.

To encourage research on the ERACODA data the Working Group offers an approach which fulfills the General Data Protection Regulation.

Submitting research proposal

1. ERACODA is an open database. Collaborators who have supplied data for ERACODA are cordially invited to submit study proposals. In addition, the Working group will invite collaborators at least once per year to submit study proposals. Research proposals can be submitted to the Working Group via COVID.19.KRT@UMCG.NL.
2. Each research proposal has to consist of:
 - Introduction with research question
 - Type of data needed
 - Type of statistical analysis needed
 - Name(s) of researcher(s)

First, the Working Group evaluates the received research proposals based on the availability of data, proposed scientific methodology, solidness, and (clinical) relevance. Subsequently, a list of study proposals with priority rating is composed (including proposals that were found not to be appropriate). This list is sent to the Advisory Board for final approval.

3. In case the Working Group or the Advisory Board rejects a research proposal, the researchers will be informed as soon as possible by the Working Group with the reasons for rejection.
4. All ERACODA collaborators will be informed by the Working Group on the priority listing that has been decided by the Advisory Board. In case of disagreement, individual ERACODA collaborators can send a letter of objection (including a rationale) to the Working Group. In case no consensus is reached, the ERACODA Collaborators can appeal to the Advisory Board. The Advisory Board will make the final decision and settle the priority listing.
5. After approval by the Advisory Board the analysis needed for the research proposal will be carried out by the ERACODA Management Team.

Performance of data analysis

6. The data analysis will be planned according to the defined priority by the Working Group and researchers will be informed about this planning.
7. The researchers can collaborate with the Management Team by remote connection.

Data processing

8. After the data analysis is finalized, only aggregated data (i.e. output of the statistical analysis) are available for the researchers who write the scientific publication.
9. The original data file of the analysis will be saved by the Management Team on a secured server. More details on data processing are included in the data transfer agreement (DTA).

Publication agreements

10. ERACODA follows the criteria of the International Committee of Medical Journal Editors (ICMJE) which state that authorship of biomedical papers should be based on:
 - a. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
 - b. Drafting the article or revising it critically for important intellectual content; and
 - c. Final approval of the version to be published.

Each author should meet conditions 1, 2, and 3.

11. On each (scientific) publication, the following persons are invited to become member of the writing committee, i.e. to become full author:
 - The site that has proposed the study + analysis, can nominate a first author and appoint one additional member.
 - The Working Group will try to accommodate up to 4 collaborators that have shown an interest to be involved (in the specific topic under consideration or to be involved more in general).
 - Those members of the Management Team who were involved in the collection, preparation, and/or analysis of the data.
 - Two members of the Working Group who participate in the interpretation of the performed data analysis.
 - The Working Group members who are not co-author, the advisory board members and the collaborators who supplied data that were used for the study will all be included as collaborative authors (this will only be possible if the publishing journal will accept this approach).
12. In each scientific publication acknowledgements to the ERACODA initiative have to be included and the methodology of ERACODA has to be described according to the protocol.

Organizational structure

Working group:

- Chair of Transplantation Subdatabase: Luuk B. Hilbrands, MD PhD - Professor of Nephrology, Radboud University Medical Center, Nijmegen, The Netherlands.
- Chair of the Dialysis Subdatabase: Casper F. M. Franssen, MD PhD - Nephrologist, University Medical Center Groningen, The Netherlands .
- Managing director of the ERA-EDTA Registry: Kitty J. Jager, MD PhD - Professor of Epidemiology, Amsterdam University Medical Centers, The Netherlands.
- Chair of the Dutch renal registry RENINE: Marc H. Hemmelder, MD, PhD - Nephrologist, MS Leeuwarden, The Netherlands
- Project lead / overall coordination: Ron T. Gansevoort, MD, PhD – ERA-EDTA council member, Professor of Internal Medicine, University Medical Center Groningen, The Netherlands.

Management Team:

- Nephrologist: Raphaël Duivenvoorden, MD PhD - Radboud University Medical Center, Nijmegen, The Netherlands.
- Epidemiologist, project coordination/communication: Marlies Noordzij, PhD - University Medical Center Groningen, The Netherlands.
- Epidemiologist, data analysis: Priya Vart, PhD - University Medical Center Groningen, The Netherlands.

Advisory Board:

- Chair: Chair of the ERA-EDTA Registry: Ziad Massy - Professor of Nephrology, Toulouse, France.
- Co-chair: Chair of the Spanish Renal Registries: Dr. Emilio Sanchez, Oviedo, Spain
- Chair of the ERA-EDTA Working Group EUDIAL (for dialysis): Carlo Basile - Professor of Nephrology, Martina Franca, Italy.
- Board member of the ERA-EDTA Working Group EUDIAL (for dialysis): Adrian Covic - Professor of Nephrology, Iasi, Romania.
- Board member of the ERA-EDTA Working Group EUDIAL (for dialysis): Sandip Mitra - Professor of Nephrology, Manchester, United Kingdom.
- Chair of the ERA-EDTA Working Group DESCARTES (for kidney transplantation): Luuk B. Hilbrands, Professor of Nephrology, Radboud UMC, Nijmegen, The Netherlands.
- Board member of the ERA-EDTA Working Group DESCARTES (for kidney transplantation): Marta Crespo – Professor of Nephrology, Barcelona, Spain.
- Board member of the ERA-EDTA Working Group DESCARTES (for kidney transplantation): Daniel Abramowicz - Professor of Nephrology, Antwerp, Belgium.