



GESUNDHEITS-
STUDIE ■■■

PUBLICATION POLICY

NAKO GESUNDHEITSSTUDIE
GERMAN NATIONAL COHORT [NAKO]

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1. INTRODUCTION

This policy describes the framework for scientific publications based on data or biosamples of the German National Cohort [NAKO Gesundheitsstudie]. A positive vote on an application by the Use and Access Committee and a subsequent data/material contract with the NAKO e.V. [registered association] is a pre-requisite for data transfer.

The German National Cohort is a long-term project, which was designed by many scientists with respect to overarching as well as specific aspects. Data collection and quality assurance efforts are implemented and optimized by scientists from 18 study centers. Therefore, we envision multi-author papers representing the collective efforts of scientists from the study centers and the central organs of the NAKO.

2. AUTHORSHIP FOR SCIENTIFIC PUBLICATIONS

2.1. General considerations

Authorship is determined based on international rules as formulated by the “International Committee of Medical Journals” (<http://www.icmje.org/>), and all authors should fulfill the following criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors carry responsibility for fulfilling these criteria as well as for the content of the publication, either entirely or in parts. Position on the publication author list shall reflect contribution to the specific research question.

An invitation to an authorship includes individuals fulfilling authorship criterion #1 above and is, thus, based on:

1. contribution to the specific research question
or
2. contributions to study design, examination modules, data collection or quality assurance.

The final author list will be composed jointly based on the fulfillment of the remaining ICMJE authorship criteria.

2.2. Who has to be offered co-authorship?

Besides the primary writing group, the opportunity to contribute as co-author has to be offered based on contributions to the design, data collection or quality assurance to:

- up to two representatives of each NAKO study center (nominated by the principal investigators of the study centers)
- additionally, representatives of the examination modules and competence units or other persons who were actively involved in designing, collecting or quality-assuring the data to be used in a specific publication, if the variables are considered as main exposures or main outcomes [i.e., consideration of examination modules or variables as confounders in the analysis plan does not mandate invitation to an authorship]

2.3. How to contact co-authors and handle co-authors' comments?



The main applicant named in the use and access application is responsible for including the appropriate NAKO co-authors in the process of final manuscript preparation according to the following guidelines:

(a) After the use and access application has been approved by the Use and Access Committee, individual NAKO investigators or representatives of examination modules [from which the main exposures or outcomes of a specific data application originate] can contact the main applicant named in the application to be included in the primary writing group at an early stage of the data analysis and manuscript preparation.

(b) When a first complete draft of a manuscript is available, the corresponding author [as nominated by the main applicant named in the respective use and access application] sends the complete draft to all principal investigators of the 18 NAKO study centers and the specific representatives of the examination modules and competence units to invite for co-authorship. It is also possible instead to send an abstract or analysis plan to invite co-authors at an earlier stage of manuscript preparation. A list with contact information of these potential co-authors can be requested from the NAKO Central Executive Office [publications@nako.de].

(c) Those who have interest in contributing as co-authors have to respond in reasonable time [within 4 weeks]. After this deadline, the enrollment as co-author for a specific manuscript will be closed. The co-authors have the opportunity to make comments to the manuscript.

(d) The initial offer of co-authorship does not automatically guarantee final authorship. The authors are jointly responsible to ensure, that only those who fulfilled the recommended criteria are co-authors. For a better interpretation, it is clarified that the criterion for substantial contribution to writing is not the extent of changed text but can also consist of comments about or approval of specific aspects of the work, helping to improve the contents of the publication.

(e) Additional authors may be added or removed during the analysis, interpretation of the data and manuscript preparation. This can occur when additional expertise is required, and new authors are included. Removal of authors can be based on the request of a co-author to be removed or can be due to lack of contribution or required response. Specifically, if a NAKO investigator invited to participate as co-author does not respond to the provided draft of the manuscript, the corresponding author may decide to remove this person from the author list.

(f) The final version of the manuscript has to be circulated prior to submission. All authors have to declare their agreement with the submission, which has to be announced with at least a two-week deadline by the corresponding author. At the discretion of individual co-authors, the agreement with submission can be declared in advance, based on a preliminary version. If an author did not formally declare the agreement to submission until the deadline, silent agreement should be assumed, if this option has clearly been indicated in the announcement of the final version by the corresponding author. In case of temporary absence of co-authors or if doubt exists about individual co-author agreements, he or she stays on the authorship list at submission but can be deleted prior to revision or print if failure to declare agreement to submission persists. No co-author can block publication of the manuscript based on a singular opinion on its scientific content. If a majority of co-authors believe the paper should be published in its final form, the paper will move forward to submission. Every reasonable effort should be made by the corresponding author to reach a consensus on the contents of the publication. However, if a final consensus with an individual co-author cannot be reached and he/she disagrees with the submission, he/she may withdraw from co-authorship.

(g) Only in case that a journal's authorship rules do not allow for the foreseen number of authors and an exception is explicitly not granted, a group authorship name ["German National Cohort (NAKO) Investigators"] should be used for all or a subgroup of co-authors,

e.g., those outside the primary writing group. This group authorship name needs to be included in the article byline (author list), and personal names of members of this group need to be included in the article text. The corresponding author has to ensure that co-authors are indeed indexed as such. This explicitly does not mean downgrading co-authors to the role of non-author contributors.

(h) Exemptions from the rules named above can be considered for consortia publications where a limited number of co-authors per contributing study have beforehand been generally defined in the consortia rules, or in case of manuscripts with methodological focus, where NAKO data is only used for illustration purposes. They need to be specified / clarified during the use and access process as part of the application. All exceptions need to be documented in a working file accessible to all members of the NAKO e.V., and members of the NAKO e.V. have to be informed about such exemptions before access to data is given.

3. AUTHORSHIP FOR PUBLICATIONS IN ORGANS OF THE GERMAN FEDERAL OR STATE MINISTRIES

Authorship by the NAKO e.V. is not required if data is used for reports assessing prevalence of exposures or disease in the German population in organs of the German federal or state ministries.

4. ACKNOWLEDGEMENTS

All publications must acknowledge the NAKO.

Publications based on the German National Cohort (NAKO) must contain both the German and the English name of the study.

German: **NAKO Gesundheitsstudie**
 English: **German National Cohort (NAKO)**

All publications based on the German National Cohort must include the following acknowledgement or an appropriate equivalent:

[Here the list of all individuals that have contributed to the NAKO has to be inserted to generally include them in the acknowledgement]

English: This project was conducted with data [Application No. NAKO-XXXX] from the German National Cohort [NAKO] [www.nako.de]. The NAKO is funded by the Federal Ministry of Education and Research [BMBF] [project funding reference numbers: 01ER1301A/B/C, 01ER1511D, 01ER1801A/B/C/D and 01ER2301A/B/C], federal states of Germany and the Helmholtz Association, the participating universities and the institutes of the Leibniz Association.

We thank all participants who took part in the NAKO study and the staff of this research initiative.

German: Dieses Projekt wurde mit Daten der NAKO Gesundheitsstudie [Nutzungsantrag Nr. NAKO-XXXX] durchgeführt [www.nako.de]. Die NAKO Gesundheitsstudie wird durch das Bundesministerium für Bildung und Forschung [BMBF] [Förderkennzeichen 01ER1301A/B/C, 01ER1511D, 01ER1801A/B/C/D und 01ER2301A/B/C], die Bundesländer und die Helmholtz Gemeinschaft gefördert sowie durch die beteiligten Universitäten und Institute der Leibniz-Gemeinschaft finanziell unterstützt.

Wir danken allen Teilnehmerinnen und Teilnehmern der sowie den Mitarbeiterinnen und Mitarbeitern der NAKO Gesundheitsstudie.

5. TRACKING OF PUBLICATIONS

All publications in progress must be traceable by the NAKO e.V. Details of this specific implementing regulation (with regard to the tracking procedure) will be further elaborated. Until then, all publications must be registered with the NAKO Central Executive Office (publications@nako.de), and the final manuscript including author-list has to be provided to the NAKO Central Executive Office prior to submission.



6. CLOSE

The publication policy is valid until substantial updates have become necessary and have been voted for in the members assembly.