Agreement for Clinical Studies

Rules for study proposals, endorsement, authorship and acknowledgment of Y-CEORL in publications

At a glance

- Within each subspecialty group, any board member can propose a study; authorship roles (PI, Collaborator, Participant) are defined at the start of every project.
- Any other Y-CEORL member can also propose a study: endorsement is granted by the relevant subspecialty group, and the proposer keeps responsibility for the study and the first-author position.
- Using the Y-CEORL mailing list requires approval by the Executive Board, which also schedules surveys to avoid overlap.
- Endorsed studies acknowledge Y-CEORL in the authors' affiliations and in the acknowledgments.
- Publishing in non-predatory journals is strongly endorsed.

1 Purpose and scope

This agreement describes how studies are proposed, reviewed and endorsed within the Young Confederation of European ORL-HNS (Y-CEORL-HNS, hereafter Y-CEORL) and its subspecialty groups, and how authorship is assigned in the resulting publications.

Its aims are to encourage collaborative research among young ORL-HNS specialists across Europe, to make expectations clear to everyone involved from the very beginning of a project, and to prevent disagreements about authorship when the final manuscript is prepared.

It applies to all study types: prospective and retrospective clinical studies, reviews (including systematic reviews and meta-analyses) and surveys.

2 Studies within a subspecialty group

The following rules apply to studies proposed by the members of a subspecialty group. They are also the recommended way of assigning authorship for studies proposed from outside the group (Section 3).

2.1 General principles

- Any board member may freely propose a study idea, whether it is a review, a survey or a multicentre clinical study.
- Studies do not have to be limited to the group: other centres known to the members may also be invited, to increase data collection and broaden collaboration.
- Roles are defined at the outset of every project, to ensure transparency about authorship and to avoid problems when the final manuscript is prepared.

2.2 Authorship roles

Role	Who	Expected contribution	Position in the byline
A · Principal Investigator (PI)	The 1–2 people who propose the study	Conception and coordination, protocol, ethics approvals, database	First and/or senior (last) author
B · Collaborator	Anyone who registers to contribute actively	Active work in at least one or two defined areas; data submission alone is not enough	Named author in a privileged position (not first or last)
C · Participant	Centres that provide data only, including colleagues outside Y-CEORL	Contribution of centre data	Named author after the Collaborators, or under the collective group name (Y-CEORL study group)

A · Principal Investigator (PI)

The person or people who propose the study (one or two individuals).

Authorship: first and/or senior (last) author of the final manuscript.

Responsibilities:

- Study conception and coordination
- Protocol development
- Submissions to ethics committees and follow-up of approvals
- Preparation and management of the study database (e.g. case report forms, REDCap)

B · Collaborator

Anyone interested in actively contributing may be a collaborator and is expected to take an active role in the project. Collaborators should state which tasks they intend to take on, so that responsibilities are clear from the start.

Authorship: named author in a privileged position (Real Co-authorship, not in the Y-CEORL group of the byline), although not as first or last author.

Required contribution: active work in at least one or two of the following areas according to regular autorship contribution rules e.g. ICMJE (submitting data alone is not sufficient):

- Recruiting additional centres in their own country
- Statistical analysis and interpretation of the results
- Literature review
- Writing the manuscript
- Revising the manuscript and submitting it to the journal

C · Participant

Anyone who contributes data from their centre without taking an active part in the study itself. This category also includes colleagues recruited outside Y-CEORL who provide data but are not otherwise involved in the project.

Authorship: may be included as named authors, in positions following the collaborators. If the byline becomes too long, participants may instead be credited collectively under the Y-CEORL group name. Their contribution is still recognised and citable, even though individual names may not appear in the byline itself; where the journal allows it, their names are listed as group members (for example, in an appendix).

2.3 Transparency

> For transparency, people who have not actively contributed to the development, conduct or completion of the work will not be included as authors simply because they are members of a Y-CEORL subspecialty group.
>
> All named authors should also meet the authorship criteria of the target journal (e.g. the ICMJE recommendations), including critical revision and approval of the final manuscript.

3 Studies proposed from outside a subspecialty group

3.1 Proposal and endorsement procedure

Any Y-CEORL member may propose a prospective or retrospective clinical study, a review or a survey, even if they are not a member of the subspecialty group the study belongs to. In that case, the following procedure applies:

1 Submit	2 Circulate	3 Review	4 Decide
The proposer sends the study protocol to the coordinator of the relevant subspecialty group.	The coordinator shares the protocol with the members of the group.	The members validate the protocol and, if the proposer wishes, suggest improvements.	The group decides whether Y-CEORL endorsement can be granted to the project. The coordinator informs the executive board

To make the review quicker, the protocol should state the study design, objectives, inclusion and exclusion criteria, expected number of centres, timeline and plan for ethics approval.

3.2 Role and responsibilities of the proposer

Endorsement by Y-CEORL does not transfer ownership of the project. The proposer :

- **remains responsible for the study** and holds the first-author position;
- **sets the criteria for co-authorship**, ideally following the framework described in section 2;
- **can count on the group's support** to promote the study (for example, by reaching other centres or survey respondents) and, if requested, for methodological support and practical help at any stage of the project, from protocol design to data analysis and writing;
- **keeps responsibility for the work** throughout, including its scientific quality and timely completion.

4 Use of the Y-CEORL mailing list and communication channels

Using the Y-CEORL mailing list to invite other centres to join a multicentre study, or to distribute a survey, must first be agreed within the subspecialty group and then approved by the Executive Board, as follows:

1 Agree	2 Report	3 Decide
The request is discussed within the subspecialty group and agreed with its coordinator.	The coordinator forwards the request to the Executive Board.	The Executive Board decides whether to grant use of Y-CEORL channels, such as the mailing list, and schedules the sending of surveys.

The request should include the protocol or questionnaire and a short description of the intended recipients.

Surveys. To avoid overlapping surveys, survey requests are presented to the Executive Board by the coordinator of the subspecialty group. The Executive Board decides whether to approve their distribution and, if approved, schedules each survey so that it does not overlap with other surveys sent through Y-CEORL channels. The information is exclusively sent by the official Y-CEORL officer (Gloria Casanova).

5 Acknowledging Y-CEORL in publications

All studies and surveys carried out with Y-CEORL endorsement must acknowledge Y-CEORL in the resulting manuscript:

- **Affiliation:** every author lists Y-CEORL-HNS as their second affiliation, using the standard wording below.

- **Acknowledgments:** the manuscript states that the study was conducted with the support of Y-CEORL-HNS.

Second affiliation (all authors)

Young Confederation of European ORL-HNS, Y-CEORL-HNS, Vienna, Austria

Suggested wording for the acknowledgments

"This study was endorsed by and conducted with the support of the Young Confederation of European ORL-HNS (Y-CEORL-HNS), [name of the subspecialty group]."

6 Choice of journal

Transparency, ethics and scientific rigour should underpin every study conducted within Y-CEORL. For this reason, authors are encouraged to submit their manuscripts to reputable, non-predatory journals.

As a practical reference, authors may consult the list of recommended journals adopted by the French Conférence des Doyens de Médecine and CNU Santé, which is updated every three months. A journal's absence from this list does not by itself mean that it is predatory.