

Upper GI International Robotic Association (UGIRA) procedures concerning data for scientific research

§1. Data ownership and Scientific Committee

Data within the registry are anonymized and will remain the property of the center that was responsible for inclusion. The first publication of registry data will be a descriptive study after inclusion of at least 500 cases. After that, participating centers can initiate studies with data from the registry by submitting a study proposal that will be reviewed by the Scientific Committee*. Once the Scientific Committee has given consent to the study idea, all contributing centers will be notified and offered the possibility to withdraw their data for the intended study. Data that are provided in this fashion will not be retraceable to the participating centers. Ensuing articles will be published according to the authorship agreements in §4.

* The founding members of the society will establish the initial Scientific Committee. The Scientific Committee will be elected by their predecessors for time periods of 1 year. The founding members of the UGIRA will stay honorary members of the Scientific Committee.

§2. Review process

Data requests should originate from health care professionals (doctors, epidemiologists, or policy makers) who work at a hospital that participates in the UGIRA Registry. Patients, students or others cannot request data.

One of UGIRA's research fellows will screen proposals for completeness. Then, at least two members of the Scientific Committee will perform an independent scientific review. However, all members of the Scientific Committee have insight in the proposals and are allowed to comment.

The study proposal is judged by the UGIRA Scientific Committee concerning the:

- Availability of requested data
- Alignment with UGIRA's aims to improve the quality of robotic esophagogastric surgery worldwide
- Feasibility (methodologically) and potential clarification of the research question
- Possible overlap with other initiatives

Complex proposals and proposals that are initially judged negatively by the reviewers of the Scientific Committee will be discussed during meetings of the UGIRA Scientific Committee. These meetings are organized 3-4 times per year and are open for everyone who registers in the UGIRA Registry. When deemed necessary by the Scientific Committee, the submitting researcher may be asked to orally elaborate on his or her study proposal.

§3. Conditions of study proposals

Senior members (at least 50 registered cases and an edited surgical video) can submit study proposals. Study proposals should meet the following criteria:

- Study proposal with background, hypothesis, methods, and required data.

- A maximum of 2 pages according to the format that can be downloaded at the UGIRA website (www.ugira.org/research-proposals).
- Before submitting a manuscript to a journal or presenting the data at a conference, its final version should be shared with the Scientific Committee. The Scientific Committee can decide to discuss the manuscript at a meeting and possibly ask the authors for revisions based on the following points:
 - Insufficient quality of the analyses.
 - Insufficient quality of the interpretation and conclusions of the study.
 - Insufficient resemblance of the manuscript with the initial study proposal.

§4. Authorship agreements

The official guidelines of the ICMJE¹ are leading to determine the co-authorships of UGIRA publications.

To be eligible for co-authorship, one should have:

- Substantially contributed to the design and set-up of the study, or the data collection, or the analyses and interpretation of the data
- Substantially contributed to the conceptualization of the article or the critical appraisal of its scientific content
- Approved the publication of the final version of the manuscript
- Taken responsibility of the entire content of the article

One who meets some but not all of these 4 conditions may be eligible as a collaborator.

UGIRA adds the following rules to the ICMJE guidelines:

1. At the time of submitting a study proposal, the submitting researcher composes an authorship list, adhering to the ICMJE guidelines.
 - a. At the time of presenting the study proposal at an UGIRA meeting, UGIRA members can indicate their wish to be actively involved in the creation of the article. They will be added to the co-authors list, provided that they meet the ICMJE criteria.
 - b. Every article should have the 'UGIRA Study Group' as a co-author.
2. After the manuscript has been written and revised by all co-authors, the manuscript should be sent to research@ugira.org. The research support staff will make sure that the manuscript is shared amongst the Scientific Committee and the contact persons of the contributing centers.
 - a. As soon as the manuscript is spread amongst the aforementioned individuals, they have two weeks time of provide input for the manuscript. If they provide explicit input to the principal and coordinating researchers, they will be added as a collaborator to the manuscript as part of the 'UGIRA Study Group' (how exactly depends on the particular journal and is the responsibility of the coordinating researcher).
 - i. A reminder will be sent after 1 week by the coordinating investigator.
 - ii. In case no response is received within two weeks, the specific member will not be included as a collaborator.

Every center that contributed to the UGIRA Registry in the year before publication is eligible for a collaborator position. In case a center contributed 1-75 cases, 1 collaborator may be provided by that center. Centers that contributed 75-150 cases can provide 2 collaborators. Centers that contributed >150 cases can provide 3 collaborators.

§5. Standard Acknowledgements section

'The authors would like to thank all surgeons, registrars, physician assistants, and administrative nurses for data registration in the UGIRA Registry, as well as the UGIRA Study Group.'

References

1. Defining the Role of Authors and Contributors, ICMJ, accessed on 7-7-2020, at: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>