

ERN GENTURIS
RULES OF RESEARCH GOVERNANCE



1. Purpose of the document

The purpose of this document is to describe the governance framework of collaborative research in ERN GENTURIS with the aim of promoting and regulating the network research activities in the field.

The relative low prevalence of the different disorders under the umbrella of ERN GENTURIS makes it very important to promote international collaborative efforts in order to be able to speed up our knowledge on the different forms of hereditary cancer. By sharing data and/or samples to a given project we will increase our statistical power and we will be able to collect broader clinical information that could eventually return to the patient.

For the ERN GENTURIS registry separate but aligned documents are established that cover the collaboration and data access policy.

Hence, the aims of this document are:

1. To provide a convenient reference for collaborative research within members* of ERN GENTURIS
2. To communicate the governance framework to others outside ERN GENTURIS who have a legitimate interest.

** In this document the term 'members' refers to Full Members, Associated National Centres, National Coordination Hubs and Supporting Partners of ERN GENTURIS.*

This document may be released into the public domain.

2. Responsibilities of Task Force 5 'Research'

The Task Force 'Research' will handle issues regarding research initiatives and will report back to the ERN GENTURIS Executive Committee.

The Task Force will:

1. Ensure that governance systems and processes are established and are sufficiently rigorous to monitor, report and respond to important issues in the operations of ERN GENTURIS.
2. Define the rules of how to use/ access/ request data from the ERN GENTURIS data registry. This is defined in the GENTURIS registry Data Access Policy and the execution of these tasks are entrusted to the registry's Data Access Committee.
3. Address ethical issues as they may arise, and call on ethical consultations where necessary.
4. Determine relationships with other stakeholders through initiating a memorandum of understanding (MOU), including commercial interests, government interests and academic interests. The Task Force will endorse relationships with external stakeholders, including any MOU and/or other arrangements involving the databases, before passing them onto the ERN GENTURIS Executive Committee.
5. Promote the public availability of the results and data of ongoing and past projects as well as of the main goals reached from past initiatives.

3. Information on available research project calls

At our public ERN GENTURIS website, there is a space dedicated to GENTURIS research projects which can easily be identified and accessed from the main homepage. In this space, information regarding past, present and future ERN GENTURIS projects will be depicted.

GENTURIS research projects are defined as projects primarily led by an ERN GENTURIS member and in which at least two Health Care Providers from two different Member States within ERN GENTURIS participate (see Annex 1).

A brief description of each project and requisites to participate, if still open, should be clearly stated there. Results of previous collaborative projects should also be summarised for the sake of transparency and motivation for the whole network.

4. How to present a new research call for a project or a proposal

All ERN GENTURIS members that have signed their respective agreement¹ with ERN GENTURIS, as well as ERN GENTURIS ePAGs, can present a project or an idea proposal or a study concept. It is desired that ePAGs and their patient organizations are involved in the research consortia of each research project.

The procedure for a new ERN GENTURIS research call is as following:

1. For a new call, either (A) a project call or (B) an idea proposal or study concept, the call request should be sent to the chair of the Task Force 'Research' for an initial review by its members.

A. A **project call** applies to specific projects with a clear research objective. For a project call the following should be prepared:

- An project description including the information detailed below:
 - Project title
 - Project leader(s)
 - Project Description
 - Start date
 - Duration
 - Funder (if available)
 - Link study web page (if available)
- Email invitation for ERN GENTURIS members to participate. The invitation should include a specific question to respond to.

B. An **idea proposal or study concept call** applies to a study concept or proposal in development. Rather than a project call to join an already existing project, ERN GENTURIS members can use this call to ask to others ERN GENTURIS members to brainstorm on the design of a new project. The purpose of the call should rather be a first step to make an inventory among the ERN GENTURIS members with interest or expertise in the topic. After the call, content and collaboration details can be discussed on among the interested ERN GENTURIS members.

For a call the following should be prepared:

- General description of a project idea or study concept
 - General aim or scope
 - Study area: thematic group or specific genturis

¹ For Full Members: the ERN GENTURIS Governance Statutes and Agreement; for Affiliated Partners: the Bilateral Cooperation Agreement; for Supporting Partners: the Supporting Partner Collaboration Agreement

- Email invitation for ERN GENTURIS members to express their interest in the topic. The invitation should contain a specific question to respond to.
2. In principle the chair of the Task Force 'Research' will approve the call for distribution. If there is a suspected conflict of interest, the chair will consult with two or more Task Force 'Research' members. If there is no consensus between the Task Force members or a negative advise, the Executive Board will decide. The person who submitted the call will be informed about the decision and reasons for the decision. In case there are multiple project calls at the same time and prioritization is needed, the chair will consult with two or more Task Force 'Research' members.
 3. After approval, one of the project managers of ERN GENTURIS will disseminate the email invitation along with the project description (A) or idea proposal/study concept (B) to all ERN GENTURIS members.
 4. When members from two or more countries/member states participate in the project, it becomes an official GENTURIS research project and the project form will be published on the public ERN GENTURIS research webpage.

5. Authorship rules

As stated in the Vancouver guidelines (<http://www.icmje.org/#author>), authorship credit should be based on:

1. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data,
2. drafting the article or revising it critically for important intellectual content, and
3. final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.

ERN GENTURIS should be acknowledged in all the papers under this umbrella and in some specific cases it can figure as group author. See different scenarios in **Annex 1** at the end of the document.

6. Conflict of interest when dealing with competing calls

Conflicts of interests would be discussed by the Task Force 'Research', who will facilitate an exchange of ideas and will pay attention to the different reasonings provided by the affected parties with the main aim of helping to achieve a win-win position for all the parties under conflict.

If a solution is not found using this instrument, the conflict will be handed over to the Executive Committee.

7. Relationship with other institutions outside ERN GENTURIS

Basic and clinical research on the conditions that are in the scope of ERN GENTURIS is performed also by institutions, European and non-European, outside of ERN GENTURIS. Some of these research projects may also involve patient data and/or biological samples.

This article applies only to research involving clinical data and samples. As stated in art. 1 of this document, given the low prevalence of the conditions dealt with by ERN GENTURIS, collaborative

research is highly desirable. Accordingly, the participation of external institutions to ERN GENTURIS projects should be viewed as potentially beneficial to their success. Likewise, ERN GENTURIS members, or the whole network, can join external research initiatives.

Research projects supported by ERN GENTURIS are performed for the exclusive benefit of patients and citizens, and do not entail any financial profit for ERN GENTURIS HCPs and their personnel. Research collaborations with profit corporate companies must adhere to this requirement, and project leaders are advised to make this explicit in the MOU that the research is not performed for profit and that clinical data and samples shall be made available only under this condition. On the other hand, the corporate partner is allowed to make profit out of any commercial product that stems from collaborative research with ERN GENTURIS, under the terms contained in signed agreements.

8. Informed consent and ethics

The research conducted within the ERN GENTURIS network shall follow internationally recognized ethical standards (Declaration of Helsinki; International Ethical Guidelines for Biomedical Research Involving Human Subjects) and must be approved by local ethical Boards, according to local and national regulations.

Annex 1: Acknowledgements ERN GENTURIS in papers

1. Acknowledgement of ERN GENTURIS

Examples for the acknowledgement section:

- "This work is generated within the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS). ERN GENTURIS is funded by the European Union."
- "This work is supported by the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS). ERN GENTURIS is funded by the European Union."
- "This research is supported (not financially) by the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS). ERN GENTURIS is funded by the European Union."

2. Monitoring Indicator "number of publications" conditions

A publication counts for the Monitoring Indicators if the all of following three conditions are met:

1. the paper includes an acknowledgement as above*
AND
2. it is published in a PubMed accredited scientific journal
AND
3. it involves as major contributors at least two Health Care Providers from two different Member States within ERN GENTURIS**

* If only condition 1 is met, the paper can be listed in the periodic Technical Report to the EC and on the ERN GENTURIS website in the Publications page.

** Papers that meet at least condition 3 can only be listed if they use an ERN GENTURIS affiliation (see below).

3. Including ERN GENTURIS as a 2nd author affiliation

In all papers that do meet all 3 Monitoring Indicators conditions listed above and in all papers that do meet at least condition 3, the authors can add, in addition to their institute's affiliation, an ERN GENTURIS affiliation like:

- Full Member of the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS)
- Affiliated Partner of the European Reference Network on Genetic Tumour Risk Syndromes (ERN GENTURIS)

This affiliation can also be used in cases where you would like to give attention to ERN GENTURIS without it acknowledging any direct input from it. All papers with such an affiliation will be listed in the periodic Technical Report to the EC and on the ERN GENTURIS website in the Publications page (under construction).