

## Procedure Application for Information HemoNED Registry

**Both national and international groups or institutes can apply to receive information from the HemoNED Registry. The application will be assessed by the Steering Committee following a predefined procedure and criteria, documented by the Steering Committee in the HemoNED Governance document (*version 1.5.2., 20-11-2018*).**

### PROCEDURE

- The applicant submits a research protocol to the Project Office (see the Application form on our website: <https://hemoned.nl/en/research/data-application/>). The application includes a list of requested registry items and a statement on potential 'Conflicts of interest'. The application form can be send to [info@hemoned.nl](mailto:info@hemoned.nl).
- The Project Office forwards the application to all members of the Steering Committee and the Board of the HemoNED Foundation.
- The application will be discussed by the Steering Committee and assessed according to the criteria as mentioned below. If necessary an additional meeting will be arranged. The Steering Committee may ask the applicant to provide additional information.
- The Steering Committee will vote on approval of the application; a majority voting is needed. If there are strong objections that have been discussed repeatedly the Board of the hemophilia patient organization (NVHP) will have a veto (for a period of 3 years, starting November 2018). If individual Hemophilia Treatment Centers (HTC) have strong objections that have been discussed repeatedly they have the right to withdraw their data from this particular application.
- The applicant will be informed about the decision of the Steering Committee.
- In case the application is approved an agreement will be signed by the applicant and the Steering Committee. The agreement will include arrangements about data analysis, data usage (exclusively for the project applied for), authorships, dissemination, and expenses that will be charged if necessary.
- The applicant will report to the Steering Committee about the results of the project by means of a report or publication(s).

### CRITERIA

Applications for (aggregated and anonymized) information from the HemoNED Registry will be assessed by the Steering Committee according to the following criteria:

- A clear and complete research protocol (application form) has been submitted.

- The application clarifies why registry information is required.
- There are no conflicts of interest.
- Approval by a medical-ethical committee is or will be arranged.
- The application includes a dissemination plan (when and how will results be made public). Preferably results will be summarized in a report, for example a (scientific) publication. The HemoNED Foundation will publish a short summary on the website [www.hemoned.nl](http://www.hemoned.nl).
- Dissemination of the results contributes to better health care for people with hemophilia or other bleeding disorders.
- It may never be possible to trace the information back to individual patients.
- The information cannot be traced back to a specific HTC, unless this is relevant and the Steering Committee approved it unanimously.
- The source of the information (“HemoNED Registry”) should always be mentioned.
- The “Steering Committee of the Dutch Hemophilia Registration HemoNED” should be mentioned in the Acknowledgements section of a publication.
- Each HTC will have the opportunity to provide a co-author when data from that HTC is included in a publication. The NVHP and NVHV (hemophilia nurses organization) may also provide a co-author if relevant. This co-author should comply to the minimal requirements of authorship as determined by the ‘International Committee of Medical Journal Editors’ (February 2006).
- The registry information may not be used for commercial purposes.
- The applicant should compensate the HemoNED Foundation if additional activities for the Project Office and/or the HTCs result from the application.
- External groups will always be charged for receiving registry information. The invoice will not necessarily fit the expenses made; these revenues can be used by the HemoNED Foundation for further development of the Registry and supporting internal research.
- Dependent on the application, but at least for external groups, the Project Office – under responsibility of the Steering Committee – will perform the data analysis and provide the applicant with the results. If necessary and approved by the Steering Committee, the data analysis can be performed by an external company, preferably a research institute affiliated to a Dutch university. In case the application comes from a participating HTC the Steering Committee may decide to provide unanalyzed anonymized data.