HISREG
REGISTER FOR HIDRADENITIS SUPPURATIVA

Disclosure of data

Guidelines for access to data from HISREG for quality assurance and/or research purposes.

The purpose of the document
The purpose of these guidelines is to explain HISREG's guidelines for ensuring a high level of availability of data from HISREG for quality assurance and/or research purposes, as well as for ensuring that the work based on the register is of high scientific quality. Another purpose of the guidelines is to ensure that the disclosure of data takes place in accordance with the applicable regulations for the processing of personal data.

The subsets of data submitted to HISREG by an entity shall be freely accessible to employees of the entity in question. The disclosure of such data subsets is therefore exempt from the regulations concerning aggregate data from several entities. Data disclosed here will be de-identified.

Access to data
Access to data is granted upon application and in accordance with an agreement entered into with HISREG's steering committee. Such agreement confers rights to investigate and publish on a specific topic. If relevant, the agreement must state the period in which a time limitation will apply.

Application requirements
An application for access to data should contain a comprehensive project description and a publication plan. The application must clearly state who the project manager is and who is professionally responsible for the project.
The application must include a description of:

- The topic
- The desired sample, and the variables that will be used in the analysis
- The publication plan – articles, the internet, target groups for publications
- For all projects, it must be considered whether the project is covered by already existing approvals/ licences, or whether a new recommendation from the relevant authorities is required. This may vary from country to country. The necessary approvals must be submitted before any data can be disclosed.

Processing of applications
Applications for the allocation of a topic with pertaining disclosure of data from medical quality registers shall be addressed to the steering committee for HISREG, or, if relevant, to the body appointed by the steering committee for this purpose.
If a situation were to arise in which several applicants apply for access to the same topic and it is necessary to prioritise between applicants, the following criteria should be emphasised:
Professional relevance
The project must be professionally well-founded and of such a nature that it is best researched within the framework of a register. Projects that comply with HISREG's primary objectives will be given priority.

Professional capacity
The project manager must substantiate that the project staff have the expertise and capacity required to analyse and publish data in a professionally satisfactory manner and within a reasonable period of time.

Considerations relating to ongoing projects
The application's project description and publication plan must not conflict with other approved application plans. If two projects have closely related topics, the steering committee will encourage the projects to cooperate.

Time limitation
Before any data are disclosed, an agreement should be entered into with the steering committee concerning a time limitation on access to data. For doctoral projects, it is normal to give sole right to the topic for five years. For other researchers, the practice is three years. For quality assurance purposes (continuous monitoring), it may be relevant to make data available without stipulating any requirements for an final date. In such case, the project should describe reporting procedures to the register in the event of significant changes and/or lack of progress.

Data disclosure
Data are disclosed as a text file and the applicant can then convert the text file to the relevant software. Personal health data disclosed for research purposes will normally be de-identified or anonymous. A serial number (a random series) will replace personal identification, so that individuals can be tracked in the data material.

Rules for publication
In connection with publication, here understood as all publication of research results or other presentations of data in which data from HISREG are used, it must be stated that the data are from HISREG.

Authorship
In connection with publication, co-authorship shall be based on the Vancouver protocols. This means that, to be entitled to demand to be credited as a co-author, the person in question must have contributed substantially to the conception and design, or the acquisition of data, or the analysis and interpretation of data. Before publication, co-authors must have approved the version submitted for publication.

Sanctions in the event of breach of contract
In the event of breach of contract, the steering committee for HISREG will contact the project owner to clarify the facts of the matter. If the parties fail to reach agreement, it may be relevant to send a written statement to the responsible parties at the project owner's institution to notify that the project owner has breached the agreement concerning the use of data. If this does not result in agreement between the parties, it may be necessary for the steering committee to revoke the rights to the data.

Appeals and reversals of decisions
The steering committee is responsible for the administration of the data in the register. Appeals against decisions made by the steering committee for the individual registers concerning the disclosure and use of data shall be addressed to the steering committee for HISREG.

1Data where names, personal ID numbers and other identifiable characteristics have been removed so that the data can no longer be linked to an individual, and where the identity can only be traced by comparison with the same information that was previously removed, cf. the Personal Health Data Filing System Act section 2.

2Information in which names, personal ID numbers and other identifiable characteristics have been removed so that the data can no longer be connected to an individual, cf. the Personal Health Data Filing System section 2.

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