SIRIS
schweizerisches implantat-register
registre suisse des implants

Foundation for Quality
Assurance in Implant Surgery

Regulations for Use

SIRIS Implant Registry

April 2022 / revision of the 2012 version

I. Preliminary remarks on the Regulations for Use

In accordance with the provisions of the Swiss Federal Data Protection Act (FADP), the statutes of March 1, 2016, and the organizational regulations of April 28, 2009, of the Foundation for Quality Assurance in Implant Surgery, the Foundation Board adopts the following Regulations for Use of the SIRIS national implant registry.
Gender-neutral wording has been used throughout the text.
Data usage is defined as the collection and processing of data as per Art. 3 FADP.

II. Purpose of the Regulations for Use

In order to promote quality in implant surgery, the Foundation is setting up a central national data pool in which clinical data and implant data on operations involving the use of implants in Swiss clinics is collected in a registry (SIRIS), processed and made available to the parties entitled to usage.
The Regulations for Use define the parties entitled to usage, the scope of access rights, and the possible use of data to ensure legal data protection. Depending on the type of use, fees may be charged for reporting from SIRIS to the entitled parties.

III. Data protection

All data is only registered in SIRIS with the consent of the patient and is pseudonymized. The data registered in SIRIS relating to the patient, procedure, surgeon, clinic and implant can be associated with the corresponding patient and procedure (data collection). Under the Data Protection Act, a patient's health data falls into a category of personal data subject to particular protection.
The use of SIRIS does not serve to evaluate personal data, but rather to ensure quality in implant surgery. In particular, SIRIS guarantees the traceability of the implant and the patient. In order to protect the privacy of the patients, the parties entitled to use must take particular account of the provisions of data protection when using SIRIS and ensure the technical and organizational measures for appropriate protection of the data that meet the requirements of the FADP (Art. 7 FADP and Art. 8 et seq. of the ordinance on the FADP), in particular to ensure the long-term confidentiality, integrity, availability and capacity of the systems and services in connection with the processing of the data.

IV. Data management

The Foundation appoints suitable companies, organizations or associations to manage the data collection in SIRIS registries. Currently, these are the SwissRDL of the ISPM of the University of Bern for hips and knees, and EUROSPINE for the spine as well as NEC Software Solutions on its behalf. Any processing of data is conducted directly by the data manager.

V. Parties entitled to usage

The data collection of the implant registry is not publicly accessible. Only the following parties are entitled to a right of use under the conditions described in these regulations:

1. Hospitals
The hospitals remain the owners of the data they have entered; hospitals have the right to inspect the use of the data they have provided. Each hospital must appoint a hospital administrator who can access the data collection directly via the internet using their personal username and password. Access is limited to the raw data provided by the hospital.

2. Doctors
Doctors have the right to inspect the use of the data they have provided. Every doctor receives a personal username and a corresponding password for accessing the data collection directly via the internet.

3. Implant manufacturers
Implant manufacturers are entitled to use SIRIS data from standardized SIRIS implant reports in relation to their implants. This is always pseudonymized, non-hospital-specific data that manufacturers require to ensure the quality of their implants. The details of use are set out in the "SIRIS guidelines for manufacturers: Evaluation of data from the SIRIS registry". This use does not include the disclosure of patients' personal data as part of a recall campaign.

4. Third parties
Upon request, third parties may be granted use of SIRIS data by the Foundation Board if needed for study and research purposes and if this serves to promote quality in implant surgery (foundation purpose), and if it complies with Art. 11 of the data regulations of the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ)1. The right of use applies only to pseudonymized personal data and is limited to the purpose specified in the request for use. Modified study or research purposes or other uses of the findings require a new request for use. The approval from the Foundation Board can be revoked at any time, particularly in the event of a violation of the provisions of these Regulations for Use. After completion of the study or research project, the Foundation must be sent, without being asked and free of charge, a specimen copy of the work that was conducted using the SIRIS data. The Foundation is authorized to publish part or all of the work in its annual report.

Use by third parties and a related publication of the research results requires compliance with the following steps and requirements:

1. Request to the SIRIS Foundation with the following items:
   a. Specification of the purpose with justification regarding to what extent the project (also) serves the purpose of the Foundation to promote the quality of implant surgery
   b. Description of the type (which data), scope and duration of use, as well as the following information:
      i. title of the research project
      ii. authors, other research institutions involved
      iii. project overview (introduction, objective, material and method, benefit)
      iv. for multi-center studies: participating hospitals/clinics
      v. declaration of consent from the clinics/hospitals involved
      vi. approval of the responsible ethics committee
      vii. confirmation that the data will not be used for marketing or advertising, but only for research and quality assurance.
2. Assessment by the SSAB. The application is evaluated by the SSAB, and a recommendation is made for the attention of the SR President.
3. Approval by the Head of SSAB and the President of the SIRIS Foundation based on the information
4. Limitations. Access to and use of the data is fundamentally limited to the purpose specified in the request for use. Modified study or research purposes or other uses of the findings require a new request for use.
5. Publication of research results based on SIRIS data:
   a. The publication must explicitly refer to the origin of the data from SIRIS.
   b. The Foundation must be sent a specimen copy of the publications resulting from the evaluation of the SIRIS data free of charge.
   c. The Foundation is entitled to publish part or all of the publication in its annual report.
   d. The costs for data processing are generally borne by the applicant. The ISPM invoices the time required according to common practice.
6. Principles of data provision
   - The data is anonymized

- The data is basic data that has been cleaned and checked for plausibility and completeness (no raw data)
- The data cannot be traced back to specific surgeons or hospitals (disclosure control rules)
- Data is adjusted to the needs of the project
  - o Prepared basic data with/without statistical analysis
  - o Selected basic data

5. Patients
Based on Art. 8 FADP, patients are entitled to information about the data concerning them. They must send a written request for information by certified mail to the data manager. A copy of an official ID must be enclosed with the application.

VI. Access to the data registry

1. Hospitals, doctors
SIRIS can be accessed via the internet using a personal username and password provided by the data manager. Each hospital receives only one password, which is assigned to a hospital administrator. The username and password must not be passed on to third parties for use. The users are responsible for the use of the existing access control systems and measures (e.g. password, password choice, structure and storage, etc.). The user is liable for damage resulting from the loss of the user credentials or from passing on the password.

2. Implant manufacturers
Implant manufacturers do not have direct access to SIRIS. After concluding a framework agreement with the Foundation, they can send a request for a SIRIS implant report to the office of the SIRIS foundation. The data manager passes on the report to the implant manufacturer in digital form and/or in paper form.

3. Third parties
Third parties do not have direct access to SIRIS. They must submit a request for use to the Foundation Board. The Foundation Board decides whether to approve the request and the scope of the data that is made available to the third party.

4. Patients
Patients have no right to inspect the data collection of the implant registry. In accordance with Art. 8 FADP, they can request information about the data collected about them.

VII. Usage fees

1. Hospitals, doctors
The SIRIS contribution covers the use of SIRIS data provided by the hospitals and doctors themselves.

2. Implant manufacturers
If the data evaluation is in the interests of all implant manufacturers and the Foundation is authorized by the requesting implant manufacturer to forward the evaluated data to all implant manufacturers, the data evaluation is free of charge. If, on the other hand, it is solely in the interest of the requesting implant manufacturer or the data may not be passed on to other implant manufacturers, a usage fee will be charged. In the event of a recall campaign, no fees will be charged.

3. Third parties
A fee is payable for general use of the data collection. The fee amount is determined by the Foundation Board. They obtain an offer from the data manager for this. Upon request, the

Foundation Board may waive the usage fee charge or grant a discount if the application for use is in line with the purpose of the Foundation.

4. Patients
Patients' requests for information are processed free of charge.

VIII. Data sovereignty

The entitled parties receive the non-transferable, non-exclusive right to access and use the data within the framework of these Regulations for Use. The SIRIS Foundation is the owner of all SIRIS data collections. All rights to the collected data which has been evaluated and processed by the Foundation or the data manager remain with the Foundation.

IX. Additional provisions

1. The SIRIS Foundation handles inquiries and requests for the use of SIRIS data addressed to it promptly and ensures these are processed without delay. If the Foundation cannot respond to an inquiry or request within 30 days, it must inform the entitled party of this immediately.

2. All security-relevant incidents (in particular loss or modification of data and programs, suspicion of misuse of one's username) must be reported immediately by the entitled party to the data manager, who must investigate the causes and take further measures, as necessary.

3. Parties entitled to usage who violate the provisions of these regulations may be excluded from further use.

X. Final provisions

These Regulations for Use come into effect immediately upon signing. The Foundation Board periodically reviews the appropriateness and practicability and makes modifications if needed.

Thun, May 25, 2022

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