**SAMPLE ETHICS APPLICATION FOR LOW-RISK PROJECTS**

Instructions are highlighted in yellow.

# **Is ethical approval required for my participation and data submission?**

The Spine Atlas protocol has been assessed and cleared by the Ethics Committee of Eastern Switzerland (EKOS; BASEC submission no. AO\_2024-00111).

In several countries, since the data collection is fully anonymous and data protection measures are in place, no further ethics clearance is needed. In some countries there may still be a legal requirement to get formal approval for the (anonymous) data collection and submission to an international project .

Please inquire with your IRB, ethics committee, spine society, research group, participants in similar projects like cancer registries, etc. if you need approval or not.

If you need a formal approval from your local Ethical Committee for data collection and submission to Spine Atlas, the following sample ethics applications may be helpful for you.

|  |
| --- |
| **Application details** |

**Title of Project**

Anonymous data collection and submission to the international Spine Atlas Initiative data call 2025 on lumbar degenerative spondylolisthesis (SAI-2025-LDS)

**Proposed start date**

01. February 2025

**Proposed end date:**

Observation period ends 30. April 2025, Data will need to be delivered by 31. May 2025, Data evaluation and corrections, if necessary, will be concluded by 31. July 2025.

**Principal Investigator (PI)**

State the local project leader (could be main contact for the SAI participant).

**Institute/Faculty/Department**

State the PI’s faculty or department (or equivalent).

**Contact Details**

State the PI’s contact details to be used for all correspondence relating to this ethics application.

**Co-investigators/partners/collaborators**

List all other co-investigators/partners/collaborators who will work on the project. (further contacts of the SAI participant) This includes those with access to the data such as transcribers

The project takes place in the framework of the Spine Atlas Initiative, lead by Dr. Christian Herrmann, PhD, Principal Investigator Spine Atlas Initiative, [spineatlas@eurospine.org](mailto:spineatlas@eurospine.org), EUROSPINE, the Spine Society of Europe, c/o Pfister Treuhand AG, Bankstrasse 4, 8610 Uster, Switzerland.

**Funded Projects**

No funding/ Funded by the department / Funded by sponsor/ Funded by…

**Name of Sponsor**

The sponsor is the PI’s local institute.

(A sponsor is the organisation taking overall responsibility for the research. This is not necessarily the same as the funder.)

|  |
| --- |
| **Project details** |

**Brief background & aims of the project**

The PI and local researchers will collect data on anonymous patient demographics and surgical procedures for adult patients treated for lumbar degenerative spondylolisthesis, check completeness, provides meta-data on the data delivery and submits it to the Spine Atlas Initiative’s (SAI) office for their data call 2025 on lumbar degenerative spondylolisthesis (LDS). The primary goal of the SAI is to establish an approach for mapping spinal care services and variations in treatments of spinal pathologies across borders. The approach shall enable individual surgeons, hospitals, spinal registries and national societies (participants) worldwide to participate in future international calls for epidemiological data, map their spine care service, benchmark them, and run epidemiological studies. In their data call 2025 the SAI focuses on adult patients surgically treated for LDS between 1 February and 30 April 2025. The study protocol for the SAI data call 2025 on LDS was assessed and cleared by the Ethics Committee of Ostschweiz Switzerland (EKOS; BASEC submission no. AO\_2024-00111). The protocol is available at <https://www.eurospine.org/fileadmin/Images/Research/Spine_Atlas/2024-10-30_Spine_Atlas_Initiative_Mapping_healthcare_services_and_practice_variation_accros_countries_v1.0.pdf>

**Methodology and Methods:**

This project is categorised as documentary analysis. It includes data collection of anonymous patient characteristics, pathology and treatment of adult LDS patients. It includes data that is routinely collected for hospital/ surgery reports and there are no interventions nor inclusion of control groups.

**Attachments**

You may attach the SAI protocol (<https://www.eurospine.org/fileadmin/Images/Research/Spine_Atlas/2024-10-30_Spine_Atlas_Initiative_Mapping_healthcare_services_and_practice_variation_accros_countries_v1.0.pdf>) and the decision by the EKOS ()

**Code of Ethics**

The PI confirms hereby to conduct the project according to the protocol, the current version of the World Medical Association Declaration of Helsinki (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects ) and the principles and procedures for integrity in scientific research involving human beings.

**Location of Research**

The data collection will take place ... (Describe the location(s) where the data collection will be conducted. )

The analysis will be performed in Switzerland. SAI team is based at EUROSPINE, the Spine Society of Europe, in Switzerland. The study protocol for the SAI data call 2025 on LDS was assessed and cleared by the Ethics Committee of Eastern Switzerland (EKOS; BASEC submission no. AO\_2024-00111).

|  |
| --- |
| **Details on Project Participants (Patients)** |

**Participant population**

Included are all patients 18 years of age or older who underwent surgery/ surgeries for LDS performed between 1 February and 30 April 2025. Patients will have one data entry per LDS surgery.

Excluded are all patients who don’t fall in the above category or did not provide resp. revoked consent to have their data included in the study.

No control groups are included in the study. No sampling will be done in this study; hence data is acquired as is.

The estimated number of patients for the PI’s institution is xxx.

**Recruitment/Sampling**

All patients of the PI/at the PI’s institution that follow the definition above will be recruited = asked to provide consent.

**Informed Consent**

At patient recruitment, the PI or the involved researchers will make clear to the patient that the provision of the consent has no effect on the course of treatment, it is voluntary, and that it can be withdrawn by the patient at any time.

The participants are provided with all the necessary information to be able to make an informed decision about whether or not to take part.

This includes information about the study in lay terms, see attached patient information sheet.

The consent procedure may take place at the surgery pre-discussion with the patient or post-op. (Describe here if this will be done in person, per email, etc. How will the consent be recorded, on paper, electronically etc.)

Data Protection and Privacy

The PI has appropriate knowledge and skills in the areas of data security and data protection or is able to ensure compliance by calling in appropriate expertise. Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project.

The PI, as well as the international project group adhering to the legal requirements set by the project protocol and terms & conditions.

Identifiable patient information is not recorded or ensured to be deleted before submission. The PI uses the submission channel defined by the international project group. The International project group ensures to provide encrypted and secured channel for submission of data. It also immediately deletes data that contains person identifying information and informs the PI about the occurrence. It furthermore has a data security concept in place, data is stored in a Swiss based secure data storage with limited and monitored access for authorised personnel. The SAI international project group has only access to anonymous data.

**Attachments**

* Information sheets and consent forms. Templates available at https://www.eurospine.org/spineatlas/registration
* Project protocol and terms & conditions, download from https://www.eurospine.org/spineatlas/registration

|  |
| --- |
| **Ethical Issues** |

**Ethical issues:**

This application seeks approval for the anonymous data collection and submission by the PI. The project is governed by the protocol of the Spine Atlas Initiative (SAI), which has been assessed by the Ethics Committee of Ostschweiz Switzerland (EKOS; BASEC submission no. AO\_2024-00111), which is the country in which the international data will be gathered and analysed. EKOS confirmed that there are no ethical objections as long as the data are anonymised, and patient consent is obtained as described in the SAI protocol. Within the field of human research in Switzerland, the project, as specified in the protocol, does not require prior/further approval from the ethics committee. Data protection must be ensured.

Conflicts of Interest: If there are conflicts of interest you should indicate how these will be managed or mitigated.

**Risks & Benefits**

By risk category and accounting for mitigating measures

* physical risk: Minimal risk added by the study, as the study is not altering the populations or treatment decision. We are merely observing patients with specific pathologies and treatments.
* psychological risk: Minimal, data for the study are routinely collected, and asking for consent to further use the patient and treatment data is standard in most hospitals, if necessary, by local law. In centres not having used informed consent forms and that would be required to do so in this project, mild stress and discomfort from the unfamiliar situation may arise.
* social risk: Minimal risk for invasion of privacy and loss of community standing, since data security measures and procedures are defined and in place.
* legal risk: Minimal risk added by the study, as it is not influencing the treatment and local procedures, with the narrow exception in project related data security. Local centres have to follow their own data protection and legal requirements, collaboration with the international project centre is governed by project terms and IT security measures.
* economic risk: Low, data entry will require personnel resources, but the amount of cases and effort per case are low (approx. 2.5h-3h per 30 cases).

Benefit category: “The research provides no prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society’s understanding of the disorder or condition under study. “

The collected data will be valuable for the planning and development of health structures as well as research. The data will give an overarching perspective to all key stakeholders on the treated study population and applied treatments, which is essential for their actions.

This data call provides a unique source of comparable treatment data for researchers worldwide. Each subsequent data call will facilitate the understanding of the evolving magnitude and patterns of spine pathologies in different regions/countries. A strict evaluation of the data quality will ensure comparability across different time periods and regions.

The data provides evidence for the origins of variability across regions, may it be due to environmental, behavioral, societal, medical school, guideline, or other reasons, and may show potential for improvement across multiple factors.

|  |
| --- |
| **Data Storage & Security** |

**Will the research involve the collection and/or use of personal data?**

No person identifiable data is collected. The following patient characteristics are collected: Age at surgery in full years, gender, smoker status, BMI category.

**Type of data:**

The following data is collected in anonymous and coded form:

* Patient age at surgery date (in whole years)\*
* Patient gender
* Surgery date
* Primary spine surgery at the same or adjacent level
* Type of spinal stenosis (central or lateral, foraminal)
* Grade of LDS (a) by Meyerding OR (b) in mm
* Surgical measures (type and level of Decompression / Fusion / Stabilisation / Dynamic stabilisation / Other surgical treatment
* optional parameters (additional spinal pathology, ASA status, Number of previous spine surgeries at the same or adjacent level, Duration of symptoms, Height and weight OR alternatively BMI, Current smoker status, (if any) Data on the implant manufacturer and article number.

**Storage of data:**

State where and in what format all data will be stored during the study

After submission of the anonymous data to the international project centre, data is stored in a Swiss based secure data storage with limited and monitored access for authorised personnel. The SAI international project team has only access to anonymous data.

**Who has access to the data:**

State who will have access to the data during the study, this includes the research team, supervisors, transcribers, etc.

After submission of the anonymous data to the international project centre, only authorized project personnel has access to the data which is kept separate from normal operations.

**Retention and destruction of data**

Specify how long you will keep the data at your location.

In the international project group, data will be kept for a period of 15 years after completion of the study.

**Data sharing policy**

After publication of the first results, the combined data will be made available by the international project group upon request. Preference will be given to hospitals and researchers who contributed data. The steering committee of the SAI will review study requests and control who does what to avoid duplication, maximise the use of the data, and ensure high quality of the data usage.