**Template for an application to ethics committees
where the full protocol is needed to be included in the application text**

**NOTE:** In most cases a simpler application for only the data collection and submission is sufficient, where the full protocol is simply attached. See our template “for low risk projects” on <https://www.eurospine.org/spineatlas/registration/> .

**General information and instructions**

This template for application for ethical clearance is based on the requirements of Swiss regulations. While the requirements are similar in most countries, please check and adapt the highlighted parts to match your local requirements.

Text in blue are instructions and indicate where you have to provide details specific to your participation.

Reporting guidelines and checklist for the main study types are listed by the Equator network (<http://www.equator-network.org/reporting-guidelines/>) and should accordingly be addressed in the project protocol (STROBE statement).

The template is intended for research projects with persons in which study specific health-related personal data are to be collected (not yet available) in order to answer a scientific question.

* Use the text passages that are written in black.
* **Delete all instructions and explanations** (written in blue), including this page**.**
* If applicable to your situation, and the protocol has to be signed by the project leader, please inquire at spineatlas@eurospine.org
* Please send a copy of the decision by the local ethics committee to spineatlas@eurospine.org. Sharing these decision will help fellow participants with their own applications by citing them.

**Change history**

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| --- | --- | --- | --- | --- |
| Version Nr | Version date | Modified without version change | Description, comments | Control |
| 1.0 | 26.11.2024 |  | Initial version | CH |
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" **….. Remove the ‘General information and instructions’
and the table ‘Change history’
and add the logo of your institution in the header** "

**Spine Atlas Initiative data call 2025 on lumbar degenerative spondylolisthesis (SAI-2025-LDS)**

Research legislation: Ordinance on human research with the exception of Clinical trials (HRO) [1].

Type of Research Project: Research project involving human subjects/ reusing of already registered data

Risk Categorisation: Provide Risk category A or B acc. to ordinance HRO Art.7

delete if not required by your ethics committee, adapt to your regulations. In Switzerland category A is „minimal risk“ and category B is „more than minimal risk“. Swissethics categorized this project as „no risk“.

Project leader: Dr. Christian Herrmann, PhD, Principal Investigator Spine Atlas Initiative, +41 78 223 71 22, spineatlas@eurospine.org

Sponsor: EUROSPINE, the Spine Society of Europe, c/o Pfister Treuhand AG, Bankstrasse 4, 8610 Uster, Switzerland

Local project center: Institution, Address, contact details, if applicable. See note below.

Local project leader: Title, Name, Position, Address, Phone, e-mail.

Local sponsor (if different from project center):

The project leader is a qualified individual by education and training (HRO Art.4), who is responsible for the whole project. In case of a multicenter project, list the centers names and the names of the local responsible project leaders. Ensure compatibility with BASEC research application form.

The sponsor is responsible for organising the research project, and in particular for the initiation, management and financing of the project in Switzerland. The project leader can assume the role of the sponsor (HRO Art. 3). It is the responsibility of the Sponsor and of the Project leader to ensure that role and responsibilities of the project leader and of the Sponsor are clearly defined in the project plan and understood by all. Ensure compatibility with BASEC research application form.

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# BACKGROUND and project rationale

This project „Spine Atlas data call 2025 on lumbar degenerative spondylolisthesis” is performed under the umbrella of the Spine Atlas Initiative (SAI). The local project leader (applicant) is responsible for data collection and submission on anonymous patient demographics and surgical procedures.

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.

Spinal surgery is one of the medical disciplines that evolves rapidly, but the degree of heterogeneity of treatments is systematically increasing. The key reasons for this include:

* A rapidly growing list of available implants, which differ across regions (for example due to regulatory and health policy protocols)
* Different clinical schools, clinical guidelines in different countries, and differences in practice across specialities (neurosurgery, orthopaedic surgery, and spine surgery)
* Differences in local health care systems, health insurance, and health political regulations
* Different healthcare structures
* Varying wealth across regions and financial abilities of the patients as well as differing patient expectations.

At the same time, the degree of heterogeneity has not been systematically explored, as there is no specific evidence or figures available on the number and types of performed treatments and treated pathologies across multiple European countries.

Currently, there is no systematic border-crossing epidemiology and research on spinal treatments. Only a few very valuable stand-alone studies have been published based on combined data from countries. These studies analysed data from 2011-2013 from the national spine registries in the three relatively homogeneous Nordic countries (Denmark, Norway and Sweden) and have shown significant differences among them in baseline patient characteristics for degenerative disc disease[[1]](#footnote-2), lumbar spinal stenosis[[2]](#footnote-3), and for sciatica with disc herniation including (unadjusted) treatment choices[[3]](#footnote-4).

## 1.1 Rationale for documenting numbers and types of performed treatments and treated pathologies across countries

This epidemiological and healthcare provision perspective is necessary to make informed (i.e. correct or better) decisions for problems that do not relate to individual cases, but that affect entire populations.

Epidemiological domain

To describe the patient population and to understand the distribution of spinal pathologies that are (surgically) treated across countries.

Health policy domain

To understand the burden of pathologies within and between countries, and to plan and facilitate the development of health care structures, education, and other related topic in the individual countries and beyond.

Clinical domain

To foster harmonisation of spinal treatment for which the big picture is required first. Surgical practice can vary greatly for spine conditions, even within the same geographical region and among colleagues at the same institution.

Research domain

To document the baseline status before initiating new projects or changing clinical practice aiming to elicit changes.

Pathology and therapy registration

To further develop and improve the registration of spinal pathologies and therapies across European countries.

Spine registries

Data extraction will support the harmonisation of the data structure within registries. This SAI follows the outcome of the 2nd meeting of Spinal Registries in Frankfurt 2023 that a standardised core dataset should be collected in every spine registry.

# 1.2 Lumbar degenerative spondylolisthesis

One of the controversially discussed questions in spine surgery in the last decade was whether to fuse or not to fuse lumbar degenerative spondylolisthesis (LDS). LDS is a well-known lumbar spinal pathology that presents a common problem in daily spinal practice. It is characterised by displacement of one vertebral body over another due to disc degeneration and facet arthropathy, most commonly in combination with various degrees of spinal canal stenosis and/or foraminal stenosis at the affected level.[[4]](#footnote-5) The symptoms are usually a combination of stenotic-type radiating buttock and leg pain and mechanical low back pain. Conservative management is usually tried first, but if unsuccessful, surgery can be advocated for and has demonstrated repeatedly good results in various studies.[[5]](#footnote-6),[[6]](#footnote-7) Although good quality randomised controlled trials (RCTs) are almost unanimous in demonstrating that fusion has no benefit over a decompression only, some trials and meta-analyses still show contradictory results and conclusions[[7]](#footnote-8),[[8]](#footnote-9). In any case, it is not known to what extent current clinical practice varies in terms of the treatment provided.

# 1.3 Risk assessment

The Spine Atlas protocol including the data call 2025 on lumbar degenerative spondylolisthesis was submitted to and assessed by the ‘Ethikkommission Ostschweiz’ (EKOS) of Eastern Switzerland through swissethics, the Swiss Association of Research Ethics Committees, BASEC submission no. AO\_2024-00111. EKOS confirmed that there are no ethical objections as long as the data are anonymised, and patient consent is obtained as described in this protocol. Within the field of human research, the project does not require prior/further approval from the ethics committee. Data protection must be ensured.

Therefore the risk of this study with its risk mitigating measures is neither falling into the categories of „with minimal risk“, or „with more than minimal risk“.

# project OBJECTIVES and Design

## 2.1 Hypothesis and primary objective

With the data call 2025, we aim to describe the spinal services and practice variation in spinal care for LDS while testing the proposed approach for data collection and submission. We hypothesise that health systems and adoption of guidelines happen at different speeds in different countries so that we see relevant differences in treatment patterns across countries.

The local project leader (applicant) and local researchers will collect data on anonymous patient demographics and surgical procedures for adult LDS patients treated by them, check completeness, provides meta-data on the data delivery and submits it to the international project office.

Delete “and local researchers” if only the project leader collects the data.

## 2.2 Primary and secondary endpoints

The exact data definitions are outlined in the Codebook of the full project protocol, and can be downloaded separately at <https://www.eurospine.org/fileadmin/Images/Research/Spine_Atlas/2024-09-19_Codebook-SAI-data_call_2025.pdf> .
The list of variables is based on the harmonisation work and output of the ISR working group and was further developed during the review rounds of the SAI proposal by the SAI steering committee, the Spine Tango Committee, the EUROSPINE Research Committee, the ISR and other involved individuals.

The selection was based on the criteria to have a core mandatory dataset, which contains the most important information to describe the patient populations, type of LDS and surgical intervention.

The optional parameters were also kept minimal and contain predictors of surgical outcome as described previously in literature and three additional questions on pathology and surgery. Outcomes are not included in the variable list.

In short, the mandatory parameters are:

1. Patient age at surgery date (in whole years)\*
2. Patient gender
3. Surgery date
4. Primary spine surgery at the same or adjacent level
5. Type of spinal stenosis (central or lateral, foraminal)
6. Grade of LDS (a) by Meyerding OR (b) in mm
7. Surgical measures
	* (if any) (a1) Decompression type and (a2) level
	* (if any) (b1) Fusion type and (b2) level
	* (if any) (c1) Stabilisation rigid type and (c2) level
	* (if any) (d1) Dynamic stabilisation and (d2) level
	* (if any) (e1) Other surgical treatment (e2) level

The optional parameters are:

1. Additional spinal pathology
2. ASA status
3. Number of previous spine surgeries at the same or adjacent level
4. Duration of symptoms
5. (a) Height and (b) weight (c) OR alternatively BMI
6. Current smoker status
7. (if any) (a) Data on the implant manufacturer and (b) article number

\*Age may be permitted to be sent in age groups if required by local data protection law.

Additionally, the local project leader will be surveyed using a set of general questions. The purpose of this set of questions is to estimate the coverage of the participants and potential biases in the data.

* Institution/organisation/participant name, incl. abbreviation used in submission files.
* Country
* Participant type (surgeon, department, hospital, regional/national spine registry, national association for spine/orthopaedics/neurosurgery, research group)
* In case of data containing multiple institutions and <100% national coverage: a list of institutions
* Estimated national coverage of spine surgeries by the participant
* Estimated annual number of cases treated total/ spine related / LDS
* Health system - questions
* (Potential) biases in the data – questions (regarding bias in patient selection, completeness etc.)

The survey will also be used to record the agreement to participate in the SAI. The local project leader is asked to confirm by ticking the respective box, that permission is granted to use the material submitted for the purposes stated in this proposal, and that patient consent was retrieved -unless not required by local law, i.e. for anonymised data from national registries. The international project centre assures that the submitted data will not be used for purposes other than those outlined above without the explicit permission of the local project leader.

## 2.3 Project design

The study design is an international cross-sectional study.

The data will be visualised for all participants’ data combined and for each one of the individual countries with representative data.

Although all hospitals, spine registries and national specialist societies will be invited to contribute their data, we expect that only selected institutions and organisations will submit data leading to an incomplete coverage of data. To assess the representativeness of the submitted data, all participants contributing data will be requested to answer a few questions on the representativeness of their data (see 7.1). The steering committee will determine if the representativeness of a country can be considered sufficient. If sufficient, the country will be shown in the country-wise study results. In any case, all available data from all participants will be used in pooled data analyses.

If data for the same participant is delivered more than once by different means, i.e. as a participant of Spine Tango and simultaneously a participant of a national registry, we will report back to the participants on the congruency of their data and use the result of that analysis as an indicator for coverage.

# PROJECT POPULATION and Study procedures

## 3.1 Project population, inclusion and exclusion criteria

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 and 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. Information about potential bias and potential under representativeness of relevant groups will be gathered via a metadata survey on the data collection.

The estimated number of patients for the applicant is xxx.

State the total expected number of participants.

## 3.2 Recruitment, screening and informed consent procedure

The local project leader explains to each patient the nature of this research project, its purpose, involved risks and the expected duration, before patients are asked to provide their consent. In particular, that this research project is a data driven project and has no impact on the treatment, that the data is collected anonymously and used to create summary statistics per country to help describe the surgery landscape for LDS patients with the goal to identify relevant treatment disparities and to enhance research and future treatment plans. Each participant is informed that the participation in the research project is voluntary and that he/she may withdraw from the research project at any time and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment. The participants are informed that he/she can ask any question. Enough time is given to the participant.

All participants are given an information document and a consent form describing the research project. The formal consent of a participant, using the approved consent form, is obtained before the participant is enrolled in the research project.

The participant should read, understand, and voluntarily agree before signing and dating the informed consent form, and is given a copy of the signed document. The consent form is signed and dated by the participant and the project leader (or her/his designee). The signed consent form it is retained as part of the investigation records.

Patients will not be compensated, as their involvement only includes providing consent on the further use of their data.

**Informed consent procedure: Please adapt to your situation (i.e. if no written consent is required in your country.** Attach the templates for writing the patient information documents and informed consent forms (ICF) that meet the legal requirements of your country. A template for patient information and ICF are available at <http://www.eurospine.org/spineatlas/registration>.

If the Sponsor or investigator plan to use an electronic ICF for the study, please mention here.

**Screening and recruitment:**

Screening and recruitment will be performed by the local project leader in the daily practice according to the inclusion and exclusion criteria. All patients matching the inclusion criteria will be informed about the study and asked to consent to the data collection and use, and to be included in the study if they provide consent.

Please adjust to your situation if necessary.

## 3.3 Study procedures

The overarching data-call project started in July 2024 with the development and implementation of communication plans and ends in December 2025 with the publication of the results.

However, for the local study leader and centre the project will start on 1. February 2025, the first possible date data could be collected according to the inclusion criteria. The observation period will end 30 April 2025 and data will be submitted to the international project centre by 31 May 2025.

By the same date the local project leader (applicant) will submit a meta-data questionnaire on the data delivery, describing the local situation and potential biases or issues with data collection.

From June to August 2025 the SAI steering committee will assess the data and potential biases and recommend measures to the analytics team and/or the local project centres to reduce or at least account for them.

After successful evaluation, the data will be grouped and analysed by country, and the outcomes be prepared for publication. All authors including the local project leader will review the draft manuscript(s).

## 3.4 Withdrawal and discontinuation

In case a patient withdraws their consent to have their anonymous data included in the project, the local project leader must ensure to either delete that data from the data collection or to not be included therein. If the data was already submitted to the international project centre, these data cannot be deleted, as the centre has no identifying information. Unless data is already published, the local project lead may decide to resubmit the data excluding data for which consent was withdrawn -if they still can identify the person, as the local project centre is advised to not include any identifiable information in the data collection.

Anonymisation takes place at the level of the local project centre. In case they keep identifying information on their side together with the project data, they are required by the study terms to delete any of that information prior to submission to the international study centre. Shall the latter receive data where still person id’s or other identifying data is still present, they immediately delete the whole (electronic) data set, no copy will be kept.

# STATISTICS AND METHODOLOGY

## 4.1. Statistical analysis plan

The representativeness of submitted data for a country will be assessed by the steering committee using the data from the participant survey. Indicators include the sum of coverage percent of all country contributors, plausible-completeness index (data volume times 4 being approximately equal to stated annual numbers of LDS surgeries), self-reported completeness, number and distribution of answers to “similarity to national average”. Representativeness will be assessed separately for single variables if indicated by participants with incomplete data parameters.

With the mandatory parameters, we will describe the characteristics of the treated patient population (age and gender distribution), and the distribution of LDS types and grades and performed treatments (type and involved levels). Descriptive statistics of the patient population overall and by country for countries considered to have representative data will be produced. Besides producing a map with the observed values, we also want to understand if there are country-wise trends in treating LDS patients. For this, we will only include countries with representative data and categorise patients into different diagnosis and treatment combinations. We want to answer the questions:

* Is the distribution of age and gender the same among countries and regions, or do statistically different patterns arise?
* Does the distribution of diagnosis and treatment combinations differ among countries or regions (after standardisation by age and gender)?
* What is the within-country variability of treatment patterns?

For the non-mandatory variables, we will re-assess if the representativeness of a country is still given. Those variables will be used to further describe the patient population and to adjust the treatment patterns further. By comparing the distribution of mandatory variables among the submissions with optional data and those without, we will estimate if the participants with the additional data may be significantly different to those without or if the additional data may be assumed to be representative of all participants. We will investigate the questions (all age and gender standardised):

* Are the distributions of the ASA status, the number of previous spine surgeries, the duration of symptoms, the BMI, and the smoker status the same among countries and regions, or do statistically different patterns arise?
* Are there patient clusters regarding the patient characteristics?
* Does the distribution of diagnosis and treatment combinations differ among countries or regions when corrected for age, gender, ASA status, previous spine surgeries, symptom duration, BMI and smoker status (each only if being a significant factor)?
* What is the variability of implants used?

To describe practice variation, we will use descriptive statistics to describe the distribution of treatment types per country and point estimates with 95% Confidence Intervals, or any other appropriate test to assess between-country variation. We will use logistic regressions or other appropriate models to identify predictors for each type of surgery and test if the country /region of treatment is a significant factor.

## 4.2. Handling of missing data

The scientific/steering committee will decide on how to deal with missing data. Missing data will be addressed and discussed in a methodological paper. If for a given country only few data are missing and no systematic bias can be determined by the meta data survey, it will be tested if methods like imputation would be applicable.

If missing data doesn’t fall into that category those variable and country wouldn’t be considered to be included in the analysis, to prevent bias.

# 5 Regulatory Aspects AND SAFETY

## 5.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki [3], the principles of Good Clinical Practice, as well as other locally relevant regulations. The project leader acknowledges his responsibilities as both the project leader and the Sponsor (if there is no separate Sponsor).

## 5.2 Notification of safety and protective measures

If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay.

The local project leader (applicant) and the local sponsor is promptly notified (within 24 hours) if immediate safety and protective measures must be taken during the conduct of the research project. The Ethics Committee will be notified of these measures and of the circumstances necessitating them within 7 days.

## 5.3 Serious events

No serious event[[9]](#footnote-10) can occur related to the research project, and no interruption or Ethics Committee involvement is needed. The project is purely observational and doesn’t modify treatment or care procedures.

In case of serious events concerning patients, hospital/institution protocols apply.

## 5.4 Amendments

Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval.

The following are considered to be substantial changes:

a. changes affecting the participants’ safety and health, or their rights and obligations;

b. changes to the protocol which concern the objectives of the research project;

c. a change of research site or conducting the research project at an additional site; or

d. a change of project leader or Sponsor.

## 5.5 End of project

The completion of the research project is defined by the last collection of health-related personal data.

# 6 FURTHER Aspects

## 6.1 Overall ethical considerations

The protocol of the Spine Atlas Initiative (SAI) has already been assessed by the Ethics Committee of Ostschweiz Switzerland (EKOS), BASEC submission no. AO\_2024-00111.
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, the project does not require prior/further approval from the ethics committee. Data protection must be ensured.

Attach the decision, you find it on <https://www.eurospine.org/spineatlas/registration/>

This application seeks approval for the anonymous data collection and submission by the local project leader.

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, behavioural, societal, medical school, guideline, or other reasons, and may show potential for improvement across multiple factors.

## 6.2 Risk-Benefit Assessment

Risk assessment

|  |  |  |  |
| --- | --- | --- | --- |
| **Identified Risks** | **Likelihood** | **Potential Impact/ Outcome** | **Risk Management/ Mitigating factors** |
| All risks related to the the surgery incl. travel risks, complications etc. for patients and researchers | n/a | n/a | Outside the scope of the study. In the study only patients are enrolled who already consented and underwent the surgery.  |
| Collection of informed consent in an unfamiliar location causing distress in patient | Medium | Patient:* Psychological stress

Researcher:* Anxiety about dealing with a complex situation
 | Offer to cease procedure, offer to postpone consent information, offer to have familiar persons present |
| Data collection taking place in anunfamiliar location with people notalready known to researcher | Low | Researcher: physical injury orpsychological harm | Data collection takes part at workplace of Researcher. Otherwise: Visit location prior to data collection to assess possible risks associated with built and social environment |
| Disclosure of information aboutpoor practice | n/a | n/a | No data concerning quality of practice is collected or submitted |
| Disclosure of unmet health or socialcare needs | n/a | n/a | Research only asks for recording and submission of routinely collected data and doesn’t interfere with any regular procedures |
| Research participant in danger ofharm to self or others | n/a | n/a | Hospital procedures apply. Research doesn’t interfere with regular procedures. |
| Local IT security breach resulting in disclosure of patient data | Low | Patient, Researcher: * Psychological stress

Immediate, urgent response required by service providers and legal experts.  | Local study center/applicant ensures that proper IT security protocols and protocols in case of breach are in place, and are followed. |
| Unauthorized disclosure of non-anonymised patient data to persons or institutions outside of the local study center | Low | Patient, Researcher: * Psychological stress

Immediate, urgent response required by service providers and legal experts. | Local study center/applicant* can’t enter those data, and ensures to delete the id column before submission if used (submission by excel template)
* adheres to the legal requirements set by the project protocol and/or Spine Tango terms&conditions
* uses the submission channel defined by the international project center

International project center* ensures to provide encrypted and secured channel for submission of data
* immediately deletes data that contains person identifying information and informs researcher
* Has a data security concept in place (swiss based secure data storage, limited & monitored access)
* Has only anonymous data
 |

Overall by risk category and accounting for mitigating measures

1. 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.
2. 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.
3. social risk: Minimal risk for invasion of privacy and loss of community standing, since data security measures and procedures are defined and in place.
4. 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.
5. 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.

Benefits include those mentioned in 6.1 Overall ethical considerations. Additionally, the hospitals will join a large network of European hospitals, which may lead to various research projects and collaborations to further the understanding and improve treatment for spine diseases. Each hospital and country will also receive a benchmarking report comparing their data with the pooled data of all other hospitals and countries.

The hospitals joining the Spine Tango platform may benefit from the platform for collecting additional data (physician-based as well as PROMs), receiving benchmarking reports, getting access to pooled international data, and thus, being empowered in quality assurance and research.

EUROSPINE and established Spine Registries advocate for the importance of disease registration in providing the necessary insight for the improvement of treatment strategy and quality insurance.

## 6.3Rationale for the inclusion of vulnerable participants

In this study, we only include patients aged 18 or older, and patients that are able to give informed consent for the data collection, either by themselves or a legal guardian. Also, only observational data after the treatment are included and the inclusion in the study doesn’t alter the treatment pathway in any kind.

Potential Inclusion of vulnerable participants:

|  |  |
| --- | --- |
| Children under 16  | EXCLUDED |
| Adults with learning disabilities | INCLUDED , based on informed consent by legal guardian |
| Adults with other forms of mental incapacity or mental illness |
| Adults in emergency situations | INCLUDED , based on informed consent |
| Prisoners or young offenders | EXCLUDED if <18years |
| Other vulnerable groups | INCLUDED , based on informed consent |
| No participants from any of the above groups | n/a |

Findings can be obtained without including vulnerable patients. However, not also including vulnerable patients may lead to distorted results and may lead to policies not taking into account specific needs of that patient population.

# 7 Quality CONTROL AND Data protection

## 7.1 Quality measures

The project leader 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.

The local project leader ensures data protection at the local project site.

Please describe measures taken for quality assurance and quality control: e.g. double data entry, project personnel trained on all important project related aspects, planned quality visits or independent data review, etc.

For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

Delete if non applicable.

## 7.2 Data recording and source data

Data will be recorded by the local project lead / local researchers.

1. Patients will be informed about the re-use collected data -for the hospital system and/or surgery reports- on their pathology, surgery characteristics, their age (in full years), gender and smoking status.

Delete if legislation in your country doesn’t require that step.

1. Patient and treatment data according to the project parameter list are collected from hospital or surgery reports and patient reports if necessary. Data is entered in a database
2. Metadata on the collected data and the local study centre is surveyed using a survey hosted on a password protected server of EUROSPINE.

To (1) The answer on whether a patient consented to the re-use of their data will be either done on paper or electronically. The electronic files are stored within the access restricted IT system of the local project centre.

For paper documentation, the data protection rules of the local project centre apply:

Delete paper collection if not applicable, otherwise describe the process i.e. The papers will be scanned, and destroyed by certified document destruction personnel./ Papers will be kept for xx years only accessible to the local project leader/ designated staff.

To (2) Choose one of the options below, delete the other.

\_\_\_\_\_\_ The data is entered in a research data base in Excel. The excel file is designed to only allow entering the available categorical levels for each variable, resp. tests if values are out of bound. The excel file is password protected in a way that only data entry is possible and predefined codes can’t be changed. The excel file doesn’t provide columns for patient identifying information, with the exception of a column where during data collection an id might be stored to avoid duplication of entries. This id-column must be deleted/emptied before submission, the column contains a reminder.

Indicate where the project data is stored (e.g. institution server, service provider, etc.).

\_\_\_\_\_\_ The data is entered in the SpineTango database. The software is accessible over secure online connection and is hosted by NEC Software Solutions based in the United Kingdom with servers in Switzerland. Data is access restricted and securely stored. The data owner is the local project leader, and the international project centre doesn’t have access to the data. The local leader will advise NEC if and when they may send the data as defined in the protocol, without patient identifying information to the international project centre.

To (3) Access to the survey will be granted individually and password protected. The data will be stored on certified EUROSPINE servers and only be accessible to authorized study personnel.

## 7.3 Confidentiality and coding

**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. Identifiable patient information not recorded.

The local study centre may use a patient identifiers during the data collection, but will delete them as soon as possible.

Describe according to your own/your hospitals policies: who stores the patient identification list, how the data is protected from unauthorized or accidental disclosure, from alteration, deletion, copying and theft. Describe the processes in place, which are essential to ensure traceability (audit trail). Mention password access and safety back-ups on storage media to prevent misuse.

## 7.4 Retention and destruction of project data and biological material

In the international project centre, the received and processed data will be kept separate from normal operations of the SAI team and it will be stored without personal data -that was removed at data collection- on a Swiss-based secure server with access control. Access will be only granted to direct SAI personnel.

Data will be kept for a period of 15 years after completion of the study.

In the local project center, the collected data will be stored for …

Specify time-period and location of archiving of the project data and documents (electronic and hard copies)

The combined data will be made available after the study period to participating and external researchers upon request.

# 8 Funding / Publication / declaration of Interest

## 8.1 Funding

The local project center (applicant) performs the data collection requiring primarily personnel resources. They will be provided by the individual local sponsor.

specify in more detail, if you receive specific/dedicated funding or funding from outside sources.

The SAI organisation and implementation are funded by EUROSPINE, the Spine Society of EUROPE. The data evaluation, presentation to the hospitals, and publication will be covered by the available Spine Tango’s budget of EUROSPINE.

## 8.2 Publication policy

The following authorship positions will be reserved:

* First author: PI
* Contributing authors:
	+ Study participants who significantly contributed to the manuscript
	+ One statistician
* Senior author: the author who has provided the most substantial intellectual contribution, which will be assessed by the first author and agreed upon by all authors

All other persons including all data contributors and steering committee members, as not included above, will be listed as the Spine Atlas Working Group (SAWG). Max. 2 persons per data contributor/institution will be named, while all other persons assisting in data contributions will be listed in the acknowledgements. For registries, more than 2 persons may be permitted on a case-by-case basis.

## 8.3 Data sharing policy

The collected data could be used in numerous analyses for the assessment of different hypotheses.

The authorship group as described in section 8.2 reserves the right to publish the first two main publications, one to describe the infrastructure and collected data, and one with the results of the data call 2025 as described in the study goals described above.

Subsequently, all involved hospitals and countries will have the equal right to use the pooled data for their research and publications. The standing steering committee (see SAI organisation) will review study proposals and control who does what to avoid duplication, maximise the use of the data and ensure high quality of the data usage. The Committee shall invite all interested colleagues from the SAWG to participate, with a priori a maximum of one representative per country. The SAWG must be included as contributing authorship.

The data pool of the data call will be made available to external researchers upon request, after participants had ample time to bring forward their own suggestions. The time frame will be defined by the SAI team depending on the volume of requests by participants and be approximately 6-12 months after publication of the data call results.

## 8.4 Conflicts of Interest

The main project centre and the Principal Investigator declare to have no conflicts of interests.

The local project centre and the local project leader (applicant) declare to have no conflicts of interests.

List your conflicts of interests here. Include also potential conflicts of interests and interests that may appear to be in conflict.

# REFERENCES

Replace [1] with the local regulations

1. Ordinance on Human Research with the Exception of Clinical trials (HRO)

<https://www.fedlex.admin.ch/eli/cc/2013/642/en>

1. Human Research Act (HRA)

<https://www.fedlex.admin.ch/eli/cc/2013/617/en>

1. Declaration of Helsinki

(<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects> )

1. STROBE statement ([doi:10.1016/j.jclinepi.2007.11.008](https://www.jclinepi.com/article/S0895-4356%2807%2900436-2/pdf))
1. Andersen MØ, Fritzell P, Eiskjaer SP, Lagerbäck T, Hägg O, Nordvall D, Lönne G, Solberg T, Jacobs W, van Hooff M, Gerdhem P, Gehrchen M. Surgical Treatment of Degenerative Disk Disease in Three Scandinavian Countries: An International Register Study Based on Three Merged National Spine Registers. Global Spine J. 2019 Dec;9(8):850-858. doi: 10.1177/2192568219838535. [↑](#footnote-ref-2)
2. Lønne G, Fritzell P, Hägg O, Nordvall D, Gerdhem P, Lagerbäck T, Andersen M, Eiskjaer S, Gehrchen M, Jacobs W, van Hooff ML, Solberg TK. Lumbar spinal stenosis: comparison of surgical practice variation and clinical outcome in three national spine registries. Spine J. 2019 Jan;19(1):41-49. doi: 10.1016/j.spinee.2018.05.028. [↑](#footnote-ref-3)
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5. Pearson et al. Spine patient outcomes research trial: radiographic predictors of clinical outcomes after operative or nonoperative treatment of degenerative spondylolisthesis. Spine (Phila Pa 1976) 2008;33:2759–2766. doi: 10.1097/BRS.0b013e31818e2d8b [↑](#footnote-ref-6)
6. Weinstein et al. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. J Bone Joint Surg Am. 2009;91:1295–1304. doi: 10.2106/JBJS.H.00913 [↑](#footnote-ref-7)
7. Kaiser et al. Decompression alone versus decompression with instrumented fusion in the treatment of lumbar degenerative spondylolisthesis: a systematic review and meta-analysis of randomised trials. Neurol Neurosurg Psychiatry 2023;94:657–666. doi:10.1136/jnnp-2022-330158 [↑](#footnote-ref-8)
8. Arimbawa et al. Comparison between Decompression Alone and with Additional Fusion for Degenerative Lumbar Spondylolisthesis: A Systematic Review and Meta-Analysis. Spine Surg Relat Res 2023; 7(1): 42-51

dx.doi.org/10.22603/ssrr.2022-0011 [↑](#footnote-ref-9)
9. A serious event is defined as any adverse event where it cannot be excluded, that the event is attributable to the sampling of biological material or the collection of health-related personal data, and which:
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;

b. results in permanent or significant incapacity or disability; or

c. is life-threatening or results in death. [↑](#footnote-ref-10)