

A-Post

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Dr. med. Susanne Driessen
Präsidentin

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St. Gallen, 21. November 2024 SD/ja

Clarification of responsibility

Request BASEC-ID	AO_2024-00111	EKOS 24/212
Project title	The Spine Atlas Initiative (SAI): Mapping spinal care services and practice variation across countries	
Submission date	13.11.2024	
Submitted documents	According to Application Form from 13.11.2024 via BASEC	
Applicant	PhD Christian Herrmann	
Ethics committee(s) concerned	Ethikkommission Ostschweiz (EKOS)	

Dear Mr. Herrmann

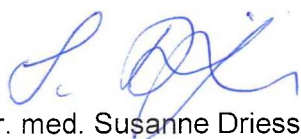
The planned project does not fall within the scope of the Human Research Act and therefore does not require the approval of the competent ethics committee before its implementation. The ethics committee EKOS is therefore not responsible for the evaluation of the project.

This statement does not convey any views of the ethics committee about the quality of the project. Data protection must be guaranteed.

Justification: As the project management receives the participants' data in anonymised form, the project is not subject to the HRA in accordance with Art. 2 (2c).

We hereby invoice the amount of 200 CHF, in accordance with the current swissethics fee schedule, for the review of this Clarification of responsibility.
The payment slip will be sent separately to the address you have provided.

Yours sincerely



Dr. med. Susanne Driessen
President



Thomas Schulz, Dipl. Biol.
Scientific Secretariat

Annex: Submitted documents

Submitted documents

PhD Christian Herrmann, EUROSPINE, Zürich

Dokument	Dok.Datum	Version
1. Cover Letter		
2024-11-04-cover-letter.docx	04/11/2024	
9. Participant information sheet and informed consent (ICF)		
informed-patient-consent.docx	19/09/2024	2024-09-19
10. Study plan (protocol)		
2024-10-30-signed-spine-atlas-initiative-mapping-healthcare-services-and-practice-variation-across-countries-v1-0.pdf		30/10/2024 v1.0
11. Investigator's CV		
christian-herrmann-cv-2024-06-17-en.pdf	17/06/2024	2024-06-17
12. Agreement between sponsor/commissioned institution/grant provider		
2024-09-19-sai-appendix1-terms-and-conditions.pdf	19/09/2024	2024-09-19
limited-trial-to-the-spine-tango-registry-general-terms-spine-atlas.pdf	19/09/2024	2024-09-19