Detailed description of the project, justification of its purpose, and feasibility assessment (1500 words):

Degenerative disc disease of the spine is one of the most common causes of lumbosacral pain syndromes and disability, and its prevalence increases with age. It is projected that in an aging society, the treatment of degenerative spinal disease will become one of the major challenges for healthcare systems.
Discogenic pain is most often caused by degeneration of the intervertebral disc due to changes in its structure and function.
Conservative treatment, including analgesics, anti-inflammatory drugs, and rehabilitation, is used first.
If conservative treatment fails, surgical methods are used — including decompression of neural structures with or without fusion of adjacent vertebral bodies.

One of the traditional surgical methods for treating discogenic pain is the **transforaminal lumbar interbody fusion (open-TLIF)** procedure, which involves discectomy and insertion of an interbody implant via a transforaminal approach, followed by pedicle stabilization using an “open” technique.
Minimally invasive techniques are increasingly being used in spinal surgery.
An example of such an approach is the **minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF or mini-TLIF)** procedure, in which the interbody implant is inserted transforaminally through a much smaller incision, and the stabilizing screws are inserted percutaneously using a transpedicular technique.
The MIS-TLIF method is an alternative to open-TLIF in the treatment of lumbosacral discopathy.

Numerous scientific studies indicate that MIS-TLIF is associated with less tissue trauma, reduced blood loss, shorter hospitalization, and less postoperative pain than open-TLIF.
Another minimally invasive procedure used in the treatment of lumbosacral discopathy is **midline lumbar interbody fusion (MIDLIF)**.
In MIDLIF, unlike MIS-TLIF, the skin incision is made in the midline, and the screws are inserted along a trajectory that uses the greatest volume of the cortical bone of the vertebral body.
Many studies have demonstrated better treatment outcomes, fewer complications, and greater cost-effectiveness in MIDLIF compared to open-TLIF.
Some scientific reports also suggest that MIDLIF is a safe alternative to MIS-TLIF for the treatment of degenerative spine disease.

There is a lack of high-quality prospective scientific studies comparing MIS-TLIF and MIDLIF in the treatment of lumbar spine discopathy.

Therefore, the aim of this project is to conduct a **prospective, randomized study comparing the results, complications, and treatment costs** between the mini-TLIF and MIDLIF surgical methods in the treatment of lumbosacral discopathy.

Study assumptions:

a. The study may bring health benefits to the participants, as participation ensures the use of minimally invasive surgical techniques currently recommended in spinal surgery.
b. The results will help determine the best surgical approach to lumbosacral discopathy.
c. The project involves very low risk for participants. The indications are the same as in routine management.
d. As the study risk is minimal, the potential benefits outweigh any possible risks.
e. The study will include only adult participants.

EXPECTED BENEFITS

1. **Expected therapeutic and/or cognitive benefits for participants:**
    a. Participation guarantees the use of established, minimally invasive methods currently recommended in spinal surgery.
    b. Participation contributes to the development of knowledge regarding these surgical methods.
    c. The study involves minimal risk, and surgical indications are identical to routine practice.
2. **Selected bibliography (up to 5 references):**

    a. Chou, R. *Low Back Pain.* Ann Intern Med 2021, 174(8), ITC113–ITC128.
    b. Wu, P.H., Kim, H.S., Jang, I.-T. *Intervertebral Disc Diseases PART 2: A Review of the Current Diagnostic and Treatment Strategies.* Int J Mol Sci 2020, 21(6), 2135.
    c. Mohd Isa, I.L. et al. *Discogenic Low Back Pain: Anatomy, Pathophysiology and Treatments.* Int J Mol Sci 2022, 24(1), 208.
    d. Mobbs, R.J. et al. *Lumbar Interbody Fusion: Techniques, Indications and Comparison of Interbody Fusion Options.* J Spine Surg 2015, 1(1), 2–18.
    e. Silva, F. et al. *Midline Lumbar Interbody Fusion (MIDLIF) with Cortical Screws: Initial Experience and Learning Curve.* Acta Neurochir (Wien) 2019, 161(12), 2415–2420.

INFORMED CONSENT OF THE PATIENT AND/OR LEGAL REPRESENTATIVES

FOR PARTICIPATION IN A MEDICAL EXPERIMENT AND PROCESSING OF PERSONAL DATA

Title of the study:
Comparison of results, complications, and treatment costs between the mini-TLIF and MIDLIF surgical methods in the treatment of lumbosacral discopathy – a prospective, randomized study.

Participant's details:
Name: _____
Surname: _____
PESEL: _____
(If no PESEL, another ID document name and number: _____)

Parent(s)/legal guardian(s) details (for minors):
Name: _____
Surname: _____
PESEL/ID: _____

(In case of minors: both legal guardians must provide written consent. For children under 13, the parents sign; for ages 13–18, both the minor and parents sign.)

Declaration:
I have been informed by _____ about the purpose, duration, procedures, expected benefits, possible risks, and inconveniences related to this study, as well as about my rights and obligations.
I have read and understood the patient information sheet for this clinical study and received satisfactory answers to my questions.
I understand that participation is voluntary and that I may withdraw at any time without giving a reason and without any negative consequences for my healthcare or treatment.
I received a signed copy of this consent form and the patient information sheet.
I was informed about the civil liability insurance policy (No. UG 500004675/2022, issued by Wiener TU S.A. Vienna Insurance Group, Warsaw).

I hereby give my full, informed, and voluntary consent to participate in this medical experiment/study.

Participant (name, signature, date)
Parent/legal guardian(s) (name, signature, date)
Researcher obtaining consent (name, signature, date)

CONSENT FOR PERSONAL DATA PROCESSING

Title of the study:
Comparison of results, complications, and treatment costs between the mini-TLIF and MIDLIF surgical methods in the treatment of lumbosacral discopathy – a prospective, randomized study.

I consent to the processing of my personal data for this study in accordance with applicable Polish and EU law (Regulation (EU) 2016/679 – GDPR).
I consent to the transfer of my anonymized data to other countries, both within and outside Europe.
Data will be accessible only in anonymized form to authorized entities (e.g., Ministry of Health representatives, study sponsor, FDA, ethics committees).

I have been informed that:
a. The data controller is the Provincial Multispecialist Center of Oncology and Traumatology named after M. Kopernik in Łódź, ul. Pabianicka 62, 93-513 Łódź.
b. The Data Protection Officer is Mr. Tomasz Zdzienicki (email: iod@kopernik.lodz.pl).
c. My data will be processed for the purpose of conducting the above-mentioned study under Art. 9(2)(a) GDPR.
d. I have the right to access, correct, delete, restrict processing, and file a complaint to the Data Protection Authority.

I was informed that in case of withdrawal from the study, the data collected so far may still be used as part of the research database.

Participant (name, signature, date)
Parent/legal guardian(s) (name, signature, date)

DECLARATION OF ACCEPTANCE OF CIVIL LIABILITY INSURANCE TERMS

Study title:
Comparison of results, complications, and treatment costs between the mini-TLIF and MIDLIF surgical methods in the treatment of lumbosacral discopathy – a prospective, randomized study.

As a participant in the above medical experiment, I confirm that I have read and accept the terms of the civil liability insurance covering the entity conducting the experiment

for damages caused to participants or affected individuals, under the insurance policy concluded with Wiener TU S.A. Vienna Insurance Group, Warsaw.
I am aware that the entity conducting the medical experiment will be covered by insurance throughout the study in accordance with Polish law.
After reading the contents of the policy, I accept its terms.

Participant (name, signature, date)
Legal representative (if applicable) (name, signature, date)
Researcher (name, signature, date)