MegaPJI Data Use Agreement

Parties and recitals

This Agreement sets the terms under which a participating centre shares anonymised patient data with the MegaPJI coordinating centre.

Between

1. **Data Recipient (Coordinating Centre):** Acıbadem University, Korhan Özkan Orthopedic Oncology Study Group, Kerem Aydınlar Kampüsü, Kayışdağı Caddesi No. 32, 34752 Ataşehir, Istanbul, Türkiye; represented by Prof. Dr. Korhan Özkan (Principal Investigator).
2. **Data Provider (Participating Centre):** [Institution name], [Department], [Address], [Country]; represented by [Name, title] (Local Principal Investigator). Centre code: [e.g. RIZZ].

Each is a “Party” and together the “Parties”.

Recitals

- The Data Recipient coordinates the international multicentre retrospective study “Microbiological Profile, Antibiotic Resistance Patterns, and Clinical Outcomes of Megaprosthesis Infections” (MegaPJI), approved by the Acıbadem University Medical Research Assessment Committee (ATADEK 2026-14/670, 24 September 2026).
- The Data Provider treats patients with megaprostheses and holds clinical data relevant to the Study.
- The Parties wish to share data for the Study in a manner that protects patient privacy and complies with applicable law.

1. Definitions

- **Study:** the MegaPJI study as described in the MegaPJI Study Protocol (version 1.0, 3 November 2026) and any approved amendments.
- **Study Data:** the pseudonymised patient-level data entered by the Data Provider in the MegaPJI datasheet and specified in Annex A.
- **Pseudonymised data:** data that cannot be attributed to an individual without a separate key, which is held only by the Data Provider.
- **Identification Key:** the list linking study codes (e.g. RIZZ-01) to patient identities. It remains at the Data Provider and is never transferred.
- **Applicable Data Protection Law:** the EU General Data Protection Regulation (EU) 2016/679 (GDPR), the Turkish Personal Data Protection Law No. 6698 (KVKK), and any other data protection law applying to either Party.
- **Steering Committee:** the Study’s principal investigators (Prof. Dr. Korhan Özkan, Prof. Dr. Santiago A. Lozano-Calderón, Dr. Andrea Sambri) and the data coordinator (Dr. Halil İbrahim Bulut).

2. Purpose and permitted use

The Data Recipient may use the Study Data only for the Study as set out in the Protocol.

1. Permitted uses: describing organisms and antibiotic resistance patterns of megaprosthesis infections, analysing risk factors, treatments and outcomes, and comparing regions (Europe vs the Americas, Europe vs Asia).
2. Any use beyond the Protocol, including secondary analyses, requires prior written approval of the Steering Committee and remains subject to this Agreement.
3. The Study Data will not be sold, licensed or used for commercial purposes.
4. The Study Data will not be shared with any third party outside the Study team, except in aggregated form in publications, or as required by law.

3. Obligations of the Data Provider

The Data Provider is responsible for sending only lawfully obtained, properly pseudonymised data.

1. Obtain local ethics approval or a documented waiver where its institution or national law requires one, before transferring any data.
2. Ensure a lawful basis for sharing the data under Applicable Data Protection Law, including any required consent or waiver of consent.
3. Remove all direct identifiers before transfer: names, initials, dates of birth, hospital record numbers, national ID numbers, addresses and contact details.
4. Use pseudonymised study codes (centre code + sequential number) and age in years instead of date of birth.
5. Keep the Identification Key securely at its own centre and never transfer it.
6. Make reasonable efforts to ensure the data are accurate and complete, and answer data queries from the Data Recipient.
7. Inform the Data Recipient promptly of any error found in data already sent.

4. Obligations of the Data Recipient

The Data Recipient keeps the Study Data confidential and secure, and will never try to identify any patient.

1. Not attempt to re-identify any individual, nor link the Study Data with other datasets in a way that could identify individuals.
2. Restrict access to members of the Study team who need it for the Study and are bound by confidentiality.
3. Store the Study Data on password-protected, access-restricted systems, with appropriate technical and organisational security measures.
4. Report results only in aggregated form; no table, figure or text will allow identification of an individual patient. Cells with very small numbers will be masked.
5. Notify the Data Provider without undue delay, and within 72 hours where required by law, of any data breach involving its data.
6. Process the data in compliance with Applicable Data Protection Law.

5. Data transfer, storage, retention and destruction

Data are sent once as a pseudonymised Excel file, kept for 3 years after the final publication, then destroyed.

1. **Transfer:** the Data Provider sends the completed datasheet, named with its centre code (e.g. MegaPJI_RIZZ.xlsx), to drhbulut@icloud.com. A password-protected file is recommended, with the password sent by a separate channel.
2. **Storage:** the merged database is held at the coordinating centre at Acıbadem University, Istanbul, Türkiye.
3. **International transfer:** where data move from the EU/EEA or another jurisdiction to Türkiye, the Parties rely on the data being pseudonymised and, where required, on appropriate safeguards (such as the EU Standard Contractual Clauses) under Applicable Data Protection Law.
4. **Retention:** the Study Data are kept for 3 years after the final Study publication, or longer if required by law or by a journal for verification.
5. **Destruction:** after the retention period, or on termination under section 7, the Data Recipient securely deletes the Study Data and confirms deletion in writing on request.
6. **Withdrawal:** the Data Provider may withdraw its data before the database is locked for analysis; data already included in completed analyses or publications cannot be withdrawn.

6. Publication and authorship

The Data Provider earns co-authorship by the number of eligible patients it contributes, and pooled results are published jointly.

Eligible patients contributed	Co-authors per centre
10–24	3
25–49	4
50–99	5
100 or more	6

1. Centres contributing fewer than 10 eligible patients are acknowledged as MegaPJI Study Group collaborators.
2. Named co-authors must meet ICMJE authorship criteria.
3. The Data Recipient circulates each manuscript draft to co-authors for review before submission.
4. The Data Provider’s institution is acknowledged in every publication using its data.

7. Term, termination and general provisions

The Agreement runs from signature until the Study Data are destroyed, and either Party may end it with 30 days’ written notice.

1. **Term:** effective on the date of the last signature, and in force until the Study Data have been destroyed under section 5.

2. **Termination:** either Party may terminate with 30 days' written notice, or immediately if the other Party materially breaches this Agreement. Sections 4, 5 and 6 survive termination.
3. **Ownership:** the Data Provider keeps ownership of its data. The pooled database and Study results belong jointly to the Study Group.
4. **No payment:** no fee is paid by either Party for the data.
5. **Liability:** each Party is responsible for its own compliance with Applicable Data Protection Law and for its own acts and omissions, to the extent permitted by law.
6. **Governing law:** this Agreement is governed by the laws of the Republic of Türkiye, without prejudice to mandatory data protection law applying to the Data Provider. Disputes are first resolved amicably; failing that, by the courts of Istanbul.
7. **Amendments:** changes are valid only in writing and signed by both Parties.
8. **Counterparts:** the Agreement may be signed electronically and in counterparts.

8. Signatures

Signed by the authorised representatives of both Parties.

	Data Recipient (Coordinating Centre)	Data Provider (Participating Centre)
Institution	Acıbadem University, Korhan Özkan Orthopedic Oncology Study Group	
Name	Prof. Dr. Korhan Özkan	
Role	Principal Investigator	Local Principal Investigator
Signature	K.OZKAN	
Date	3.11.2026	

	Data Coordinator	Institutional representative (if required by Data Provider)
Name	Dr. Halil İbrahim Bulut	
Role	Data Coordinator, MegaPJI Study	
Signature	Drhbulut	
Date	3.11.2026	

Annex A — Data specification

The Study Data are the pseudonymised variables of the MegaPJI datasheet (v4.2), one row per patient for the first PJI episode of the megaprosthesis.

- **Identification:** centre code, country, pseudonymised study code.

- **Patient and comorbidity:** sex, age in years, BMI, smoking, Charlson components, ASA score, preoperative laboratory values.
- **Tumour and treatment history:** indication, histology, chemotherapy, radiotherapy, previous operations.
- **Index surgery and postoperative course:** site, implant, fixation, coating, prophylaxis, soft-tissue reconstruction, operative details, complications.
- **PJI episode and microbiology:** diagnostic criteria, McPherson stage, laboratory markers, cultures, up to two organisms with resistance categories and antibiograms.
- **Treatment and outcome:** surgical strategy, spacers, antibiotics, infection status, recurrence, salvage procedures, failures, follow-up, vital status, MSTS score.

Dates (index surgery, PJI diagnosis, PJI surgery, recurrence, last follow-up) are used only to calculate intervals and are never published.

Excluded data: names, initials, date of birth, hospital record numbers, national ID numbers, addresses, contact details, images and any other direct identifier.