Informed Consent Form (ICF) for Data Registration on Shoulder and Elbow Pathology

Dear Participant,

You are invited to have the data related to the treatment of your shoulder or elbow condition registered in a dedicated database. This database is established by SECEC (Société Européenne de Chirurgie de l'Epaule et du Coude), also known as the European Society for Surgery of the Shoulder and the Elbow (ESSSE), with its registration office at 69 Boulevard des Canuts, Lyon 69004, France.

The purpose of this database is to measure and register data to offer feedback for monitoring of care and improvement of the quality of healthcare.

Before deciding whether to give your consent, please read this information carefully and discuss any questions with your physician or research team. This is part of the process known as "informed consent." If you agree to participate, please sign the form at the end of this document.

Participant Information

Subject: Consent for the registration of data related to shoulder and/or elbow pathology in a SECEC registry

You are invited to give your consent for the storage of your data related to shoulder and/or elbow pathology in a secure SECEC registry. Please read the following information carefully. You are under no obligation to participate.

Purpose of Data Registration

Your data related to your shoulder and/or elbow condition—such as test results, treatments, and possibly additional information (e.g. via questionnaires)—will be stored to support scientific research and healthcare improvement.

Your data may be used for:
- Evaluating treatment outcomes
- Education and training of healthcare professionals
- Scientific publications or presentations (always anonymized)
- Future research (subject to ethics committee approval)

Your Participation

- Your participation is completely voluntary.
- You may be asked to complete a questionnaire, either in writing or digitally via a secure platform.
- You may withdraw your consent at any time, without providing a reason and, without any consequences for your treatment or your relationship with your healthcare provider.

Confidentiality and Data Protection

Your personal data will be handled in compliance with:

- The EU General Data Protection Regulation (GDPR)
- National laws on privacy and patient rights
- Medical Ethics Committee, national and international
- International Conference on Harmonization of Good Clinical Practice (ICH/GCP)
- The Declaration of Helsinki.

All data will be stored in pseudonymized form: your identity is known only to your treating physician or a designated authorized person. The data controller is the institution of the lead researcher. Members of the local research team will have access to your personal data. Pseudonymized data may later be anonymized and possibly shared with academic partners nationally or internationally, always with prior ethics committee approval. Your data will be securely stored for **a minimum of 20 years**.

Your Rights

- You have the right to access your personal data.
- You may request the correction of inaccurate information.
- You may contact the Data Protection Officer for more information about data protection.

Insurance

In the event of any harm or injury due to participation, you are insured under applicable legal regulations.

Contact Information

For questions about this registration or your rights, please contact:
- Researcher's name: [to be completed]
- Email / phone number: [to be completed]
- Institution: [to be completed]

Consent Declaration

Please tick the boxes if you agree:

☐ I have read and understood the participant information sheet.
☐ I voluntarily agree to the registration of my data in the SECEC registry.

☐ I understand that I can withdraw my consent at any time.
☐ I consent to the use of my email address for receiving questionnaires.
☐ I agree to share my anonymized data with academic institutions.
☐ I agree that my anonymized data may be shared with commercial partners (subject to ethics approval).

Participant’s full name: .....

Signature: .....

Date: .....

Researcher’s full name: .....

Signature: .....

Date: .....

Note: Please keep a signed copy for your own records. A second copy will be stored by the research team.