ERN CPMS 2.0 PATIENT CONSENT FORM EU

[Name of the hospital]

WHAT ARE THE EUROPEAN REFERENCE NETWORKS AND HOW CAN THEY HELP YOU?

European Reference Networks (ERNs) are networks of healthcare professionals working with rare diseases across Europe. ERNs allow healthcare professionals to discuss rare/complex clinical cases like yours, helping your doctors to correctly diagnose or establish a care plan for your health problem.

For an ERN to advise your doctors, the relevant data collected about you in this hospital must be shared with healthcare professionals in other hospitals, some of which may be located in other EU countries.

WHICH DATA ARE PROCESSED?

If you give explicit consent, your health data will be pseudonymised and uploaded to a secure EU based IT platform. Only pseudonymised medical data relevant for the purpose of diagnosis and treatment of your disease will be uploaded. This may include age, sex, medical images, laboratory reports and biological sample data. It may also include your clinical history.

This happens in a secure IT platform that ensures protection of your data and your privacy, which is used by the healthcare professionals of the ERNs to participate remotely in the discussion of your case.

After the discussion is closed, your doctor may download an outcome report with the relevant advice.

Your case will be discussed by EU experts inside the IT platform only if you consent. However, your care remains the responsibility of your doctors in this hospital and even if you choose not to give consent, your doctors will continue to care for you to the best of their knowledge.

If you gave consent for your case to be discussed and you accept to contribute to the advancement of knowledge on rare cases like yours, you may give additional consents, as specified below. Both are optional and do not affect the discussion of your case for diagnosis and treatment:

a) if you give explicit consent for your clinical case to be used for educational purposes, your data will be fully anonymised and may be used to educate other healthcare professionals, including young doctors or medical students, for advancing their knowledge and education on rare cases like yours.

b) if you give explicit consent for your data to be exported to ERN registries, your pseudonymised data may be exported to registries of rare/complex diseases, to be used for scientific research.

WHAT ARE YOUR RIGHTS?

Your data will be processed in compliance with EU data protection legislation, including Regulation 2016/679 (GDPR) and Regulation (EU) 2018/1725. The European Commission and each EU healthcare provider processing patient data in the IT platform are joint controllers.

You have the right to give or refuse your consent. You can also withdraw your consent at any time, but please note that the withdrawal of your consent will not affect the lawfulness of the data processed before the withdrawal.

You have the right to request and receive more information about the data that is shared, to access your data and to request the correction of any errors. You also have the right to request the erasure of your data. The point of contact for exercising your rights is your healthcare provider. You also have the right to lodge a complaint with a national supervisory authority or the European Data Protection Supervisor.

Your data will be retained only for as long as necessary for the purposes to which you consented, with a review of the necessity to retain it at least every 15 years.

Primary consent (diagnosis and treatment):

The primary consent is mandatory for your case to be discussed.

I consent to my pseudonymised data being shared for my diagnosis and treatment. I am aware that my data may be shared with healthcare professionals in other hospitals, in some cases in other EU countries, so that they can discuss my case and advise my treating doctors.	☐ Yes ☐ No

Secondary consents (education, export to registries):

If you gave the primary consent above AND you accept to contribute to the advancement of knowledge on rare cases like yours, you may give additional consents, as specified below. Both are optional and do not affect the discussion of your case for diagnosis and treatment:

Consent for education: I consent to my clinical case being fully anonymised and then used for educational purposes.	☐ Yes ☐ No
Consent for export to registries: I consent to my pseudonymised clinical data being exported to ERN registries for the purpose of scientific research.	☐ Yes ☐ No

PATIENT DETAILS:

First and last name: _____

☐ I am the patient.

☐ I am_____ and I witnessed that the patient was not able to sign by his/her means and gave consent by the following means: _____

☐ I am a parent/guardian of the patient, or I have power of attorney and I am attaching the supporting documents to this form.

WITNESS/PARENT/GUARDIAN/ATTORNEY DETAILS:

First and last name: _____

Date: _____ Signature: _____

CONTACT DETAILS OF THE JOINT CONTROLLERS:

Healthcare provider:

- [Name of the hospital]
- [Address of the hospital]
- Data Protection Officer contact: [email address]
- National Supervisory authority contact: [email address]

European Commission:

- Directorate-General for Health and Food Safety
- 1049 Bruxelles/Brussel, Belgium
- Data Protection Officer contact: data-protection-officer@ec.europa.eu
- European Data Protection Supervisor: edps@edps.europa.eu

ERN CPMS 2.0

Patient consent form template EU

Instructions for healthcare providers

According to the ERN legal base, each healthcare provider (HCP) acts as joint data controller for patient information processed in the context of the work of the ERNs using the CPMS 2.0 platform. As joint controller each HCP is responsible for creating and managing their own patient consent form and archiving all signed forms. The National supervisory authorities oversee compliance of patient consent forms with the General Data Protection Regulation (GDPR). The European Commission recommends using this template, which is aligned with all functionalities of CPMS 2.0. However, the choice to use this template or another one remains at the discretion of each HCP.

Regardless of the chosen template, the patient consent form must include the official contact details for both joint data controllers: the HCP and the European Commission. The primary consent (consent for care) is required for enrolling patients in CPMS 2.0 and allowing discussion of their cases. The secondary consents (education and export to registries) are optional and not mandatory for patient enrolment and case discussion.

These instructions are separate from the template itself. For any questions, please contact sante-ern@ec.europa.eu.

Instructions for healthcare professionals

1. Before signing the form, the patient should be well aware of its contents. If needed, the form should be read aloud and explained to the patient. Any questions the patient may have should be answered appropriately.

2. If the patient is unable to sign the form, consent can be given by other means, in front of a witness (e.g. by speaking, nodding, waving, etc.). The witness must be chosen by the patient and cannot be a hospital employee. The witness must:
    a) state their capacity (relative/friend of the patient, lawyer, etc.);
    b) explain by which means the patient gave their consent;
    c) date and sign the consent form.

3. If the patient is unable to give consent, a third party (the patient's parent/legal guardian or a person with power of attorney) can give consent on the patient's behalf. This person must:
    a) declare their status (parent/legal guardian/power of attorney);
    b) date and sign the consent form;
    c) attach the relevant supporting documents.

4. Once signed, this form shall not be uploaded to the platform or sent to the European Commission, but rather archived by the HCP in accordance with the applicable data protection regulations.