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:
	1. state their capacity (relative/friend of the patient, lawyer, etc.);
	2. explain by which means the patient gave their consent;
	3. 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:
4. declare their status (parent/legal guardian/power of attorney);
5. date and sign the consent form;
6. attach the relevant supporting documents.
7. 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.