

## **CPMS 2.0 DATA PROTECTION**







## ERN-RND — LEGAL BASIS AND "JOINT CONTROLLERSHIP"

• For all ERN activities a **joint controllership** was put in place in the legal base of the ERNs. Joint controllers are the European Commission and every HCP (= ERN member hospital).



- Joint controllers have different responsibilities.
   The allocation of responsibilities between the European Commission and each HCP is defined in the legal base of the ERNs (see Annex 1 of the <u>COMMISSION IMPLEMENTING DECISION</u> (EU) 2019/1269, of 26 July 2019, amending Implementing Decision 2014/287/EU).
- Summary: the European Commission is responsible for all the processing happening inside the IT platform (= CPMS 2.0) and each HCP (= ERN member hospital) is responsible for all the processing happening outside the IT platform!
- The European Commission has ensured that data processing inside the IT-platform is GDPR-compliant and safe. A Data Protection Impact Assessment (DPIA) for the IT-platform CPMS 2.0 has been conducted.
- The European Commision provides more information here (requires CPMS access): Supporting Documents - CPMS 2.0



## LOCAL/NATIONAL RESPONSIBILITIES

The HCP's (= member hospital) clinicians, not the ERN or European Commission, are responsible for the compliance of their own activities with all applicable rules, laws or regulations of their home institution and country.



- This includes protecting their **patient's data** according to the EU's General Data Protection Regulation (GDPR) and their **specific local and national data protection regulations**.
- If **no local processes and permissions** are **in place** concerning CPMS 2.0 usage, it is the **HCP's responsibility** to define/obtain them. This includes how to **obtain the patient's consent**, and to **assess the need** for a local Data Privacy Impact Assessment (**DPIA**) for data **processing outside the IT platform**.
- ERN-RND helpdesk is **not responsible** for local tasks, but **may support** them, e.g. provide the CPMS 2.0 **Privacy Statement**, the IT-platform's **DPIA outcomes** and **consent form templates**.
- Suggestion: refer to the hospital's ERN representatives to learn if these tasks have been conducted and what protocol to follow, and to the hospital's Data protection officer for support if not conducted yet.



the European Union

## **OBTAINING PATIENT CONSENT**

- Obtaining appropriate consent for data transfer / discussion via CPMS from a patient is a requirement according to the EU's General Data Protection Regulation (GDPR).
- Each HCP (= member hospital) must define for themselves how to obtain patient's
  informed consent for a CPMS 2.0 consultation, in accordance with all applicable rules,
  laws or regulations of their home institution and country.
- ERN-RND CPMS helpdesk can provide you with a GDPR-compliant consent form template (translated in the 24 official EU languages) which however requires local completion (as is the GDPR requirement) and alignment/approval according to local procedures!
- ERN-RND CPMS Helpdesk is not informed about local procedures and local consent forms for CPMS 2.0. We suggest to contact your local ERN-RND representative and/or Data Protection officer if in doubt!



