

Legal Advisor proposal (for EJP RD - AREB)

The Advisory Regulatory and Ethics Board (AREB) is seeking to include a member with Legal Expertise. The member shall be part of the EJP RD Consortium.

Please see the AREB description below and click on next to submit your proposal.

AREB Description & Operational work

In order to ensure compliance of the project and its activities with ethical and regulatory requirements, a project 'Advisory Regulatory Ethics Board' (AREB) has been set up in 2019. It is composed of internal EJP RD ethics and regulatory experts, including members with recognised expertise from involved European Research Infrastructures. It is in charge of ensuring compliance with all international and European relevant rules and ethical norms, including but not limited to fundamental and patients' rights, data management, protection and confidentiality, of the EJP RD as well as of the projects founded within EJP RD.

In particular, the AREB is in charge of overseeing ethical issues and regulatory procedures envisaged in the EJP RD four Pillars and by assisting partners. Specifically, the AREB has to:

- Collaborate with Pillar 1 to ensure that the Joint Transnational Calls for collaborative research projects include all relevant requirements in the call text and guidelines for applicants;
- Verify that the collaborative research projects funded in Pillar 1 as well as pilot project/proof of concept foreseen in Pillars 2 and 4 activities are regulatory- and ethically-compliant and that they properly address patient rights and the necessary regulatory procedures, e.g. ethical approval, authorisation from competent authorities, regulatory advice from EMA or national agencies (Scientific Advice/Protocol Assistance, EMA qualification opinion, certification of ATMP quality etc.), Paediatric Investigation Plan (PIP) or waiver, pharmacovigilance obligations;
- Ensure that data handling carried out in Pillars 2 and 4 and projects funded in Pillar 1 comply with GDPR and national laws, including requirement for special declarations or authorisations;
- Inform and update EJP RD consortium partners on the advancements, changes and news from the regulatory, ethical and legal framework during the yearly EJP RD Consortium meetings;
- Support EJP RD partners with ethical and legal advice whenever requested;

- Provide recommendations in case of detection of possible gap in the regulatory/ethical/legal framework to be applied in multi-national biomedical research in the context of the EJP RD;
- Ensure that the H2020 framework for ethics is fully applied to the planned subsidiary projects, and the ethics management of these should be carried out within the H2020 framework.

The AREB operates as follows:

- Members are invited to participate in periodical TCs (every two months).
- Members participate in annual face to-face meetings. The AREB meetings, lasting 2-3 hours, are scheduled before or after the annual Executive Committee meeting in July. Additional meetings may be scheduled upon request of the majority of the AREB members in order to address possible specific topics.
- The AREB prepares periodical reports (D4.2, D4.3, D4.4, D4.5).
- The AREB strictly works with the Ethics Advisor and the project operational group.
- The AREB revises documents and deliverables with reference to regulatory and ethical aspects upon request by WP/Task Leaders and provides specific feedback to possible emerging issues.
- The AREB informs and updates the EJP RD consortium partners on the advancements, changes and news from the regulatory, ethical and legal framework during the yearly EJP RD Consortium meetings.

EXPECTED EFFORT (for the whole duration of the project): 0,8 PM

Legal Advisor Proposal

1. First Name of the survey respondent

2. Last name of the survey respondent

3. Institution of the survey respondent (as named in EJP RD)

4. Please indicate possible candidates with legal expertise, from your institution, you suggest to include in the AREB (first name, last name, institution, email address)

The candidate has to be chosen among members of institutions already part of the EJPRD Consortium