



Rare Disease Patient and Ethics Council (RD-PEC)

TERMS OF REFERENCE





About the Rare Disease Patient and Ethics Council (RD-PEC)

The Rare Disease Patient and Ethics Council (RD-PEC) identifies and examines ethical and social aspects of the work taking place in the context of RD-Connect, NeurOmics and EURenOmics to ensure that practical ethical issues are handled in a carefully planned process. The aim of each project is as follows:

- **RD-Connect:** to create an integrated platform connecting databases, registries, biobanks and clinical bioinformatics for rare disease research.
- **NeurOmics:** to revolutionize diagnostics and develop new treatments for major neuromuscular and neurodegenerative diseases.
- **EURenOmics:** to develop novel tools that will enable faster and more accurate diagnoses, predict the disease course and the efficacy of available treatments for rare kidney diseases.

The RD-PEC will provide a forum for formulation of responses to questions posted by all stakeholders as well as reviewing the guidelines produced by the Ethical, Legal and Social Issues (ELSI) work package before approval by the Governing Board (GB). Questions from can be submitted to the RD-PEC via the RD-Connect [website](#).



Objectives and responsibilities of the RD-PEC

- The RD-PEC is a high-level advisory group offering advice and guidance on ethical, social and participatory issues arising within NeurOmics, EURenOmics and RD Connect.
- It will be the responsibility of individual ethics and patient boards/councils within each project to keep well informed about the ethical regulations relevant to their own area of expertise.
- The RD-PEC will be responsive to specific requests for advice, clarification and information from project partners and those with an interest in the work of the projects.
- Where appropriate the RD-PEC, in conjunction with project partners, and any relevant external agencies, will contribute to maintaining researchers' awareness of ethical issues.
- The RD-PEC will contribute towards a project ethics and governance policy and advise on, and where appropriate, contribute to the ethics training of project partners.
- Communication will be maintained between RD-PEC members by a members' only distribution list. Communication with the wider rare disease community will be via common e-mail distribution list and via the project web-sites.
- Training for RD-PEC members will be initiated from expertise within the RD-PEC membership.
- Reporting responsibilities are to the Executive Management Committees (EMC) of each project, in the form of minutes of each RD-PEC meeting and the minimum of one annual report to the Executive Committee (EC).
- Privacy and confidentiality – it is agreed that in the interests of openness the business of the RD-PEC may be openly discussed outside of the RD-PEC group unless explicit agreement has been reached that an item or issue is confidential. Minutes of the meetings will be copied to the EMC and may be available for wider disclosure on request.



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- It should be presumed that public statements regarding the RD-PEC activities are made in the spirit of corporate representation and such statements must be clearly distinguished from any statements made in a personal capacity.

Structure and membership of the RD-PEC

Membership of the RD-PEC is voluntary and includes members of the Ethics Boards and Patient Councils of RD-Connect, NeurOmics and EUrenOmics, as well as some co-opted members. The RD-PEC is chaired by the RD-Connect ELSI work package leader and will work closely with the EMC and report to the GB. The RD-PEC reports will be part of the contractual periodic reports due to the EC.

Outputs of the RD-PEC

The RD-PEC will make use of a bottom-up approach, generating knowledge triggered by questions submitted via the RD-Connect website from Stakeholders. Each question will be discussed amongst the RD-PEC and relevant results will be publicly available through the RD-Connect website.