



831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP6 - PROMS

D6.9 - Ethics D1a, GEN-Requirement: Independent Ethics Advisor appointed to participate in the independent external expert panel

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	V1.0	02/11/2018

Document History

Version	Date	Description
V1.0	6 Nov 2019	First Draft
V2.0	11 Nov 2019	Final Draft

Background

Ethical guidance for the Trials@Home project is built into the project in several manners. One request from the IMI during the grant negotiation phase was to include the appointment of an independent Ethics Advisor, to monitor the ethics issues involved in this project and how they are handled, as a separate Deliverable. As it was already planned within the project to set up an independent external expert panel, comprising of at least 4 members including ethicists, it has been agreed to keep the Independent Ethics Advisor as part of this independent external expert panel, but to report on the appointment of the Ethics Advisor as a separate deliverable.

Methods

Within the UMCU and the Utrecht University ethics departments, WP6 made an inventory who would be most suitable to perform this task. UMCU ethics professor Hans van Delden and Ghislaine van Thiel aimed for synergy in the search for a suitable expert.

Results/Conclusion

Upon recommendation by UMCU, Federico de Montalvo Jääskeläinen, who is professor of Faculty of Law at Universidad Pontificia Comillas (ICADE), made himself available for serving the SAB/IEEP. Federico is already a member of External Advisory Board in two IMI BD4BO projects.

Please find below a short biosketch of Federico.

Federico de Montalvo Jääskeläinen, professor of the Faculty of Law (ICADE), has been appointed member of the International Bioethics Committee of UNESCO (IBC), the highest advisory body on bioethics worldwide. De Montalvo, expert in health law, is Vice President of the Bioethics Committee of Spain, since January 2013.

The committee, which was created in 1993 to ensure respect for the dignity and freedom of human beings in the progress of life sciences and their applications, is made up of 36 members from different countries, representing all continents. Among its main functions is to advise Unesco in matters related to bioethics, promote reflection on ethical and legal problems in life sciences and their applications, and exchange ideas and information to respect the freedom and dignity of being humans.

In recent years, this body has focused its work on four areas: informed consent, social responsibility and health, respect for the vulnerability of human beings and their personal integrity and non-discrimination and non-stigmatization. Among future works, De Montalvo highlights the sharing of the benefits derived from biomedical research. "One of the most difficult tasks will be to reach meeting points in terms of reflections and proposals between members who belong to very different countries and contexts; above all, taking into account that we will work together representatives of countries with a high economic level with representatives of developing countries," he says.