Biomedical Research Training Workshop Week

Implementing Biomedical Research Projects:
The Complete Workflow from Concept, ELSI and Privacy Considerations to High-Quality Biobanking

11 - 14 May 2020, 14:00 – 17:30

Online Workshop

Jointly organised by
EJP RD, BBMRI-ERIC, EASI-Genomics

with support from
Medical University Graz, BBMRI.at, CBmed GmbH and QIAGEN GmbH

This workshop has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 825575 European Joint Programme for Rare Diseases and No 824110 – EASI-Genomics
ABOUT THE TRAINING WORKSHOP

This workshop is aimed at biomedical researchers, medical professionals and biobank managers who want to organise biomedical research projects on human biological samples. We welcome the participation of representatives from patient organisations, as well.

In two modules we will use several use-cases to address the key issues in biomedical research involving human subjects, human biological samples and associated medical data: ethics, legal issues, privacy and data protection, data standardisation and the implementation of sample workflows in a clinical context that are compatible with the In Vitro Diagnostic Regulation.

In the first module we will show participants how to obtain ethical, legal and regulatory counsel for their projects, since regulations vary widely between European countries. In addition, we will provide practical guidelines on how to manage genetic data from human samples. The goal is to arrive at a logically organised checklist that prevents us from overlooking important issues that may be particularly challenging, e.g. in transnational collaboration. The second module will deal with procurement of samples and data in a workflow in a clinical context aligned with current CEN/ISO standards for pre-analytical procedures.
Preliminary Program

Monday 11 May 2020 (Module 1)
13:40 – 14:00 Online system, connection and sound testing for participants

Opening Session
14:00 – 14:15 Michaela Th. Mayrhofer (BBMRI-ERIC, EJPRD) Welcome address; role of human biological samples in biomedical research, goals of the workshop
14:15 – 14:30 Mary Wang (FTELE, EJPRD), Peter M. Abuja (MUG, EASI-Genomics), Brief presentations on EJP RD and EASI-Genomics
14:30 – 14:50 Lennart Johansson (UMCG, EJPRD) Genomics in health research; potentials and challenges
14:50 – 15:00 Mary Wang Presentation of the Problem Cases. Introduction to Problem-Based Learning
15:00 – 15:30 Moderated Discussion I: Problem Analysis Discussion on the problem case, identification of knowledge gaps and questions.
15:30 – 15:45 Break

ELSI Considerations
15:45 – 16:05 Michaela Th. Mayrhofer Lecture on an overview of ELSI in biobanking and privacy management
16:05 – 16:25 Irene Schlünder (BBMRI-ERIC ELSI Services & Research) Lecture on GDPR
16:25 – 16:45 Lorena Casareto (TNGB, EJPRD) Lecture and examples of biobank societal engagement
16:45 – 17:00 Moderated discussion II: ELSI aspects regarding the problem case
17:00 End of day 1

Tuesday 12 May 2020 (Module 1)
14:00 – 14:05 Mary Wang Recap of day 1, aims of day 2

Data Management Considerations
14:05 – 14:25 Esther van Enckevort (UMCG, EJPRD) Data management of samples/biobank, BIMs, Catalogue and data mapping
14:25 – 14:45 Nancy Mah (Charité, EJPRD) Lecture on coding unstructured data using ontologies
15:05 – 15:25 Carles Garcia Linares (CRG-CNAG, EJPRD) Genomic data management considerations; existing standards and resources
15:25 – 15:40 Break
15:40 – 16:20 Moderated Discussion III Data aspects regarding the problem case

Ethics Compliance in Practice
16:20 – 16:40 Josef Haas (Ethics board of the Med Uni Graz) The role of ethics committees in biomedical research
16:40 – 17:00 Peter M. Abuja The Study Protocol – key elements and a description of the whole workflow (ethics, data management, privacy protection, patient selection, sample management and analysis)
17:00 – 17:30 Q&A, feedback, quiz
17:30 End of day 2

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Wednesday 13 May 2020 (Modules 2)
14:00 – 14:05 Michaela Th. Mayrhofer, Recap on Module 1
14:05 – 14:10 Peter M. Abuja, Overview on Module 2

Standards for Sample Procurement

14:10 - 15:00 Uwe Oelmüller (QIAGEN GmbH) Rationale for defining standardized pre-analytical workflows in light of the requirements of the IVDR.

15:00 – 15:30 Conny Stumptner (MUG, BBMRI.at) presents the CEN/ISO standards’ common structure and a tool that allows self-assessment whether a workflow is compliant with a particular standard

15:30 – 15:40 Break

15:40 – 16:10 Peter M. Abuja Significance of standards in clinical collaborations

16:10 – 16:40 Christian Gülly (MUG, Biobank Graz) State-of-the-art in standardized biobanking at the Graz Biobank

16:40 – 17:10 Amin El-Heliebi (MUG, CBmed GmbH), Peter M. Abuja Presentation of the use-cases based on actual collaborative research with clinical departments

17:10 – 17:30 Wrap-up day 3 and open questions

Thursday 14 May 2020 (Module 2)

Setting up standardised sample procurement in practice

14:00 – 14:30 Peter M. Abuja Setting up standard-compliant sample procurement with clinical partners

14:30 – 15:00 Prisca Pondorfer-Schäfer (MUG) Sample procurement in cooperations with clinical partners – the clinical point of view

15:00 – 15:50 Peter M. Abuja, Christine Ulz (CBmed GmbH), Christina Skofler (CBmed GmbH) Practical implications for the implementation of a standardized workflow in the preparations for patient inclusion and sample collection: the use of flow charts and process slips

15:50 – 16:00 Break

16:00 – 16:50 Peter M. Abuja, Christine Ulz (CBmed GmbH), Christina Skofler (CBmed GmbH) Organizing the collection, transfer and storage of samples

16:50 – 17:30 Wrap-up of day 4 and open questions