Webinar 2 ELSI – Topic 3
Presentation of the Ethical and Legal Framework

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October 27, 2016

B3 Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH
ACROSS EUROPE AND AFRICA

Topic 3: Presentation of the Ethical and Legal Framework

Learning objectives. At the end of the training session, participants will be able to:

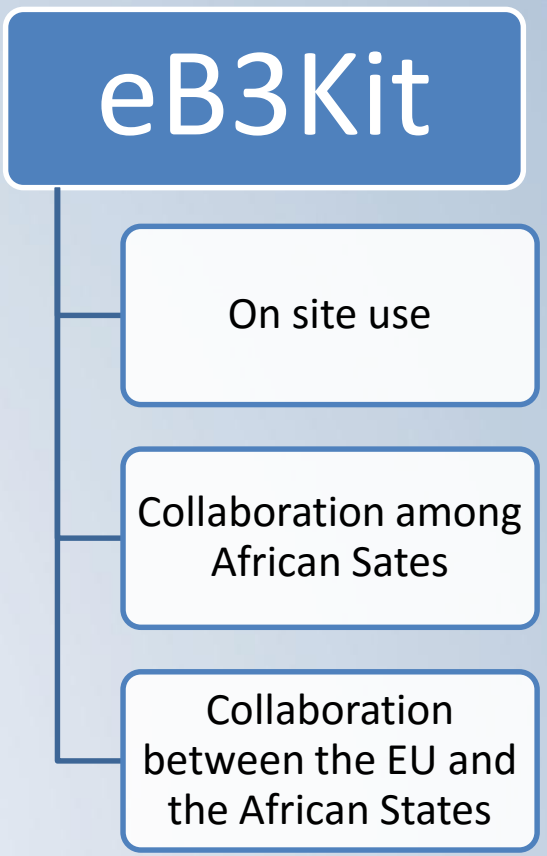
- Understand the key components of B3Africa Legal and Ethical Framework.
- Apply the key components in practice.

Target audience: biobankers, researchers, research administrators, members of ethics review boards and similar bodies

B3Africa

The Project

- Aim
- Core elements
  - Ethical and legal issues
  - eB3Kit
    - Information and sample management
    - Data analysis
  - Training and capacity building



Aim

Sharing bio-resources, data and knowledge between Africa and Europe

* By Roxana M Martinez

Challenges

On site use	Collaboration among African Sates	EU Member States	Collaboration between the EU and the African States
Vague regulations with rare exceptions, such as Nigeria	Non existent or vague regulations with rare exceptions	CFREU, DPD, GRPR ECHR, DPC, DR DPC, Recommendations National law	
International law and guidelines			

Cross-continental collaboration

Agreements

Minimum requirements

Minimum requirements: I

Informed consent for all data

A freely given consent by a person to use his or her biological samples and associated data for health care or research purposes.

The person, or where applicable, his or her legal representative, should be given appropriate information beforehand as to the purpose of the research, the nature of the procedures to be conducted, as well as on its risks and consequences. The consent may be withdrawn freely at any time.

Limited and proportionate exceptions might be applicable where appropriate, after approval by an Ethics Review Board. Ethics Review Board could further set requirements in regards to form and content of the information given and the drafting of the consent form.

Minimum requirements: II

Ethical approval

Ethical approval is a decision or opinion from an ethics review board that has been authorized to independently review and approve research studies from an ethical point of view. The board consists of competent experts as well as lay persons or religious representatives, as appropriate.

Equivalent to an ethical approval is a decision or opinion issued by a Data Protection Authority, if in accordance with the applicable law.

B3Africa Legal and Ethical Framework

Project number: 654404
Project Acronym: B3Africa

Project Title: Bridging Biobanking and Biomedical research across Europe and Africa
Project website URL: http://www.b3africa.org/
Project Coordinator: Erik Bongcam-Rudloff
Organization: SLU
E-mail: Erik.Bongcam@slu.se

Work Package 1
Draft report of legal and ethical framework and an analysis of ethical viability

Work package Leader: Jane Reichel
Organization: UU
E-Mail: Jane.Reichel@jur.uu.se

Project Deliverable

D1.1: Draft report of legal and ethical framework and an analysis of ethical viability

Deliverable due date: 2015-09-31
Deliverable due month: M3

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Work Package 1
Ethics and Regulations

Work package Leader: Jane Reichel
Organization: UU
E-Mail: Jane.Reichel@jur.uu.se

Project Deliverable

D1.2: Data model for personal data protection and data sharing and integration

Deliverable due date: 2016-06-30
Deliverable due month: M10

Basis for collaboration

* By Roxana M Martinez

Case analysis

Dr. Anna is a distinguished scientist who works in a local hospital and a research center. She intends to examine Alzheimer's disease (ε2, ε3, and ε4 variants). The hospital has a collection of samples from patients suffering from Alzheimer's and Anna wants to conduct research using the eB3Kit.

Anna wonders, if and how she could obtain access to the samples and use the eB3Kit, when she does not know whether the samples are collected with informed consent.

A quiz question

Dr.Anna:

- Can use the samples and no further authorisation is required
- Needs to have the study approved and to request consent waiver

A quiz answer

Dr.Anna:

- Can use the samples and no further authorisation is required
- Needs to have the study approved and to request consent waiver

Questions?

Thank you!

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