LEGAL AND ETHICAL GOVERNANCE OF INTERCONTINENTAL BIOBANKING – SOME EXPERIENCES FROM A H2020-PROJECT*

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1. Introduction

Biobanks exist today on every continental though they have evolved differently in different parts of the world.[1] The African States have been involved in biobank research for a considerable time but for decades large volumes of data and samples have been transferred outside the continent to developed countries for their storage and eventual further use, thus affecting the capacity-building and development for researchers in Africa.[2] Currently, there are ongoing projects to build biobank research capacity within the regions where they are at an early developmental stage and collaborate transnationally in that regard.[3] One of them is B3Africa, an EU-funded project that aims to facilitate collaboration between selected EU Member States and the African States and enhance mutual data and sample exchange between the EU and African States. Within the project, an informatics platform, the eB3Kit, is being developed. The platform integrates available open-source software, services and tools for biobanking and bioinformatics. Further, an ethical and legal framework for collaboration is being drafted that may bridge biobank research activities in the EU Member States and the African States. This article focuses on the latter, the ethical and legal framework.

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1 Christopher Thomas Scott and others, 'Personal Medicine—the New Banking Crisis' (2012) 30 Nature biotechnology 141.

2 Ciara Staunton and Keymanthri Moodley, 'Challenges in Biobank Governance in Sub-Saharan Africa' (2013) 14 BMC medical ethics 35.

3 For example, H3Africa is the US funded project that seeks 'to facilitate a contemporary research approach to the study of genomics and environmental determinants of common diseases with the goal of improving the health of African populations.' H3Africa, available http://h3africa.org/, accessed 21 December 2016. MalariaGen 'is investigating how genetic variation affects the biology and epidemiology of malaria, and using this knowledge to develop tools to control the disease'. MalariaGen, available https://www.malariagen.net, accessed 21 December 2016. HapMap project sought to develop a haplotype map of the human genome. HapMap, available https://www.genome.gov/10001688/international-hapmap-project/, accessed 21 December 2016.

Transnational collaboration is becoming an essential part of genetic and genomic research,[4] and since medical research involving human beings generally is highly regulated, transnational collaboration also necessitates administrative law solutions for cross-border situations. In order to facilitate research possibilities, calls for global governance of biobanks by stakeholders have become common.[5] However, due to such reasons as limited competence and authority of the lawmakers, regulatory responses have as of yet not followed. As a result, biobank research is international while research governance remains national. Biobank research creates a number of ethical and legal concerns which require consideration of the international, regional and national legal norms that govern them.[6] When transnational collaborations are envisaged, appropriate governance mechanisms need to be established, with due regard to the existing challenges for transnational collaboration and specific features of the envisaged project.

The aim of this article is to share experiences of carrying out transnational medical research projects involving human biological samples and associated data in states that have differing legal, social and cultural traditions. B3Africa aspires not only to build on-site biobank research capacity in the states that are located in different regional legal systems but also enable mutual collaboration in that regard. More specifically, the project aims at enabling transfer of health and genetic data, both of which are sensitive in nature, between the participating states in Africa and the EU.

Medical research on biobanks is dependent on national administrative approval and/or oversight, both in regards to ethical approval of the research and in regards to requirements for transfer of health data. The latter is especially relevant in relation to EU data protection law. A basic point of departure for legal analysis on appropriate cross-border administrative tools is that all states are to be considered sovereign and thereby independent of each other. One feature of sovereignty is the capacity to decide on legal matters which arise within the borders of that state.[7] In order for administrative approval

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4 Adrian Thorogood and Ma'n H Zawati, 'International Guidelines for Privacy in Genomic Biobanking (or the Unexpected Virtue of Pluralism)' (2015) 43 The Journal of Law, Medicine & Ethics 690.

5 For example, Haidan Chen and others, 'A Call for Global Governance of Biobanks' (2015) 93 Bulletin of the World Health Organization 113. See also the Bartha M Knoppers, 'International Ethics Harmonization and the Global Alliance for Genomics and Health' (2014) 6 Genome Medicine 13. Edward S Dove, 'Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework' (2015) 43 The Journal of Law, Medicine & Ethics: A Journal of the American Society of Law, Medicine & Ethics 675, 679.

6 Thorogood and Zawati (n 4).

7 Herwig CH Hofmann, 'Dealing with Trans-Territorial Executive Rule-Making' (2013) 78 Mo. L. Rev. 423, 428–9.

and oversight to function in a cross-border setting, there is a need to find a model for connecting the law of the involved states. Wenander has identified two general approaches to such collaboration.[8] First, the involved states can establish a common rule, or at least a common understanding, for all entities to apply. This can be labelled a network approach.[9] The abovementioned call for a global governance regime for biobanks would, if realised, be an example of this approach. Secondly, the collaboration can be built on a conflict of laws approach, leaving it up to each state to decide for themselves how to govern the issue at hand and to develop tools to connect to other administrative orders, for example, via agreements in each individual case.[10] The current practice of Material Transfer Agreements (MTAs) and Data Transfer Agreements (DTAs) within cross-border biomedical research can be seen as an example of this.[11]

The B3Africa ethical and legal framework is built on a dual approach, incorporating elements of both a network approach and a conflict of laws approach. Firstly, through the collaborative efforts of the participating research institutions, minimum threshold principles that all users must abide by are identified. The threshold principles are implemented in the eB3Kit via a Model Data Management Policy. Secondly, conflict of laws solutions are to be used in the individual cases. In this solution, DTAs have central role. The article builds on the ongoing work within the project, which has been presented in two deliverables submitted to the EU Commission.[12]

This article begins by mapping out the challenges that a transnational biobank research project could face. It considers eventual challenges that could emerge for transnational research and specifically considers concerns that have been identified within B3Africa project (section 2). Subsequently, it examines how a common understanding for addressing the concerns that relate to enabling the use of the B3Africa technical solution, the eB3Kit, can and has been developed in the B3Africa project. Likewise, it presents an implementing strategy of the common understanding in the form of a Model

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8 Henrik Wenander, 'A Toolbox for Administrative Law Cooperation beyond the State' in Anna-Sara Lind and Jane Reichel (eds), *Administrative law beyond the state-Nordic perspectives* (Liber 2013). See also Henrik Wenander, 'Recognition of Foreign Administrative Decisions: Balancing International Cooperation, National Self-Determination, and Individual Rights' (2011) 71 Zeitschrift für ausländisches öffentliches Recht und Völkerrecht.

9 Wenander, 'A Toolbox for Administrative Law Cooperation beyond the State' (n 8) 51.

10 Ibid 60.

11 Deborah Mascalzoni and others, 'International Charter of Principles for Sharing Bio-Specimens and Data' (2015) 23 European Journal of Human Genetics 721.

12 B3Africa D1.1 Draft report of legal and ethical framework and an analysis of ethical viability, October 2015 and B3Africa D1.2 Data model for personal data protection and data sharing and integration, July 2016.

Data Management Policy (section 3). In section 4, focus is placed on EU law requirements for transfer of research data. The theoretical strategies and technical and legal solutions that are used within the project could be seen as relevant to similar types of capacity-building activities and intercontinental collaborations in the sphere of medical research in general and biobank research in particular.

2. Challenges in transnational research

Transnational biobank research could face various challenges. These are dependent on what national legal orders they involve, which regional legal orders they belong to, what legal requirements are applicable to the research in the respective legal orders, and what biobanks are in place in the countries of interest and how they operate. Overall, these challenges can be grouped into two categories – those relating to transnational research and those relating to a specific project.

2.1 General ethical and legal challenges in transnational biobank research

The ethical and legal issues that biobank research raises have received considerable scholarly attention.[13] While these issues tend to be specific according to the type of sample and data collection,[14] there are certain elements that are common to the various types of biobank research. These include safeguards for the research participants which aim to provide safeguards to their privacy and enhance public trust,[15] as well as the return of information and benefit sharing.[16] Consensus appears to have been reached among the stakeholders on the need to protect the sample donors' privacy. However, discussion as to the best approach that exists as well as balancing the protection of the sample donors with the scientific aspirations is still unresolved. In particular, it reflects on such questions as the most appropriate type of consent to biobank

[13] For example, Susanne B Haga and Laura M Beskow, 'Ethical, Legal, and Social Implications of Biobanks for Genetics Research' (2008) 60 Advances in genetics 505. Henry T Greely, 'The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks' (2007) 8 Annual Review of Genomics and Human Genetics 343. Alice Hawkins Virani and Holly Longstaff, 'Ethical Considerations in Biobanks: How a Public Health Ethics Perspective Sheds New Light on Old Controversies' (2015) 24 Journal of Genetic Counseling 428.

[14] Bartha Maria Knoppers, Ma'n H Zawati and Emily S Kirby, 'Sampling Populations of Humans Across the World: ELSI Issues' (2012) 13 Annual Review of Genomics and Human Genetics 395.

[15] Mats G Hansson, 'Ethics and Biobanks' (2008) 100 British Journal of Cancer 8.

[16] Ibid.

research,[17] the best way to return information to the research participants and the handling of incidental findings do not seem to have been agreed upon.[18]

For an individual, biobank research presents very little, if any, risk of direct physical harm but a palpable risk of indirect physical harm.[19] For example, when samples are collected directly from donors for biobank research, minor physical harm could occur due to interference with the donor's spatial privacy.[20] Further, there is a risk of non-physical harm or harm that is related to the data in relation to an individual[21] and, more generally, their informational privacy. Therefore, at the centre of biobank research is the sample donor and the question of what protection should be given to the sample donors and how this protection should be balanced against the other rights and interests at stake. In other words, how the informational and spatial privacy should be safeguarded.

In the legal arena, privacy has long been acknowledged as a fundamental right. Article 12 of the UDHR[22] and Article 17 of the ICCPR prohibits arbitrary interference with privacy.[23] However, as privacy can be categorized as a qualified right, which entails a balancing of competing interests and rights, the expression of this right in the regional and national instruments could differ depending on such factors as cultural beliefs and public opinion. For example, in the Western world, individual privacy has been a cherished value.[24] In the European context, it has found its legal expression in EU and Council of Europe legal orders. It is protected under the domain of private life, with further regulatory requirements for specific dimensions of privacy (spatial and informational) as well as the protection of privacy in different contexts. In the Council of Europe legal order, Article 8 of the ECHR protects the right to private life, which encompasses privacy.[25] The European Court of Human Rights has held that privacy is not subject to an exhaustive

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17 Kristin Solum Steinsbekk, Bjørn K Myskja and Berge Solberg, 'Broad Consent versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem&quest' (2013) 21 European Journal of Human Genetics 897.

18 Jennifer Viberg and others, 'Incidental Findings: The Time Is Not yet Ripe for a Policy for Biobanks' (2014) 22 Eur J Hum Genet 437.

19 Stefan Eriksson and Gert Helgesson, 'Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research' (2005) 13 European Journal of Human Genetics 1071.

20 On spatial and informational privacy see Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge University Press 2002) 6.

21 Eriksson and Helgesson (n 19).

22 UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III).

23 International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171.

24 Santa Slokenberga, *European Legal Perspectives on Health-Related Direct-to-Consumer Genetic Testing* (Jure 2016).

25 *X and Y v. the Netherlands* 1985 Series A no. 91, p. 11, para 22.

definition and embraces the right to the protection of personal data[26] and the protection of personal integrity.[27]

Data protection is especially addressed in the Data Protection Convention[28] as well as the Medical Data Protection Recommendation,[29] both of which are currently undergoing revision.[30] The protection of bodily integrity is, for example, dealt with in the Biomedicine Convention.[31] Furthermore, the questions that relate to biobank research are specifically addressed in the Council of Europe recommendation on research on biological materials of human origin.[32]

Similarly, in the EU legal order, the Charter of Fundamental Rights provides for the protection of privacy[33] and personal data,[34] which are to be distinguished in the EU legal order,[35] and integrity.[36] With due regard to the principle of conferral, these aspects are further addressed in the secondary law. While the EU has acquired competence in the area of data protection and has acted therein extensively, its contributions to addressing the protection of spatial privacy have been more than modest.[37]

In contrast to the European regional legal orders, the right to the protection of private life and privacy do not feature in the African Charter on Human and Peoples' Rights. However, they are addressed in other treaties in Africa. In addition, the right to integrity is protected under Article 5 of the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women

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26 *S. and Marper v. the United Kingdom* [GC] ECHR 2008-V, para 67.

27 *Pretty v. the United Kingdom* ECHR 2002-III, para 61.

28 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data [1985] ETS 108.

29 Recommendation No. R (97) 5 of the Committee of Ministers to member states on the protection of medical data [1997].

30 Draft Recommendation on the protection of health data [2016] 09 May 2016 T-PD(2016)04rev, http://www.coe.int/t/dghl/standardsetting/dataprotection/TPD_documents/T-PD33/T-PD(2016)04Rev_Health%20recom_En.pdf, accessed 18 September 2016. Working Document Consolidated version of the modernisation proposals of Convention 108 with reservations [2016] 03 May 2016 CAHDATA(2016)01.

31 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine [1997] ETS 164.

32 Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin [2016].

33 Charter of Fundamental Rights of the European Union [2000] OJ C 364/1, article 7.

34 Ibid Article 8.

35 Joined Cases C-203/15 and C-698/15 *Tele2 Sverige AB v Post- och telestyrelsen and Secretary of State for the Home Department v Tom Watson, Peter Brice, Geoffrey Lewis* EU:C:2016:970, para 129.

36 Charter of Fundamental Rights of the European Union (n 33), Article 3.

37 Slokenberga (n 24) 7, 8.

in Africa.[38] Data protection is specifically addressed under the African Union Convention on Cyber Security and Personal Data Protection,[39] although this is yet to enter into force. Despite their acknowledgment in the legal instruments, it is necessary to be mindful of the culture-specific context in which the notion of privacy and concepts that relate to it in biobank research are being used. Particularly, while the notion of privacy in the EU and Council of Europe legal orders is considerably aligned,[40] it can be different in the African context where such values as communitarianism are present.[41]

2.2 Project-specific challenges: B3Africa project

A number of other challenges could emerge depending on such factors as the aim of the transnational research project, the involved national legal orders, as well as technical solutions and preconditions for carrying out the intended project. Appropriate technological solutions need to be designed given that the aim of the B3Africa project is to build biobank capacity in the selected EU Member States and African States, as well as serve for collaborative purposes. In using the technical solution, particular considerations should also be given to the collections of samples the biobanks have and their origins. Likewise, in carrying out collaboration, one should be mindful of research integrity questions. Lastly, as the EU funds the B3Africa project, the obligations that stem from the agreement with the EU Commission should be observed.

2.2.1 Technical solution: the eB3Kit

The technical solution that was created for the B3Africa project is the eB3Kit. The eB3Kit is a powered computer (physical or virtual) that has installed on it a set of software tools integrated into a workflow that covers several relevant processes of a biomedical research ecosystem: biobanking, experiments management, bioinformatics analysis, and raw and process data management. It will be used to store data and samples, carry out research in the use case states, as well as collaboration, including the exchange of data and samples in research studies between the states within the same regional system, and the exchange of data and samples between African States and EU Member

[38] African Union, Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa, 11 July 2003.

[39] African Union Convention on Cyber Security and Personal Data Protection. Date of Adoption: June 27, 2014.

[40] Slokenberga (n 24) 8.

[41] Mahomed Aslam Sathar and Ames Dhai, 'Laws, Regulations and Guidelines of Developed Countries, Developing Countries in Africa, and BRICS Regions Pertaining to the Use of Human Biological Material (HBM) in Research' (2012) 5 South African Journal of Bioethics and Law 51.

States. Because of the multiple applications and the number of jurisdictions involved, it can be difficult to set out a stringent set of rules for the operation of the platform and the processing of data that could be relevant for all situations where the platform will be used.

2.2.2 Research integrity

Biomedical research involving human study participants has at least two major dimensions: that relating to the researchers and that relating to the study participants. The former focuses on the research integrity vis-à-vis other researchers and the prevention of research misconduct. Especially in the context of research involving African researchers, one needs to be aware of the previously experienced power asymmetries in the international collaborative research.[42] This is at the core of the B3Africa project as among the project's objectives is the facilitation of a two-way collaboration between the researchers in the African States and EU Member States. For this reason, the fulfilment of the aim of the B3Africa project to enable data and sample exchange by sending the samples and data to the African States should also be carried out to the maximum extent possible.

2.2.3 The collections of cellular samples

Given that biobank laws have developed at a different pace and level of stringency in different countries, different strategies have been put in place to collect, process, store and distribute biospecimens and associated data. As a result, it is quite possible for biobanks to hold the samples and associated data that have been collected without appropriate safeguarding mechanisms for individuals being in place. Therefore, for the study participants the risk of infringement of privacy in the research such as facilitated those by the eB3Kit can emerge in at least the following situations. Firstly, depending on what samples are placed in the biobank and how they are collected, the collection and retention may infringe upon the spatial privacy of the research participant, which can be understood as physical and moral integrity.[43] Secondly, the examination of an individual's genome relates to the informational privacy of an individual for the personal data that the analysis of a cellular sample can deliver.[44] As the research can put at stake an individual's privacy, mechanisms

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42 Keymanthri Moodley and Shenuka Singh, '"It's All about Trust": Reflections of Researchers on the Complexity and Controversy Surrounding Biobanking in South Africa' (2016) 17 BMC Medical Ethics 57.

43 Laurie (n 20) 6. Slokenberga (n 24) 124–9.

44 Ibid.

that allow the involved legal orders to cooperate and that hinder any unwarranted processing of data should be established.

2.2.4 Jurisdictional challenges

At the national level, the B3Africa project involves several national legal orders, each having a different approach to handling the situation. The selected EU Member States (Lithuania and Poland) are not only members of the EU legal order but also members of the Council of Europe and signatories of several relevant treaties therein. Consequently, they are obligated to secure the protection of the fundamental rights that stem from relevant Council of Europe instruments, as well as the protection of fundamental rights to the extent that EU law is applicable.[45] As Article 8 EU Charter of Fundamental Rights can be regarded as a principle, its expression is given in the secondary law, the Data Protection Directive and the General Data Protection Regulation. As a result, both of these legal orders have considerable influence on how privacy is protected at the national level and the EU, particularly in the area of data protection.

The selected African States (The Gambia, Ghana, Nigeria, Uganda, Kenya and South Africa) that participate in the B3Africa project have all signed and ratified the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa and are obligated to ensure the protection of integrity in their legal orders.[46] The specification of further requirements for biobank research lies with the national legislatures. As a result, among the use case states different approaches exist for regulating biobank research and protecting the privacy of individuals. Some countries, such as Nigeria, have opted for hard law measures whereas others have chosen guidelines as the most appropriate legal solution for regulating biobank research.[47] Given the different means of governing biobank research, the detailed requirements for the protection of privacy also differ at the national level.[48]

The different regulatory approaches and the different legal requirements could work well in a national setting for the purposes of protecting individuals in biobank research. For example, in line with the reported desires of

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45 Charter of Fundamental Rights of the European Union (n 33), Article 51.2. Case C-617/10 *Åklagaren v. Hans Åkerberg Fransson,* EU:C:2013:105, para 18.

46 Ratification Table: Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, available http://www.achpr.org/instruments/women-protocol/ratification/, accessed 1 November 2016.

47 Aminu Yakubu and Clement A Adebamowo, 'Implementing National System of Health Research Ethics Regulations: The Nigerian Experience' (2012) 1 BEOnline: journal of the West African bioethics training program 4.

48 Alex B Makulilo (ed), *African Data Privacy Laws* (Springer 2016).

researchers, national lawmakers could opt to refrain from adopting hard law measures and instead allow concerns to be addressed through soft law measures. In the international setting, the lack of a competent legislator may in itself necessitate the drafting of soft law measures by the research community itself. As explained by Mayrhofer and Prainsack, soft law tools are commonly used in the area and they can be seen as a by-product of the harmonising and standardizing activities of collaborating biobanks across borders.[49] It is, however, not possible to rely completely on these soft law mechanisms. From an external perspective, with a view to creating a platform for building trust among the use case states, which is at the core of cross-border collaboration, shared values and consensus on their meaning is a necessary starting point. Likewise, the requirement to observe the EU imperatives that are below considered when implementing the B3Africa project mandates assessing whether the national regulatory approach can be deemed ethical. In the plurality of approaches, a common denominator can be seen as the lowest threshold for meeting the necessity of compliance with ethics.

2.2.5 The EU imperatives

The EU has an extremely limited competence to act in the sphere of research. Nonetheless, there is a considerable link between the EU research policies and funding and the regulation of ethical questions that biobank research gives rise to.[50] The B3Africa project is funded by the European Commission. Consequently, the activities within the project should comply with ethical principles and relevant national, EU and international legislation.[51] In a project such as B3Africa which involves two continents and several national legal orders, and where the international and regional regulatory arena is fragmented, establishing common requirements to achieve the goals of a project is a challenging task. Therefore, a question that needs to be addressed is how to ensure that not only the national and international laws but also the laws of the EU are observed. While the EU has contributed only modestly to addressing spatial privacy, it has contributed extensively to addressing privacy. In fact, some have claimed that it has the strictest privacy requirements in the world and that the Commission can be described as being the 'gold standard'.[52]

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[49] Michaela Th Mayrhofer and Barbara Prainsack, 'Being a Member of the Club: The Transnational (Self-) Governance of Networks of Biobanks' (2009) 12 International journal of risk assessment and management 64.

[50] Jane Reichel, 'Alternative Rule-Making within European Bioethics–Necessary and Therefore Legitimate?' (2016) 21 Tilburg Law Review 169.

[51] Article 19 Regulation 1291/2013 of the European Parliament and of the Council establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014–2020).

[52] Commission to renegotiate Council of Europe Data Protection Convention on behalf of EU,

2.3 Interim conclusions

Although there is a prevailing view that safeguards for an individual should be in place in biobank research, what they are could differ significantly depending on the regional system, rules therein and the national laws. Consequently, the challenge that needs to be addressed in transnational research is how to reconcile these requirements so that they serve as the basis for building mutual trust among the transnational research project partners. In the context of B3Africa, the challenge is to enable the use of the eB3kit on-site in the use case states while ensuring the privacy of the sample donors, and enabling a two-way collaboration between the African States and the EU Member States for the exchange of specimens and data for biobank research. These two challenges faced by the B3Africa project will be examined in the subsequent sections of this article.

3. Collaborative efforts to build a common understanding

In order for international collaboration in research to work smoothly, a certain level of trust between the partners involved is necessary. One way to build such trust may be to establish a common understanding of the basic legal and ethical components that all partners agree upon and further to develop tools to ensure that they are applied consistently though out the collaboration.

3.1 Requirements and possible solutions

There are two basic notions that can be considered to be universally accepted for biobank research: the need for informed consent, and ethical approval to allow a safe and legitimate handling of biological samples and data within research.[53] However, in the context of transnational research, one needs to be mindful of the origins and current state of bioethics. Even if acceptance could be said to be universal, the development of bioethics is a Western product so the established frameworks often reflect these values. Therefore, in order to carry out a transnational project in the absence of a common regulatory framework, an approach that allows various cultural perspectives to be accommodated, the simultaneous safeguarding of the values that are at stake in biobank research should be established.

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available http://europa.eu/rapid/press-release_MEMO-12-877_en.htm, accessed 15 September 2016.

[53] Jane Reichel, 'Oversight of EU Medical Data Transfers – An administrative law perspective on cross-border biomedical research adminstration!' [forthcoming] Health and Technology, DOI: 101007/S12553-017-0182-6.

3.2 B3Africa project solution

In order to reach a common understanding of the concepts of informed consent and ethical approval, a workshop with all participating research institutions, both use cases and the B3Africa participants, was organized in Gambia in April 2016.[54] The purpose of the meeting was to identify legal and ethical issues relating to the implementation of the concepts and try to establish definitions to be used within the project. As will be discussed below (section 3.3), the concepts are an important part of the Model Data Management Policy, a technical tool for reporting the use of informed consent and ethical approval within the platform, the eB3Kit.

3.2.1 Setting the minimum rules for collaboration

In biobank research involving human samples, the notions of informed consent and ethical approval seek to protect the individuals involved. As a result, the privacy of individuals, and specifically their samples and data, are protected. The legal implementation of these notions is carried out within each national legal order by the national authorities enacting administrative decisions applicable within the state.[55] As was elaborated in the previous section, some states have addressed these requirements through legislative means while others have opted for adopting guidelines on the issue. The concepts of consent and ethical approval are thereby not unequivocal.[56] Some states have opted for a specific and informed consent while others have adopted a broad consent,[57] and within some several types of consent coexist.[58]

As there are neither universally agreed definitions on consent in biobank research and ethical approval, nor is there a shared definition among the use case states, a solution that enables using the eB3Kit for the intended purpose as well as one that serves as a basis for further collaboration between the states within a continent and across the continents needs to be sought. Therefore,

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54 For the purposes of this article data collected during the Gambia meeting in April 2016 are used. Particularly, data provided by Dr. EA Abayomi in regards to South Africa, data provided by Dr. Zivile Gudleviciene in regards to Lithuania, data provided by Dr. Mwaka Erisain relation to Uganda.

55 Reichel (n 53).

56 Steinsbekk, Myskja and Solberg (n 17). For varieties of consent and diversities of defining broad consent see Paulina Tindana and Jantina de Vries, 'Broad Consent for Genomic Research and Biobanking: Perspectives from Low-and Middle-Income Countries' [2016] Annual review of genomics and human genetics.

57 On broad consent on this issue see Moa Kindström Dahlin, 'Breda samtycken inom biobanksforskningen'.

58 Nchangwi Syntia Munung and others, 'Obtaining Informed Consent for Genomics Research in Africa: Analysis of H3Africa Consent Documents' [2015] Journal of Medical Ethics medethics.

for the purposes of the B3Africa project, a common definition of the concept of consent and ethical approval have been agreed upon.[59]

3.2.2 Informed consent

Among the use case states, several approaches to consent and definitions of informed consent can be found. Uganda, for example, lacks legislation that specifically addresses health research. Certain types of research are regulated in area-specific laws. For example, Section 30 (1)(a) of the HIV and AIDS Prevention and Control Act 2014 stipulates that HIV and AIDS related human biomedical research on another person or any tissue or blood can be carried out if infomed consent is given.[60] In South Africa, both broad and tiered consent are permitted, depending on the type of intended research.[61] For example, in Lithuania:

> Informed consent to participate in biomedical research (…) means a voluntary, explicit and knowing written consent by a person or, in the cases and in accordance with the procedure provided for by this Law, by another person entitled to give a person's consent to participate in biomedical research, by the surviving spouse or, where the person was not married, marriage has ceased, the spouse has been declared missing or the spouses lived separately – by a close relative, to participate in biomedical research.[62]

To reach a common understanding of the principle, a common denominator had to be established that simultaneously allows accommodating other approaches and detailed requirements. Therefore, for the purposes of the B3Africa project, the use case state representatives agreed on setting informed consent as the highest threshold, albeit to which exceptions could apply. In the B3Africa project, informed consent of an individual is defined as follows:

> 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 in beforehand be given appropriate information as to the purpose of the research, the nature of the pro-

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59 B3Africa D1.1 Draft report of legal and ethical framework and an analysis of ethical viability, October 2015 and B3Africa D1.2 Data model for personal data protection and data sharing and integration, July 2016.

60 The HIV and AIDS Prevention and Control Act 2014 Sec 30 (1)(a).

61 No. 61 of 2003: National Health Act, 2004, sections 56 and 62. Depart of Health (DOH) – 2015 Ethics in Health Research Principles, Processes and Structures Guidelines, available http://www0.sun.ac.za/research/assets/files/Integrity_and_Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf, accessed 23 December 2016.

62 Republic of Lithuania Law Amending Law No VIII-1679 on Ethics of Biomedical Research, section 2.13.

cedures to be conducted, as well as on its consequences and risks. The consent may freely be withdrawn at any time.

Limited and proportionate exceptions might be applicable where appropriate, after an 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.

This definition ensures that the person concerned is duly informed about the research in which they are asked to participate. However, to accommodate various national legal requirements and practices, an Ethics Review Board is entrusted to examine these possibilities and consider whether, for example, the informed consent requirement could be waived. This is particularly important for those states in which the informed consent requirement for collecting samples to store them for research purposes is relatively new and the awareness of the need to protect the privacy of persons being involved in research is not as recent as their collections of the samples and data. Therefore, the minimum understanding of the informed consent not only allows accommodating various regulatory approaches but also enables the use of previously collected samples whose handling can be subject to appropriate safeguards through the decision of the Ethics Review Board. It is argued that the Ethics Review Board is well placed to carry out the assessment.[63] It would then be in a position to find a balance between the research interests, the safety, personal integrity (including privacy) and autonomy of research participants, and the preservation of public trust in biomedical research.[64]

3.2.3 Ethics approval

In the absence of universal bioethics and legal norms,[65] the ethical, legal and societal issues (often referred to as ELSI) that surround biobank research are highly context and culture-specific. Whilst some concerns could be insignificant in the European context, they might have particular importance in some cultures in African States and vice-versa. Therefore, they can best be addressed at a national level by ethics review boards.[66] The importance and role of ethics

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63 Daniel Strech, 'Ethical Review of Biobank Research: Should RECs Review Each Release of Material from Biobanks Operating under an Already-Approved Broad Consent and Data Protection Model?' (2015) 58 European Journal of Medical Genetics 545.

64 Gert Helgesson and others, 'Ethical Framework for Previously Collected Biobank Samples' (2007) 25 Nature Biotechnology 973.

65 Sirkku K Hellsten, 'Ethics: Universal or Global? The Trends in Studies of Ethics in the Context of Globalization' (2015) 11 Journal of Global Ethics 80.

66 On the Swedish regulatory framework on this issue see Mats Johansson, 'Etikprövningslagens efterlevnad – Tillsyn i teori och praktik'.

review boards in safeguarding an individual has been widely accepted in the international arena and strengthened in such global soft law instruments as the Declaration of Helsinki[67] and CIOMS International Ethical Guidelines for Health-related Research involving Humans.[68] They can now be seen as essential elements in biobank governance.[69] As ethical approval is aimed at safeguarding the persons involved in research, it is crucial to afford flexibility to enable various perspectives to be accommodated. Therefore, for the purposes of the B3Africa project, ethical approval is defined as follows:

> The ethics approval is a decision or opinion from an ethics review board that has been authorized to independently review and approve research the 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.

Ethics approval as defined in B3Africa enables the researchers to use the eB3Kit for newly-collected samples and data, as well as those previously stored in biobanks where it is unclear whether and to what extent consent requirements have been observed.

3.3 Model Data Management Policy

To enable the use of the eB3Kit for the storage of and access to personal data, the mere adoption of minimum requirements is insufficient to ensure the protection of the privacy of the research participants. For that reason, a procedure to control whether or not the requirements are met must be followed, which was the reason for the development of the Model Data Management Policy.

The Model Data Management Policy is a technical tool for ensuring that the threshold requirements will be upheld when using the eB3Kit. It provides a set of formal rules, criteria and priorities for the processing of data whereby the researchers, before being allowed to use the eB3Kit, must provide the necessary information and documentation in regards to the research project. For example, documentation of consent and ethical approval need to be uploaded into the eB3Kit.

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67 WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, section 23.

68 CIOMS International Ethical Guidelines for Health-related Research involving Humans, available http://www.cioms.ch/ethical-guidelines-2016/, accessed 28 December 2016.

69 Satori, Ethics assessment in different fields Biobanking, available http://satoriproject.eu/media/2.c.4-Biobanking.pdf, accessed 28 December 2016.

Further, the Model Data Management Policy differentiates between users of the eB3Kit, allocating constraints and responsibilities to the different roles (see fig.1). The eB3Kit has two main users: researchers who conduct studies and bioinformatics analysis, and biobank staff who manage bio-resources in the biobank. As an accepted member of the platform, a user can upload, download, update and process data. These actions can be easily identified with roles that should be specifically managed by the system. However, all management of the information related to personal data protection can only be conducted by one specific role, the *data responsible*. The organization using the kit must, therefore, appoint persons to upload data to the platform. Other users of the eB3Kit can be platform administrators, i.e. persons representing organizations that want to be a member of the platform and persons from the ethics board that want to execute some audit processes. Their access to the platform will be limited with due regard to users' specific roles.

The information and documentation sought by the Model Data Management Policy is built on a project deliverable 'ethical and legal framework', including the common definitions of informed consent and ethical approval. The documentation will thus ensure a transparent and accountable processing of data on the eB3Kit, both internally within the organization and externally vis-à-vis other partners with whom the users may want to collaborate.

In order to ensure effective practical application of the Model Data Management Policy, appropriate training needs to take place in regards to the eB3Kit and in regards to the ethical and legal issues that are addressed in the ethical and legal framework and put into operation through the Model Data Management Policy. In that regard, the B3Africa project includes an education and training dimension that organizes interactive webinar sessions and face-to-face training.[70] While the former is commonly preferred for addressing the ethical and legal aspects of the project, the latter, in combination with webinars, is often preferred when using the eB3Kit.

[70] See, for example, Training & Education, available http://www.b3africa.org/?cat=16, accessed 28 December 2016.

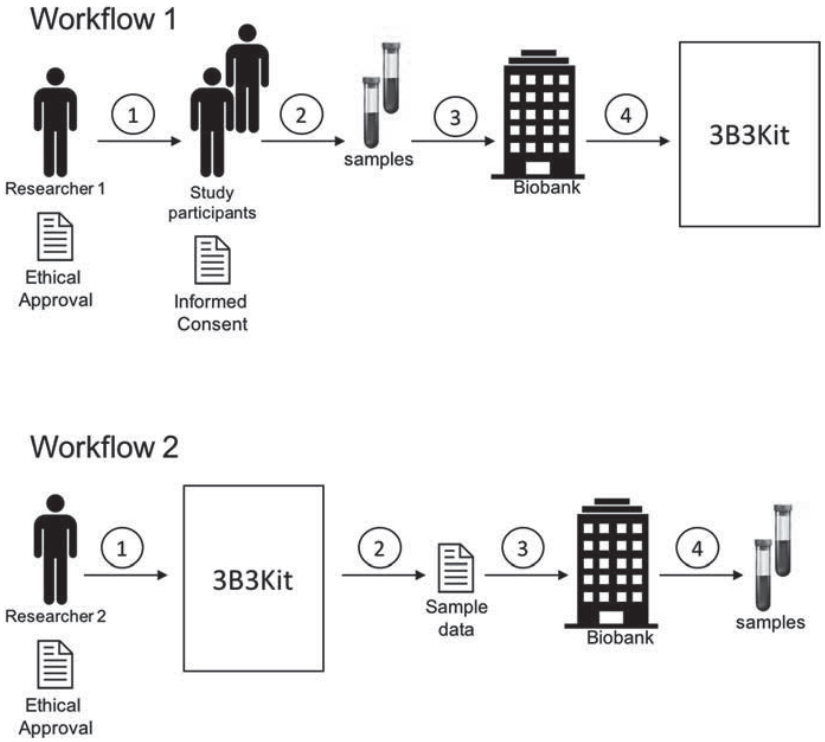

Fig 1. Example of implemented ethical and legal framework in the eB3Kit for sharing samples. **Workflow 1** represents the process of collecting samples for research studies: (1) Researcher 1 with ethical approval to collect samples for a specific study. (2) Study participants give their consent for the specified type of research study. (3) Samples are collected and stored in a Biobank. (4) The Biobank uses the Lab Information Management System (LIMS) from the eB3Kit to manage the samples and associated data. **Workflow 2** represents the process of retrieving samples from a Biobank to conduct a research study: (1) Researcher 2 with login credentials in the eB3Kit, searches for samples based on a specific criteria and request the available samples. (2) The eB3Kit provides sample data from samples that are consented for that specific type of study and are available for sharing. (3) Sample information is provided to the Biobank for retrieving. (4) The Biobank ships the samples following a Sample Material Transfer Agreement (SMTA) to the requester.

3.4 Interim conclusions

Two definitions have been elaborated in order to enable the use of the eB3Kit in use case states. These definitions do not in any way change or diminish the duty to observe national requirements when the research is carried out in the respective states. Rather, they are constructed in a way that allows various

national legal solutions to be accommodated, simultaneously allowing compliance with the national laws and the B3Africa project-specific requirements. In contrast, the Model Data Management Policy serves as a means to ensure that the requirements are observed. The practical effect of the latter is that on-site use of a technical solution is enabled and, in the absence of common rules, the common denominator allows for transparency and as such helps to create a positive environment for further collaboration. Further work will be necessary to trace how these definitions are applied in practice and what, if any, further measures or procedures should be in place to safeguard the sample donors' privacy.

4. Conflict of laws solutions: requirements for transfer of EU data

Even if the partners involved in an international collaboration develop mechanisms to ensure mutual trust, as described in the previous section, each partner remains under the obligation to abide by the law of its own land. It is therefore necessary to define tools to connect the administrative legal orders in collaborating countries, for example, when research data is to be transferred from one state to another.

4.1 Requirements and possible solutions

Further to enabling the on-site use of the eB3Kit, the B3Africa project aims to enable collaboration between the EU Member States and the African States in exchanging samples and data, thus contributing to building biobank research capacity in both continents in a significant way and promoting research integrity vis-à-vis the researchers in Africa. To enhance the research in Africa, B3Africa seeks to develop routes for sending the data and samples not only from Africa to Europe but also from Europe to Africa. In the absence of a sole legal instrument governing the issue, and in order to allow sharing of data across borders and across legal systems, it is necessary to find tools to connect the legal systems involved. Each transfer of data must, therefore, be governed by a legal tool, which traditionally has taken the form of a DTA.[71]

As explained above, the practices for safeguarding data within African states vary and there is currently no standardized guidelines that are commonly used.[72] On the other hand, the EU is said to have the strictest data

[71] Deborah Mascalzoni and others, 'International Charter of Principles for Sharing Bio-Specimens and Data' (2015) 23 European Journal of Human Genetics 721.

[72] Staunton and Moodley (n 2).

protection law in the world.[73] As the EU research funding obligations and the involvement of the EU Member States mandate compliance with the EU data protection laws, it should be considered whether and how the exchange of data, particularly health and genetic data that are treated as sensitive data, and samples, could occur under EU law. Once the B3Africa project is completed in June 2018, and the General Data Protection Regulation will have entered into force, the requirements that stem from the General Data Protection Regulation will then be observed.[74] For the purposes of this article, the analysis will focus entirely on EU law requirements since they can be identified as the main legal hurdle to the B3Africa project.

4.2 The EU imperatives for exchanging the data

The point of departure in EU data protection law is that transfer of personal data outside the EU to third states is only permitted if there is an applicable legal ground.[75] The General Data Protection Regulation sets out procedures for allowing transfer which may be divided into three main categories. These are hierarchical, with the first category offering the most effective and thorough protection which should therefore be selected first, if possible.

First, transfer may take place if the Commission has enacted an *adequacy decision*, meaning that the Commission has found that "a country, a territory or one or more specified sectors within that country … ensures an adequate level of protection" (Article 45).[76] The Safe Harbor Agreement, annulled by the Court of Justice of the European Union (CJEU) in the *Schrems* case, is an example of this.[77] The CJEU found two main reasons for annulling the Safe Harbor Agreement. First, the agreement did not ensure the protection that is granted in Articles 7 and 8 of the EU Charter of Fundamental

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[73] Dan Jerker B Svantesson, 'Extraterritoriality of EU Data Privacy Law-Its Theoretical Justification and Its Practical Effect on US Businesses, The' (2014) 50 Stan. J. Int'l L. 53, 55. See also Slokenberga (n 24) 9.

[74] Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119, 4.5.2016, p. 1–88, hereinafter General Data Protection Regulation.

[75] Article 44 General Data Protection Regulation, corresponding to Article 25.1 in the Directive (EC) 95/46 of the European Parliament and the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281, 23.11.1995, p. 31–50, hereinafter the Data Protection Directive.

[76] Corresponding to Article 25.2 in the Data Protection Directive (n 75).

[77] Commission Decision 2000/520/EC of 26 July 2000 pursuant to Directive 95/46 on the adequacy of the protection provided by the safe harbour privacy principles and related frequently asked questions issued by the US Department of Commerce (C (2016) 4176 final) (Safe Harbor Decision).

Rights, the right to privacy and data protection. According to US law, entities within the US are entitled to disregard the Safe Harbor principles in the event that "national security, public interest, or law enforcement requirements" so require it.[78] According to the court, this meant that US legislation permitted public authorities such as the NSA "to have access on a generalised basis to the content of electronic communications", which constituted a breach of the EU right to privacy rights.[79] There is no legal basis in EU data protection law that would render such indiscriminate surveillance of personal data lawful. Secondly, the fact that the US legal system did not provide for any effective remedy for EU data subjects was contrary to Article 47 of the EU Charter and the right to effective judicial protection.[80]

Second, in the absence of such a decision, data may be transferred if *appropriate safeguards* are available on the condition that enforceable data subject rights and effective legal remedies for data subjects are available.[81] These safeguards may be legally binding and enforceable instruments between public authorities, binding corporate rules, standard data protection clauses adopted by the Commission, or on the basis of specially approved codes of conduct. Contractual clauses between the sender and recipient, subject to the authorization of a competent supervisory authority (for example, a DTA), also fall into this category.

Third, in the absence of either an adequacy decision or appropriate safeguards, *derogations* envisaged in Article 49 of the General Data Protection Regulation could also be relied upon.[82] There are seven specific situational derogations which can be grouped into two categories. One is the existence of an explicit informed consent from the data subject where the subject has been informed of the possible risk of transfer. The other is where the transfer is necessary due to a contract involving the data subject, an important reason of public interest or in connection to a legal claim. In that regard, Article 49.1(2) of the General Data Protection Regulation contains the second category of derogations. This is open but can only be used under rather limited circumstances:

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78 Case C-362/14 *Schrems v Data Protection Commissioner*, EU:C:2015:650, paras 85–86 referring to Safe Harbor Decision, Part B of Annex IV (n 77).

79 Ibid para 94.

80 Ibid para 95.

81 Article 46 General Data Protection Regulation Previously regulated in Article 26.2 in the Data Protection Directive, however the requirement to ensure that the rights of the data subject are enforceable was not explicitly mentioned. See further section 4.3.

82 Corresponding to Article 26.1 Data Protection Directive (n 75).

> [O]nly if the transfer is not repetitive, concerns only a limited number of data subjects, is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject, and the controller has assessed all the circumstances surrounding the data transfer and has on the basis of that assessment provided suitable safeguards with regard to the protection of personal data.

The controller must then inform the competent supervisory authority as well as the data subjects concerned.

A fourth and final procedure is mentioned only briefly here. The transfer of judgments and official decisions, requiring a controller or processor to disclose personal data, is permitted if based on an international agreement such as a mutual legal assistance treaty (Article 48). If none of the abovementioned grounds are available, the transfer of EU data outside the EU is not allowed.

4.3 Challenges for B3Africa project

EU data protection law, as seen in the *Schrems* case and in the recently-enacted General Data Protection Regulation, is aimed at protecting the rights of EU data subjects even when their data is processed within a jurisdiction outside the EU. In other words, it claims extraterritoriality. Accordingly, EU data subjects' rights are to be upheld wherever they are processed, including a right to redress.[83] In the context of research, the General Data Protection Regulation acknowledges the need to make exceptions for research, which will be implemented via national law. The challenge for the B3Africa project is how these general requirements concerning the transfer of EU data can be applied in the context of biomedical research when samples and data are intended to be transferred to the use case states in Africa.

Transfer of data within medical research from the EU must fall within one of the mechanisms set out in section 4.2. As also pointed out, the three main mechanisms for transfer are to be seen as hierarchical; the best protection is provided by an adequate decision and, after this, via appropriate safeguards. Only if the first two are not available, an adequate decision or an appropriate safeguard, may a derogation in Article 49 be used.[84] In regards to the African use case states, an adequacy decision has not yet been enacted. Therefore, the possibility of relying on the appropriate safeguard clause and derogations should be considered.

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[83] Reichel (n 53).

[84] General Data Protection Regulation (n 74) recitals 108–112 of the preamble.

An appropriate safeguard clause has commonly been applied for the purposes of research; it entails contractual clauses that have been authorized by a competent supervisory authority, i.e. a research ethics committee.[85] These contracts are DTAs which regulate the obligations of both the sender and recipient of the data.[86] The application of an appropriate safeguard clause under the General Data Regulation is conditioned on the availability of "enforceable data subject rights and effective legal remedies for data subjects".[87] This condition is neither explicitly laid down in the Data Protection Directive[88] nor does the Directive explicitly require this in reference to the assessment for an adequacy decision.[89] Nonetheless, the CJEU placed considerable weight on these issues in *Schrems*:[90]

> Even though the means to which that third country has recourse, in this connection, for the purpose of ensuring such a level of protection, may differ from those employed within the European Union in order to ensure that the requirements stemming from Directive 95/46 [Data Protection Directive] read in the light of the Charter are complied with, those means must nevertheless prove, in practice, effective in order to ensure protection essentially equivalent to that guaranteed within the European Union.

Because of the discretion that the General Data Protection Regulation leaves to the EU Member States in relation to research, it remains to be seen how the more detailed rules for processing health and genetic data in research will be regulated in the EU Member States. In relation to B3Africa and transfer of health and genetic data for research purposes from the EU to African states, the main hurdle seems to be the requirement for an effective legal remedy. Access to legal remedies for research subjects/data subjects is, as far as we have been able to ascertain, not always available. However, it seems unlikely that an exception to the right of an effective remedy could be considered acceptable from an EU point of view on a more general scale, that is, within the mechanisms for an adequacy decision or an appropriate safeguard. This means

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85 Data Protection Directive (n 75) Article 26.2 and General Data Protection Regulation (n 74) Article 46.3(a).

86 See for example, Mascalzoni and others (n 11) 722, 724.

87 General Data Protection Regulation (n 74) Article 46(1).

88 Data Protection Directive (n 75) Article 26.2.

89 According to Article 25(2) Data Protection Directive, the assessment is to be based on the following: "The adequacy of the level of protection afforded by a third country shall be assessed in the light of all the circumstances surrounding a data transfer operation or set of data transfer operations; particular consideration shall be given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third country in question and the professional rules and security measures which are complied with in that country."

90 C-362/14 *Schrems* (n 78) para 74.

that the only mechanism available for transferring health data for research outside of the EU to an African state is via derogation according to Article 49 General Data Protection Regulation. This would, however, mean that transfer of health data for medical purposes under the regulation would be given a weaker protection than in the present situation under the directive, which in itself seems less likely to be considered acceptable. The task of defining an appropriate legal conflict of laws tool that would satisfy the requirements of EU data protection law remains to be resolved. In the long term, one way forward may be for BBMRI-ERIC, an EU Research Infrastructure set up by the EU for the purposes of enhancing medical research on biobanking, to adopt a code of conduct under Article 40 General Data Protection Regulation.[91] Such a code may in turn serve as an appropriate safeguard for the transfer of personal data according to Article 46 of the regulation.

5. Concluding analysis

This article aims to share experiences of carrying out a transnational project in medical research in states that have differing legal, social and cultural traditions in general, and capacity-building research in biobanks in particular. This article demonstrates that, even if the legal hurdles may be significant, especially when it comes to transferring EU data to third countries, there may be ways to move forward. The approach that has been taken for the purposes of the B3Africa project is to apply two strategies, a dual approach: both to elaborate a common understanding of basic concepts and develop tools to safeguard their implementation in the project, and to develop a legal conflict of laws solution to be applied in specific cases. In this way, we hope to overcome the existing challenges and be able to ensure that also the part of the project that requires exchanging the data between the African States and the EU Member States can be carried out as intended.

From our experience with the B3Africa project, we have found that the far-reaching requirements for protection of EU data subjects wherever their data is processed in the world raises some questions. The ethical and legal framework in the B3Africa project develops from the necessity to safeguard privacy for the biobank research participants, which is a shared aspiration among the EU Member States and the African States. However, the expression of this value in the regulatory frameworks and specific rules that are relevant for biobank research differs considerably in different regions and also different national legal orders. Therefore, the minimum rules that the

[91] Reichel (n 50) 191.

use case states should abide by can be regarded as a solid starting point for the purposes of carrying out the part of the B3Africa project that relates to on-site use of the eB3Kit. Likewise, they are a solid base for building trust between the use case states, which is an essential element in cross-border collaboration. However, as the data protection requirement analysis has demonstrated, the minimum requirements are insufficient for ensuring cross-border collaboration, especially in the case of transferring personal data out of the EU.

In principle, to enable mutual collaboration in the exchange of data between the African States and the EU Member States, the EU mandates to ensure an adequate level of protection of European subjects' data in Africa. While adequate does not mean the same, it could involve rather similar requirements.[92] They arguably could be satisfied to the extent that they are shared values. However, it might be rather challenging if those values are subjected to the accommodation of cultural values and practices. It could be that the imposition of EU rules on data protection prevents the strengthening of research integrity vis-à-vis the researchers in Africa by enabling them to use the EU research subjects' data. It is suggested that an attempt to export the data protection requirements to another culture, therefore, could be seen as disrespectful towards national values and cultural diversity. To enable a two-way collaboration between the continents, other governance mechanisms could be used that provide for room to develop a dialogue between the involved continents and states. In the European context, such an infrastructure is BBMRI-ERIC, which has a strong ELSI component that could be used as a platform for dialogue and to bridge the two continents in the area of biobank research. There may be an important window of opportunity in the General Data Protection Regulation and the possibility for the BBMRI-ERIC to adopt codes of conduct for processing of data in accordance with Article 40, which may also function as legal grounds for the transfer of data outside the EU.[93] It could also be open for other participants, such as the US, which has considerable collaboration with the EU Member States in biobank research and an interest in biobank research in Africa.

[92] C-362/14 *Schrems* (n 78) para 74.
[93] General Data Protection Regulation (n 74) Article 46.2 (e). See further, Reichel (n 50) 191.