European Journal of Medical Genetics 59 (2016) 295–309

Contents lists available at ScienceDirect

European Journal of Medical Genetics

journal homepage: http://www.elsevier.com/locate/ejmg

Review

A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development process

D. Strech [a, *], S. Bein [b], M. Brumhard [c], W. Eisenmenger [d], C. Glinicke [e], T. Herbst [f], R. Jahns [g], S. von Kielmansegg [h], G. Schmidt [i], J. Taupitz [j], H.D. Tröger [k]

[a] Hannover Medical School (MHH), Institute for History, Ethics, and Philosophy of Medicine, Germany
[b] University of Duisburg-Essen, Ethics Committee of the Medical Faculty, Germany
[c] University of Gießen, Research Ethics Committee, Germany
[d] Ludwig Maximilians Universität München (LMU), Ethics Committee, Germany
[e] University of Kiel, Ethics Committee of the Medical Faculty, Germany
[f] Humboldt-Universität zu Berlin, Faculty of Law, Germany
[g] University Hospital of Wuerzburg, Interdisciplinary Bank of Biomaterials and Data Wuerzburg (ibdw), Germany
[h] University of Kiel, Chair of Public and Medical Law, Germany
[i] Technische Universität München (TUM), University Hospital Klinikum Rechts der Isar, Germany
[j] University of Mannheim, Professorship for Civil Law, Law of Civil Procedure, Private International Law and Comparative Law, Germany
[k] Hannover Medical School (MHH), Research Ethics Committee, Germany

ARTICLE INFO

Article history:
Received 2 February 2016
Received in revised form
15 April 2016
Accepted 25 April 2016
Available online 26 April 2016

Keywords:
Biobank
Biospecimen
Genetic research
Broad consent
Consent form
Ethics

ABSTRACT

Background: Biobanks increasingly presume long-term storage of biomaterials and data that shall be used for future research projects which are today unspecified. Appropriate consent documents for sample donors must therefore explain the breadth of consent and other elements of the biobank governance framework. Recent reviews demonstrated high variability in what issues these documents mention or not and how the issues are explained. This might undermine the protection of sample donors, complicate networked biobank research, create research waste and impact on public trust.
Methods: A systematic analysis of international research guidelines and existing broad consent templates was performed. Based on this information an interdisciplinary expert group from the AKMEK (Permanent Working Party of German RECs) developed a draft template and organized a comprehensive stakeholder consultation. After revision the final template was consented by all 53 German RECs.
Results: This paper briefly explores the spectrum of potentially relevant issues for broad consent forms. It then elaborates the template and how it was designed to be applicable in different types of biobanks.
Discussion: To further improve the validity and applicability of broad consent forms in biobank and other big data research, practice evaluations are needed. We hope that in this regard the presented template supports the development of new consent forms as well as the evaluation and revision of existing ones.

1. Background

Biobanks are collections of human biological samples and related health and personal information for use in research. High quality biobanks are important resources for health research, including basic research, questions in personalized or stratified medicine (genetic and other biomarkers) and research in widespread diseases (Zika et al., 2010; Asslaber and Zatloukal, 2007).

The development of large-scale population-based as well as disease-specific biobanks brings new ethical, legal and social challenges. These include issues around the role of ethics committees, data protection, dealing with incidental findings, public involvement measures, and particularly the need for new, or at least updated, models of informed consent for the donors of biomaterials (Herbert, 2012; Budimir et al., 2011).

* Corresponding author. Medizinische Hochschule Hannover (MHH), Institut für Geschichte, Ethik und Philosophie der Medizin, Carl Neuberg Str. 1, 30625 Hannover, Germany.
E-mail address: strech.daniel@mh-hannover.de (D. Strech).

http://dx.doi.org/10.1016/j.ejmg.2016.04.002
1769-7212/

Several stakeholders in the field of biobank research and whole-genome sequencing are developing innovative consent documents and procedures (Ayuso et al., 2013; Salvaterra et al., 2008). One major reason that these differ from standard documents in the context of clinical research is the increasing number of research biobanks that presume long-term storage of biomaterials and data. Such materials and data can be used for future research projects which are today unspecified and to some extent unforeseen. In these cases, donors of biomaterials are asked to give 'broad consent' to a framework for future research of certain types, instead of the standard narrow consent to one specific research project. Appropriate consent documents must therefore explain the breadth of consent and other elements of the framework for future research such as, for example, cross-border use of biomaterials and/or data, property rights, commercial use, and data protection (Budimir et al., 2011; Ethikrat, 2011; OECD, 2009; Greely, 2007; Hansson, 2009; Cambon-Thomsen et al., 2007; Pawlikowski et al., 2011; Beskow et al., 2010; McGuire and Beskow, 2010; Hoeyer et al., 2005). Further, a degree of harmonization of the broad consent forms used for biobanks with similar purposes and procedures will be essential to cooperation and networking at the national and international level.

Though information and consent documents do not replace the discussion between biobank researcher and study participant, they are an important component ("a first step") of the informed consent procedure and its documentation, not least legally. Several empirical studies have shown that consent forms are often uncomprehensive, incomprehensible or impractical, and fail to meet participants' needs (Brehaut et al., 2012; Mandava et al., 2012; Padhy et al., 2011; Jefford and Moore, 2008; Lavori et al., 1999). Improvements are necessary to support a balanced and evidence-based decision-making process by participants.

Existing studies of biobanks and their governance strategies indicate challenges in consent procedures (Zika et al., 2010; Herbert, 2012; Hirtzlin et al., 2003). Researchers have proposed a unified consent model and possible content for a consent form in biobank research (Salvaterra et al., 2008; Porteri and Borry, 2008) and for whole-genome sequencing studies in the clinical context (Ayuso et al., 2013). Further consent particularities have been outlined for biobank research with children (Kranendonk et al., 2016; Giesbertz et al., 2016).

As both the general principle and specific requirements of broad consent have generated complex discussion, it is no surprise that biobank chairs at academic sites in Germany reported substantial differences in local RECs' willingness to approve biobank research operating under a broad consent model. Some RECs unwilling to approve biobank research with a broad consent model have referred to the Declaration of Helsinki (DoH) and to different types of data protection regulations, noting that consent to research or to the use of health-related data requires specific information about the project. "Specific" can mean that the objectives of research, the principal investigator and the project's duration are specified. Exemptions for research are possible, but must be justified case by case. Because broad consent does not fulfil these requirements, it is argued that its authorization would contravene current interpretation of data protection laws or the DoH.

Even those German RECs that approved broad consent forms for biobank research differed on what the consent forms should include. A similar controversy exists in the USA. There, a workshop of experts in research ethics, funded by the NIH Department of Bioethics, argued recently that broad consent is ethically acceptable as long as participants are provided with sufficient information to make a reasonably informed decision (besides other safeguards) (Grady et al., 2015). This expert group listed 13 issues that such broad consent forms might need to cover. Similarly, in 2015 the WMA published a draft "Declaration on Ethical Considerations regarding Health Databases and Biobanks" (World Medical Association (WMA), 2015). This declaration also considers broad consent to be ethically acceptable if individuals are "informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected and about who will have access to the Health Database or Biobank. They must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information."

Several sets of ethical guidance currently define the required criteria for consent in clinical research, e.g. (Council for International Organizations of Medical Sciences (CIOMS), 2002; World Medical Association (WMA), 2008). Some guidelines also explicitly mention required criteria for consent in biobank research, e.g. (OECD, 2009). At present, however, there is no specific guidance on biobank research and consent procedures that can be used to assess consent forms. Furthermore, we currently lack a broadly accepted "best practice" model for consent forms in biobank research (Herbert, 2012).

Against the background of this controversy, and because of the increased number and scope of biobank projects in Germany, such as the "National Biobank Initiative" and the "National Cohort" (both funded by the German Federal Ministry of Education and Research, BMBF) the Permanent Working Party of the German Medical Ethics Committees (AKMEK, Arbeitskreis Medizinischer Ethik-Kommissionen) established a task force to develop a template for broad consent forms acceptable to all 53 German RECs. This template should address all relevant legal and ethical requirements and be applicable to several types of biobank, with alternative text provided to suit varying ethical and legal requirements.

This paper presents the developed template, and describes its evidence and consensus-based development process.

2. Methods

The development process was informed by two empirical studies: the results of a systematic analysis of international research guidelines (Hirschberg et al., 2014), and a survey and content analysis of existing broad consent templates from German biobanks (Hirschberg et al., 2013). The expert group chose one existing consent form that captured most of the potentially relevant issues, as derived from the first empirical study. Based on this consent form a first draft was developed in six meetings between August 2012 and September 2013. This draft was then circulated for stakeholder consultation, including a working group for biobank research at the TMF (Technology, Methods, Infrastructure for Networked Medical Research), other biobank researchers, all German RECs, data protection experts, and the German association of the pharmaceutical and medical device industry (vfa). The expert group also presented and discussed the draft at an annual meeting of the "Science" working group of the Federal data protection agencies.

After revision the final template was presented and discussed and finally agreed at the annual conference in November 2013.

3. Results

In the following we briefly introduce core findings from the two empirical studies that informed the template's development (Hirschberg et al., 2013, 2014). We then discuss how the final template deals with crucial issues such as differences in biobank characteristics, and hotly-debated topics such as reporting of incidental findings and biobank-related risks.