Europe and tissue research: a regulatory patchwork

Evert-Ben van Veen

Abstract

Many tissue research projects are under way in Europe. All major projects are part of the Biobanking and Biomolecular Resources Research Infrastructure, in short BBMRI-EU. The regulatory landscape is complex. The European Union can only act within the authority attributed to it by the European Union Treaties. Ethics as such is not part of its competences. It can regulate the free flow of services and regulated the processing of personal data in 1994. A major overhaul is under way which could seriously hamper research. Research with tissue as such is regulated at the national level and through international non-binding instruments. Different approaches can be seen, in combination with new approaches to governance. Data protection is a key component in biobanking projects. It is proposed to focus less on the vain quest for anonymity of data before they reach the research domain, but instead on the safety of personal data once there.

Keywords autonomy; biobanks; consent; Council of Europe; data-sharing; ethics; European Union; GDPR; governance; privacy; solidarity

Introduction

The enormous benefits which research with tissue and accompanying data will have for healthcare have not been lost on Europe. An inventory has been made of major biobanking projects in Europe.[1] According to the Biobanking and Biomolecular Resources Research Infrastructure, (BBMRI-EU) business plan, Europe might even have world's highest density of biobanks.[2]

The regulatory landscape, however, is very diverse. This diversity corresponds with the variety of nations and historical and cultural backgrounds in Europe, with related varying constitutional and legal traditions. As stated by Weiler there is not one 'demos', one people, in Europe.[3] This does not mean that there are not common values overriding particular differences. Europe was the first continent to establish a Treaty on human rights with a European Court of Human Rights (ECHR), which can address complaints from individuals and make binding recommendations to national governments.[4] The Council of Europe, where the ECHR is situated, still plays an important role in addressing ethical issues that are common to the affiliated states.

The Western European states started to organize free trade in the early fifties of the last century. A long, complex and incremental decision-making process of more than 40 years culminated in the present Treaties on the European Union (EU). Not only politicians and sometimes the population by referendum, but also the European Court of Justice played an important role in shaping the European Union. The different ideologies as to what this EU is meant to be, are still influencing its governance structure.[5]

Behind these two major players — the European Union and the European Court of Justice — (or in the foreground, depending on how one sees European cooperation) there are the national governments in the constitutive patchwork of European states, which can still make their own regulations insofar as they are not contrary to EU law or binding international instruments.

National and international decision-making will also be influenced by an 'avalanche' of non-binding international instruments relating to the use of tissue for research.[6]

Against this background this paper will explore and evaluate the present regulatory trends in Europe. As research with tissue is research with data most of all,[7] a large section will be devoted to possible changes in the EU data protection regime.

The Council of Europe

The Council of Europe (CoE) comprises 47 member states of wider Europe; 20 more than are in the EU. Its mission is to create greater unity between the member states by furthering democracy, human rights and the rule of law in Europe.[8] It does so mainly by proposing texts for new European treaties on mentioned aspects and assuring the process of signing such treaties or by issuing Recommendations by the Council of Ministers.

In 1997 the CoE issued a Treaty on human rights and biomedicine.[9,10] This Treaty does not address biobanking as such. Article 21 states an important principle, seen throughout European law also in the context of blood donation, that the human body and its parts shall not, as such, give rise to financial gain. Article 22 states that residual tissue can only be used for purposes than that for what it was removed if this is done with other appropriate information and consent procedures. In later years, the Treaty was followed by Protocols. In 2005 the Protocol on biomedical research was issued.[11] The protocol relates to interventional research (Art. 2) and does not directly address biobanking. Use of tissue for research was specifically addressed in the CoE Recommendation on research on biological materials of human origin of 2006.[12] There is a tension between the Protocol on biomedical research when tissue is taken out specifically for research and this Recommendation.[13] The Recommendation did not seem to allow for blanket consent but did allow for layered consent. Opt-out as a consent modality for the use of residual tissue was discarded. The Recommendation is at odds with earlier and later legislation in some European countries and is under revision at the moment. Possible viewpoints for such a revision were discussed at a conference in Strasburg, the seat of the CoE, in 2012.[14] On that occasion a booklet on 'Biobanks for Europe' was presented.[15] Remarkably, the conference did not look back on how the Recommendation has been implemented in various countries and more specifically why certain countries haven chosen for a more lenient regime. There is no indication when a draft of the new Recommendation will be issued.

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The European Union

In general

The complex organization of the EU cannot be discussed here. The EU can only operate within the competences set by the European Treaties. The main Treaty relevant here is the Treaty on the Functioning of the European Union (TFEU). When it operates the EU should act in conformity with the EU Charter of Fundamental Rights (hereinafter: the Charter). The EU cannot regulate healthcare as such (art. 168 TFEU) but can regulate goods and services, in order to promote free trade within the EU, which relate to healthcare. In all its policies the EU should aim for a high level of health protection (art. 168 and 114. 3 TFEU).

Additionally, it can regulate certain common safety concerns regarding products used in healthcare (art. 168.4 TFEU). In that context a large body of law regarding pharmaceuticals has been established, a more concise body of law regarding medical devices (under revision) and also Directives concerning blood products and human tissue products as an aspect of common safety concerns. Research as such cannot be governed by binding EU policies. It may come back through the articles on the free provision of services and goods, as the cornerstones of all the successive Treaties, through the harmonization of laws and the common safety measures as required by art. 168.4 TFEU. The present proposal for a new clinical trial regulation is an example.[16] This example also shows that ethics as such cannot be regulated by the EU either, as long as the proposed measures remain within the broad clauses of the Charter.

The binding regulatory measures of the EU consist mainly of Directives and Regulations (art. 288 TFEU). A Directive contains norms which must be implemented in the national laws of the member states. Therefore it requires a translation in those national laws. Depending on the language of the Directive and the leeway for national exemptions, this may cause quite a variety in national laws, which were supposed to be harmonized on the European level. Medical data for research under Directive 95/46/EC, the present data protection Directive, has been subject to this national variation. This is one of the reasons why the European Commission wants this Directive to be replaced by a Regulation. A Regulation is binding directly and does not need to be transposed into national law. The proposed general data protection regulation (GDPR) will have a huge impact on biomedical research and will be discussed in the following sections.

There are many areas where the EU or better the European Commission and its staff use indirect means to regulate. This is by so called 'soft law'[17] or by its policies on funding projects. Many, if not most, biobanking projects in Europe have profited from the European Framework programs. Proposals require an assessment of the ethical aspects and then international non-binding instruments on research will enter EU policies through the backdoor. A criticism of such non-binding instruments when applied to observational research has been made elsewhere.[6,7,18]

The EU data protection regime

Research with tissue is research with data.[7] The EU, then European Communities, enacted comprehensive data protection legislation already in 1995. The Directive states consent for the use of personal data as the prime principle and explicit consent for the use of sensitive data such as data regarding health. Personal data should be collected for 'specified, explicit and legitimate purposes' (art. 6.1 at b). In a remarkable decision the Swedish Data Protection Authority (DPA) concluded that the collection of data from volunteers for 'LifeGene', the new general Swedish biobank, did not meet this requirement,[19] as the specific research questions which could be set loose on the combination of data and tissue were not defined yet. If the DPA's in other countries would have taken the same approach, biobanks such as the UK biobank[20] or Lifelines in the Netherlands[21] would not have been possible. All national DPAs meet in the so called art. 29 Data Protection Working Party, which regularly issues Opinions on certain general issues. In April 2013 it issued an Opinion on purpose limitation.[22] This Opinion mentions that 'future research' "will — without more detail — usually not meet the requirement of being 'specific'". In the Swedish case as in all other cases of population biobanks, the data were collected for health research and that research uses rather specific means. The Opinion does not discuss this example and hence it is unclear whether the Opinion is less extreme than the decision of the Swedish DPA. The Opinion discusses 'Big Data' which by definition contains a broad, unspecified collection of data. Such a collection would be allowed if the data will only be used for statistical analysis and the analysis will not result in individual decisions. This supports an interpretation that the Opinion allows for more room than the Swedish DPA did. As purpose limitation should be read in conjunction with the consent principle, the idea being that one cannot consent to something unspecific, the Swedish DPA acknowledged that a special law might override the difficulties of consenting to, as they saw it, unspecified research. That law is in the making now in Sweden.[23]

This can be done under the research exemption of Directive 95/46/EC. It might not be possible anymore under the coming GDPR. The GDPR as proposed by the European Commission still leaves room for research without consent as specified in the GDPR (art. 83). The European Parliament, which is the body to discuss the proposal in the next phase of the proceedings, issued a report which would narrow down this exception very much. This so called LIBE report proposed more amendments to the original proposal which would be very detrimental to medical research.[24] The LIBE report has been criticized by the research community from various angles.[25–27] Research plays a minor role in the GDPR, which is mainly about data protection for consumers in this digital age. The GDPR contains 139 Recitals and 91 articles. Over 4000 amendments have been proposed to those provisions by the EP, obviously many overlapping and many contradictory. The vote on the amendments has been continuously postponed and will probably take place in September 2013. When the EP has drawn up a new amended draft GDPR, the Council of Ministers, composed of the responsible ministers of the member states, will propose a third draft, taking that of the EP into account. Then a second round between the EP and the Council of Ministers will start, coordinated when necessary, and that will surely be the case here, by the European Commission. As the next round of discussions in the EP will most probably take place with a new EP, given the elections in May 2014 for the EP, the outcome of this process is still very unclear.

More about the GDPR and the issues insofar as related to research, can be found in the paper referred to earlier.[24] Some issues will come back in the analysis at paragraph 4 of this paper.