

MEETING THE STANDARD: AN OVERVIEW OF EUROPEAN BIOBANK REGULATION AND A COMPARISON TO THE CURRENT SOUTH AFRICAN POSITION

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I. INTRODUCTION

Due to the fascinating new developments in biomedicine such as stem cell therapy and tissue engineering, contemporary medicine is moving away from being a reactionary process to being a process which focuses on the maintenance of health by being personal, predictive, preventative and participatory.¹ This means that medicine is moving away from the traditional forms of treatment, to a point where treatment and experimentation almost merge, and thus it is also moving away from the known forms of regulatory frameworks and mechanisms. In fact, the proper and best method of regulating biomedicine is uncertain and will be subject to a process of trial and error for many years. This is true on a global scale and also on a local South African one. This regulatory process is also slowed down and delayed to some extent while each role player, be that an authority or institution or practitioner or researcher or even country, attempts to solve all the issues individually since this leads to a nonconformist and confusing mass of incoherent binding and nonbinding legal and ethical documents, guidelines and rules. This in turn hinders sharing of information, data and ultimately knowledge and subsequent development.² A uniform system would encourage and

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¹ This may be referred to as “P4 medicine.” See L. Hood, L. Rowen, D. Galas, J. Aitchison, Systems biology at the Institute for Systems Biology, *Briefings in Functional Genomics and Proteomics* (2008) 239 –248 and J. Loscalo, A. Barabasi, Systems biology and the future of medicine, 3(6) *Wiley Interdisciplinary Review of Systems Biology Medicine* (2011) 619 – 627.

² A real world example of this may be seen in the contradictory Regulations which were published in the *Government Gazette* No.29526 of 5 January 2007. The titles of the Regulations are Regulations regarding the

facilitate sharing and this would lead to collaboration and better and faster development of biomedicine.

South Africa is the African leader in the field of biomedicine and thus must set an example.³ But where should South African biomedical legislators and regulators turn and on what example should the South African model be based? The European model is perhaps the best bet as it encompasses a wide variety of jurisdictions with different legal traditions which to some extent resembles the hybrid system of law in South Africa which forms a single system. There is also the parallel of the European Union and African Union and in future South African and the other members of the AU will be in the same position as the members of the EU in finding a common outlook on health matters. Lastly, the European community has been active in not only the scientific biomedical field but the regulatory aspects also for a longer and undisturbed period.⁴ It could be argued that medical interventions of this kind started in the 1970s in England with the birth of the first test tube baby, Louise Brown in 1978 and the first regulatory model was developed during the 1980s as a result of the work of the Committee of Inquiry into Human Fertilisation and Embryology as chaired by Mary Warnock from 1982 to 1984 which ultimately gave rise to the Human Fertilisation and Embryology Act of 1990. The aim of this article is therefore to provide an overview of the European regime of regulation of a certain aspect of the biomedical environment, namely biobanks and a comparison thereof to the South African instruments and position. This is

Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics and the Regulations regarding Artificial Fertilisation and Related Matters. Two working groups, one based in Gauteng and the other in the Western Cape, had been independently and unaware of the others existence working on the Regulations. The groups only became aware of one another when their Regulations appeared in the same *Gazette*. The two Regulations obviously do not conform and may in some instances lead to confusion.

³ J. Kassah, 'Stem cell legislation in South Africa', available at <http://embrybros.wordpress.com/2011/03/16/stem-cell-legislation-in-south-africa/> (accessed 7 September 2013).

⁴ Biomedicine in the United States of America for example suffered a blow under the Bush administration and only recovered under the Obama administration and could therefore almost be described as being on a similar path of discovery, regulation wise, as South Africa.

done to enhance understanding of the regulatory environment in order to direct development in South Africa towards one which is in unison, or at least on par, with European development. This overview aims at clarification of what might be a complex system to grasp as an outsider and so hopes to ease replication of or inspiration by certain of its instruments, tools and principles. Ultimately, this article attempts to illustrate aspects which have been addressed by the European instruments and which are lacking in the South African system. Due to various social, economic and perhaps even political reasons, South Africa is not yet able to contend with European countries when it comes to the science of biomedicine. An aspect of biomedicine which has however been practiced in South Africa for a number of years now is that of banking biological material.⁵ This article as mentioned however focuses on a single aspect of biomedicine, namely biobanks and some attention must be given to this concept.

A. Biobanks

Biomedicine itself relies on research and research is based on research subjects. In the case of biomedicine, the subject is biological material. Obviously, biological material in some quantity is necessary and thus, a place of keeping such material is also necessary. This place is then none other than a bank and more specifically, a biobank.

What is a biobank? The term “biobank” may be understood as an umbrella term which includes “human genetic research databases,” “biorepositories,” “population genetic databases” or “tissue banks” which is the term used in South Africa. The term “biobank” will however be used in this article. Biobanks may be differently characterised based on various

⁵ See in general B. Lindeque, A. Lindeque, H. Hausner and T. Le Roux, Tissue banking in South Africa: A 19-year history, 6(11) *Cell Tissue Bank* (2005) 65 – 70.

grounds⁶ and these grounds will influence the scope of activities undertaken by the biobank⁷ and vice versa. Some common traits do however exist which apply to all biobanks. They are:⁸

- The collection of biological samples;⁹
- Biobanks are not static projects and continuously and on a long- term basis collect samples;
- The banks are associated with a purpose;¹⁰
- Some form of data coding is used to de-identify the sample and ensure data privacy but the data is also be re-identifiable; and
- Governance structures and procedures are in place to ensure ethical and legal operation of the bank.¹¹

For the purpose of this article, a biobank must be understood as a facility which, in accordance to its existential purpose, procures and distributes¹² biological materials or samples and associated data in an organised manner and is subject to governance structures and procedures.

The ultimate aim of this article is to provide an explanatory overview of the European system in order to provide some direction for South African development and for this reason

⁶ These include: size, research design, types of biological samples which are collected, the sample collection methods employed by the bank processing of samples, storage of samples and any disease or research focus which may be relevant. On this basis a distinction could be made between population- based biobanks, disease-orientated biobanks, case- control biobanks, tissue banks etcetera.

⁷ Such as the donor recruiting process, consent procedures, the scale of support required, governmental infrastructures necessary and the potential to be commercially exploited.

⁸ European Commission Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, *Biobanks for Europe: A challenge for governance*, Publications Office of the European Union (2012) 1.

⁹ These samples are linked to both medical and epidemiological data.

¹⁰ Which could include currently defined or future, not yet specified research.

¹¹ An example of a governance structure is an ethics review committee and an example of a procedure to be in place is the obtaining of consent.

¹² Or, differently stated, collects and supplies.

the currently existing South African regulatory tool regarding biobanks should be briefly discussed, namely the Regulations relating to Tissue Banks.

II. SOUTH AFRICAN REGULATIONS RELATING TO TISSUE BANKS

There are two Regulations in South Africa dealing with Tissue Banks. The first appeared in the *Government Gazette* on the 1st of April 2001 and the second on the 2nd of March 2012. Both the 2011 and 2012 Regulations will be briefly discussed here. The purpose of this discussion is to outline the current position in South Africa in order to illustrate what still needs to be done and developed. Once the shortcomings of the South African instruments have been identified, it becomes simpler to determine where South Africa stands developmentally and to decide which aspects of the European regulatory tools should be copied. The Regulations relating to Tissue Banks have been created under the National Health Act¹³ and are first- of- its- kind in the South African health law context. Here, the Regulations will be discussed briefly and chronologically.

The 2011 Regulations relating to Tissue Banks¹⁴ define a tissue bank as “an organization, institution or person registered in terms of regulation 3 of these regulations as a tissue bank.” The Regulations consist of four chapters which provide for the registration of an organisation, institution or person as a tissue bank. An organization, institution or person must register where it or they acquire or import human tissue; preserve, screen, test, process, store, label, separate, pack or supply or dispose of human tissue; or produce, pack, seal and label any tissue product.¹⁵ Registration is not required where the tissue product is used for educational or scientific purposes only or where the tissue is transported in the normal course

¹³ National Health Act, Act 61 of 2003. For more on the National Health Act, see L. Prinsen, *An Analysis of the Proposed Regulatory Framework for the Procurement and Distribution of Stem Cells*, LLM Thesis, University of Pretoria (2010), available at <http://upetd.up.ac.za/thesis/available/etd-07122011-115208/unrestricted/dissertation.pdf> (accessed 17 September 2013).

¹⁴ The Regulations relating to Tissue Banks of 1 April 2011, *Government Gazette* No. 34159.

¹⁵ *Ibid.*, at regulation 2.

of business.¹⁶ The Regulations provide for the application procedure for registration¹⁷ as well as provisions for the suspension and revocation of registration.¹⁸

Chapter 2 of the 2011 Regulation deals with the duties of a tissue bank.¹⁹ These duties include *inter alia* keeping a register of tissue donors; keeping a record and a record of statistics of tissue donations and a record of untoward reactions. Chapter 3 handles matters concerning the quality and safety of tissues. A tissue bank must therefore have a policy of quality management as well as a person in charge thereof.²⁰ Furthermore, the bank must establish criteria for the recruitment of tissue donors and this entails creating standards of practice for the acceptance or deferral of such donors.²¹ Tissue banks are also required to perform mandatory tests on tissue and tissue products.²² Lastly, chapter 4 provides for appeals, delegation of powers and general provisions.²³

The 2012 Regulations²⁴ provide for a different definition of a tissue bank and states that it is “an organisation, institution or person that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes and is registered in terms of regulation 3 of these regulations.”²⁵ The 2012 regulations further provide for a definition of tissue which was not provided for in the 2011 Regulations. According to regulation 1 of the 2012 Regulations, tissue means “a functional group of cells.” This term is used collectively in the Regulations to indicate both cells and

¹⁶ *Ibid.*, at regulation 2(2).

¹⁷ *Ibid.*, at regulation 3.

¹⁸ *Ibid.*, at regulation 4.

¹⁹ *Ibid.*, at regulation 6(1).

²⁰ *Ibid.*, at regulation 7.

²¹ *Ibid.*, at regulation 8.

²² *Ibid.*, at regulation 9.

²³ Regulations 10– 12.

²⁴ The Regulation relating to Tissue Banks of 2 March 2012, *Government Gazette* No. 35099.

²⁵ *Ibid.*, at regulation 1.

tissue.²⁶ Almost 30 new definitions were created, some definitions were broadened²⁷ and others which had appeared in the 2011 Regulations were not included in the 2012 version.²⁸

The 2012 Regulations furthermore provide for the use of human tissue and states that the uses of tissue²⁹ are subject to certain requirements such as authorisation by the Department of Health, adherence to the Regulations and that laboratory tests for infections agents which may cause transplantation transmitted diseases have to be completed and the results of these test must be available.³⁰

The 2012 Regulations provide for the information which an application for authorisation must contain.³¹ Once authorisation is granted however, it may be suspended or withdrawn on certain grounds which include violation of the rights of the donor or recipient of tissue.³²

A completely new aspect which is regulated by the 2012 regulations is that of the organisational structures of a Tissue Bank. A provision which is rather progressive as it explicitly mandates adherence to an instrument of International law is regulation 5(2). This regulation states that “all activities of an authorisation [*sic*] tissue bank relating to cell and/or tissue procurement, processing and distribution shall comply with the Guiding Principles of the W.H.O. as contained in the Declaration of Istanbul on Organ trafficking and Transplant

²⁶ Some ambiguity thus still remains in this definition.

²⁷ For example, in the 2011 Regulations a donor is defined merely as “a person who has donated tissue in terms of the Act” while in the 2012 Regulations the definition reads that a donor is “a person from who tissue, blood, blood products or stem cells is donated in terms of this regulation.”

²⁸ For example, the 2012 Regulations do not contain definitions for “inspector,” “standard practice” or “vascular organ.”

²⁹ The uses are: removing, acquiring, importing, preserving, screening, testing, processing, storing, separating, producing, labelling, packing, supplying, distributing, exporting or releasing for transplantation.

³⁰ Regulation 2, *supra* note 24.

³¹ This is the name and nature of the applicant, location of the premises where business is to be conducted, an indication of how records and data shall be kept, the quality management system to be used, details of the responsible person and any other information the Director General may consider necessary for the consideration of the application. See regulation 3(2)(a)-(f), *supra* note 24.

³² Regulation 4(1)(c), *supra* note 24.

Tourism of 2009.”³³ The main objective of the Declaration seems to be the regulation and control of the movement of tissue which would then influence any import and export of tissue. A further new and interesting provision is that Tissue Banks must have a designated person who is responsible for policy- making. This may indicate a more ethical and transparent, responsible method of tissue banking practice.³⁴ In a similar vein to this, the Regulations of 2012 also provide for the duties and reporting obligations of a Tissue Bank. A tissue Bank now has a duty regarding donor particulars which are required to be kept in a register,³⁵ holding documentation regarding the tissue banking processes for which the Tissue Bank is responsible,³⁶ maintaining a record of statistics regarding tissue donations,³⁷ keeping a system with the purposes of sharing information regarding serious adverse events of quality and safety issues with the Director- General,³⁸ creating a fast and accurate recall procedure³⁹ and distribution records.⁴⁰ Additional duties of the health officer are also provided for.⁴¹

New inspection and control measures are provided for namely that Tissue Banks must be inspected at least every year in order to ensure compliance with all relevant requirements of such a bank. Quality management⁴² and quarantine⁴³ are some of the elements which may be inspected. Individual and specific provisions are made regarding processing;⁴⁴ storage conditions;⁴⁵ labelling, documentation and packaging of tissues⁴⁶ as well as distribution and

³³ The Declaration emphasises the need to prohibit organ trafficking and transplant tourism as it is in violation of the principles of equity, justice and respect for human dignity. The Declaration asserts that since the commercialisation of transplantation often targets vulnerable donors, it leads to inequality and injustice and should also be prohibited.

³⁴ Regulation 5(3), *supra* note 24.

³⁵ *Ibid.*, at regulation 6(1)(a).

³⁶ *Ibid.*, at regulation 6(1)(b). Informed written consent is explicitly required by regulation 6(1)(b)(i), *supra* note 24.

³⁷ *Ibid.*, at regulation 6(1)(c).

³⁸ *Ibid.*, at regulation 6(1)(d).

³⁹ *Ibid.*, at regulation 6(1)(e).

⁴⁰ *Ibid.*, at regulation 6(1)(f).

⁴¹ *Ibid.*, at regulation 7.

⁴² *Ibid.*, at regulation 9.

⁴³ *Ibid.*, at regulation 10.

⁴⁴ *Ibid.*, at regulation 11.

⁴⁵ *Ibid.*, at regulation 12.

dispensing.⁴⁷ Further brand new and specialised provisions are those regarding traceability⁴⁸ and data protection and confidentiality.⁴⁹

Research is also specifically provided for and the Regulations of 2012 require that all activities practiced at a Tissue Bank which involves research and development of tissue samples must be done in accordance with the National Health Act, must be approved by a relevant ethics committee and must be supervised by a registered scientist. All such research must also be recorded and documented.⁵⁰ The Regulations lastly provide for appeals, delegations and offences.⁵¹

As the South African instruments have now been discussed, it becomes necessary to examine the European regulatory mechanisms to determine where South Africa is on par and what and where more attention is needed. The European legal instruments dealing with biomedicine is a complex combination of general and specific documents from differing authorities and each will be discussed in the course of this article.⁵²

III. EUROPEAN GOVERNANCE

European law relating to biobanks draws greatly from jurisprudence and legal traditions which have been developed in context of promoting public health and protecting human rights. As mentioned previously, the regulative landscape of medical research contains various specific and general legal instruments of which some of the more foundational documents are provided for by two very important European entities namely the Council of

⁴⁶ *Ibid.*, at regulation 13.

⁴⁷ *Ibid.*, at regulation 16. See also regulation 18 regarding third parties as this goes hand in hand with distribution of tissues.

⁴⁸ *Ibid.*, at regulation 14.

⁴⁹ *Ibid.*, at regulation 15.

⁵⁰ *Ibid.*, at regulation 17.

⁵¹ *Ibid.*, at regulation 19 – 21.

⁵² This article is based on the 2012 Report of the European Commission Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research on biobanks in Europe and how governance is challenged. See European Commission Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, *supra* note 8.

Europe and the European Union. It is interesting to note that the legal instruments of the Council of Europe are not binding. In certain instances however, which includes biomedicine, the Council's Conventions may be indirectly binding on European Union Member States by being referred to in European Union legislation.⁵³ Some attention must be given to each one of these governing entities and their respective contributions to the biobank regulatory *corpus*.

A. The Council of Europe

The Council of Europe was founded in 1949 by the Statute of the Council of Europe, also known as the Treaty of London (1949), after Winston Churchill had called for a "United States of Europe" during a speech made at the University of Zurich on the 19th of September 1946.⁵⁴ The objectives of the Council are to protect and promote human rights, democratic development, co-operation and the rule of law. The Council has 47 Member States of which 28 are also members of the European Union.⁵⁵ The Council however, is separate from the European Union and cannot make binding laws. The Council of Europe must also not be confused with the Council of the European Union which is a European Union institution.⁵⁶ The Council is seated in Strasbourg, France.

⁵³ L. Paula, The Oviedo Convention from the perspective of DG Research, 16(1) *Medical Ethics & Bioethics* (2009) 7 – 9.

⁵⁴ Churchill had previously spoken of a Council of Europe in a radio broadcast in 1943. The other founding fathers of the Council are Konrad Adenauer, Robert Schuman, Paul- Henri Spaak, Alcide de Gasperi and Ernest Bevin. See Council of Europe, 'Founding Fathers', available at <http://www.coe.int/aboutCoe/index.asp?page=peresFondateurs&l=en> (accessed 11 August 2013). See also The Centre Virtuel de la Connaissance de l'Europe, 'The Zurich Speech', available at http://www.cvce.eu/obj/the_zurich_speech-en-4665d9b1-1459-446f-aaa8-549630b2759a.html (accessed 11 August 2013).

⁵⁵ Council of Europe, 'Who we are, what we do', available at <http://www.coe.int/aboutCoe/index.asp?page=quisommesnous&l=en> (accessed 11 August 2013).

⁵⁶ European Union, 'Council of the European Union', available at http://europa.eu/about-eu/institutions-bodies/council-eu/index_en.htm (accessed 11 August 2013). The other Institutions of the European Union are the European Commission, the Council of the European Union, the European Council, the Court of Justice of the European Union, the European Central Bank, the Court of Auditors, and the European Parliament.

The Council's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, also known as the Oviedo Convention,⁵⁷ forms the basis whereby the rights of a human subject in a scientific process is protected within the territory of Europe. The Convention does so by providing general principles⁵⁸ which are then further supplemented by additional protocols.⁵⁹ The Convention however is limited in effect as adherence to its provisions is only mandatory for members of the Council who have ratified the Convention.⁶⁰

In 2006 the Council was the first European intergovernmental organisation to propose a general recommendation on research on biological materials of human origins⁶¹ which explicitly deals with biobanks and deals with issues such as independent oversight of biobanks, auditing, record keeping as well as the measures to be taken to facilitate access to the biobank and the information held thereby and also the transfer procedures as well as steps to be taken in the event of closure. The Recommendation is strengthened by being linked to

⁵⁷ Oviedo Convention, STE 164. Oviedo, April 1997. Council of Europe, '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 in Biomedicine', available at <http://conventions.coe.int/Treaty/fr/Treaties/Html/164.htm> (accessed 17 September 2013).

⁵⁸ These include primacy of the human being; equitable access to health care; professional standards; consent, including the protection of persons not able to consent and protection of persons not able to consent to research; private life and right to information; human genome issues such as non-discrimination, predictive genetic tests, interventions on the human genome and non-selection of sex; scientific research and the protection of persons undergoing research; research on embryos *in vitro*; organ and tissue removal from living donors for transplantation purposes and prohibition of financial gain.

⁵⁹ To date, the additionally adopted protocols are: the Protocol on Cloning (1998), the Protocol on Transplantation (2002), the Protocol on Biomedical Research (2005) and the Protocol on Genetic Testing for Health Purposes (2008).

⁶⁰ To date, 35 Members of the Council of Europe have signed the Convention but it has been ratified by only 29. See Council of Europe, '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 in Biomedicine', available at <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=&DF=&CI=ENG> (accessed 17 September 2013).

⁶¹ Recommendation Rec (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies.

the Convention and the Protocol on Biomedical Research but it is currently being re-examined.⁶²

B. The European Union

The European Union, or EU, is an intergovernmental economic and political union and was established by the Treaty of Maastricht in 1993. The EU however has its origins in the European Coal and Steel Community (ECSC) and the European Economic Community (EEC) which were both founded by the Council of Europe.⁶³ The EU has 28 Member States and is based in Brussels, Belgium.⁶⁴ The EU is based on various treaties which grant certain powers to the EU, one of which is the ability to make and enact legislation which may directly affect all the Member States in that the courts of Member States who have ratified the treaties are required to enforce the treaties under the principle of supremacy.⁶⁵ The EU has become a role player in the field of health and is now also involved in public health and research. The EU formulates policies to be used as common tools to protect public health but the application thereof lies with each of the Members through the principle of subsidiarity.⁶⁶

Biobanks are not specifically provided for by the existing biomedical regulatory framework of the EU. In spite of this however, some general foundations may be found in the

⁶² The Recommendation is under review as new issues have arisen out of biobanking which are not covered under the scope of the Recommendation. These include ownership of samples, reporting responsibilities regarding incidental findings and genome sequencing issues.

⁶³ Council of Europe, *supra* note 54.

⁶⁴ EurActive, 'Brussels' EU capital role seen as irreversible', available at <http://www.euractiv.com/pa/brussels-eu-capital-role-seen-ir-news-494302> (accessed 11 August 2013).

⁶⁵ An EU treaty supersedes national legislation which is in conflict with the treaty. This principle was first established by the European Court of Justice in *Falminio Costa v ENEL* [1964] ECR 585.

⁶⁶ This means that issues must be dealt with at the smallest, the lowest or least centralised level which is able to effectively address the issue.

Data Protection Directive,⁶⁷ the Clinical Trials Directive⁶⁸ and the Tissue and Cells Directive⁶⁹ which provide for broad procedural rules which protect persons who participate in biobank-based research. These Directives as legal instruments are discussed in the course of this overview.

IV. LEGAL INSTRUMENTS

Various legal instruments exist which could be applied in general in an attempt to regulate biobanks. These instruments may be distinguished from one another in that there are broadly speaking two groups of instruments. Firstly, there are EU Directives and secondly, domestic laws enacted in individual countries by their own respective governments. Both of these groups will be discussed here starting with the EU Directives chronologically and then a brief discussion of selected domestic laws related to biobanks. It is however necessary to briefly discuss the forms of EU legal Acts and given an indication of the reach of these documents.

The legal instruments of the EU take three forms namely Regulations, Directives and Decisions.⁷⁰ These legal documents are equal in status and do not fall into a hierarchical order. Regulations automatically and without requiring any further implementing procedures⁷¹ become law in all Member States the moment it comes into force and also supersedes any conflicting national legislation.⁷² Directives allow Member States somewhat

⁶⁷ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of data.

⁶⁸ Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementations of good clinical practice in the conduct of clinical trials on medicinal products for human use. The provisions found in this Directive do not apply to biobank-based research and also do not provide for the use of biological samples for research purposes.

⁶⁹ Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue cells. This Directive does not address the issue of research which makes use of human tissues and cells.

⁷⁰ The EU also creates instruments in the form of recommendations and opinions.

⁷¹ *Variola v. Amministrazione delle Finanze* [1973] ECR 981.

⁷² Article 288 of the Treaty on the Functioning of the European Union.

more freedom but still demand a certain result in a certain timeframe. The manner in which this result is to be achieved is left to the Member State and thus some freedom is given. When the allotted time to achieve the required result has passed the Directive may have a direct effect on the domestic law of the Member State. Decisions only apply to specified individuals or companies or Member States.

As mentioned previously, three EU Directives provide for a broad regulatory framework in the absence of specific instruments. These are the Data Protection Directive, the Clinical Trials Directive and the Tissue and Cells Directive and will now be discussed.

A. The Data Protection Directive

The Data Protection Directive is applicable to biobanking since, in the course of testing and or processing biological material, certain sensitive information may come to light regarding the donor of the material. It is thus important to mention from the onset that the issue when it comes to biobank-based research is not the sample itself but rather the content of the sample, meaning that it is the information derived from the sample⁷³ which then constitutes the data which must be protected.⁷⁴ The importance of this is that principles which may be applicable to the retention or circulation of samples derived for biobanking purposes should not differ greatly from the principles which relate to data protection, even where the individual legal framework of a Member State of the EU is not directly applicable to the personal data at

⁷³ This opinion was adopted by the Working Party which was established by article 29 of the Data Protection Directive in “Working Document on Genetic Data” of 17 March 2004 (WP91). The Working Party is the independent European Union Advisory Body on Data Protection and Privacy and it comprises of representatives from the EU Member States. This approach is also followed in the Danish Data Protection Act and in Italy by way of a general authorization 24th of June 2011.

⁷⁴ This position was also confirmed in the European Court of Human Rights in the cases of *Van der Velden v. The Netherlands* 7 December 2006 case No. 29514/05 and *S and Marper v. UK* 8 December 2008 case No.30562/04 and 30566/04 wherein the court held that “fingerprints, DNA profiles and cellular samples constitute personal data within the meaning of the Data Protection Convention as they relate to identified or identifiable individuals.”

hand. This means that the major principles of a data protection regulatory framework which may include *inter alia* fairness, lawfulness, transparency and security, apply across the board.

The European legal system relies greatly on the Data Protection Directive which provides the principles applicable to the protection of personal data. The provisions provided by this Directive are relevant to biobanking as banks deal with information of a sensitive nature. The Directive provides not only the principles of fair processing⁷⁵ but also stipulates that data protection supervisory authorities should oversee the activities in such a supervisory role. This model is mirrored at the highest level as Article 8 of the Charter of the Fundamental Rights of the European Union⁷⁶ states that every person has the right to protection of personal data concerning himself⁷⁷ and that such data must be processed fairly, for a specified purpose and on the basis of the consent that person or some other legitimate basis determined by law and that every person has the right of access to data which has been collected concerning themselves and the right to have it rectified.⁷⁸ Compliance with these rules is subject to control by an independent authority.⁷⁹ Article 16 of the Treaty on the Functioning of the European Union also reflects the model established by the Directive and provides that everyone has the right to the protection of personal data which concerns themselves⁸⁰ and that the European Parliament must lay down rules for protecting data in processing and movement of the data in activities which fall within the scope of EU laws.⁸¹

In terms of the Data Protection Directive, personal data, including sensitive data, may be used for research purposes provided that “suitable safeguards” have been adopted by the

⁷⁵ This may include that data is fairly and lawfully processed; processed for limited purpose; not kept for longer than is necessary and in a manner which is in line with the subject's rights.

⁷⁶ Charter of Fundamental Rights of the European Union (2000/C 364/01).

⁷⁷ *Ibid.*, at article 8(1).

⁷⁸ *Ibid.*, at article 8(2).

⁷⁹ *Ibid.*, at article 8(3).

⁸⁰ *Ibid.*, at article 16(1).

⁸¹ *Ibid.*, at article 16(2).

Member States according to Article 6 of the Council of Europe Convention of 28 January 1981 No.108. A wide discretion is provided for as the Directive also allows for the use of personal data for secondary research with historical, statistical or scientific purposes provided that suitable or appropriate safeguards are in place.⁸² This constitutes exceptions to the principles of fair processing since data may now be kept for longer periods of time and the results or information regarding the processing need not be given to the research participants. This may have an influence on consent and revocation.

The Directive thus provides a margin of manoeuvre to Member States to adopt domestic legislation and this discretion, in turn, lends enough flexibility to individual States to ensure that data protection principles and research needs are balanced in a manner which satisfies the protection of basic values, guards medical and scientific research and which is in line with public health goals.

B. The Clinical Trial Directive

A clinical trial is defined as “any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy,” according to Article 2(a) of the Clinical Trial Directive. This includes trials carried out in a single site or multiple sites or in a single or multiple Member States.

⁸² See articles 6(1)(b), 6(1)(e) and 11(2) of the Council of Europe Convention.

Biobanking and biobank- based research may be distinguished from clinical trials in that after a sample has been collected for the purpose of banking, no further direct physical intervention is required. The inherent risks of biobanking, unlike in the case of clinical trials, is not physical in nature but relates to the possibilities that the privacy or ability to make future decisions regarding the sample, may be violated.

The Clinical Trials Directive does however, in spite of the differences mentioned, provide primary principles of medical research: firstly, that informed consent⁸³ must be obtained from any person participating in research procedures and that such consent may be withdrawn and secondly, that research must be reviewed and approved by an ethics committee⁸⁴ before the research may commence. Applying these principles to biobanks means that any person making use of such biobank must provide the bank with their informed consent. It is interesting to note that the requirement of informed consent is an example of a traditionally medical principle, from the doctor- patient relationship, being transported into the research and biomedical arena. This is part of a greater trend of incorporating autonomy into research. Informed consent is mandated by Article 3(2) of the Charter of Fundamental Rights of the European Union which reads as follows:

“Right to the integrity of the person

- (1) Everyone has the right to respect for his or her physical and mental integrity.
- (2) In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law,

⁸³ Informed consent is defined as a “decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation. Article 2(j) of the Clinical trials Directive 2001/20/EC.

⁸⁴ See article 3 and article 6(2) of the Clinical trials Directive 2001/20/EC. An ethics committee is “an independent body in a Member State, consisting of healthcare professionals and nonmedical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.” Article 2(k) of the Clinical Trials Directive 2001/20/EC.

- (3) The prohibition of eugenic practices, in particular those aiming at the selection of persons,
- (4) The prohibition on making the human body and its parts as such a source of financial gain,
- (5) The prohibition of the reproductive cloning of human beings.”

The second application of this Directive to biobanks means that an ethics committee must have reviewed and approved the activities which the biobank will be conducting. With specific regard to research activities, the Directive does not apply to biobank- based research since it does not provide for the use of the banked samples for research purposes as it does in the case of clinical trials.

C. The European Union Tissue and Cells Directives

The EU Tissue and Cells Directives (EUTCD) were issued under the Human Tissue (Quality and Safety for Human Application) Regulations 2007,⁸⁵ sometimes referred to as the Q & S Regulations, with the goal of establishing a harmonised approach to the regulation of tissues and cells in Europe.⁸⁶ These Directives are thus relevant to biobanking as it deals with the biological material which is kept in the bank. It thus, in broad terms, provides for guiding principles in relation to which biobanks may be regulated. The Directives set the bar for the standards to be met in all activities related to tissues and cells which are intended for human applications. The Directives also requires that a trace link should exist between the donor of tissues and cells and the recipient thereof. The EUTCD is comprised of three Directives namely the parent Directive⁸⁷ which establishes framework legislation and two technical directives which provide detailed requirements which must be met.⁸⁸

⁸⁵ Human Tissue (Quality and Safety for Human Application) Regulations of 5 July 2007.

⁸⁶ The Human Tissue Authority, ‘EU Tissue and Cells Directives’, available at <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/eutissueandcellsdirectives.cfm> (accessed 13 August 2013).

⁸⁷ Directive 2004/23/EC.

⁸⁸ Directives 2006/17/EC and 2006/86/EC.

Biobanks are not specifically regulated in the parent Directive but it does provide for various general rules ranging from the supervision of tissue and cell procurement to accreditation of tissue establishments⁸⁹ to quality management to processing, storage and even to distribution. Some provisions which may have a bearing on biobanks are those regarding traceability, consent and data protection and confidentiality. Article 8 relates to traceability and requires that Member States ensure that all tissues and cells procured, processed, stored or distributed in their territory are traceable from the donor to the recipient and vice versa.⁹⁰ Consent is set as a prerequisite for the procurement of human tissue and cells.⁹¹ What is of some importance here is that this consent must be informed consent as the Annexure to the Directive stipulates that the donor must be provided, by a trained person prior to the donation, of the following information:⁹²

- The purpose and nature of the procurement;
- The consequences and risks of the donation;
- In the case thereof, the existence of analytical tests which are performed;
- The recording and protection of donor data;
- The arrangements surrounding medical confidentiality;
- The therapeutic purpose and potential benefits of the donation; and
- Information on the applicable safeguards intended to protect the donor.

Data protection and confidentiality is also provided for in that Member States are required to ensure that data is rendered anonymous to the extent that neither the donor nor the recipient are identifiable. This is done by taking data security measures such as safeguards

⁸⁹ A tissue establishment is defined in article 3(o) of the Directive as “a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells.”

⁹⁰ By way of an identification system which assigns a unique code to each donation.

⁹¹ Article 13, *supra* note 87.

⁹² *Ibid.*, at article A3 of the Annex.

against unauthorised additions or modifications to data, procedures must be in place to resolve any data discrepancies should they appear and no information is disclosed which has not been authorised.⁹³

The technical Directives, in brief provide for definitions, requirements for the procurement of human tissues and cells, selection criteria for donors, required laboratory tests, procurement and reception procedures, direct distribution requirements and transposition.⁹⁴ Furthermore the requirements of accreditation, designation, authorisation and licencing is provided for as well as notifications in the event of serious adverse reactions or events, annual reporting, communication between the authorities and the Commission of the European Communities and a single European coding system is provided for.⁹⁵

This then concludes the discussion on the various EU Directives and attention must now be given to the domestic laws enacted in individual countries by their own respective governments in regards to biobanks and biobanking activities.

D. Domestic Legislation

Some European governments have, despite the wide discretion given to Member States and perhaps due to the lack of specific biobank legislation, implemented their own domestic legislation. Two trends have emerged in that States adopt either a very specific, focused approach to biobanking and adopt legislation solely centred on biobank activities. Some of these States include Estonia,⁹⁶ Hungary,⁹⁷ Sweden,⁹⁸ Iceland,⁹⁹ Spain¹⁰⁰ and Belgium.¹⁰¹ On

⁹³ Article 14, *supra* note 87.

⁹⁴ Technical Directive 2006/17/EC.

⁹⁵ Technical Directive 2006/86/EC.

⁹⁶ Estonian Human Genes Research Act RT I 2000, 104, 685.

⁹⁷ Hungarian Parliamentary Act, Act No XXI of 2008 on the Protection of Human Genetic Data and the Regulation of Human Genetic Studies, Research and Biobanks.

⁹⁸ Swedish Biobank Act, 2002:297.

⁹⁹ Icelandic Act on Biobanks, Act no.110/2000 of 13 May 2000.

¹⁰⁰ Biobank Research Act 2007.

the other hand, some States have integrated biobank related provisions into their broader legislative body. These include France¹⁰² and the United Kingdom.¹⁰³ To illustrate the two regulatory trends found in Europe, the one of specific legislation versus the broad provisions in general legislation, a few individual countries will be briefly discussed here. First Hungary, Spain and Iceland are discussed, each of whom have opted to specifically regulate biobanks.

According to the Hungarian Protection of Human Genetic Data and Regulation of Human Genetic Testing, Research and Biobanking Law, a biobank may be described as a reserve of genetic specimens and related personal and genetic data for the purpose of human genetic research and/or examination in accordance with the law.¹⁰⁴ The 2003 Medical Research on Human Subjects decree laid the foundation of later activities surrounding genetic testing and biobanking and may be described as the groundwork for the Protection of Human Genetic Data and Regulation of Human Genetic Testing, Research and Biobanking Law which took effect on the 1st of July 2008. This Law regulates diagnostic genetic testing, certain aspects of genetic research and the establishment and operation of biobanks.¹⁰⁵

In Spain, there are three possibilities for the handling of samples namely gathering the samples for use in a project,¹⁰⁶ storage in a collection¹⁰⁷ and storage in a biobank. A biobank

¹⁰¹ Law on Biomedical Research 14/2007 July 3rd, on Biomedical Research.

¹⁰² Law n° 2011-814, 7 July 2011 on Bioethics, JORF n°0157 of 8 July 2011 page 11826. Journal officiel "Lois et Décrets" - Official Journal of Laws and Decrees.

¹⁰³ United Kingdom Human Tissue Act, 2004.

¹⁰⁴ The original text reads as follows: "genetikai mintát és az kapcsolódó genetikai és személyazonosító adatokat az e törvény szerinti humángenetikai vizsgálat, illetve humángenetikai kutatás céljából tartalmazó mintagyűjtemény." Translation provided by D. Fenyvesi.

¹⁰⁵ As of the 20th of October 2009, the Medical research on Human Subjects and Clinical Trials of Drugs and Medical Equipment decree is also in effect. For more on sample collection, access availability and sample sharing, consent and data protection in Hungarian biobanks see E. Zika, D. Paci, T. Schulte in den Bäumen, A. Braun, S. Rijkers-Defrasne, M. Deschênes, I. Fortier, J. Laage-Hellman, C. Scerri and D. Ibarreta, *JRC Scientific and Technical Reports- Biobanks in Europe: Prospects for Harmonisation and Networking*, Publications Office of the European Union (2010) 59 – 62.

¹⁰⁶ This is time restricted and the sample must be destroyed at the end of the particular project.

¹⁰⁷ This is where samples are used in a research line and indicates longer term storage than with the use of samples in a particular project. A collection is a legal entity, like a biobank, and may be defined as "an orderly and permanent set of human biological samples that are stored outside the Biobank regime." See J. Arias-Diaz,

is a legal entity and refers not only to a facility but also to the management of samples stored under such a label and particularly to the requirements for their cession. It is required by Spanish law that a biobank must be authorised and registered in a public registry. Biobanks are provided with a defined structure in terms of the Spanish regulation thereof and must ensure compliance with the quality, legal and ethical requirements. Consent must be provided in a manner which is broad without being blank and external ethics committees must supervise the adequacy of sample cession and use in addition to the supervision of the target protocol.

The Icelandic definition of a biobank reads that it is “a collection of biological samples which are permanently preserved.”¹⁰⁸ As with the Spanish Act, attention is given to the period of time which the samples are intended to be stored. This is also explicitly indicated in Article 2 of the Icelandic Act which states that the act applies to the collect of samples and the storage of such samples in a biobank but that the Act does not apply to the temporary keeping¹⁰⁹ of biological samples for clinical testing purposes or to the keeping of gametes and embryos.

The second trend, of regulation based on broad principles is used in the United Kingdom and is visible in the Human Tissue Act of 2004. The Human Tissue Act was assented to on the 15th of November 2004 and is a consolidation of previous legislation created by the Human Tissue Authority to regulate the removal, storage, use and disposal of human bodies, organs and tissues. This is an Act of the Parliament of the United Kingdom and does not extent to Scotland. The Scottish counterpart is the Human Tissue (Scotland) Act

M. Martin-Arribas, J. Garcia del Pozo and C. Alonso, Spanish regulatory approach for Biobanking, 21 *European Journal of Human Genetics* (2013) 708 – 712.

¹⁰⁸ Article 2(2) of the Icelandic Act on Biobanks, *supra* note 99.

¹⁰⁹ Temporary keeping means storage for up to five years and in the case of any long-term of samples, the samples will be stored in a biobank.

of 2006. The English Act includes various provisions which deal with a wide variety of matters and thus generally regulates biobanks. It contains rules regarding the removal and storage of human organs and other tissue,¹¹⁰ regulation of activities involving human tissue which includes licensing, codes of practice and even trafficking.¹¹¹ Lastly miscellaneous and general provisions are provided for. The Scottish Act is an Act of the Scottish Parliament which consolidates all previous legislation dealing with human tissue. The Scottish Act creates broad rules which deal with, *inter alia*, transplantation,¹¹² post- mortem examinations¹¹³ and tissue samples or organs which are no longer necessary for procurator fiscal purposes.¹¹⁴

It is clear from these different approaches to biobank regulation that one approach is not appropriate for everyone and it reflects each State's legislative style. Each different State will have its reasons for choosing a certain legislative path but the ultimate inconsistencies between national laws may be directly attributed to the fact that the Data Protection Directive allows a margin of freedom in implementation of the Directive and also due to the fact that its provisions are of a general nature. Flexibility may be beneficial but in the case of biobanks and biobank- based research, this may be problematic as it may hamper cross border research and collaboration. It has been suggested that a common approach to regulation be developed which may lead to standardisation of for example, data processing and the use of samples.¹¹⁵

¹¹⁰ Part 1 of the United Kingdom Human Tissue Act of 2004.

¹¹¹ *Ibid.*, at Part 2.

¹¹² Part 1 of the Human Tissue (Scotland) Act of 2006.

¹¹³ *Ibid.*, at Part 2.

¹¹⁴ *Ibid.*, at Part 3.

¹¹⁵ European Commission Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, *supra* note 8, at 40.

Although the various legal instruments adopted by individual States differ greatly from one another, some common traits have however started to emerge, such as:¹¹⁶

- That biobanks should be accredited by a national authority;
- The creation of a biobank should be notified and registers of biobanks should be set up accordingly;
- Biobanks should be supervised by a competent national body;¹¹⁷
- Biobanks should be managed by an individual or an entity from a medical or biological background;
- The necessary security measures must be taken to protect biological samples;
- That where the nature of the envisioned research cannot allow for complete de-identification of the data or biological samples, the data or samples should be “coded” or pseudonymised
- Research ethics committees should assess the purpose of the biobank and also individual projects;
- Specific safeguards and limitations are set on the transfer of samples abroad;
- The use of samples from a deceased person is expressly regulated;
- That proxy consent is permissible in cases of minors or when dealing with other persons who are involved in research and cannot give consent on their own; and
- The research participant may freely and at any time withdraw their consent.¹¹⁸

These shared principles could in future form the basis of a uniform instrument of regulation of biobanks and it is safe to say that these shared principles form a checklist of aspects which ought to be covered in any biobank regulatory instrument. The implementation of these

¹¹⁶ *Ibid.*

¹¹⁷ This could be a shared supervisory role along with a national data protection authority.

¹¹⁸ This normally also means that the relevant sample is destroyed as well as any related data.

instruments will then greatly rely on regulatory bodies and some attention must be given to these bodies in the European biobank regulatory context.

V. REGULATORY BODIES

Biobanks must be formally overseen on a national level and an important part of this control measure is that all research protocols must be reviewed by a Research Ethics Committee, REC, or an equivalent independent body such as a Data Protection Authority. Across Europe RECs and Data Protection Authorities are commonly responsible for the oversight of data and reviewing biobank protocols. RECs or in some cases, institutional review boards (IRBs) are well known in most European jurisdictions and have considerable power and may be regarded as key in all decision making processes in reviewing and approving research protocols. RECs are thus essential in governing biobanks. Some States have sanctioned additional bodies such as the Human Tissue Authority in the United Kingdom to help oversee biobanks. The Human Tissue Authority or HTA for example is a regulator and watchdog and aims to set clear and reasonable standards which support public confidence in organisations that use and store human tissue for research purposes, treatments, teaching and even public exhibitions. The HTA also approves organ and bone marrow donations from living donors. The HTA was established in 2005 by the Parliament of the United Kingdom as an executive agency of the Department of Health.¹¹⁹ Where biobanks are based at certain institutions, such as hospitals, this also provides an extra level of oversight as the institutional authorities will also review the activities of the bank. National Bioethics Committees have also aided in developing guidance for banking activities.

¹¹⁹ Human Tissue Authority, 'About the HTA', available at <http://www.hta.gov.uk/aboutus/aboutthehta.cfm> (accessed 7 September 2013).

VI. HOW DOES SOUTH AFRICA MEASURE UP?

In the course of this article the South African regulations and the European structures and instruments have been discussed. The discussion pertaining to the European legal instruments entailed a list of common traits which have started to emerge in biobank regulatory tools and it was stated that these shared principles could form the basis of future instruments whereby biobanks are to be regulated and that the list of commonalities may be perceived as a checklist of essential elements on biobank regulatory instruments. It may then be argued that if this is a checklist, or wish list of sorts, for the European community that it should also be a measuring device and checklist for the South African instruments. What follows is thus an evaluation of how the South African Regulations measure up. This evaluation has been done in a table format in order to minimise repetition while immediately answering whether or not South Africa is up to standard on a certain aspect.

Shared principles observed amongst the European domestic Acts	The current South African position
Accreditation of the Biobank by national authority:	According to the South African Regulations 2011 and 2012, any person, institution or organisation wishing to undertake banking activities must be authorised to do so by the Director- General. The Director- General is the head of a national department.
Notification of creation and register of Biobanks:	Neither the 2011 nor the 2012 has Regulations set this requirement.
Supervision of Biobank by a competent	According to both the 2011 and 2012

national body:	Regulations, Banks in SA are subject to inspections and control measures which are imposed by the Director- General under the Minister of Health
Management of Biobanks by an individual or an entity from a medical or biological background:	The Regulations of 2012 state that tissue bank shall have an appointed registered medical practitioner who has experience in the science of human tissue transplantation to fulfil the duties of a Medical Director to advise and oversee the authorisation's medical activities. The same Regulations also require the designation of a person especially intended to develop policy in the Bank.
Necessary security measures to protect biological samples:	The 2012 Regulation contains various provisions regarding the requirement of both a system of quality management as well as a safety system.
Coding of samples	The Regulations of 2012 require that activities 21abc must be traceable from donor to recipient, that a unique donor identification system is created which assigns a code to each donation and that the data which is needed for traceability is kept for 30 years.

<p>Assessment of the Biobank activities by research ethics committees:</p>	<p>The 2012 Regulations requires that all research and development activities undertaken by a Bank must be approved by a relevant research ethics committee.</p>
<p>Safeguards and limitations on the transfer of samples abroad:</p>	<p>In a direct manner the Regulations of 2012 provide therefore that a Bank must ensure the quality and safety of tissue during distribution and ensure that it is not compromised. This includes cold chain maintenance and any import or export of samples must be done in accordance to the National Health Act. Indirectly, this requirement is also met as banking activities in South Africa are required to be in accordance to the Declaration of Istanbul on Organ trafficking and Transplant Tourism of 2009.¹²⁰</p>
<p>Express regulation of samples from deceased persons:</p>	<p>Both the 2011 and 2012 Regulations make provision for tissue removed or acquired from a deceased person.</p>
<p>Provision for proxy consent:</p>	<p>Consent is required for a donation but no specific provisions are made regarding proxy consent in instances where the donor</p>

¹²⁰ See paragraph II *supra*.

	themselves are not capable of giving consent.
Withdrawal or revocation of consent by the research participant or donor of the sample:	No specific provisions are made regarding the revocation of consent.

Figure 1: Comparison between European share principles and current South African provisions.

This comparison illustrates that South Africa has, for the most part, already provides for the ideal principles to be in place in the regulation of Biobanks and their activities. However, the comparison also clearly identifies that there are aspects which are regulated in European framework which are not provided for in South Africa. These aspects are related to consent and notification of the creation of a Biobank and do require attention in South Africa should South Africa wish to participate in this field of science and medicine on a global scale. It is therefore recommended, firstly, that provisions should be created which deal with consent in more detail and that this should prescribe who should obtain consent and when, the type of consent to be obtained be that broad or generic consent, the position regarding proxy consent where a person is not able to personally consent and the options and possibility of revoking consent in future. A second recommendation is that a register of Biobanks be established wherein all authorised banks are kept record of and that notification of the authorisation of a new Biobank take place via public media and the Government Gazette. Should these recommendations be adhered to South Africa, which is not too far behind the European community, will be brought up to standard in terms of Biobank regulation.

VII. CONCLUSION

The fascinating new developments in biomedicine hold the potential of changing traditional medicine to personal, predictive, preventative and participatory health management. The novelty of this new biomedicine health regime however also entails new and unfamiliar

issues surrounding the manner whereby biomedicine ought to be regulated at an international level as well as on an individual State by State basis. This uncertainty is slowing down progress and development and in certain instances, attempts of role players, be they scientists or legislatures or countries, to create rules and regulations on their own, without consultation with other such role players have lead to more confusion and incoherent instrument that do not correspond to one another. This hinders information and data sharing. A uniform system of regulation would encourage and facilitate sharing and ultimately lead to faster and better developments in the field of biomedicine. This applies not only to the European, American or Asian countries, but also to the African countries that are already practicing aspects of biomedicine such as South Africa. It is thus important that South Africa, as the African leader in biomedicine, be able to equally participate in the biomedicine community. Although some of the science and research is not currently possible in South Africa, the practice of biological banking has been active for some years now and it was this aspect which therefore received attention in this article. The purpose of this article was thus to broadly examine the European regulation of Biobanks in order to gain firstly, an understanding of this complex system which operates on many binding and non- binding, European and domestic levels and secondly, to then identify in what aspects South Africa was not on standard and to then be able to make recommendations to address these issues in order to make it possible for South Africa to participate globally in biomedicine.

This article explained the term biobank and identifies elements whereby a biobank may be characterised. The South African Regulations relating to Tissue Banks were discussed and illustrated the current South African position. This was followed by a discussion of European governance in the shape of the Council of Europe and the European Union. The European legal instruments used to regulate Biobanks namely the Data Protection

Directive, the Clinical Trial Directive and the European Union Tissue and Cells Directives. This was followed by an examination of selected domestic Acts regulating banking practices either directly and specifically or indirectly and in broad terms. Here, a list of shared principles was established and it was stated that this list may be viewed as the foundation of future regulatory instruments and should be seen as a checklist of essential element to any Biobank regulations. The regulatory bodies were discussed and finally the question as to how South Africa measured up was addressed.

When a comparison was made between the European shared principles and the current South African position, it was clear that South Africa is not far behind in regulatory terms and that for the most part meets the standards which have been set globally regarding necessary regulatory measures. One of the aspects which do however require legislative attention in South Africa is that of consent. It was recommended that provisions should be created to address consent in more detail. The second recommendation concerned notification and it was recommended that a register of Biobanks be established as well as a system of notification of the establishment of Biobanks. Hopefully, a uniform system of regulation will begin to emerge in the near future and biomedical development as well as the solving of the unfamiliar regulatory issues will be a shared venture.