

Northern (region c) Stage II Report: Regulation of biobanks and genetic databases

Draft of 'Element 1': The description of the regulation within and between the regional member states

Description and comparison of three countries: England, Germany and Netherlands, Japan summarised separately (Austria and Belgium haven't sent their reports yet)

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1. BBGD research using personal information and privacy protection by the law

1.1 The scope of the law

Each of the three countries have implemented the Data Protection Directive 95/46/EC by a specific new act. First the UK Parliament passed the 1998 Data Protection Act (further referred as 'DPA'), the Netherlands uses the 2001 Personal Data Protection Act, *Wet bescherming persoonsgegevens* ('PDPA'), and Germany uses the 2003 Federal Data Protection Act, *Bundesdatenschutzgesetz* ('FDPA').

1.1.1 The scope of protection

Personal data:

The definition of 'personal data' has been implemented in the national legislation of all three countries. In the UK the definition is in the DPA, and has been further defined in court cases. In Germany the definition is in the FDPA, and in the Netherlands in the PDPA.

The definitions of 'personal data' are as follows:

- UK DPA: "data which relate to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual"
- German FDPA: "any information concerning the personal or material circumstances of an identified or identifiable individual (the data subject)"
- Dutch PDPA: "as information relating to an identified or identifiable natural person"

Personal data of the deceased:

However, in all three countries the definition of 'personal data' has not been implemented by the data protection acts to include information (or samples) relating to deceased persons. The DPA specifically defines 'personal data' as belonging to 'a living individual'. However, certain protection of privacy of deceased persons is covered by other legislation; the 'German Basic Law' (*Grundgesetz*) in Germany and in the Netherlands this protection follows from the law on medical confidentiality and related court decisions. In Germany the deceased has to be treated with human dignity, his/her right of personality must be considered, and the data subject's rights still need to be

respected according to German Basic Law. In the Netherlands medical confidentiality remains even after the death of a patient according to the rule of ‘medical secrecy’. However, data might be released to family members or other parties, if the authorisation of the deceased can be presupposed or if there is an overriding interest.

Group (family) personal data:

In none of the countries has the directive been implemented in the national data protection acts in a way that either explicitly or implicitly recognises family members ever to be ‘data subjects’ with respect to data obtained from a relative. And in none of the countries could data protection legislation hold that data might be equally related to more than one identifiable individual, and consider that ‘group’ data to be personal data.

However, in all three countries other legislation suggests that this might be possible. There is nothing in the national data protection acts that excludes the possibility that personal data could be related to other individuals. Indeed the UK Information Commissioner’s Office endorsed the idea that certain information could be personal data for two or more people. Similarly the English Common Law on confidence states that a duty of confidence may persist beyond an individual’s death. And in the Netherlands the ‘parliamentary documents’ explain that it can happen that data can relate to more than one person.¹ For example certain rights of data subjects, such as the right of data subjects to access their personal information, can in certain circumstances be exercised by the data subject’s family members. The German Federal Constitutional Court (*Bundesverfassungsgericht*) has ruled that the personal data of the deceased may include information on living family members. As a result, the personal data of a deceased person are protected by the German Basic Law (*Grundgesetz*) as long as they relate to living relatives.

Identification and anonymisation:

The terms ‘identifiable’ and ‘identification’ are not defined within the national data protection acts of any of the three countries. However, it is mentioned on several occasions in all three acts, even as part of the definition of personal data. In fact, the definitions of ‘personal data’ stand on the fact that the data subject must be ‘identifiable’. In the Netherlands the ‘Explanatory Memorandum to the Act’ regards personal data as ‘identifiable’ when a person’s identity can be reasonably determined without disproportionate effort. The term ‘coded data’ is further used in the Dutch law in relation to medical research.

Anonymisation is not defined in the Dutch PDPA or the UK DPA. The Dutch partner reports that it depends on context and is widely discussed in literature at what point

¹ What is meant by ‘parliamentary documents’ are proceedings of the parliament, including explanatory memorandum etc. to a pending bill, in which the government provides guidance on how the bill (after acceptance and enactment) should be interpreted and applied.

should ‘coded data’ or ‘anonymised collections’ be regarded as personal data. The UK partner reports that the fact that personal data has to be identifiable suggests that data that would be held ‘anonymous’ would fall outside the DPA. However, the partner also reported that in the UK there is disagreement in interpretation on what constitutes ‘anonymous’ data. On the contrary, the German FDPA defines anonymisation in Section 3 (6) as “modification of personal data so that the information concerning personal or material circumstances can no longer or only with a disproportionate amount of time, expense and labour be attributed to an identified or identifiable individual.” And Section 40 (2) further specifies that personal data collected and stored for research purposes should be anonymised as soon as possible.

1.1.2 Is there any other law extending the scope of protection?

In all three countries the law on protection of personal data in the context of research using biobanks and genetic databases is also regulated by other legislation than the data protection acts.

In England the law is further extended by the English Common Law, the Human Tissue Act 2004, and the NHS Act 2006. The law is further influenced by the UK Information Commissioner’s Office (ICO) 2007 Data Protection Technical Guidance: Determining What is Personal Data. In the Netherlands the Medical Contract Act (*Wet inzake de geneeskundige behandelingsovereenkomst*) includes a specific provision on research using patient data (art. 7: 458 Civil Code.) Other relevant regulation includes the Medical Research involving Human Subjects Act 1998 (*Wet medisch-wetenschappelijk onderzoek met mensen*) and the Dutch Civil Code. In Germany other relevant legislation includes the regional Laender Data Protection Acts (*Landesdatenschutzgesetze*), the Genetic Treatment of Humans Act 2008 (*Gesetz über genetische Untersuchungen bei Menschen*), and the above mentioned German Basic Law (*Grundgesetz*) that acknowledges the general right of personality and respect of human dignity.

Austria, Belgium, Germany, UK and the Netherlands have also signed and ratified of the ‘Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data of the Council of Europe’ 1981.

1.2 The nature of the protection

1.2.1 Consent

The German and English partners reported that consent is not really defined by the FDPA and DPA. In the Dutch PDPA consent is defined only in general terms as “any freely-given, specific and informed expression of will whereby data subjects agree to the processing of personal data relating to them.”

In none of the three countries does the national data protection act specify what is required for either ‘unambiguous’ or ‘explicit’ consent (as the terms are used in the Directive.) The German FDPA doesn’t specify that consent should be as specific as possible, but states that it should be based on data subject’s free decision. The UK DPA uses the term consent for personal data, and explicit consent for sensitive personal data. The Dutch PDPA also mentions, but doesn’t define, explicit consent, and so does the Dutch Medical Contract Act. The Medical Contract Act states that explicit consent is not necessary when it is impossible or too difficult to obtain it, however, the privacy of the data subject shouldn’t be disproportionately affected. How explicit the consent must be is further addressed in the Dutch ‘parliamentary documents, where it is explained that it should be clear to the data subject what data will be processed, in what forms of processing and what will be the purpose of the processing.

None of the partners thinks that there is a suggestion in the data protection acts that particular processing, such as disclosure to insurers, researchers of genetic conditions, or forensic use of material, must receive specific consent. And in none of the countries is there any suggestion that consent is relevant to any processing of anonymised or reference data.

Finally, regarding legal consent age, in the DPA and FDPA there is no suggestion that consent can only be given by a person above a certain age. However, in both countries this is addressed by other regulations and guidance. On the contrary, the Dutch PDPA specifies that the consent age for processing data is 16, and the Medical Contract Act even lowers the consent age to 12 for the purposes of processing personal medical data for research.

1.2.2 Provision of information prior to consent

In all three national data protection acts there is a suggestion that particular processing of data does not require specific consent, such as in the case of processing of data for monitoring purposes or in substantial public interest in the UK (DPA and the UK Information Commissioner’s Office Guidance).

In the Dutch Law there is a suggestion that an individual contributing towards either a bio-bank, or a genetic database, ought to be informed of anything in particular to guarantee fair processing in the context of BBGD research, as the “respect to the data subject” as well as processing “in a proper and careful manner” is mentioned in the PDPA. However, this is not addressed in the DPA or FDPA.

Also none of the data protection acts suggest that an individual ought to be informed about any potential adverse consequences associated with participation for either themselves or others, such as the possibilities of genetic discrimination. However, the Dutch partner reported that although this is not explicitly provided in the act, giving full information about adversary consequences is certainly part of an adequate informed

consent and required by the law as it stands. The danger of stigmatisation based on collection of data isn't mention in any of the acts.

In none of the data protection acts is there also any suggestion that an individual (or group) ought to be informed about any possibility that the research might be of commercial value. However, the German FDPA states that when data is stored for commercial purposes, the data subject may request information on their source and recipient "only if there is no overriding interest in protecting trade secrets." However, the possibility of possible financial benefits from commercial use of data is not addressed in the FDPA.

None of the data protection acts suggest that an individual ought to be informed about the circumstances where access to information or material held by the BBGD might be permitted without seeking their consent. However, the Dutch Medical Contract Act allows use of patient data without consent in specific cases defined by the law (see under 1.2.1) where the patient has been informed and didn't object to the use of the data.

1.2.3 Provision of information post consent

In the UK as well as the Netherlands a data subject can be entitled to access any information stored in a BBGD about themselves that they did not already know, as long as the data is stored in an identifiable form. However, the German FDPA is not explicit in this area. An entitlement to access information kept in a BBGD that was contributed by their relative is not regulated or guaranteed by the FDPA or the PDPA or other national legislation. On the contrary, the UK Information Commissioner's Office Guidance suggests this possibility.

In none of the countries does national legislation provide any further requirements for those operating BBGDs to provide information to data subjects about the purposes of the processing.

1.3 The research exemption

1.3.1 Describing and comparing the research exemption

In all three countries the national legislation has recognised a research exemption from the requirement to notify data subjects that their personal data is to be processed. The exception is for research purposes that include statistical and historical purposes according to the DPA, in cases where the scientific interest of the research project substantially outweighs the data subject's interests according to the FDPA, and for research and statistics in cases of secondary data (not collected by the data receiver directly from data subjects) according to the PDPA. This means that the UK and Dutch

national legislation recognises a distinction between the information that data controllers collected directly from the data subject, and data that controllers received indirectly via a third party. Data controllers who have received data indirectly must provide data subjects with information about scientific purposes, as the DPA and the PDPA 'research exception' only applies to 'further processing'.

Regarding other safeguards for research exemptions, no additional provisions have been put in place in Germany, but in the UK DPA there are several conditions, such as that results must be treated with respect and without distress to the data subject, and cannot be made available in a form which identifies data subjects. Similarly the Dutch Medical Contract Act states that if the data is identifiable, it should be encoded before disclosure to researchers, and an information document should be sent to patients. Additionally, the research must serve a public interest, and the data must be necessary for the research. Finally, the patient must not have objected to the use of his/her data for research purposes.

In the national data protections Acts there is no indication that there are circumstances when an individual would not have to be informed of an intention to process data for exceptional research (statistical or historical) purposes in cases when that intention is known at the time that the data is collected. However, this is addressed in the Dutch Medical Contract Act. And there is nothing in the German or Dutch law that indicates that it would not matter if, at the time that the information/sample was taken (and the possibility of research anticipated) it was originally gathered for specific non-research purposes, for example for the purposes of a forensic collection. The exception is the UK where collection of biological samples and processing of genetic and other data for the UK National Police DNA Database are not consented.

2. BBGD research using biological material and privacy protection by the law

This second part is supplementary to the first part, as the regulation of BBGD using biological material is often subject to regulation using personal information described in previous part one.

2.1 The scope of the law

The elementary English law in this area consists of the English Common Law, Human Tissue Act 2004, and the NHS Act 2006. The Common Law extends the scope of the DPA, while the Human Tissue Act both extends and alters the protection. In Germany it is the above mentioned 2008 Genetic Treatment of Humans Act, and the German Basic Law. In the Netherlands the Medical Contract Act is mainly about duties of caregivers towards patients. It includes specific provisions on research using anonymous biological materials removed from patients originally for medical diagnosis and treatment (secondary collections), and its provisions are sometimes stricter than the PDPA. The Dutch Medical Research Involving Human Subjects Act governs the situation in which biological materials are especially removed for the purpose of a research biobank.

The national data protection acts are relevant in some cases, as the collection of biological material for research usually includes the collection of personal data (at least name and address on the consent form), while most genetic research is based on collection of wide range of personal data such as medical history, family information or lifestyle habits. However, the collection, storage and use of biological materials, as well as access to biological material stored in a BBGD, do not fall within the data protection acts, as these don't regulate the processing of any data that isn't personal data.

In none of the three countries has the definition of 'personal data' been implemented in national legislations to include a biological sample. However, the Dutch PDPA addresses the collection and processing of personal data attached to or extracted from biological materials.

2.1.1 The scope of protection: What determines when the activities of researchers using biological material for BBGD research will be regulated?

Anonymisation and referencing:

In the Netherlands collections of human tissue which are stored anonymised or as a 'reference collection' (meaning only accompanied by any given number and pure medical data) are considered to be 'non-personal' and therefore most likely fall outside the scope of the PDPA. However, whenever such collections could be related to individuals without making a disproportionate effort, they need still to be considered identifiable as tissue (and data) collections.

The Dutch law also uses the terms ‘coded data’ and ‘coded tissues’ to data/ tissue to which a code has been attached by the supplier or an independent third party in such a way that it can be traced back to the data subject or the donor of the tissue (also referred to as ‘two-way coding’). The party who receives the data and materials does not have access to the unique identifier that leads to the identity of the data subject/donor (‘linked anonymisation’ according to Privileged guidance.) Finally, the Dutch partner reported that neither the PDPA or the Medical Contract Act regulates the position of donors towards their tissue stored in a biobank or tissues of relatives stored in a biobank. This gap in the law has been criticised and there is a call for developing guidance on rights of donors with regard to their stored biological material.

As stated above, the Medical Contract Act does not regulate the research use of identifiable biological materials of patients. The government is currently working on a new relevant law.

In England the collection, storage and use of human biological tissues is regulated by the Human Tissue Act 2004. This act covers tissues of living and dead people, and makes special provisions for the collection, storage and use of tissues for research purposes.

2.2 Nature of protection

2.2.1 Consent

There is no suggestion in the data protection acts of the three countries that consents obtained should be “as specific as possible with regard to any foreseen research uses and the choices available in that respect”, as stated in the 2006 Recommendation of the Committee of Ministers to member states on biological material of human origin. The use by third parties of identifiable biological material collected for medical purposes is not currently explicitly regulated by Dutch law, however, it follows from both the Medical Contract Act and Dutch Constitution that explicit consent from donors of residual biological tissues is required.

In England, consent is necessary for collection of biological material for research. However, the Human Tissue Act makes several exceptions (mentioned in part 2.3 Research Exemption below). Research using biological material is also regulated through either the system of research ethics committee (REC) approvals, or through licensing process. Storage of biological material taken from living individuals to be held for non-specific future research will require a license.

According to the Dutch Medical Contract Act, the consent age for the purposes of processing tissues for research is 12, the same as in case of medical data. However, this only applies to leftover biological tissues. If tissues need to be collected specifically for research purposes, then the consent age is 18 according to the Medical Research involving Human Subjects Act. Before this age, both the research subject and their legal

representative have to authorise any collection, processing and storage of biological samples.

2.2.2 Provision of information prior to consent

As discussed in the first part, there is some suggestion that an individual contributing towards either a bio-bank or a genetic database could be informed of anything specific to guarantee fair processing in the context of BBGD research. In the UK any collection of human tissues for research purposes has to be approved by a research ethics committee (REC). In some cases, such as storage of tissues for non-specific future research (e.g. the UK Biobank), a licence is required.

2.2.3 Provision of information or access post consent

Under current English, German and Dutch legislation an individual doesn't have an entitlement to access biological material stored within a BBGD. The possibility of a tissue donor benefiting from commercial or financial benefits of research using his/her tissues isn't discussed in the national legislation.

2.3 The research exemption

2.3.1 Describing and comparing the research exception

In the UK the research exemptions from obtaining consent are described in the Human Tissue Act and covers: material already stored before the Act came to force; residual tissue from living individuals that is used anonymously for research that has approval from research ethics authority or approval is pending; the tissues is imported or comes from imported body; the tissue that comes from a body of a person who died before 1 September 1906. In addition, the Human Tissue authority can allow residual biological tissue to be used without consent if the donor cannot be traced or does not respond to repeated attempts to obtain consent.

Also, as stated above, collection of biological samples from suspects for the UK National Police DNA Database is not currently consented. This database is used for statistical and other research purposes. The police don't currently destroy samples and with it associated data, regardless of whether the suspects are charged or convicted. The European Court of Human Rights has recently ruled keeping biological samples and genetic data of innocent people as violation of Article 8 - the right to respect for private and family life - of the European Convention on Human Rights. As a result, the UK Home Office is currently reviewing the practices of the National Police DNA Database.

As stated above, the Dutch Code for Proper Secondary Use of Human Tissue of the Dutch Federation of Biomedical Scientific Societies allows secondary use of coded

biological material if there is no objection from the donor, provided that the system of no objection is based on sufficient information and a low threshold of objection. Such use of tissue without consent must also serve the general interest of obtaining new scientific results, thus cannot have purely commercial purpose.

3. Is there any 'practical guidance' in your country on research using BBGDs?

The relevant guidance is:

In Germany

- Model guidance of the Competence Network on Parkinson's Disease
- 2003 Memorandum on Predictive Genetic Diagnosis by the Senate Commission and the German Research Foundation:
http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2003/download/predictive_genetic_diagnosis.pdf

In England

- 2002 Use and disclosure of health data: Guidance on the application of the Data Protection Act 1998 (guidance of the UK Information Commissioner's Office ICO):
http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/health_data_-_use_and_disclosure001.pdf
- 2006 Human Tissue Legislation (guidance of the BMA's Medical Ethics Department):
<http://www.bma.org/ap.nsf/Content/Humantissue?OpenDocument&Highlight=2.human.tissue.legislation>
- 2007 UK Biobank Ethics and Guidance Framework (protocol of the UK Biobank):
http://www.ukbiobank.ac.uk/ethics/documents/20071011_EGF_Version_3_1_00ctober_2007withTOR.pdf
- 2007 Data Protection Technical Guidance: Determining what is personal data (guidance of the UK Information Commissioner's Office ICO):
http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_specialist_guides/personal_data_flowchart_v1_with_preface001.pdf

In the Netherlands

- 2001 Code for Proper Secondary Use of Human Tissue of the Dutch Federation of Biomedical Scientific Societies:
<http://www.federa.org/?s=1&m=78&p=&v=4%3E%3E>

3.1 Are there legal rules that have been described supplemented by other kinds of rule that modify the position in practice?

The UK has codes of good practice (such as various Medical Research Council's good practice guides). However, there isn't a specific guide to good practice of the use of samples and data for research involving BBGDs. The UK Biobank, that aims to collect samples and data from half million UK adults, has its own guidance and protocol. The UK Information Commissioner has published guidance on collecting, processing and disclosing of medical data.

In the Netherlands the Code for Proper Secondary Use of Human Tissue of the Dutch Federation of Biomedical Scientific Societies states that secondary use of identifiable biological material can be used only with explicit consent of the donor or their legal representative. Coded or anonymised biological material can be used unless the donor objects. Several Dutch national collections of biological materials (Brain Bank, Life-Lines, String-of-pearls) are presently developing additional practical guidelines.

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Draft of 'Element 1': Japan

1. BBGD research using personal information and privacy protection by the law

1.1 The scope of the law

Similar to the European Data Protection Directive 95/46/EC, Japan has the Personal Information Protection Act (PIPA) that came into effect on 1 April 2005. This legislation has no specific provision applicable to genetic data.

1.1.1 The scope of protection

Personal data:

Just like in England, Germany and the Netherlands, the definition of 'personal data' has been implemented in Japanese legislation. The PIPA defines personal information as "the information about a living individual, which contains the name, the date of birth and/or any other descriptions by which a specific individual can be identified (including information that can be easily collated with other information so that a specific individual can be identified)."

Regarding personal data of the deceased, the PIPA definition of personal information does not include information of dead individuals.

Identification and anonymisation:

Both 'anonymised and 'reference' collection fall outside the scope of the PIPA. However, material (information or sample) held in either anonymised or reference collection might be considered to be personal data. As the template for informed consent document for the 1000 Genomes Project indicates, there is a small possibility that the sequence data obtained from the analysis of a whole genome derived from an anonymised or reference sample can be identified with a specific individual. This consent document states that although no names or medical information will be collected, and many measures will be taken to protect donors' privacy, lots of genetic information will be generated. This information will be put into open access scientific databases. Although only experts know how to interpret this information, the consent document admits that there is a chance that somebody could connect donors with the information, and the information could then be used

to discriminate against donors or their families. To minimise this risk, donors are advised to limit the number of people they tell about their participating on this study.

1.2 The nature of protection

1.2.1 Consent

The Japanese personal information legislation has no specific provisions regarding unambiguousness or explicitness for consent.

Section 18, subsection (1) of the PIPA states that “when having acquired personal information, an entity processing personal information must, except in cases in which the purpose of information processing has already been publicly announced, promptly notify the person of the purpose of processing or publicly announce the purpose of processing.”

The Genome Guidelines that include provisions concerning informed consent are mostly about fair collection, storage and use of human tissues (discussed later in part 2). However, protection of personal information is also covered by these Guidelines. For example the Guidelines state that when personal information is processed jointly by other institutions in joint research project, then the explanatory document that is given to a donor or her/his personal representative should include information such as 1) the fact of joint research; 2) items of personal information that will be processed jointly; 3) specification of the person involved in the processing; 4) purpose of processing for involved person; and 5) name of the person or that will be responsible for the control of the personal information.

1.2.3 Provision of information post consent

The Guidelines also state that information regarding request of disclosure of personal information (among others, where and how disclosure request should be made; means of assuring the identity of donor or her/his representative; that fee will be charged for disclosure). Other provisions regarding personal data include information whether and how a donated human specimen or genetic information derived will be anonymized; information regarding disclosure of genetic data, and information about whether the genetic data derived from human specimens might, after anonymisation, be made public in an academic society.

According to the Genome Guidelines, when the donor or her/his representative requests disclosure of the donor's identifiable personal information in possession, the head of the organization conducting the research must without delay disclose the personal information in writing. However, the head may refuse disclosure of all or part of the information concerned if a) disclosure may adversely affect the life,

health, property, or other rights or interests of the donor or a third party; or b) disclosure violates statutes or regulations.

1.3 The research exemption

The Genome Guidelines state that the principal investigators shall not, in the absence of consent from the donor, disclose genetic information of the donor to any person other than the donor. However, the Guidelines also state that in certain situations an individual may have an entitlement to access information in a BBGD that they had not themselves contributed if the donor's representative requests genetic information of the donor to be disclosed, though this is very limited. This must be based on the opinions of the ethics review committee, and can be only done in cases when a) the disclosure is necessary to protect the life, health or property of individuals, and it would be difficult to obtain the consent of the donor; b) disclosure is particularly necessary to improve public health, and it would be difficult to obtain the consent of the donor; c) the donor's surviving blood relative requests genetic information of the donor to be disclosed, d) the donor is a minor and her/his representative requests genetic information of the minor to be disclosed.

The Guidelines also state that the principal investigators may after consulting the research ethics committee inform the blood relative of the genetic information (even against the will of the donor). The conditions include situations when it is discovered that the genetic information has a serious impact on lives of the donor's blood relatives and, at the same time, there is an effective method of treatment, and the principal investigator seeks the understanding of the donor again and makes efforts to obtain consent regarding the disclosure of necessary information to the blood relative

Section 50 of the PIPA provides exceptions in cases when the purpose of processing personal information fits into one or more of these categories: 1) Broadcasting institutions, newspaper publishers, news agencies and the other press; 2) An entity who conduct literary work as their business; 3) Colleges, universities, other institutions or organizations engaged in academic studies for the purpose for academic studies; 4) Religious organizations with the purpose for religious activities; and 5) Political organisations with the purpose for political activities.

The above listed entities processing personal information must take by themselves the necessary and appropriate measures for controlling the security of personal data, and the necessary measures for the processing of complaints about the processing of personal information and the other necessary measures for ensuring the proper processing of personal information, and must also endeavor to publicly announce the content of those measures concerned.

The Japanese partner reported that regarding providing information to data subjects about processing data for historical, statistical or scientific purposes, their national

legislation doesn't recognise a distinction between the data that data controllers collected directly from the data subject, and the data that data controllers received indirectly via a third party. And there is no indication that there are circumstances when an individual would not have to be informed of an intention to process that data for historical, statistical or scientific purposes when that intention is known at the time that the data is collected.

2. BBGD research using biological material

2.1 The scope of the law

Under Ethics Guidelines for Human Genomic/Genetic Analysis Research that were promulgated in March 2001 and revised in accordance with personal information protection legislation in December 2004 only *generally identifiable*, or *identifiably coded* samples are interpreted to be personal information.

2.2 Nature of protection

2.2.1 Consent

The Japanese Genome Guidelines state that “the principal investigator shall receive a human specimen (together with clinical and other information) after she/he gives a donor adequate explanation of such matters as the significance, objective(s), method and expected results of research, disadvantage that the donor might incur, and the method of preservation and use of a human specimen, and obtains voluntary written consent from the donor.”

The above mentioned Guidelines include provisions concerning informed consent. This information that should be provided to the donor or their legal representative (exceptions are allowed depending on the nature of the research, described below in part 2.3 Research Exemption) include: human tissue donation should be voluntary; the person asked to donate human specimen should not be treated in a disadvantageous manner because of their refusal; the donor or their legal representative may withdraw their informed consent at any time without incurring any disadvantage; when a donor or their legal representative withdraws consent, the human specimen(s) and research results related to the withdrawn consent will be discarded (unless they have been anonymized in an unlinkable fashion); reason(s) for being selected as a donor; significance, objective(s) and method of the research; expected research results and expected risk or disadvantage to a donor or others; method of preservation and use or discarding of human specimens after completion of research; and information regarding the provision of genetic counseling service (note: this is not a full list of provisions).

The partner knows of no provision that entitle the donor to access to her/his own biological samples.

2.3 The research exemption

The Genome Guidelines include provisions concerning informed consent. This information should be provided to the donor or their legal representative, but the Japanese partner reports that certain modifications are allowed depending on the nature of the research.

When research is proposed in spite of the fact that obtaining informed consent from a donor is difficult, then the Genome Guidelines require justification of the significance of the proposed research, and reason(s) why the research could not be conducted without human specimen donation from the donor.

3. Are there legal rules that have been described supplemented by other kinds of rule that modify the position in practice?

Additionally, Ethics Guidelines for Epidemiological Research that had been promulgated in June 2002 were revised in accordance with personal information protection legislation in December 2004. These revised Guidelines were characterized as the “necessary measures for ensuring the proper processing of personal information” prescribed in the subsection 3 of the section 50 of the Act. The partner reports that the revision of these Guidelines “imposed on the head of the organization conducting the research most of the obligations and responsibilities provided for entities processing personal information but explicitly made inapplicable to academic institutions by the Act.”