2.10 Using biobank data for research

The biobank governing body will establish clear policies, guidelines and procedures, consistent with the governance aims of the biobank, for access by researchers to data/samples. First, access must be consistent with participants' consent and will require ERB approval and undertakings that privacy and confidentiality will be guaranteed. Secondly, biobanks will have privacy enhancement technology systems for anonymisation of data, including systems for re-anonymisation of tissue samples after later re-identification of a participant (provided consent permits such recontact for future research projects). Access by researchers will be recorded and may be granted under a licence setting out the duties and obligations of the researcher.[107]

Biobank governance arrangements will prescribe the proper and allowable research purposes for the data/samples (see also 2.7 above). Nevertheless, concerns exist about the possible misuse of biobank data focus on possible improper access to the data by enforcement authorities or, possibly private health care providers, interested in direct marketing. In addition, insurance companies, employers, litigants in paternity disputes or immigration departments could be interested in biobank records. As noted at 2.7 above, privacy legislation provides that information collected for one purpose should not be used for other purposes. While biobanks may not prevent access by law enforcement agencies, their governance arrangements should specify that access would be for approved research purposes and not for other purposes.

2.11 Transfer of samples and data within and between countries

Transnational Recognition of Research Ethics Approvals

[107] The UK Biobank has so decided "because this would reduce the value of the resource for research", Ethics and Governance Framework, Version 2.0, July 2006 at 14-16

It is also becoming common for data collections to be linked through formal exchange and co-operation agreements to facilitate research and to enable large-scale research and comparative work on the collaborating datasets. In these cases, the collaborating partner institutions should develop formal exchange agreements. These exchange agreements between collaborating institutions should also include reciprocal access and release agreements. Importantly, licences or materials transfer agreements (MTAs) should be in place and each MTA recorded[108] All access to and release of information from data collections should be strictly recorded so providing a guaranteed, continuous "chain of responsibility" [109] for all access and release dealings in relation to the storage, handling and use of body material and personal data. Access to and release of information must be able to be tracked and audited[110].

The Organization for Economic Cooperation and Development (OECD) *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data*. 1980 was influential in the revisions of national privacy legislation to ensure conformity to standards for trans border flows of data.

The MTA should set out conditions on the processes for transfer of the data, data security, use and release of the data, approved research uses, intellectual property rights and duties, liability arrangements, termination and, finally, requirements for the data on completion of the project.[111] As a general ethical principle, a researcher

[108] See Appendix 2 'Material Transfer Agreement for Human Biospecimens" in First-Generation Guidelines for NCI-Supported BioRepositories April 2006, National Cancer Institute, National Institutes of Health, U.S Department of Health and Human Services
http://biospecimens.cancer.gov/biorepositories/First%20Generation%20Guidelines%20042006.pdf

[109] The German National Ethics Council and the French National Consultative Ethics Committee for Health and Life Sciences a joint Declaration The European Group on Ethics (EGE) in Science and New Technologies to the European Commission Ethically Speaking Newsletter, Issue 5, August 2005 at 27.

[110] See SECTION I. INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSTITORIES (ISBER). "Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research" (2005) 3 *Cell Preservation Technology* 1, 5-48.
http://www.isber.org/Pubs/BestPractices.pdf

[111] *First-Generation Guidelines for NCI-Supported BioRepositories* April 2006, National Cancer Institute, National Institutes of Health, U.S Department of Health and Human Services
http://biospecimens.cancer.gov/biorepositories/First%20Generation%20Guidelines%20042006.pdf
INTERNATIONAL SOCIETY FOR BIOLOGICAL AND ENVIRONMENTAL REPOSTITORIES (ISBER). "Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research" (2005) 3 *Cell Preservation Technology* 1, 5-48.

should not transfer tissue or data to another research group unless an ERB has approved the research and the genetic material and data is provided in a form, which ensures that participants cannot be identified. Some national codes for ethical research recognise a system of centralised ethical review for multicentre research. Under these arrangements, guidelines usually allow the acceptance of a central ethical assessment or adoption of the decision of another research review committee. This avoids duplication and enables common monitoring and reporting responsibilities to be undertaken.

With the growth of biobanks and cross-border collaborations, there is a need for greater international harmonisation of regulation[112]. There is already considerable harmonisation between the codes of research guidelines of most nations[113]. The CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002 establishes standards but the operation of national codes often uncovers significant divergences in practice. International cooperation has already been well established with the international HapMap Consortium and the development of the P3G Consortium. In addition, statements of general principles are developing in the Human Genome Organisation (HUGO) *Statements on Human Genomic Databases on DNA Sampling: Control and Access*, and, *on the Principled Conduct of Genetic Research* and UNESCO's *International Declaration on Human Genetic Data* (2003), and *Declaration on the Human Genome and Human Rights*,[114]

2.12 Collaboration between academic and commercial partners

Biobanks have a primary public research focus. This does not preclude private companies that may apply, subject to conditions, to use biobank data and resources. The pharmaceutical industry is interested in biobanking with hopes that pharmacogenomic research may herald a new generation of medicines tailored to

http://www.isber.org/Pubs/BestPractices.pdf

[112] Knoppers, BM, et al "Genomic Databases and International Collaboration" (2007) 18 *King's Law Journal*, 291-311; Knoppers, B 'Biobanking: International Norms' (2005) 33 *Journal of Law, Medicine & Ethics* 7; Kaye, J " Do we need a uniform regulatory system for biobanks across Europe?" (2006) 14 *European J of Human Genetics* 245-248

[113] See Chalmers, D "Ethical Principles for Research Governance of Biobanks" (2006) 3 *International Journal of Biotechnology Law* 221-230. See also, Quebec Network of Applied Genetic Medicine *Ethical Conduct of Human Genetic Research Involving Populations*.

[114] Promulgated by the General Conference of UNESCO at its 29th Session on 11 November 1997.

individual needs. If not individualised medicine, this research may enable better patient stratification thus achieving better patient outcomes from the drug administration. Commercial collaborations may arouse, in the words of the German National Ethics Council, "anxiety and distrust".[115] Similarly, the Australian Law Reform Commission public consultation process uncovered public scepticism about the continuing "heavy degree of commercialisation of [medical and genetic] research" and that people did not want their "altruism to lead to billion dollar profits for multinational pharmaceutical companies"[116] Recognising that commercialisation challenges public trust in science,[117] a policy of transparency and public engagement by biobanks in relation to their commercial activities is advisable. The Generation Scotland project is carrying out an on-going programme of public engagement, focussing especially on issues and concerns about commercialisation[118].

Commercialisation. Some biobanks have been established as research platforms to support both public and private research. Some of this research therefore may have commercial outcomes.[119] There is evidence of community concerns with commercialisation of research that must be tackled by demonstrating the public benefits that may flow from this research.[120] A distinction can be drawn between the intellectual property rights in the databases and intellectual property arising from research using these databases. In the former case, the European Union Directive on the *Legal Protection of Databases* (96/9/EC) provides that the ownership of the intellectual property in the database vests in the "maker" of the database, giving 50 years protection for work and costs in compiling, verifying and presenting data. So, the governing foundations of some biobanks (e.g. Iceland, Estonia and UK) establish that the intellectual property accruing from the creation and development

[115] Opinion on *Biobanks for Research* at 27.

[116] Cited in Weisbrot, D 'Public Conspiracy, Genetic Counselling and the Required Legal Infrastructure', Symposium on Taiwan's Private Project, unpublished paper ALRC Sydney, 8 August 2005 at p19

[117] Chalmers, D and Nicol, D (2004) "Commercialisation of Biotechnology: Public Trust and Research", 6 *Int.J.biotechnology* 116.

[118] See Generation Scotland website: http://129.215.140.49/gs/gpce.htm

[119] See OECD Creation and Governance of Human Genetic Research Databases (2007) Chapter 6 *Commercialisation Considerations*.

[120] Haddow, G, Laurie, G et al "Tackling community concerns about commercialization and genetic research: A modest interdisciplinary proposal" (2006) *Social Sciences & Medicine* (forthcoming)

of the database accrues to the biobank. In the case of intellectual property arising from research using these databases, the arrangements for access and use of the biobank data will set out the intellectual property arrangements. Generally, the biobank will expect some share of the IP rights with the researcher/research organisation . Generally, IP rights are clearly stated by the biobank to remain with the researcher/research organisation (or, in some cases shared with their assignees) and not with the participant.

Conflicts of interest Potential conflicts of interest must be audited and managed in collaborations and partnerships between commercial organisations and biobanks. The general principle of disclosure of interest is recognised in national codes for the responsible conduct of research[121]. There are also well-established policies of science and medical research journals requiring declarations of financial associations with commercial organizations before, and as a condition of, publication.

Ownership of samples. The question of ownership of body parts and tissue remains unsettled in both common and civil law jurisdictions[122]. The better view is that a biobank is trustee/steward of the samples for the purposes set out in the consent. In any case, the data created from the research will be owned by the researcher or subject to some special agreement between the biobank and the researcher. The sample donor does not have any claims in the eventual product of the research. Some biobanks have tried to clarify these positions. The UK Biobank states that participants "will have no property rights in the samples"[123] and this will be explained in the consent process. Similarly, the Estonian Genome Projects states that ownership to samples vests in the Project. This does not preclude the capacity of sample donors to have agreed rights of access to information or to withdraw from the project, or, in some cases, have the sample destroyed. Importantly, consent documents will clarify that the sample donor does not have and will not obtain any

[121] See as example, Australian Code for the Responsible Conduct of Research 2007.

[122] For a discussion of property and donor samples see J Bovenberg "Inalienably Yours? The New Case for an Inalienable Property Right in Human Biological Material" (2004) 1 *SCRIPT-ed* 545.

[123] The UK Biobank, Ethics and Governance Framework, Version 2.0, July 2006 Section A "Stewardship of Data and Samples at 14

intellectual property rights in the database, in research results or in any product arising from the research use of the biobank.

The commercialisation of biobank results is quite separate from the issue of fees for service. Many biobanks have a tiered pricing system for different researcher categories.

2.13 Public Dissemination of Research Results

As a general ethical standard, participants should be provided with information about the results of the research.[124] As a general accepted ethical principle, the results of research should normally be published and disseminated to contribute to the advancement of public knowledge.[125] Biobanks should commit to this principle and encourage research to be published in the scientific literature or in other ways that allow assessment and scrutiny of the results. The International Haplotype Mapping Project[126] and GenBank [127] accept this publication policy. On the other hand, where a biobank is operated as a private resource, for example by a pharmaceutical company, there may be policies or restrictions on publication and dissemination of results. [128]

2.14 Requirements regarding coding and anonymisation

[124] See for example, in Australia, *National Statement on Ethical Conduct in Human Research* 2007, Sec 1.5 "Research outcomes should be made accessible to research participants". However, with large-scale biobanks, such as the proposed 500,000 volunteers on the UK Biobank, such participant consent may become difficult and impractical. Some biobanks, and the UK Biobank is an example, of chosen, that they will not provide "participants with information, genetic or otherwise, derived from examination of the database or samples by research undertaken after enrolment". See UK Biobank *Ethics and Governance Framework* at 8. However, the initial laboratory analysis results will be provided to participants at the physical assessment preliminary stage.

[125] Australia, *National Statement on Ethical Conduct in Human Research*, Sec 1.3(d) " disseminating and communicating, whether favourable or unfavourable, in ways which permit scrutiny and contribute to public knowledge."

[126] The successor to the Human Genome Project, see http://www.hapmap.org/ Access attracts a "clickwrap" licence to protect the data from bogus patent claims.

[127] The Human Genome Project's public domain sequence data site at http://www.ncbi.nlm.nih.gov/Genbank/

[128] See generally, Chalmers D and Nicol D, "Commercialisation of Biotechnology: Public Trust and Research" (2004) 6 *International Journal of Biotechnology* 116-133.

Privacy and confidentiality of data are critical for biobanks. Biobanks should have explicit policies about coding and data linking to sample donors to safeguard privacy and confidential handling of and access to the data. Standard operating procedures for biobanks will include explicit conditions for maintaining privacy by coding and de-identifying data.[129] The use of unique identifiers and security access codes for authorised users are essential. Computing programmes will also include password and other restricted access systems to limit or block data access only to authorized users.

National codes of research ethics distinguish generally between *identified, de-identified* and *re-identifiable* information but the use of these terms are not consistent and may pose difficulties for developing an international framework.[130]. In the latter, the tissue and data are coded, but the code can be reversed and the participant's identity revealed. The UNESCO *International Declaration on Human Genetic Data* (2003) adopts similar distinctions between "(ix) *Data linked to an identifiable person*: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified; (x) *Data unlinked to an identifiable person*: Data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code; (xi) *Data irretrievably unlinked* to an identifiable person: Data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample'

The NBAC referred to *unidentified samples* that can sometimes be termed "anonymous" human biological specimens; *unlinked samples* that can sometimes be termed "anonymised" because they lack identifiers or codes that can link a sample to an identified person; *coded samples* that can sometimes termed "linked" or

[129] *First-Generation Guidelines for NCI-Supported BioRepositories* April 2006, National Cancer Institute, National Institutes of Health, U.S Department of Health and Human Services http://biospecimens.cancer.gov/bionrepositories/First%20Generation%20Guidelines%20042006.pdf http://www.isber.org/Pubs/BestPractices.pdf

[130] See Knoppers, BM and Saginur, M "The Babel of genetic data terminology" (2005) 23 *Nature Biotechnology* 925-927; Elger, B and Caplan, A "Consent and anonymization in research involving biobanks. Differing terms and norms present serious barriers to an international framework". (2006) 7 *EMBO reports* (7) 661-666; [130] Knoppers, BM, et al "Genomic Databases and International Collaboration" (2007), 18 *King's Law Journal*, 291-311;

"identifiable" that link identified specimens to a code and then to personally identifying information; and, *identified samples* that include a personal identifier (such as a name or patient number) to link the biological information directly to the individual from whom the material was obtained[131].

2.15 Withdrawal of consent and its effect on research

Biobank standards, policies and procedures generally allow participants to withdraw from biobank studies and projects. This is consistent with accepted international ethical research standard requiring participants be free, at any time to withdraw consent and to withdraw from further involvement in the project. In the case of a biobank research, it will not be possible to withdraw data from previously completed studies. Therefore, the ethical (and possibly contractual) right to withdraw must be contextualised to biobanks and may involve withdrawal of consent, samples and data at different levels, depending on the consent and choice of the participant. These levels of withdrawal are:

- *No further contact* – with the participant directly but allowing retention and use of previously provided data/samples with permission to obtain health-relevant records.
- *No further access - allowing* retention and use by the biobank of the data/sample but no participant contact and no permission to obtain health-relevant records, or
- *No further use* – no further contact with, or information from, the participant, including the destruction of samples and health-related information (but not data already used),[132]

2.16 The completion of a project and its effect on samples and data

As a general principle, biobanks should have policies and guidelines dealing with the possibility of transfer, closure of assets and these should be communicated to the

[131] See National Bioethics Advisory Commission Report *Research involving Human Biological Materials: Ethical Issues and Policy Guidance* Vols 1& II Bathesda, Maryland August 1999 pp 16-17

[132] UK Biobank *Ethics and Governance Framework*, Version2.0 July, 2006 at 10 http://www.ukbiobank.ac.uk/ethics/egf.php

participants at the time of recruitment. Similarly, any variation in the arrangement for the maintenance or storage or stewardship of the data for samples should be communicated during the currency of the biobank.

3 USE OF PREVIOUSLY COLLECTED SAMPLES

Collections of human tissue[133] have been a common place in hospitals and specialist clinics from the 19th century when preservation techniques were introduced.[134]. In 1998, the former National Bioethics Advisory Committee (NBAC) estimated that there were more than 282 million specimens stored in the United States and further estimated that the accumulation rate from blood tests, surgery and other medical procedures was probably in the region of 20 million specimens per year.[135] This NBAC report outlined the types of existing collections of human tissues as follows

- Pathology samples - clinical/diagnostic purposes;
- Researchers'/ pharmaceutical company collections for unique/ longitudinal research studies;
- Newborn screening tests (Guthrie cards);
- Forensic DNA banks;
- Umbilical cord blood banks;
- Organ, sperm, embryo and now stem cell banks;
- Blood banks

To this list should be added specialised human tissue collections, particularly of cancer tissue, used for specialist research.[136] Each of these samples can be further

[133] See, Medical Research Council policy and guidance on human tissue: http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/UseofHumanTissue/index.htm For example, the tens of millions of cervical cell samples collected each year are invaluable archival samples for research that can be linked to cancer registries, Arbyn, M et al *Methods in Molecular Biology* 2007 at Chapter 17 "Cervical Cytology Biobanks as a resource for Molecular Epidemiology"

[134] See R Scott, *The Body as Property*, Alan Lane, London 1981, Ch 1.

[135] National Bioethics Advisory Commission *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* Vol I Maryland 1999 at 13-15. See comments in B Knoppers "DNA banking: A retrospective-prospective" in Burley J and Harris J *A Companion to Genethics* Blackwell Publishing 2002, 379-386..

[136] See generally, Knoppers, B, Laberge C and Hirtle, M, *Human DNA: Law and Policy International and Comparative Perspectives* Kluwer Law International The Hague, 1997

divided onto slides, paraffin blocks, frozen or formalin-fixed or extracted DNA. DNA test results from these divided samples forms another further data set.

3.1 Using samples and data without consent or without renewed consent

These collections of tissue and data, held in long-term storage, are often not covered by patient consent. However, it is common for these tissue collections, that were originally collected for clinical or diagnostic purposes, to be used for other undefined research. This is frequently the case with hospital pathology samples that were usually collected for routine diagnostic and clinical purposes but may now used for research. Historically, hospitals and other institutions holding tissue did not presume refusal, or implied refusal, of consent by patients but presumed, in the absence of consent that it was "consistent with good stewardship to allow reasonable and respectful use [in research] of such legacy tissue collections for the greater public good".[137] The debates about biobanking have focused discussion on how existing tissue collections may be best managed ethically recognizing that in such cases, the issue of participant consent may be problematic. Generally, most countries allow stored tissue to be used in research provided the project is scientifically assessed, approved by an Ethics Review Boards and the samples de-identified[138],

The distinction between these *existing* collections of human tissue and *future* collections developed specific research purposes is significant in law. Under existing privacy legislation discussed at 2.7, the privacy rules and principles restrict data and information from being used *except* for the purpose for which it was collected. In effect, this rule of privacy precludes the use of data and information for any *secondary* purpose.

[137] See the helpful discussion on this point in Bioethics Advisory Committee (BAC) in Singapore, Report on *Human Tissue Research* (2002) (http://www.bioethics-singapore.org/resources/reports.html) at paras 9.1 - 9.6). This Report interestingly describes existing collections as "legacy tissue"

[138] Ibid, BAC, Report on *Human Tissue Research* (paras 9.1 - 9.6) felt that it was unjustified to equate absence of consent with refusal of consent and therefore allowed research if the stipulated safeguards of IRB approval and anonymization were in place.

Waiver Of Consent The use of human tissue samples in existing collections for research purposes will usually be accompanied by the express consent of the participant. However, ethical approval for the research may be granted by an ERB, in the absence of express consent. In such case the ERB may waive express consent.[139] Where researchers propose to use existing collections for other *secondary* research purposes, national codes of research ethics generally allow researchers to apply to an ERB for approval of a project. In these cases, the ERB may *waive* the requirement for individual consent. Waiver of consent is not uncommon in epidemiological research and human tissue research. In such cases, ERBs may waive consent after carefully considering a number of factors. Generally, the most important factor is whether the public benefit interest[140] in the value of the research *outweighs* the private interest in personal privacy. The types of factors that will be considered are:

- the nature of existing consents relating to the collection,
- the justification presented by the researcher for the waiver,
- the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy
- the extent to which the proposed research poses a risk to the privacy and well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the relationship of the project to an existing project
- the possibility of commercial exploitation of the sample;
- statutory provisions.
- most importantly, whether the public interest in the value of the research *outweighs* the requirements of personal privacy.

[139] Zeps, N et al "Waiver of Individual Patient Consent in Research: When do Potential Benefits to the Community Outweigh Private Rights?" (2007) 186 *Med J Aust* 88-90. See Australia, *National Statement on Ethical Conduct in Human Research*, Ch 2.3 on qualifying or waiving conditions of consent.

[140] Beyleveld D, "Data Protection and Genetics: Medical Research and the Public Good" (2007) 18 *King's Law Journal* 275-289

Where a research project is approved and allows the project to proceed without individual consent, the ethics committee may impose conditions on the methods for the data collection, use and protection. Most obviously, the ERB may require that the data be only accessed in a de-identified form. The access to the data may be restricted to certain researchers only. Certainly, the research data must only be used for the research purposes specified in the ethics approval and cannot be used for further research projects without a new ethics approval.

3.2 Role of Ethics Review Boards in selection of appropriate information and consent procedures

For existing collections, ERBs also have the traditional role, discussed at 2.6 above, of protection of the welfare of the sample contributors. The ERB has the usual role to scrutinise and assess the ethical acceptability of submitted research projects using the existing stored data and tissue and decide whether the project involves proper participant consent and ethical conduct before deciding whether a researcher is permitted to carry out the research.

4 SOLIDARITY, DIGNITY AND BENEFIT-SHARING

Biobanking research will involve large-scale population cohorts. The scale of this type of research will challenge traditional notions of individualistic research and many social ideas[141]. New ideas within the new trilogy of "solidarity', and "benefit-sharing" are emerging. So, the UNESCO *International Declaration on Human Genetic Data* (2003) aims "(a) … to ensure the respect of *human dignity* and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples …in keeping with the requirements of equality, justice and *solidarity*..."(emphasis added)

[141] See Glasner, P Atkinson, P and Greenslade, H *New Genetics, New Social Formations* Routledge London, 2006

The term "solidarity' invites discussion about the social, family, political, legal and other factors that promote and maintain integration and trust in society. However, social solidarity in some countries can be used "in a somewhat stronger and more egalitarian sense, [to] require that so much help is provided that the gap between the under-privileged and the others is reduced or eliminated."[142] Biobanking is also about social trust, as discussed in section 2.2 above. This should require biobanks to consider ways in which public trust and engagement can be maintained to promote social solidarity. Similarly, there are deeper issues of the ethical principles to apply to biobanking research. In particular, there are genuine questions about a rigid adherence to individual rights and autonomy in the pursuit of the long-term public health goals of these research tools. Some conventional conceptions of consent may be difficult to accommodate. In some biobanking research[143]the traditional individualist principle of autonomy may be at odds with Asian[144], Melanesian and Pacific approaches to decisions made harmoniously within the family and group.

"Benefit Sharing' has found expression in guidelines prepared by UNESCO[145] and the Human Genome Organisation[146]. The principle of benefit sharing promotes the equitable distribution of benefits from research. UNESCO's *International Declaration on Human Genetic Data* is one of the most emphatic assertions of the principle and states that "benefits...from the use of human genetic data.... should be shared with the society as a whole and the international community." However, the principle is amorphous, particularly in relation to the operation of intellectual property protections and licensing[147]. Nevertheless, the principle encourages

[142] The European Group on Ethics in Science and New Technologies to the European Commission, General Report 2000-2005, *European Communities* 2005 at 3.

[143] See Thomasma, D, 'Proposing a New Agenda on Bioethics and International Human Rights' (2001) 10 *Cambridge Quarterly of Health Care Ethics* 299-310. The author proposes some procedural and substantive rules for the basis of an international multicultural bioethics (the rule of peaceful dialogue; rule against xenophobia; rule of respect for cultural pluralism; rule of the common good; rule of cultural apprehension; rule of respect for persons in context; and, rule of existential A Prioris).

[144] But see Jing-Bao Nie "The specious idea of an Asian bioethics" in Ashcroft R et al *Principles in health Care Ethics* John Wiley, 2007

[145] UNESCO *Universal Declaration of Bioethics and Human Rights* 2005.

[146] HUGO *Statement on Benefit Sharing* 2000.

[147] Chadwick, R and Berg, K, 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases' (2001) 2 *Nature Reviews Genetics* 318; Simm, K, 'Benefit-sharing: an Inquiry regarding the Meaning and Limits of the Concept in Human Genetic Research' (2005) 1 *Genomics. Society and Policy* 29; Knoppers, BM,'Biobanking: International Norms' (2005) 33

researchers and research organisations to consider ways in which the benefits of the biobank research may be equitably distributed. It has been argued[148] that the rhetoric of this principle should be replaced with the implementation of appropriate and practical mechanisms for benefit sharing. Benefit sharing also arises in relation to the public or private benefits[149] to be derived from biobanking research and whether those benefits will accrue for the public good.[150] The French National Ethics Committee has commented that "resources used by private genomic laboratories, ...are not to be compared with those of public sector activity... private laboratories tend to keep their biological resources and their data banks to themselves. [and] the powerful bio-computerised genomic analysis tools are mainly developed in the private sector (using for the most part, for that matter, data and algorithms produced by the public sector). Such a situation could lead to a form of capture of this research domain by the private sector, and, because public and private strategies differ, the risk of impoverishment of scientific or conceptual quality".[151] This comment emphasises that there are general advantages from the public and private research that can lead to specific development of new health care products.[152]

5 CONCLUSION

Biobanks have the potential to enable a dramatic increase in the quantity of genomic research, as well as significantly improving the quality of the research

Journal of Law, Medicine & Ethics 7; D Nicol "Public trust, intellectual *Property and human genetic Databases; the need to address benefit sharing' (2006)* 3 J of International Biotechnology Law 89-103

[148] Knoppers, BM and Sheremeta, L "Beyond the Rhetoric: Population genetics and Benefit-sharing" (2003) 11 *Health L J* 89

[149] Brownsword, R "Genetic Databases: One for All and All for One?" (2007) 18 *King's Law Journal* 247-273

[150] Beyleveld D, "Data Protection and Genetics: Medical Research and the Public Good" (2007) 18 *King's Law Journal* 275-289

[151] Ethical issues raised by collections of biological materials and associated information data;"biobanks' and "biolibraries"Opinion 77, Comité consultatif national d'éthique pour les sciences de la vie et de la santé, France, 2003 at 22

[152] see Nicol, D "Public trust, intellectual Property and human genetic Databases; the need to address benefit sharing' (20060 3 J of International Biotechnology Law 89-103; Haddow, G Laurie, G et al "Tackling community concerns about commercialization and genetic research: A modest interdisciplinary proposal" (2006) *Social Sciences & Medicine* (forthcoming)

outcomes. Public trust[153] will be an imperative for biobanks. Public trust is a fundamental cornerstone in genetic science and biobanking. Equally importantly, good research data should inform discussion on the development of biobanking.[154] Generally, the limited empirical research that has been undertaken indicates a cautious level of public confidence in favour of the development of databases for medical research. Empirical research[155] supporting this view of public support has been undertaken in Canada, Iceland,[156], Ireland,[157] Australia[158]and Sweden[159] Two projects in Britain have been especially concerned about public engagement. The funders of UK Biobank and the project's Ethics and Governance Council have commissioned public opinion surveys, while the set-up of the Generation Scotland project includes a specific branch dedicated to public engagement.[160] Biobanks must commit to their duties of good governance, probity, transparency and security[161]. There are a host of other unique questions raised by biobanks,

[153] Chalmers, D and Nicol, D "Commercialisation of biotechnology: public trust and research" (2004) 6 *International Journal of Biotechnology* , 116-133; On the importance of public trust see J Bovenberg "Towards an International System of Ethics and Governance of Biobanks: A "Special Status" for Genetic Data?" (2005) 15 *Critical Public Health* 369-383. See also J Bovenberg "Inalienably Yours? The New Case for an Inalienable Property Right in Human Biological Material" (2004) 1 *SCRIPT-ed* 545.

[154] See Hirtzlin, I, et al, "An empirical survey on biobanking of human genetic material and data in six EU countries" (2003) 11 *European Journal of Human Genetics* (6) 475-488.

[155] See Caulfield, T and Outerbridge, T "DNA Databanks, Public Opinion and the Law" (2002) 25 *Clinical and Investigative Medicine* 252-256

[156] Caulfield, T "Perceptions of Risk and Human Genetic Databases: Consent and Confidentiality Policies" in G Armason et al (eds) *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases* University of Iceland Press and Centre for Ethics Reykjik 2002 at 283-289 and Kaiser, J "Population Databases Boom, From Iceland to the U.S" (2002) 298 *Science* 1158-1161

[157] Cousins, G et al "Public Perceptions of Biomedical Research: A Survey of the General Population in Ireland", Health Services Research Centre, World College of Surgeons in Ireland, Dublin 2005.

[158] See Williams "Australian Attitudes to DNA Sample Banks and Genetic Screening" (2005) 21 *Current Medical Research and Opinions* 1773-1775 and J Fleming "Issues with Tissues: Perspectives of Tissue Bank Donors and the Public Towards Biobanks and Related Genetic Research" in *Biobanks* Centre for Law and Genetics Symposium, September 2007.

[159] Kattis-Lindbland, A et al "Perceptions of Potential Donors in the Swedish Public Towards Information and Consent Procedures in Relation to Use of Human Tissue Samples in Biobanks: A Population-Based Study" (2007) 35 *Scandanavian Journal of Public Health* 148-156.

[160] See Generation Scotland website: http://129.215.140.49/gs/gpce.htm

[161] Other suggestions for the regulation of biobanks have included possible national registration. For example, the Australian Law Reform Commission *Essentially Yours: The Protection of Human Genetic Information in Australia* Report 96 2003, recommended that the registration of these databases on the public register (Recs 18-1, 18-3). This would enable the NHMRC not only to track the genetic research undertaken in Australia but also ensure greater transparency and accountability for the biobanks. Registration would provide an effective and inexpensive audit trail in annual reports to the NHMRC.

including autonomy and consent, public engagement, data-sharing, benefit-sharing, and international harmonisation There should be a renewed debate on ideas about the public good[162] with particular focus on compulsory participation, even a duty[163] to participate, in research for public health purposes and benefits. [164]Appropriate and effective regulation is a prerequisite to the development of the research potentialities of genetic research biobanks and, to a similar degree the development of the genomics industry. International harmonisation and consistency of biobank regulation on access to database information, transfer between countries, privacy regimes and policies are essential to realise the promise of biobank research.[165]

[162] See, Beyleveld D, "Data Protection and Genetics: Medical Research and the Public Good" (2007) 18 *King's Law Journal* 275-289;Campbell, AV "The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust" (2007) 18 *King's Law Journal* 227-245;Brownsword, R "Genetic Databases: One for All and All for One?" (2007) 18 *King's Law Journal* 247-273; and,; Caulfield, T "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" (2007) 18 *King's Law Journal* 209-226

[163] Harris, J 'Research on Human Subjects', in Freeman, M and Lewis, A (Eds) *Law and Medicine*, Current Legal Issues Volume 3 OUP 2000 at 379-397.

[164] Brownsword, R "Genetic Databases: One for All and All for One?" (2007), *King's Law Journal*, 247-273.

[165] See comments Reymond, M et al "Ethical, Legal and Economical Issues Raised by the Use of Human Tissue in Postgenomic Research" (2002) 20 *Digestive Diseases: Clinical Reviews* 257-265.

Result of the Questionnaire on the Japanese Guidelines on Genomic/Genetic Research - with a proposal of amendments –

- Kitetsu Takahashi*
  Kazuto Kato*
  Ryuichi IDA+
- * Graduate School of Biostudies, Kyoto University
- +Comparative Law Center / School of Government, Kyoto University

- Research Project on "Ethical Issues on New Medicine Using Genomic information"
- Grant-in-Aid for Scientific Research, Ministry of Health, Labour and Welfare

- 高橋喜哲*、加藤和人*、
  位田隆一+
- *京都大学大学院生命科学研究科
- + (財)比較法研究センター・京都大学公共政策大学院

- 厚生労働科学研究費補助金による研究「ゲノム情報を用いた新しい医療の推進における倫理問題に関する研究」

Objectives of the Questionnaire 目的

Questionnaire on the Experiences and the Expectation of Researchers for the Reform of the Guidelines on Genomic/Genetic Research
(Common Guidelines of Three Ministries)

Background
- Gap between the advancement of genomic/genetic research and the provisions of Guidelines
  The Guidelines cannot catch up the advancement ?
- Possibility of new developments (especially, Human Whole Genome Re-sequencing)
- To offer a basis for discussion for the reform of the Guidelines
- To aim at making a new guidelines for clinical use of genomic information

「ヒトゲノム・遺伝子解析研究に関する倫理指針(三省指針)改善のための研究者の経験と希望調査」

背景
- ヒトゲノム・遺伝子解析研究の進展状況と3省指針の乖離
- 今後の研究の新しい展開の可能性(特に全ゲノム再解析)

狙い
- 今後の指針改定作業の基礎資料
- 臨床研究から応用への橋渡しの模索

Questionnaire – Method アンケートの方法

- Questionnaire on 8 important issues in the Guidelines
  Ask researchers problems encountered in the experiences
  multiple choice + free written answer
  Aim at clarifying the current situation and the problems which researchers face in their research
  Try to avoid statistic data processing in order to clarify concrete situations
- Ask opinions on the Guidelines
  1. Necessity of matching the provisions of the Guidelines : On which points?
  2. Difficulties encountered in the research in the application of the Guidelines
  3. Examples of useful concepts / provisions
  4. Other opinions and suggestions

- 8つの重要問題についての経験調査
  多肢選択式＋自由記述式
  経験や問題点を事由に記述してもらうことによって、状況を明らかにしようとした
  （統計処理では捕捉しにくい具体的状況）
- 三省指針全体への意見
  1. 新時代への対応
  2. 研究上の困難
  3. 三省指針が役に立った例
  4. 三省指針に対する意見
  5. 他の参考法令、文書、ガイドライン（外国のものを含む）

Outline of the Answers 回答概要

Addressees : Researchers in genomic and genetic research in Japan (Names are picked up from different sources and covers leading researchers
Response : 212 / 942 22.2 %
Types of research
1) Multifactorial diseases (57.1)
2) Monogenic disorders (36.8)
3) Side effects (27.8)
4) Tracking research (21.7)
Insufficiency of the Guidelines (Q.4-1) : 12.7
Difficulties in Informed Consent Procedure : 12.7
Disclosure of personal genetic information : 32.5 (from participant 91.3, family 37.7)
Difficulties in Ethical Review Procedure : 11.3
Difficulties in Joint research : 83.0 (with abroad 35.2)
Difficulties in Genetic Counseling : 25.5 (with aprticipant 85.2, blood relatives 64.8)
Issues relating to and necessity of provisions on Bank / Data base : Protection of samples and genetic information 66.0, Management and use 62.3, Collection of samples 47.2

- 送付先 942
- 回答：212通 約20%の回答率
- 研究タイプ
  1）多因子疾患（57.1）、2）単一遺伝子疾患（36.8）
  3）副作用（27.8）、4）追跡型研究（21.7）
- 三省指針の対応不足、困難（問4-1）：12.7
- インフォームド・コンセントでの困難：12.7
- 遺伝情報の開示要求：32.5 （提供者91.3）家族（37.7）
- 倫理審査上の困難：11.3 （内容＝別紙参照）
- 共同研究：83.0 （海外35.2）
- 遺伝カウンセリングの希望：25.5 （提供者85.2、血縁者64.8）
- バンク・DBの必要措置：
  試料・データの保護66.0、管理運営62.3、サンプル収集47.2

Insufficiency of the Guidelines
指針の不十分さ

A. Limited scope of the Guidelines to research
⇒ Need of the guidelines for clinical use of genetic information
B. Insufficient response to "genetic business"
C. Excessively rigid provisions
= Need of attention to promote research
D. Coordination with other relevant guidelines
E. Insufficient response to pharmaco-genomics
F. Too narrow discretion of the researchers

A.研究と臨床との区別⇒医療への応用が困難
B.遺伝ビジネスへの対応
C.規定が厳格すぎる＝研究への配慮不足
D.他の指針との整合性
E.ファーマコゲノミクスへの対応
F.現場の裁量権の狭隘さ

Points for reform 改善するべき点

- Informed Consent Procedure
- Treatment of samples and data
- Joint research with foreign institutions
- Ethical review system
- New Types of research = biobank and database

- インフォームド・コンセント
- サンプルとデータの取り扱い
- 海外との共同研究
- 倫理審査制度
- 新しいタイプの研究
＝バイオバンク、DB

Informed Consent インフォームド・コンセント

Prior, informed and free consent

Current procedure

= One sample, one research, one informed consent

No multiple use, no deposit after research

New possibility

= general / blank / broad consent

conditions : sufficient information should be given on future possibilities of research

No easy use of blank consent = risk of abuse

- 事前の、十分な説明の上での自由意思による同意
- 現行の手続

＝1試料・1研究・1同意の対応

多目的利用・研究後の保存は認めない

- 新しい可能性

＝包括同意／広範な同意

条件：将来の研究の可能性への十分な説明、バンク

包括的同意は慎重に

⇒濫用の危険

Samples and Data 試料とデータ

1) Linked anonymisation as principle

So far, unlinkable anonymisation has been the principle, linkable anonymisation as exception

2) Safety of storage of samples and data

3) Quality control of samples and data

4) Renewable system of collection

This point relates to the biobank issue.

1）連結可能匿名化＝原則

現行＝連結不可能匿名化が原則、連結可能が例外

2）試料とデータの保管の安全性

3）試料とデータのクウォリティ・コントロール

4）定期的試料採集

この問題はバイオバンクの問題と関連

Joint Research 海外との共同研究

Current Guidelines requirement

Application of stricter rules among rules applicable in the relevant countries

However, such requirement is not realistic, so that we may propose that each research team of each country should apply the rules applicable to that country, regardless of the degree of strictness of rules.

現行の指針の条件

海外との共同研究の場合には、厳しい方の国の指針を適用する

しかし、こうした条件は現実的ではない

⇒各国の研究者はその国の指針に従う。(厳しいかどうかを問わない)

問題＝厳しい国に厳しくない国のサンプルやデータを譲渡・移送できるか？

Ethical Review System 倫理審査制度

The most important issue

= knowledge and ability of the members of IRB

Often members of the IRB are not truly aware what is the ethical review.

The quality of discussion is not assured.

⇒ Training system of the members of the IRB may be needed.

問題＝IRB委員の審査能力

IRB委員は時に倫理審査の意味を十分に理解していないことがある

IRBにおける質疑応答や議論の質は保証されていない

→IRB委員に対する研修が必要

biobank and database
バイオバンクとデータベース

Current situation in Japan

- No national regulation on biobank so far.
  Each so-called biobank has or has not it's own regulation.
- Size, objective, scope of use and accessibility are diversified.
- Cooperation is not always assured among researchers. Small size biobank is in many cases closed to the third party researchers.

日本の現状

- 国家レベルでのバイオバンク規則はない
  自称バイオバンクがそれぞれ独自の規則を設定（規則ない場合もある）
- バンクの規模、目的、利用範囲、アクセス等はさまざま
- 研究者間の協力は必ずしも十分ではない。小規模のバイオバンクは多くの場合に閉鎖的で、外部の研究者にアクセスが開かれていない。

Elements to be included in the biobank regulation
バイオバンクの規律に含まれるべき要素

- Informed Consent Procedure
  Broad consent
  good understanding on what is the biobank
- Linkable Anonymisation of samples
  Protection of samples and personal information
- Samples and Data collection
  Quality control needed
- Accessibility to samples and data
  Openness is required. However, the data quality should be universally (nationally) uniform.
- Governance system more than ethical review system
  Size, substantial elements and social impact are so important that traditional ethical review system may not be adequate or sufficient.

- インフォームド・コンセント手続
  広範同意
  バイオバンクの意味の理解が前提
- 連結可能匿名化
  試料・個人情報の保護
- 試料とデータの収集・保管
  QCが不可欠
- 試料・データへのアクセス
  公開性が前提
  しかし、データの質は全国的に一律でなければ利用の際に支障
- ガバナンス・システム＞倫理審査制度
  規模、実質的内容、社会的インパクト等の重要性はきわめて大きい　→従来の倫理審査制度を凌ぐ

ゲノム関連トピックス（1999 年～2009 年）

T99.26
クローン人間の法規制で合意／科学技術会議生命倫理委員会
科学技術会議生命倫理委員会クローン小委員会・ヒト胚研究小委員会合同委員会は、クローン人間を生み出す行為を禁錮などの罰則付きで規制することで合意した。(日本経済新聞99. 7. 28)
→科学技術会議生命倫理委員会クローン小委員会(第11回)・ヒト胚研究小委員会(第5回)合同委員会議事録
http://www.mext.go.jp/a_menu/shinkou/shisaku/clogij11.htm
<その後の経過>
T99.245 クローン人間作り規制を法制化へ／科学技術会議
[キーワード]行政 人間 科学技術

T99.69
遺伝子組換え表示の法制化／農水省
農林水産省は、8月4日、遺伝子組み換え食品の表示の義務化に関する原案を「食品表示問題懇談会」に提示、8月10日、食品表示問題懇談会遺伝子組換え食 品部会は「遺伝子組換え食品の表示のあり方」を報告した。表示対象は、一般消費者向けの遺伝子組換え農作物とその加工品のみ。2001年春から実施を予定 している。
→「遺伝子組換え食品の表示のあり方」(食品表示問題懇談会遺伝子組換え食品部会報告)
http://www.maff.go.jp/soshiki/syokuhin/hinshitu/990824-01.html
<その後の経過>
T99.225 遺伝子組み換え表示の基準案に意見を公募／農林水産省
[キーワード]法制 行政 科学技術

T99.117
遺伝子組み換え作物の国際基準作り／OECD・FAO・WHO
経済協力開発機構(OECD)、国連食糧農業機関(FAO)、および世界保健機関(WHO)は、遺伝子組み換え作物の取引の円滑化をめざし、生産・開発や 商品認可の国際ルールの策定に乗り出した。具体策を2000年7月の沖縄サミットまでに打ち出す予定。(日本経済新聞99. 9. 16)
[キーワード]行政 科学技術 情報

T99.225
遺伝子組み換え表示の基準案に意見を公募／農林水産省
農林水産省は、11月29日、日本農林規格(JAS)法に基づいた遺伝子組み換え食品の品質表示基準案を公表し、意見募集を行った。2001年4月から食 品メーカーに義務づける遺伝子組み替え食品表示の細目で、大豆やとうもろこしが主たる原料の加工食品24品目が対象である。(日本経済新聞 99. 11. 30)
農林水産省は、2000年3月31日、遺伝子組換え食品に関する品質表示基準(「加工食品品質表示基準第七条第一項及び生鮮食品品質表示基準第七条第一項 の規定に基づき遺伝子組換えに関する表示に係る加工食品品質表示基準第七条第一項及び生鮮食品品質表示基準第七条第一項の農林水産大臣の定める基準」)を 告示した(平12農林水産省告示517)。
→遺伝子組換え食品に関する品質表示基準
http://www.maff.go.jp/soshiki/syokuhin/heya/hinnpyou-idennsikumikae.pdf
【関連トピックス】
T99.69 遺伝子組換え表示の法制化／農水省
[キーワード]行政 科学技術 情報

T99.245
クローン人間作り規制を法制化へ／科学技術会議
科学技術会議生命倫理委員会クローン小委員会は、11月17日、人クローン個体の産生は法律

により禁止することが妥当とする「クローン技術による人個体の産生等に関する基本的考え方」をまとめた。
→生命倫理委員会クローン小委員会報告書「クローン技術による人個体産生の産生等に関する基本的考え方」
http://www.mext.go.jp/a_menu/shinkou/shisaku/clorinhi.htm
これを受けて、科学技術会議生命倫理委員会は、12月21日、この報告を了承するとともに、この報告を踏まえて、クローン技術による人個体の産生には法律により罰則を伴う禁止がなされるべきであるとする報告書「クローン技術による人個体の産生等について」をとりまとめた。
→クローン技術による人個体の産生等について
http://www.mext.go.jp/a_menu/shinkou/shisaku/clo00215.htm
政府は、2000年4月14日、「ヒトに関するクローン技術等の規制に関する法律案」(第147回国会閣法第94号)を閣議決定し、衆議院に提出した。しかし、6月2日の衆議院の解散により廃案となった。
→ヒトに関するクローン技術等の規制に関する法律案
http://www.shugiin.go.jp/itdb_gian.nsf/html/gian/honbun/houan/g14705094.htm
<その後の経過>
T00.779 ヒトに関するクローン技術等の規制に関する法律が成立
<これまでの経過>
T99.26 クローン人間の法規制で合意／科学技術会議生命倫理委員会
T00.128 ヒト胚研究を認める中間報告書／科学技術会議
T00.333 ヒトのES細胞の研究を容認へ／科学技術会議
[キーワード]法制 行政 人間 科学技術 情報

T00.51
遺伝子組み換え食品、安全審査違反に罰則／厚生省
厚生省は遺伝子組み換え食品の安全審査義務付けを検討してきたが、安全性確認の基準と違反者への罰則案を具体的にまとめ、1999年12月14日、食品衛 生調査会バイオテクノロジー特別部会に示した。食品衛生法に基づく厚相告示において、食品や添加物の規格基準に遺伝子組み替え食品を追加し、審査を義務付 け、審査抜きの販売、輸入を禁止、違反業者には懲役1年以下、10万円以下の罰金を科すこと等が同法案には盛り込まれている。(読売新聞 99. 12. 14)
→食品衛生調査会バイオテクノロジー特別部会平成11年12月14日会議議事録
http://www1.mhlw.go.jp/shingi/s9912/txt/s1214-1_13.txt
<その後の経過>
T00.127 遺伝子組換え食品の安全性審査の法的義務化についての意見募集／厚生省
T00.346 遺伝子組み換え食品の安全性審査義務づけ／厚生省
[キーワード]行政 科学技術

T00.126
遺伝子解析研究の指針案の意見募集／厚生省
難病の治療や新薬の開発につながる遺伝子研究の拡大に対応するため、厚生省は、2月4日、「遺伝子解析による疾病対策・創薬等に関する研究における生命倫 理問題に関する調査研究」中間報告書をまとめ、「遺伝子解析による疾病対策・創薬」の研究を行う際、統一的に適応する指針の素案(遺伝子解析研究に付随す る倫理問題等に対応するための指針(案))を公表し、意見募集を行った。(1)プライバシー保護、(2)インフォームド・コンセントの徹底、(3)倫理審 査委員会の審査、(4)遺伝カウンセリング体制の整備、などが基本方針。
→「遺伝子解析研究に付随する倫理問題等に対応するための指針(案)」に関する意見の募集について
http://www1.mhlw.go.jp/topics/bosyuu/tp0203-1_6.html

厚生省は、4月28日、厚生科学審議会先端医療技術評価部会の了承を受け、5月30日付で厚生省大臣官房厚生科学課長より関係機関へ「遺伝子解析研究に付随する倫理問題等に対応するための指針」の通知を出した。
→「遺伝子解析研究に付随する倫理問題等に対応するための指針」について(厚生省大臣官房厚生科学課長通知・平成12年5月30日付厚科第305号)
http://www1.mhlw.go.jp/topics/idensi/tp0530-1_6.html
[キーワード]行政　人間　科学技術

T00.127
遺伝子組換え食品の安全性審査の法的義務化についての意見募集／厚生省
食品衛生調査会バイオテクノロジー特別部会は、1月21日、いわゆる遺伝子組換え食品について食品衛生法の規格基準に規定を設けることにより安全性確認を法的に義務づける「組換えDNA技術応用食品・食品添加物の安全性審査の法的義務について」の報告書をとりまとめた。
これを受けて、厚生省は、2月2日、遺伝子組換え食品の安全性審査の法的義務化について意見募集を行った。
→バイオテクノロジー特別部会報告書「遺伝子組換え食品の安全性審査の法的義務化について」
http://www.mhlw.go.jp/topics/idenshi/anzen/houkoku.html
http://www.mhlw.go.jp/topics/idenshi/anzen/pdf/houkoku.pdf
<その後の経過>
T00.346　遺伝子組み換え食品の安全性審査義務づけ／厚生省
【関連トピックス】
T00.51　遺伝子組み換え食品、安全審査違反に罰則／厚生省
[キーワード]行政　人間　科学技術

T00.128
ヒト胚研究を認める中間報告書／科学技術会議
科学技術会議生命倫理委員会ヒト胚研究小委員会は、2月2日、ヒト胚性幹細胞を中心としたヒト胚研究についての基本的な考え方について、一定のガイドラインの下に認める報告書案を公表し、意見募集を行った。
→科学技術会議ヒト胚研究小委員会報告の公表と意見募集について
http://www8.cao.go.jp/cstp/cst/rinri/iken00207/index.html
http://www.mext.go.jp/b_menu/houdou/12/02/000210.htm
<その後の経過>
T00.333　ヒトのES細胞の研究を容認へ／科学技術会議
T01.167　ヒトES細胞研究のガイドライン案について意見募集／文部科学省
T01.588　ES細胞ガイドラインを了承／総合科学技術会議
【関連トピックス】
T99.245　クローン人間作り規制を法制化へ／科学技術会議
[キーワード]行政　人間　科学技術

T00.129
ヒト組織の移植のガイドライン原案の意見募集／厚生省
厚生省は、ヒト組織の移植等への利用に係る安全性、有用性等を確保し、組織バンク事業の適正な発展を図る観点からガイドラインを検討している「厚生科学審 議会先端医療技術評価部会ヒト組織の移植等への利用のあり方に関する専門委員会」の報告書の原案「ヒト組織の移植等への利用のあり方について(案)」をとりまとめ、意見募集を行った。ヒト組織の移植等への利用に係る基本原則を、(1)ヒト組織の提供に係る任意性の確保、(2)無償の提供、(3)ヒト組織の 採取及び利用の際のインフォームド・コンセント、(4)個人情報の保護、(5)情報公開など7つを示し、組織バンクがヒト組織採取を行う際の手続、処理・ 保存方法、採取されたヒト組織を移植施設

に提供する場合に遵守すべき事項、組織バンクの運営等について定めることとしている。
→ヒト組織の移植等への利用のあり方に関する専門委員会第3回議事録(2000年2月3日)
http://www1.mhlw.go.jp/shingi/s0002/txt/s0203-2_11.txt
[キーワード]行政 人間 科学技術

T00.143
個人差に関するDNA配列も特許の対象に/特許庁
特許庁は、ある長さの配列のうち1個だけが異なる個人差部分(一塩基多型)でも、病気の診断や治療に役立つとわかれば特許の対象になるとの方針を決めた。DNAの基本部分については既に日米欧特許庁間で配列そのものは特許の対象になりえず、その配列がもつ産業的な有用性が明らかにされた場合のみ特許を認め ることで一致しているが、その考えが個人差DNAにも援用された。(朝日新聞2000. 1. 15)
[キーワード]行政 科学技術 情報

T00.145
遺伝子組み換え食品の表示統一徹底に新規則/EU
EU委員会は2000年1月11日付 Official Journal で、遺伝子組み換え食品のラベル表示基準を示す新規則を公布した。4月より遺伝子組み換え作物を1%以上使用した原材料を含む食品については、食品ラベルへの表示が義務付けられることになる。
→Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC
http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_006/l_00620000111en00130014.pdf
Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms
http://europa.eu.int/eur-lex/pri/en/oj/dat/2000/l_006/l_00620000111en00130014.pdf
[キーワード]法制 科学技術 情報

T00.210
連邦職員の雇用・昇進に「遺伝子差別」を禁止する大統領令に署名/アメリカ
クリントン米大統領は、2000年2月8日、遺伝子診断の結果を連邦職員の採用や昇進に利用する「遺伝子差別」を禁止する大統領令に署名した。(毎日新聞2000年2月9日)
→Executive Order 13145 of February 8, 2000
To Prohibit Discrimination in Federal Employment Based on Genetic Information
(Federal Register Vol. 65, No. 28 Thursday, February 10, 2000)
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=00-3331-filed.pdf
[キーワード]紛争 人間

T00.217
遺伝子や指紋を用いた電子署名
中央大学、NTTデータテクノロジー、NECソフトウェア、京都工業繊維大学は、産学協同で、遺伝子や指紋を認証に利用する電子署名を開発した。(日本経済新聞2000. 2. 20)
[キーワード]経済 科学技術 情報

T00.275
名古屋地裁平12・3・24判決:治験段階の抗ガン剤使用の副作用による死亡に医師の説明義務違反を認める
愛知県がんセンターに入院していた卵巣ガンの女性患者が十分な説明や同意のないまま臨床試

験段階の抗ガン剤を投与され副作用により死亡したとして、遺族 が、県や主治医に賠償を求めた訴訟で、名古屋地裁は、主治医は、患者の自己決定権を無視し、インフォームド・コンセントを得る義務に違反したとして、計 3400万円の賠償の支払いを命じる判決をした。治験の実施要綱(プロトコール)に違反して投与した違法性も認定した。
→判例時報1733号70頁(平成5年(ワ)第2218号)
[キーワード]紛争　人間　情報

T00.333
ヒトのES細胞の研究を容認へ／科学技術会議
科学技術会議生命倫理委員会のヒト胚研究小委員会は、3月6日、条件付きで研究を認める「ヒト胚性幹細胞を中心としたヒト胚研究に関する基本的考え方」を取りまとめた。
→ヒト胚性幹細胞を中心としたヒト胚研究に関する基本的考え方
http://www.mext.go.jp/b_menu/shingi/kagaku/rinri/ki00306.htm
これを受けて、科学技術会議生命倫理委員会は、3月13日、小委員会の報告を了承し、規制の枠組みの整備などを求める「ヒト胚性幹細胞を中心としたヒト胚研究について」をまとめた。
→ヒト胚性幹細胞を中心としたヒト胚研究について
http://www.mext.go.jp/b_menu/shingi/kagaku/rinri/ken00313.htm
ヒト胚研究小委員会は、4月11日、指針となる「ヒトゲノム研究に関する基本原則(案)」を公表し、意見募集を行った。
→「ヒトゲノム研究に関する基本原則(案)」の公表と意見募集について
http://www.mext.go.jp/b_menu/houdou/12/04/000413.htm
＜その後の経過＞
T00.448 ヒトゲノム研究の倫理原則を決定／科学技術会議生命倫理委員会
＜これまでの経過＞
T00.128 ヒト胚研究を認める中間報告書／科学技術会議
【関連トピックス】
T99.245 クローン人間作り規制を法制化へ／科学技術会議
T99.26 クローン人間の法規制で合意／科学技術会議生命倫理委員会
[キーワード]行政　人間　科学技術

T00.346
遺伝子組み換え食品の安全性審査義務づけ／厚生省
厚生省の食品衛生調査会は、4月25日、遺伝子組み換え食品の輸入・製造業者に安全性審査を義務づける答申を行った。これを受けて、厚生省は、2001年4月から食品衛生法に基づく国の安全性審査を義務づけることを決めた。(朝日新聞2000. 4. 26)
→「組換えDNA技術応用食品・食品添加物の安全性審査の法的義務化」及び「食品添加物の指定品目の削除及び整理」に関する食品衛生調査会の答申
http://www1.mhlw.go.jp/houdou/1204/h0425-1_13.html
＜これまでの経過＞
T00.127 遺伝子組換え食品の安全性審査の法的義務化についての意見募集／厚生省
【関連トピックス】
T00.51 遺伝子組み換え食品、安全審査違反に罰則／厚生省
[キーワード]行政　人間　科学技術

T00.403
福岡地裁飯塚支部平12・5・17判決:家族へのがんの不告知は違法
医師がガンの悪性腫瘍がある事実を患者とその家族に告知しなかったため治療法の選択権ならびに人生の決定権を侵害されたとして、患者が、病院医師らを相手 に3000万円の損害賠償を求めた裁判で、福岡地裁飯塚支部は、5月17日、1995年当時においても患者の自己決定権とインフォームド・コンセントの考 え方は定着していたと認定、患者側の自己決定権が侵害され、そ