For Official Use **C(2009)119**

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

29-Sep-2009

English - Or. English

COUNCIL

Council

DRAFT RECOMMENDATION OF THE COUNCIL ON HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

(Note by the Secretary-General)

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JT03270553

English - Or. English

1. Innovation in the life sciences, particularly in biotechnology and genetics, contributes significantly to sustainable growth and development of economies as well as addressing social and global challenges. Biomedical research involving human genetic or genomic information analyzed in conjunction with individual's personal or health data is particularly promising and will be critical to improvements in the prevention, detection, diagnosis, treatment, and cure of disease and for the development of new products and services in the health sector. Human biobanks and genetic research databases (HBGRDs), which bring together and allow the sharing of human biological material and information derived from its analysis, are a key element of the scientific infrastructure underpinning such research.

2. The use and exchange of human genetic material and the information derived from it is not without some controversy, however, and in 2004, ministers of health and of science from the OECD countries agreed action[1] in three areas. To facilitate the diffusion and use of innovations in genetics in OECD countries and protect the public interest, the OECD Council adopted a *Recommendation on the Licensing of Genetic Inventions* in February 2006 [C(2005)149/REV1]. A *Recommendation on Quality Assurance in Molecular Genetic Testing* was adopted by the OECD Council in May 2007 [C(2007)48]. The current document setting out the draft *Recommendation for Human Biobanks and Genetic Research Databases* ("draft Recommendation"), in Appendix I, addresses the third area identified by ministers for action.

3. Within the scientific community, there is consensus that progress in understanding disease will depend on the establishment, harmonisation and broad use of HBGRDs.

4. However, consensus is sought on issues pertaining to the establishment, management, governance, operation, access, use and discontinuation of HBGRDs. The draft Recommendation seeks to provide countries with guidance on this range of issues. The draft herein draws on a high-level expert workshop held in Japan[2] and substantive analysis, as well as detailed country to country negotiations and broad stakeholder consultations. The process was overseen by the Committee for Scientific and Technological Policy (CSTP) and its Working Party on Biotechnology (WPB).

5. Experts elaborated draft guidelines for human biobanks and genetic research databases contained within this draft Recommendation (see the Annex of Appendix I) through a series of meetings held from 2007 to 2008. Participants in the expert discussions included representatives from national governments from OECD Members and non-Members, the biobanking, genetic databases and research communities, academia, the public sector, and industry.

6. In Spring 2008, extensive consultations were carried out with stakeholders on an advanced draft of the Recommendation. Over 500 individualised packages of documents were sent to entities around the world, inviting them to submit comments.

7. Comments were received from approximately 110 entities representing over 30 jurisdictions (both OECD and non-OECD). The consultations generated comments from managers and operators of biobanks (*e.g.*, tissues banks, tumour banks, disease-specific banks, *etc.*) and research databases; directors of laboratories; patient and user associations; medical genetics commissions and associations; privacy commissions; data protection authorities; medical and professional associations; entities involved in ethical and legal issues; government agencies; professional associations; the private sector; researchers and physicians; academia; university and teaching hospitals; and regional and international organisations. The comments were overwhelmingly supportive of the guidelines and commended this initiative; there was considerable support for the publication of the guidelines, in final version, at the earliest possible

1 OECD (2004), *Biotechnology for Sustainable Growth and Development*, Paris.

2 OECD (2006), *Creation and Governance of Human Genetic Research Databases*, Paris.

opportunity. The WPB took these comments into account in finalising the draft Recommendation and related complementary information (see Appendix II).

8. Efforts were made to involve those countries participating in the accession process and enhanced engagement dialogue in the development of the draft guidelines. Chile, Israel, the Russian Federation and South Africa, as observers to the WPB, actively participated in discussions and they, as well as Estonia and India, submitted input during the stakeholder consultation exercise.

9. OECD's Health Committee has been informed throughout the process and the WPB has made efforts to encourage intra-governmental consultation as the draft Recommendation has approached finalisation.

10. The WPB, at its meeting of 8-10 June 2009, agreed the draft *Recommendation of the Council on Human Biobanks and Genetic Research Databases* set out in Appendix I hereto. The CSTP endorsed it and agreed, via written procedure on 14 September 2009, to its transmission to Council for adoption. [See DSTI/STP/BIO/M(2009)1]

11. The draft Recommendation provides guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases. The draft guidelines addressing these elements are set out in the Annex of this draft Recommendation and form an integral part thereof. They have been developed to aid policymakers and practitioners who are establishing new HBGRDs, although it can also be usefully applied to HBGRDs already in existence. The draft Recommendation, as a whole, recognises that one of the fundamental objectives of an HBGRD is to foster scientific research. Overall, it seeks to facilitate wide access to data and materials for biomedical advances while ensuring that research is conducted in a manner respectful of participants, and that upholds human dignity, fundamental freedoms and human rights.

12. Appendix II reproduces document DSTI/STP/BIO(2008)34/REV2 agreed by the CSTP, via written procedure. This document sets out complementary information that includes an introduction, explanatory annotations, and a glossary, which were developed to provide explanations and examples for a wider audience and is intended to be disseminated with the Recommendation. Appendix II is not formally part of the draft Recommendation but, having been developed in support of this Act, is submitted to Council for declassification.

13. Following the adoption of this draft Recommendation, which directs the CSTP to report to Council on progress regarding its implementation within five years from adoption, the following activities are contemplated:

i. publication of a booklet that would include the *Recommendation for Human Biobanks and Genetic Research Databases* set out in Appendix I, and the complementary information, such as explanatory annotations and glossary, contained in Appendix II;

ii. publication of the information mentioned in (i) on the OECD website;

iii. participation in conferences, workshops and discussions to (a) stimulate dialogue, (b) share and disseminate knowledge and information on the Recommendation and related material and (c) provide assistance to jurisdictions wishing to develop and implement policies pertaining to human biobanks and genetic research databases;

iv. monitoring the implementation of this Recommendation, with the assistance of the WPB.

Proposed Action

14. In the light of the preceding, the Secretary-General invites the Council to adopt the following draft conclusions:

THE COUNCIL

a) noted document C(2009)119;

b) adopted the draft *Recommendation of the Council for Human Biobanks and Genetic Research Databases* set out in Appendix I of document C(2009)119;

c) agreed to declassify the said Recommendation as well as the other documents accompanying it, as set out in Appendix II of document C(2009)119.

APPENDIX I

DRAFT RECOMMENDATION OF THE COUNCIL ON HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

THE COUNCIL

Having regard to Article 5b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

Having regard to Rule 18 b) of the OECD Rules of Procedure;

Recognising that advances in biotechnology and genetics offer much promise for sustainable growth and development;

Recognising that the establishment, harmonisation and broad use of human biobanks and genetic research databases will contribute to the understanding of disease;

Recognising that research involving data and samples from human biobanks and genetic research databases analysed in conjunction with personal or health data is important for research and will be increasingly important not only for healthcare but also to drug discovery;

Recognising that research must respect the participants and be conducted in a manner that upholds human dignity, fundamental freedoms and human rights;

Recognising that providing guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases may contribute to public confidence and foster the willingness of participants to contribute in the research;

Recognising that human biobanks and genetic research databases may provide platforms for broad international collaboration;

Recognising that governments and public and private institutions (profit and not-for-profit) may therefore benefit from international guidance on human biobanks and research genetic databases;

On the proposal of the Committee for Scientific and Technological Policy:

RECOMMENDS that Member countries promote good practice in the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases and take due account of and implement the *Guidelines on human biobanks and genetic research databases* set out in the Annex hereto and which constitutes an integral part of this Recommendation;

INVITES non-Members to take due account of and disseminate this Recommendation among public and private (profit and not-for-profit) sector institutions that are involved with human biobanks and genetic research databases;

INVITES the Committee for Scientific and Technological Policy to review this Recommendation in light of scientific and technological developments and societal needs, within five years of adoption and periodically thereafter;

INSTRUCTS the Committee for Scientific and Technological Policy to monitor the implementation of this Recommendation and to report thereon to Council within five years of its adoption.

ANNEX

GUIDELINES ON HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

A. Scope

This Recommendation applies to human biobanks and genetic research databases (HBGRDs), which are structured resources that can be used for the purpose of genetic research and which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information.

It is intended that this Recommendation be applied as broadly as possible. It is recognised, however, that the Recommendation may not be fully relevant for all HBGRDs, given their diversity of structure, purpose and operation. In particular, the Recommendation may not be fully applicable to those HBGRDs established principally for non-research purposes (such as for diagnostic, therapeutic, treatment, forensic, transplantation, transfusion, audit, public health surveillance purposes, for marketing authorisation or quality assurance purposes or as teaching materials). The Recommendation has been developed to aid policymakers and practitioners who are establishing new HBGRDs, although many of the principles and best practices can also be usefully applied to HBGRDs already in existence.

B. Principles and Best Practices

1. General Elements

Principles

1.A The objective of an HBGRD should be to foster research.

1.B HBGRDs should be established, governed, managed, operated, accessed, used and discontinued in accordance with applicable legal frameworks and ethical principles.

1.C The operators of the HBGRD should strive to make data and materials rapidly and widely available to researchers so as to advance knowledge and understanding.

1.D Throughout its existence, the operators and users of the HBGRD should respect human rights and freedoms and secure the protection of participants' privacy and the confidentiality of data and information.

1.E The operators of the HBGRD should consider and minimise risks to participants, their families and potentially identifiable populations or groups whose specimens and data are included in the HBGRD.

1.F The operators of the HBGRD should develop and maintain clearly documented operating procedures and policies for the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, use and destruction of human biological materials, data and/or information.

1.G The operators of the HBGRD should be explicit and transparent about the nature and source of its financing/funding.

1.H The operators of the HBGRD should ensure that aggregate and general results of research conducted using its resources, regardless of outcome, are made publicly available either in the form of publications or through other means.

Best Practices

1.1 The operators should make available information on the scientific rationale underlying the HBGRD, and on the scientific and business uncertainties and risks associated with the establishment, operation and use of the HBGRD.

1.2 The establishment, governance, management, operation, access to, and use of the HBGRD and its protocols and processes for research activities, should be approved or reviewed, as applicable, by an independent research ethics committee.

1.3 The operators of the HBGRD should take reasonable measures to avoid discrimination against or stigmatisation of a person, family or group, whether or not they have contributed to the HBGRD.

2. Establishment of HBGRDs

Principles

2.A The purpose, both current and for the foreseeable future, of the HBGRD should be clearly formulated and communicated.

2.B The operators of the HBGRD should ensure that sufficient professional staff and resources are available to operate effectively.

2.C The operators of the HBGRD should develop a strategy for ensuring its long term sustainability, which also addresses the event that funding is terminated or its nature changed.

2.D In the establishment of a new HBGRD, the operators should consider which relevant stakeholders, including the general public, should be consulted.

Best Practices

2.1 The operators of the HBGRD should make information publicly available in easily accessible form detailing its background, purpose, scope, ethical and governance framework, name(s) of senior management, answers to frequently asked questions (FAQs) as well as contact information of a representative who will answer questions from the public.

2.2 The practical and financial feasibility of the HBGRD should be assessed and the financial resources to support the infrastructure should be secured as early as possible.

2.3 The operators of the HBGRD should ensure that appropriate staff and resources are available to maintain records, data and human biological materials appropriately, and to handle requests for access to data and human biological materials.

2.4 Where the operators of the HBGRD foresee attracting private investment or entering in commercial collaborations, this should be clearly articulated and communicated before such collaborations have been established, especially to participants.

2.5 The extent and types of consultations with relevant stakeholders should be based upon consideration of the nature and design of the proposed HBGRD; the risks involved to participants, their families and to identifiable groups; any particular sensitivities related to the individuals and groups under study; and the types of research to be conducted with the HBGRD.

2.6 The operators of the HBGRD should clearly indicate during any consultation how they will take account of stakeholders' views.

2.7 In establishing new HBGRDs, the operators should develop criteria for sampling and participant selection.

2.8 In establishing new HBGRDs, consideration should be given to future collaboration and cooperation, especially in regards to database compatibility and interfaces. Appropriate design elements providing for such compatibility and interfaces should be incorporated when creating the databases. The operators of the HBGRD should give consideration to using standardised approaches for the collection, storage and analysis of human biological materials and/or data so as to facilitate cross-HBGRD data exchange and sharing.

3. Governance, Management, and Oversight

Principles

3.A The HBGRD should be governed by the principles of transparency and accountability.

3.B The operators of the HBGRD should clearly formulate its governance structure and the responsibilities of its management and should make such information publicly available.

3.C The governance structure should be designed to ensure that the rights and well-being of the participants prevail over the research interests of the operators and users of the HBGRD.

3.D The operators of the HBGRD should have in place oversight mechanisms to ensure that the governance, management, operation, access to, use of and discontinuation of the HBGRD comply with legal requirements and ethical principles.

Best Practices

3.1 Review processes, in accordance with applicable law, including research ethics committees or comparable oversight mechanisms, should be in place for use in cases where human biological materials or data are to be used in a manner not anticipated in the original informed consent process, including:

- for previously collected human biological materials or data where the use might deviate from the original consent;
- for cases where informed consent may not have been obtained at the time of collection;
- for determining when to seek re-consent;
- for use of human biological materials or data where consent was obtained using a broader or layered format for uses unspecified at the time of collection, especially in the case of large-scale genetic epidemiology studies.

3.2 All HBGRD professional personnel, researchers and partners should carry out their activities in accordance with legal requirements and ethical principles, and the operators of the HBGRD should establish clear responsibilities to ensure that this is accomplished.

3.3 The individuals selected to be involved in the oversight process should be drawn from diverse areas of expertise of relevance to the nature and purpose of the HBGRD.

3.4 The operators of the HBGRD should ensure that participants have access to regularly updated information about the type of research being carried out with the human biological materials and data contained within the HBGRD.

3.5 The operators of the HBGRD should ensure that information is made publicly available about any significant modifications to the HBGRD's policies, protocols, and procedures, and that where these affect the interests of participants, that there are appropriate mechanisms to inform participants about such modifications.

3.6 The operators of the HBGRD should anticipate that over its lifespan there will be a need to review and modify its policies, protocols and procedures. A process should be in place for undertaking such review and modification.

4. Terms of Participation

Principles

4.A Participant recruitment should be carried out in a non-coercive and equitable manner that respects individual freedom of choice.

4.B Prior, free and informed consent should be obtained from each participant. The HBGRD may provide for obtaining consent/authorisation from an appropriate substitute decision-maker, or for obtaining waiver of consent from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects.

4.C The operators of the HBGRD should give careful consideration to any special issues related to the participation of vulnerable populations or groups, and their involvement should be subject to protective conditions in accordance with applicable law and ethical principles.

4.D The operators of the HBGRD should have a clearly articulated policy on whether participants may be re-contacted during the course of the HBGRD's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact.

4.E The operators of the HBGRD should disclose to participants, insofar as possible, the exceptional conditions under which researchers may be provided access to human biological materials or data that is not coded or anonymised.

4.F Participants should be provided with explicit information on whether and under what circumstances the operators of the HBGRD may be obliged legally to provide their human biological materials and data, in whole or in part, to third parties (e.g., law enforcement agencies, employers, insurance providers) for non-research purposes.

4.G The operators of the HBGRD should inform participants of their right to withdraw, of the nature of and modalities for exercising that right, as well as the implications of and limits to exercising that right.

4.H The operators of the HBGRD should provide participants with information about commercial products that may arise from research conducted using its resources**,** including human biological materials, data derived from the analysis of samples, data or other information provided by or about the participant. Information should also be provided on the benefits, if any, the participant may receive.

Best Practices

4.1 During the informed consent process, the HBGRD should provide potential participants with sufficient information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation and can make an informed decision on whether to participate. This information should be presented so as to not constitute an improper inducement to participate in the research.

4.2 Reimbursement of reasonable costs incurred by participants should not be of a magnitude so as to constitute an inducement to participate in the HBGRD.

4.3 The informed consent materials should be written in clear, concise and simple language.

4.4 The informed consent process should cover the human biological materials and data to be collected, data anticipated to be derived from the analysis of samples, and the health and other records to be accessed, their intended uses, storage and duration of storage.

4.5 Where subsequent use of human biological materials or data is envisaged that would not be consistent with the original informed consent, a new consent should be obtained from the participant or from the appropriate substitute decision-maker, or a waiver of consent should be obtained from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects.

4.6 Where authorised by applicable law and the appropriate authorities, the operators of the HBGRD could consider obtaining a consent that will permit human biological specimens and/or data to be used to address unforeseen research questions. Participants should be fully informed of the breadth of such consent and there should be additional safeguards in place to ensure that participants are protected.

4.7 The operators of HBGRDs involving participants who are minors should have a clearly articulated policy on whether, when and how the minor's assent will be obtained, in accordance with applicable law and ethical principles.

4.8 The operators of HBGRDs involving participants who are minors or with impaired decision-making capacity should have a clearly articulated policy on what steps will be taken, in accordance with applicable law and ethical principles, once such participants become legally competent to consent.

4.9 The operators of the HBGRD should have a clearly articulated policy on feedback and the nature of the feedback, if any, that will be provided to participants.

4.10 The HBGRD should have in place policies and procedures for ensuring that any re-contacting is not unduly burdensome for participants and is carried out by HBGRD representatives or designees trained in dealing with sensitive issues and impartial in regards to the outcome of the research.

4.11 Throughout the existence of the HBGRD, communication strategies should take into consideration the different needs of the participants. Consideration should be given to employing different formats and modes for providing information to participants.

4.12 Where applicable, participants should be provided with the opportunity to communicate with representatives of the HBGRD or its designees to discuss its nature and scope.

4.13 The operators of the HBGRD should inform participants that they may exercise their right to withdraw without any explanation being required and that there will be no negative consequences for themselves or their family in regards to the provision of healthcare services.

4.14 In certain circumstances, as permitted by applicable law and the appropriate authorities, where the participants may be provided with feedback of individual-level results arising from research, the operators of the HBGRD should provide clear information to the participant of the consequences of receiving such results and should inform the participant of their right to opt out from receiving such results. Non-validated results from scientific research using an HBGRD's human biological materials and data should not be reported back to the participants and this should be explained to them during the consent process.

5. Contents of HBGRDs

Principles

5.A Throughout the existence of the HBGRD, the operators should ensure that the collection and use of participants' human biological materials and data are scientifically, legally and ethically appropriate.

5.B The operators of the HBGRD should have a clearly articulated policy of whether data will be accessed from health or other records, and/or be independently assembled, and whether or not these data will be linked with or stored in the HBGRD.

5.C The operators of HBGRDs releasing human biological materials and/or data should have a clearly articulated policy on whether and how the results of research and analyses carried out using its resources should be returned to the HBGRD, incorporated into its databases and how access to such results for further research will be managed.

5.D All human biological materials and data within the HBGRD should be subject to proper quality control measures at every stage of processing to ensure high standards of quality.

5.E To foster the interoperability of systems and facilitate the scientific exchange of data and human biological materials, the operators of the HBGRD should strive to collect, process, handle and store human biological materials and data in a manner consistent with internationally-accepted technological standards and norms.

Best Practices

5.1 Where the operators of the HBGRD intend to access data from health or other records, participants should be duly informed in advance, where applicable at the time of consenting, about what types of data will be extracted from such records, by which entity, through which processes, and for which purposes the data will be employed. For access and use of such health and other records, the participant's consent should be obtained, unless waiver of consent is obtained from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects. Policies related to data from health records should also address the issue of secondary use of health and other records, especially when combined with other data.

5.2 The operators of the HBGRD should have in place protocols and processes to protect participants' personal and medical information, including, but not limited to genetic information.

5.3 The operators of the HBGRD should ensure that its policies on procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, and use of human biological material and data

take into consideration cultural heritage and/or religious beliefs known or disclosed by participants and/or their representative groups.

5.4 All of the resources held by the HBGRD should be maintained and tracked through an information management system that includes administrative data, the human biological materials and data derived from their analysis, phenotypic data, and any other information collected from or about the participant or their human biological materials.

6. Protection of Human Biological Materials and Data

Principles

6.A The HBGRD should be established, managed, governed, and operated in such a way as to prevent inappropriate or unauthorised access to or use of participants' human biological materials and personal data and/or information.

6.B The operators of the HBGRD should establish and implement specified policies and procedures for the protection of human biological materials and data, especially those potentially permitting, whether directly or indirectly, the identification of the participant**.**

6.C Prior to the collection of human biological materials or data, the operators of the HBGRD should make available to participants information about how their materials and data will be protected.

6.D The operators of the HBGRD should have a clearly articulated policy on the duration of storage of human biological materials and data.

6.E The collection, processing, handling, storage, transfer and destruction of human biological materials and data should be conducted in a manner that protects the privacy of the participants and the confidentiality of their specimens and data.

Best Practices

6.1 The operators of the HBGRD should assign to a specific position the responsibility for ensuring the protection of data and privacy.

6.2 Quality assurance measures should be in place for the collection, processing, storage, handling, transfer and destruction of the human biological materials and data.

6.3 The operators of the HBGRD should consider the extent to which the genetic data held by it might allow the identification of participants, either alone or in combination with other available data and reference samples. The HBGRD should establish a clearly articulated policy of whether certain data or combinations of data will not be made available and for which reasons.

6.4 Data protection should involve, where appropriate, the separation of information that can readily identify an individual from other data, including genotypic data.

6.5 The operators of the HBGRD should protect privacy and confidentiality through a combination of mechanisms including, for example: secure storage of human biological materials and data, coding and encryption of these, logging of any access to specimens or data, data enclaves, and honest broker systems.

6.6 Where feasible, participant indentifying data should be encrypted from the point of collection through all phases of data handling including storage, manipulation and transfer of data.

6.7 The HBGRD should have in place a robust infrastructure, including equipment and software, so as to prevent unauthorised access to its databases.

6.8 The operators of the HBGRD should ensure that only a restricted number of properly authorised staff, and in accordance with obligations of confidentiality, have access to information identifying or potentially identifying participants. Such access should be monitored and documented and only be exercised when necessary.

7. Access

Principles

7.A Access to human biological materials and data should be based on objective and clearly articulated criteria, and should be consistent with the participants' informed consent.

7.B The operators of the HBGRD should require that access requests include a scientifically and ethically appropriate research plan.

7.C Human biological materials and data should only be transferred when the recipient has adequate standards in place regarding privacy and confidentiality.

7.D Researchers should only have access to human biological materials or data that are coded or anonymised, such that the participant cannot be identified, and researchers should be required to not attempt to re-identify participants. However, under exceptional conditions, researchers may be provided with access to human biological materials or data that are not coded or anonymised.

7.E Given the potentially finite nature of some human biological materials, the operators of the HBGRD should formulate criteria for prioritising applications for access to the human biological materials.

7.F Except when required by law, the operators of HBGRD should not make accessible or disclose participants' human biological materials or data to third parties (e.g., law enforcement agencies, employers, insurance providers) for non-research purposes.

Best Practices

7.1 The operators of the HBGRD should make publicly available its access policies and procedures as well as a catalogue of the resources accessible for research purposes.

7.2 The operators of the HBGRD should have in place mechanisms to review applications for access to human biological materials and/or data.

7.3 The operators of the HBGRD should have in place mechanisms to review the envisaged uses of the human biological materials and/or data for consistency with the types of research uses agreed to by a participant.

7.4 The operators of the HBGRD should ensure that any stratified access or fee policies are fair, transparent and do not inhibit research.

7.5 The terms of access for researchers to the whole or a part of the database(s) of the HBGRD should be set out in an access agreement. Users of data should sign confidentiality agreements when access pertains to data that are not publicly available.

7.6 The terms of access for researchers to specimens and samples collected from participants, should be set out in a material transfer agreement or other agreement appropriate for that purpose.

7.7 To enable the tracking of data and sample usage, the participant's consent on the type of research for which his/her human biological materials and data can be used should be incorporated into the HBGRD's information management system.

7.8 The operators of the HBGRD should formulate policies and procedures setting out the manner in which an individual participant can request information and data about him/herself contained in the HBGRD, how those requests will be handled, and which information and data, if any, can be made available.

8. Qualifications, Education and Training

Principles

8.A The management of the HBGRD should have the qualifications, training and experience requisite to carry out the HBGRD's mandate.

8.B The operators of the HBGRD should employ professional and technical staff with the appropriate competency to carry out their duties effectively and safely.

8.C The operators of the HBGRD should ensure that all of its personnel are knowledgeable about its goals and purpose and are made aware of their duties to protect the privacy of participants and the confidentiality of data and human biological materials.

8.D The operators of the HBGRD should ensure that any conflict of interest involving its personnel are disclosed and suitably managed.

Best Practices

8.1 HBGRD personnel should have appropriate professional qualifications that meet recognised standards, education, and training and should be assigned responsibilities commensurate with their capabilities.

8.2 The operators of the HBGRD should ensure that staff receives appropriate and timely training (for example on technical matters, applicable law and ethical principles), in order to ensure knowledge and practice are kept up to date. Such training should also address the management of conflicts of interest and communication with participants and the public.

8.3 Training should form an integral part of the HBGRD's quality system.

8.4 Technical staff should be responsible for the implementation of policies and procedures as established by the management of the HBGRD.

9. Custodianship, Benefit-sharing and Intellectual Property

Principles

9.A The operators of the HBGRD should encourage appropriate access to and use of human biological materials, data, and information with a view to sharing benefits which may include, as applicable, building resource capacity or expertise including in non-OECD Members.

9.B Benefits arising from research using the HBGRD's resources should be shared as broadly as possible, including by the sharing of information, licensing, or transferring of technology or materials.

9.C The operators of the HBGRD should have a clearly articulated policy and explicitly indicate to participants whether they and/or the HBGRD retain any rights over the human biological materials and/or data and the nature of such rights.

9.D The operators of the HBGRD should have a clearly articulated policy that is communicated to participants relating to the commercialisation of its own resources, research results derived from those resources, and/or commercial products, if any, that may arise from research using its resources.

9.E The operators of the HBGRD should have a clearly articulated policy in regards to intellectual property rights, which should address the rights, if any, of the HBGRD, researchers and participants.

Best Practices

9.1 The operators of the HBGRD should have a clearly articulated policy regarding benefit sharing. This policy should address, inter alia, whether tests or products arising from research using its resources might be shared with the community and/or the general population, and how such sharing will be effected.

9.2 Where applicable, the operators of the HBGRD should negotiate benefit sharing agreements before a study begins, especially in the case of population-level studies where there may be vulnerable populations or unique concerns.

9.3 Researchers should submit to the HBGRD an annual progress report and a report at the termination of a research project. Such reports should list publications, published patent applications and patents issued arising from research accessing the HBGRD's resources**.**

9.4 Summary results arising from research conducted using the HBGRD's resources should be made available in easily accessible forms, such as through a newsletter or website.

9.5 In publications and presentations, researchers should acknowledge the HBGRD whose resources they have used or relied on, and the HBGRD should provide researchers with guidance on how it wishes to be acknowledged.

10. Discontinuation of the HBGRD and Disposal of Materials and Data

Principles

10.A The operators of the HBGRD should plan for its possible discontinuation and should have a suitably detailed policy setting out the manner in which the human biological materials and data that it holds will be dealt with in the event of its discontinuation.

10.B Where an HBGRD of scientific value can no longer be supported by its current operators, efforts should be made to transfer the human biological materials and data to another HBGRD or another entity.

10.C Once an HBGRD is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the human biological materials should be disposed of in an appropriate manner, consistent with the principles of consent, privacy and confidentiality.

Best Practices

10.1 The HBGRD's discontinuation plan should include details as to the appropriate disposition or destruction of the human biological materials and data where the HBGRD no longer meets a continued scientific need.

10.2 Where the discontinuation of the HBGRD results from insolvency, the operators of the HBGRD should be aware that under applicable insolvency law the liquidator may be permitted or required to sell the assets of the HBGRD to commercial buyers, subject to any constraints in the participants' consent or under the law. The operators should consider what steps should be taken to provide for this and make information available to participants.

10.3 The HBGRD's policy on the destruction and disposal of human biological materials and data should take into consideration cultural heritage and/or religious beliefs known or disclosed by the participants, and/or their representative groups.

10.4 The operators of the HBGRD should ensure that all information and data it holds is destroyed in a manner not permitting its recovery in accordance with the state of the art and technology.

10.5 The operators of the HBGRD should dispose of human biological materials in accordance with legislation and regulation applicable to the disposal of human materials and bio-hazardous waste.

APPENDIX II

COMPLEMENTARY INFORMATION

[For Declassification]

INTRODUCTION

This Recommendation aims to provide guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases (HBGRDs), which are structured resources that can be used for the purpose of genetic research and which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information.

It is intended that this Recommendation be applied as broadly as possible. It is recognised, however, that the Recommendation may not be fully relevant for all HBGRDs, given their diversity of structure, purpose and operation. In particular, the Recommendation may not be fully applicable to those HBGRDs established principally for non-research purposes (such as for diagnostic, therapeutic, treatment, forensic, transplantation, transfusion, audit, public health surveillance purposes, for marketing authorisation or quality assurance purposes or as teaching materials). The Recommendation has been developed to aid policymakers and practitioners who are establishing new HBGRDs, although many of the principles and best practices can also be usefully applied to HBGRDs already in existence.

This Recommendation in not intended to exhaustively cover all aspects of HBGRDs. The OECD *Recommendation on Quality Assurance in Molecular Genetic Testing*, adopted by the OECD Council in 2007, sets out, *inter alia*, a number of principles and best practices for governments, professional bodies and providers of molecular genetic testing services. The OECD *Recommendation on the Licensing of Genetic Inventions*, adopted by the OECD Council in 2006, provides guidance on licensing, transferring agreements and joint development activities in regards to genetic inventions. The OECD *Best Practice Guidelines for Biological Resources Centres*[1] (BRCs) set out further complementary quality assurance and technical aspects for the acquisition, maintenance and provision of high quality biological materials in a secure manner.

Research in Human Health and Human Biobanks and Genetic Research Databases

Research involving human genetic or genomic information analysed in conjunction with other personal or health data has become increasingly important for the understanding of complex (multi-factorial) diseases. Such research will be critical to improvements in detection, prevention, diagnosis, intervention, treatment, and cures, including for the development of new products and services. To support these research endeavours, great emphasis has been placed on the establishment and sharing of resources comprised of data, human biological samples and information derived from their analysis.

There is consensus in the scientific community that progress in understanding disease will depend on the establishment, harmonisation and broad use of HBGRDs. Current uses of HBGRDs are already contributing significantly to our understanding of genetic and environmental factors that influence disease

[1] OECD (2007), *OECD Best Practice Guidelines for Biological Resources Centres*, published under the responsibility of the Secretary-General.

risk and treatment including a better understanding of the reasons for drug reactions. To serve these purposes, HBGRDs may be established in diverse forms. For example, HBGRDs may be any of the following, or a combination thereof: cross-sectional, longitudinal, large-scale, disease-specific, or population-based. Such data resources will provide platforms for international collaboration on a scale not previously attained.

It is clear that wide access to such data and materials for biomedical advances must be balanced by concern for the interests of research participants (*i.e.*, those individuals from whom biological materials and data are obtained). The ability to establish biobanks and genetic research databases will depend in part on participants' willingness to contribute. Research must respect the participants and be conducted in a manner that upholds human dignity, fundamental freedoms and human rights and be carried out by responsible researchers.

Nature of the Document

The *Recommendation on Human Biobanks and Genetic Research Databases* was adopted by the OECD Council on xxx.[2] This Recommendation is intended to be evolutionary in nature and should be reviewed in light of relevant scientific and societal developments. Thus, there will be a need for the Recommendation to be assessed, five years after adoption at the latest, and periodically thereafter, in order to ensure that it is fostering the desired objectives.

[2] While a Recommendation of the OECD Council is a non-legally binding instrument, it represents an important political commitment on the part of the Member countries.

ANNOTATIONS

1. These Annotations to the *Recommendation on Human Biobanks and Genetic Research Databases* aim to provide additional information, such as clarifications, explanations and examples. The Recommendation provides guidance on the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases (HBGRDs).

2. For the purpose of this Recommendation, HBGRDs are considered to be structured resources that can be used for the purpose of genetic research, and which include: a) human biological materials and/or information generated from their analysis; and b) extensive associated information.

3. It is intended that this Recommendation be applied as broadly as possible. This Recommendation has been developed to aid policymakers and practitioners who are establishing new HBGRDs, although many of its principles and best practices can also usefully be applied to HBGRDs already in existence.

4. It is recognised, however, that the Recommendation may not be fully relevant for all HBGRDs, given their diversity of structure, purpose and operation. In particular, the Recommendation may not be fully applicable to those HBGRDs established principally for non-research purposes (such as for diagnostic, therapeutic, treatment, forensic, transplantation, transfusion, audit, public health surveillance purposes, for marketing authorisation or quality assurance purposes or as teaching materials).

5. Examples of different models of HBGRDs for whom this Recommendation may be useful include: large-scale collections of human biological material representative of a population or part of a population; epidemiological collections; collections of carriers of specific genetic mutations/markers/ profiles; and collections of samples and data from individuals with a certain disease or taking specific medications. The resources of an HBGRD may be used for a variety of research purposes to advance our understanding of human health and the life sciences, including in emerging "omics" fields (e.g. proteomics, transcriptomics, metabolomics, cytomics, and microbiomics).

6. This Recommendation in not intended to exhaustively cover all aspects of HBGRDs. The OECD *Recommendation on Quality Assurance in Molecular Genetic Testing*, adopted by the OECD Council in 2007, sets out, *inter alia,* a number of principles and best practices for governments, professional bodies and providers of molecular genetic testing services. The OECD *Recommendation on the Licensing of Genetic Inventions*, adopted by the OECD Council in 2006, provides guidance on licensing, transferring agreements and joint development activities in regards to genetic inventions. The OECD *Best Practice Guidelines for Biological Resource Centres*[1] (BRCs) sets out complementary best practices for the acquisition, maintenance and provision of high quality biological materials (including human biological material) in a secure manner. They provide technical best practices including on hygiene, premises, equipment, documentation management, informatics, preparation of media and reagents, deposits to the BRC, preservation and maintenance (e.g., storage conditions), supply of biological materials (e.g., packaging, transportation) and quality audit and quality review.

1. General Elements

7. This Recommendation recognises that one of the fundamental objectives of an HBGRD should be to foster scientific research. Research resources are built on the contributions of participants and should be used as effectively as possible to advance knowledge and understanding.

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[1] OECD (2007), *OECD Best Practice Guidelines for Biological Resources Centres*, published under the responsibility of the Secretary-General.

8. The Recommendation also recognises that an HBGRD will follow applicable domestic legislation, regulation, policies and frameworks. Depending on the nature and scope of the HBGRD, it may also follow international guidelines or frameworks, such as this Recommendation. Some HBGRDs have found it useful to make information available about the frameworks within which they operate. For example, in the situation where an HBGRD comes into existence through a legislative act, the statute creating the HBGRD could be made available, for instance, on the HBGRD's website. Similarly, the HBGRD may also consider indicating on a website or in public information, for example, the elements of this Recommendation that it will follow.

9. The HBGRD should respect the rights of research participants. The HBGRD will need to protect the privacy of the participant and the confidentiality of the human biological materials and data. In some jurisdictions, legislation may provide for the exceptional release of information in certain circumstances. For example, information may exceptionally be released in the context of public health emergencies or outbreaks.

10. Research pertaining to a large portion of a population, especially amongst those sharing common characteristics, may raise issues of potential discrimination and stigmatization. For example, an association between a specific heritage and a particular disease may lead to discrimination from insurers or employers. The initiators and operators of the HBGRD should take into consideration potential consequences not only for participants but also individuals, families and groups who may not have participated in the HBGRD. In addition, the HBGRD should make information publicly available about the possibility that research results generated from population-based human genetic data may have repercussions for individuals, participants, their family, groups to which they belong and the community as a whole. Examples of repercussions may include loss of dignity or community stigmatization.

11. The initiators of the HBGRDs should provide information on the scientific rationale underlying the establishment of an HBGRD, as well as the scientific and business uncertainties and risks. They should also indicate the possibility that the purpose and scope of the HBGRD may evolve over its lifespan. For instance, scientific findings may show that the materials collected by the HBGRD are no longer suitable for its scientific purpose. An example would be where an HBGRD decides to collect samples for DNA isolation, but later determines that RNA is required to pursue its scientific objective. As the need for RNA was scientifically not foreseeable at the time of specimen collection, this is an example of a subsequent modification to the HBGRD's scope. At the time of establishment of the HBGRD, the initiators may not be able to provide participants with detailed information on future scientific and technological developments. However, they should make clear that continuous scientific and technological developments may necessitate adaptations/modifications of the HBGRD during the course of its existence.

12. In regards to business risks, initiators may choose to highlight that there may be changes over the lifespan of the HBGRD. Examples of areas where change may occur include in regards to ownership of the HBGRD. For instance, over the lifespan of the HBGRD, public enterprises/universities may become privatized or *vice versa*. The HBGRD could provide information that ownership could change and explain the uncertainties associated with the establishment and operation of the HBGRD.

13. The operators should ensure that the HBGRD has a policy in regards to dealing with aggregate and generalised research findings. The establishment and broad use of HBGRDs will contribute to numerous objectives including the scientific community's pursuit and understanding of disease. To achieve this objective, the HBGRD may benefit from ensuring that aggregate and generalised results arising from research conducted using its resources be added back into its database(s) in order to continue to build itself. The HBGRD should also encourage the dissemination of aggregate and general research results. Different means can be used to disseminate research results including publication through newsletters, websites containing research summaries, and lists of publications.

2. Establishment of HBGRDs

14. Creating an HBGRD may require considerable resources both prior to and in the course of its establishment. In order to use limited research funds in the most effective manner, the scientific and financial feasibility of the HBGRD should be assessed as early as possible so as to not undertake projects that are not viable. This early assessment can also assist in securing long-term funding for the HBGRD. To ensure that resources are expended usefully, the establishment of the HBGRD should involve sufficient properly qualified professionals with relevant experience.

15. The initiators and operators of the HBGRD should develop a business plan and strategy which should take into account and set out the economic, financial and scientific feasibility and viability of the HBGRD. The business plan should set out the goals, how they will be achieved and the manner in which the HBGRD will be operated. A business plan will draw on different disciplines including: scientific expertise, finance/accounting, human resource management, and operations management. It should set out the assumptions and risks inherent to the establishment of the HBGRD. The business plan should also include consideration of the procedures essential for safekeeping all confidential information including personal and genetic data.

16. This Recommendation sets out that the HBGRD's operators should develop a strategy to ensure its long term sustainability. The strategy may include identifying operating costs, sources of funding, and any needs for additional funding in order to attain its objectives. The strategy should also set out the manner in which the operators will deal with unforeseen events, such as termination of funding. This could, for example, include information on the business plan both for the short term (*e.g.* for 5 years) and long term.

17. Some HBGRDs may be established in collaboration with for-profit entities, for example to diversify their sources of funding. Additionally, the operators of the HBGRD may consider collaboration with commercial undertakings during the course of its existence. In the event that such activities are contemplated, the HBGRD should clearly communicate its actual or potential commercial activities to participants at the earliest possible opportunity. While many participants may be indifferent as to whether or not the HBGRD will be involved in commercial activities, some may choose not to participate in the HBGRD in such situations.

18. This Recommendation indicates that the extent and type of consultations should be determined by the purpose, nature and type of the HBGRD. Determining the breadth of consultations should also take into consideration the risks involved in sharing human biological materials and data and the sensitivity of the data being collected. The greater the breadth of targeted participants, the more extensive the information and data to be collected , the more important it is that that broad consultations be carried out and with diverse groups. The consultations should be carried out with diverse stakeholders which could include representatives from the public, patient groups, industry, government, staff from other HBGRDs, and the research community.

19. Consultations may assist in communicating information about the nature, purpose, and scope of the HBGRD as well as in identifying needs and concerns. However, the HBGRD should guard against inflating the future and potential benefits of the HBGRD itself, and of participation in the HBGRD. Prior to carrying out consultations, the operators should consider the manner in which the input received from these will be taken into consideration.

20. Consultations may be carried out through a variety of approaches and more than one approach may be used in the course of consultations. For example, consultations may be carried out through focus groups, surveys, interviews, and web-based discussions. Moreover, consultations should aim to cover a

variety of issues. For example, consultations could cover scientific, legal, regulatory and ethical subjects, especially where concerns have been identified.

3. Governance, Management, and Oversight

21. The Recommendation indicates that the HBGRD should have a governance structure and that the responsibilities of its management should be set out. The nature of the governance structure for any HBGRD will be influenced by numerous factors including its objective, scope, and size. Overall, the governance structure will aim, *inter alia*, to ensure the protection of the rights and well-being of the participants.

22. One element that the HBGRD may consider within its governance structure, for example, is the manner for providing participants with a means of recourse for redressing breaches of the applicable legislation, regulation, and policy, including those relating to ethical or financial matters. The means of recourse may be established solely within the HBGRD or may be through existing bodies, such as judicial courts or data protection commissioners. Another element for consideration within its governance structure is, for instance, a mechanism for reviewing applications for access to its holdings of human biological materials, information and/or data.

23. In ensuring the daily operations of the HBGRD, management may establish position(s) responsible for ensuring compliance with legal requirements and ethical principles as well as for specific areas of operation. Specific roles and chains of responsibilities should be established. For example, within the HBGRD, a position may be established that is responsible for ensuring the security and custodianship of the human biological materials, information and data held by the HBGRD.

24. The Recommendation sets out the need for oversight mechanisms to ensure compliance with applicable legislation, regulation and policies. There are different models of oversight mechanisms serving diverse purposes. For example, oversight may be for scientific, ethical, social and/or regulatory purposes. The different models may include, for example, institutional review boards, ethical review boards, scientific peer-reviewed committees, scientific advisory committees, *etc.*

25. The oversight bodies of HBGRDs could include expertise from diverse relevant fields, as well as representatives from different stakeholder groups. Expertise may be drawn from various medical and scientific specialities such as genetics/genomics, pathology and laboratory medicine, epidemiology, as well as other fields such as law, ethics, informatics, accounting, *etc.* Depending on the nature of the HBGRD, representatives might also include non-experts or patient groups.

4. Terms of Participation

26. The fundamental precept of prior, free and informed consent forms the basis for the involvement of human subjects in medical and scientific research. This principle is recognised in international legal instruments, including those applicable in international public or human rights law. Examples of some international legal instruments that make reference to informed consent include the UNESCO *Universal Declaration on Bioethics and Human Rights* (2005), UNESCO *Universal Declaration on the Human Genome and Human Rights* (1997), *Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects* (1964, last revised 2008). The common practice is to obtain the informed consent from the participant to be involved in the research. However, in some circumstances, informed consent may not be obtained directly from the participant due to incapacity to give such consent. For example, a minor or an individual with impaired decision-making capacity may not be able to provide the needed consent. In such circumstances, applicable law may permit that the informed consent be sought from the appropriate substitute decision-maker, who is authorised to consent in the place of the participant.

In some jurisdictions, this may be permitted only in exceptional situations. The conditions under which a substitute decision-maker will be able to give consent on behalf of the participant are subject to applicable law and ethical principles pertaining to the protection of human subjects and will vary from jurisdiction to jurisdiction.

27. The requirement for informed consent may be waived in some circumstances. For example, in some jurisdictions, consent may be waived when it cannot be obtain, the risk to the participant is deemed minimal, and the rights and welfare of the participant are not adversely affected. In such cases, the informed consent may be waived by an authorised entity such as a research ethics committee in accordance with the applicable law and ethical principles pertaining to the protection of human subjects and will vary from jurisdiction to jurisdiction.

28. In some situations, where authorised by applicable law and the appropriate authorities, an HBGRD may consider obtaining a relatively broader consent from the participant. For example, the relatively broader consent may be obtained to enable the use of human biological specimens and/or data to address unforeseen research questions. In some jurisdictions, obtaining this broader consent typically will involve that (a) the participant understand and consent to participating on this broader basis; and (b) additional safeguards are in place to ensure that the interests of the participant are protected. For example, the additional safeguards can include the use of oversight mechanisms to verify that access to human biological materials, data and/or information is provided in a manner consistent with the participant's wishes. Where an HBGRD chooses to seek a relatively broader consent from participants, participants should be given a range of possible scopes of consent to choose from and the HBGRD should put in place mechanisms for ensuring that participants' decisions and instructions are respected.

29. The purpose of the informed consent process is to ensure that potential participants are able to make a voluntary decision about whether to participate, based on the provision of relevant information. Within certain cultures, however, it is more common that decisions are considered at the community or group level rather than at the individual level. An HBGRD involving different cultural groups should take into account the different approaches to decision-making. This may involve, for example, additional discussions with the community. While researchers should be cognisant of the importance of involving the community or group, as appropriate, they must be respectful of the need to obtain individual consent.

30. Research involving vulnerable populations brings to light the need for additional considerations on the part of the operators of HBGRDs and researchers. Examples of vulnerable populations can include minors, individuals with impaired decision-making capacity, military personnel and the elderly. For vulnerable populations, additional considerations should include the well-being of such participants, the type of information that should be communicated to them, and the approach for communicating with these groups. The involvement of vulnerable populations or groups in an HBGRD should be subject to protective conditions in accordance with applicable law and ethical principles.

31. For minors, especially for very young children, it is common that a substitute decision-maker, usually the parents, make the decision for the minor's participation in the research. The conditions that govern the participation of the minor in research are subject to applicable law and ethical principles and will vary from jurisdiction to jurisdiction. However, in light of the minor's age and autonomy, the HBGRD could consider ways in which the minor can play a more active role. For example, in some jurisdictions, depending on their age, a minor may be able to provide their assent for participating in research.

32. Where substitute consent has been obtained for a participant lacking capacity (*e.g.* a minor or individual with impaired decision-making capacity), consideration will need to be given to what will occur once the participant gains or re-gains capacity to consent. In accordance with applicable law and ethical principles, consent may need to be obtained from the participant to continue in the research or to collect

further data or human biological materials from them or their withdrawal of consent. For example, particular consideration may be needed in situations where a minor has been recruited as part of family studies.

33. In some circumstances, there may be the need to obtain anew the consent from the participant. This need may arise, for example, where the type of the research being carried out has changed over time, or where the manner in which the human biological materials, information and/or data being used has changed. Often such situations arise, for instance, when a collection developed many years ago is now considered to be a valuable resource and there is interest in re-using these resources for different purposes. In the situations of HBGRDs established from existing collections, the operators will need to consider whether the intended scope and purpose of the HBGRD and the intended research uses of the human biological materials and/or data are consistent with the original informed consent. Where the intended scope of the HBGRD or its intended uses are not within the ambit of the original informed consent or none was obtained, for example, the human biological materials and/or data may only be used if a new consent is obtained or if a waiver of consent is obtained from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles.

34. During the consent process, HBGRDs should provide information to participants on whether human biological materials or data will be made available for non-research purposes. For example, human biological materials or data may be made available for non-research purposes such as for proficiency testing or public health emergencies. Similarly, the participant should be informed during the informed consent process whether the HBGRD is required by law to make available human biological materials or data to third parties such as insurers, employers, law enforcement agencies or other civil-law agencies, for non-research purposes.

35. The informed consent process should provide information to the potential participant in a simple and easily understandable manner and on a variety of subjects. Depending on the nature of the HBGRD, this may include:

- The purpose of the HBGRD and foreseeable risks and benefits of taking part.
- The types of human biological materials and data that will be collected at enrolment and afterwards at subsequent follow-up points, which may include data that some participants consider especially sensitive (with options to avoid certain questions and measurements), and may be linked to health and other records.
- Where applicable, the fact that the HBGRD will be the legal custodian of the human biological materials, data, and the collection, and that the participant may not retain all rights in these.
- The intended uses of the human biological materials and data.
- The general procedures and safeguards used to protect privacy and confidentiality.
- The policy with respect to benefit sharing.
- Where applicable, the expectation that commercial entities may be granted access to the human biological materials, data and information contained within the HBGRD's database(s).
- The policy and means for ongoing communication with participants.
- Information for contacting the HBGRD.
- The policy with regards to sharing human biological materials and data for non-research purpose with third parties such as insurers, employers or law enforcement agencies or for public health emergencies.

- The policy in regards to feedback of results to participants.
- The policy with respect to re-contact and the purposes for which such re-contact will be undertaken.
- The policy applicable to the use of human biological materials and data of a participant in the event that they become incapacitated or die.
- The storage and period of storage of the human biological materials and data.
- Their right to withdraw, the nature and modalities of this right and how to exercise this right, including options for dealing with any samples and non-anonymised data, that were given away to third parties (especially, but not limited to, researchers). Participants should be informed that the exercise of the right to withdraw will not entail consequences in regards to the provision of medical care services.
- The policy in regards to intellectual property.
- The policy on the commercialisation of its resources; on commercial products, if any; the modalities of such commercialisation; and the benefits, if any, the participant may receive.

36. The informed consent process should include information on the human biological material and data to be collected, their intended uses, storage, transfer and their disposal techniques. In addition, this information should take into consideration the participant's cultural and/or religious beliefs.

37. In some situations, the HBGRD may choose to reimburse reasonable costs for participants to contribute to the HBGRD. The reimbursement of such reasonable costs should not be of a magnitude so as to provide inducement to participate in the HBGRD.

38. During the informed consent process, participants should have the opportunity to meet with HBGRD staff in order to discuss the nature and scope of the HBGRD. Where for reasons of confidentiality, the HBGRD's staff may not meet with participants, such participants should be provided with the opportunity to discuss with appointed designees. The HBGRD should ensure that such meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the HBGRD. The HBGRD should ensure that potential participants are provided with reasonable time periods for providing their consent. The HBGRD should always make clear to the potential participant that agreement or refusal to participate in the HBGRD and its research will not affect medical care services that will be or could have been provided to them, nor prejudice or disadvantage them.

39. While the goal of the informed consent process should be to provide as much information as is relevant, the consent document should remain straight-forward, readable and accessible. The HBGRD should aim to make the informed consent document publicly available. However, for certain HBGRDs, there may be protected or proprietary information in the consent form that cannot be rendered public. Participants should be given time to consider the information provided before being asked to sign the consent document. Participants should also be provided with a copy of their signed consent document, where applicable.

40. In developing the consent document, consideration should be given to the different needs of participants, especially the elderly or non-native speakers. For example, for an HBGRD collecting human biological materials and data predominantly from a specific community whose mother language is not the official language of the country, it may be desirable to translate the consent document and relevant information into the mother language of that community.

41. As many HBGRDs will be longitudinal in nature, situations may arise over the course of the HBGRD's operation, where re-contacting participants becomes important. For example, it may be that the HBGRD intends to carry out research that is significantly different from that originally contemplated, research that was not covered during the original informed consent process, or research based on new information about disease diagnosis. Participants should be offered, at the time of consenting, the option to refuse to be re-contacted, provided that the possible implications of such refusal are explained to the participant. Moreover, participants should be provided information pertaining to re-contact. For example, they should be informed of the circumstances under which they will be re-contacted, whether re-contact is obligatory for participation in the HBGRD, and by whom they will be re-contacted. The HBGRD should put in place a process for recording a participant's decision in regards to re-contact.

42. At the time of consenting, the HBGRD's policy on a participant's right to withdraw should be explained to him/her. Some possible options for participants exercising their right of withdrawal include:

a) No further contact with/participation by the participant, but permits the continued retention and use of the previously obtained specimens, samples and data, and if applicable, links to records from third parties.
b) No further contact with the participant, no further collection of specimens or data, and destruction or anonymisation of all specimens, samples and data.
c) Complete withdrawal including the destruction of samples and data.

43. In some situations, the right to withdraw may be circumscribed, and participants should be informed of this as well. For example, where samples have been anonymised and/or distributed, or results are in the public domain or have been published, complete withdrawal may not be possible. Participants need to be informed about these situations and that complete withdrawal may not be possible. However, participants should also be reassured that confidentiality and protection of their specimens, samples and data will continue. Participants should also be provided with contact information in case they wish to withdraw.

44. The HBGRD's policy should also address the situation where participants become legally incapacitated or die. It is essential that the HBGRD provide information on their policy to the participant or the appropriate substitute decision-maker at the time of consenting. There are a variety of approaches for how these situations may be handled. For example, some HBGRDs may offer the option for participants to be withdrawn from a study after death or loss of capacity by a next of kin or close friend (possibly someone named by the participant during the consent process). Other HBGRDs make explicit to participants during the consent process that their data and samples will continue to be included in the HBGRD after they lose capacity or die. An HBGRD's policy could also indicate that participants' data and samples will be irreversibly anonymised at the point at which their death becomes known to the HBGRD. The HBGRD should also consider whether it will reassess mental capacity during any re-contact of a participant and/or what the effect of a participant being found to lack capacity on re-contact will be (e.g. whether further data or samples might be collected thereafter, or whether the fact of their incapacity will be recorded and included in the research database).

45. At different points during the existence of the HBGRD, it will communicate with participants and the public. For example, the HBGRD will communicate with participants during the informed consent process; it may chose to provide updates of the research carried out using its resources; or it may provide information to participants if its nature or purpose were to be modified. When undertaking to communicate with participants and the public, various means of communications should be considered. Moreover, consideration should be given to employing environmentally-sound and cost-efficient means of communication. For example, this could include information via websites, TV, *etc*. Decisions on the communication approaches to be employed should also take into account the diversity of the audience. For

example, consideration should be given to the technological means for communication (*e.g.*, paper versions of documents could be made available for those not familiar with information technologies; or video formats for certain groups), and to language problems (*e.g.*, the documents may need to be translated into the language(s) of a large segment of the population, or into Braille for the visually impaired).

46. In certain circumstances and where authorised by applicable law and the appropriate authorities, participants may be provided with individual-level research results. The operators of an HBGRD that envisages providing participants with individual-level results should give special consideration to the numerous complexities that doing so presents. Examples of factors that the HBGRD needs to address include: ensuring the participant is provided with validated results; providing sufficient information to the participant on the implications of receiving such results; explaining to the participant that the results may have implications for his/her family and relatives; and providing the participant with the option to not receive the individual-level results. The HBGRD should also consider whether it is appropriate for a trained professional to provide the feedback and/or to counsel the participant and which additional services may be useful for the participant receiving this feedback. For example in some jurisdictions, the feedback of individual results may be provided to the participant by their physician. Further guidance on providing feedback and results to participants is set out in the OECD *Recommendation on Quality Assurance in Molecular Genetic Testing*, adopted by the OECD Council in 2007.

5. Contents of HBGRDs

47. The HBGRD should have a clearly articulated policy which provides information to participants on the human biological materials, data and information that it will collect from them and on the method(s) for collection. The types of human biological materials and data collected and stored in an HBGRD should meet specified criteria based on the scientific objectives and purposes of the HBGRD. The HBGRD could also provide information about what data, information or samples will be derived from the specimen, if any. Moreover, the HBGRD should provide an explanation to participants of how the human biological materials will be employed.

48. The HBGRD's policy could also include reference to the diverse types of data and information elements that will be collected. Examples of types of data that may be collected include medical/health, biochemical, life-style, genealogical, family-history, genetic, physiological and other demographic and personal data. The HBGRD's policy could also specify the source from which the data will be collected. For example, it can specify that data and information may be collected from the participant or from other sources, such as health records. For pre-established HBGRDs, data from health or other records should only be accessed in accordance with applicable law or regulation.

49. The HBGRD's policy could also set out details about the types, quantities and quality of the specimens to be collected, and general information on whether there will be direct or indirect links to identifying information. For example, an HBGRD's policy could indicate the type of specimens that it intends to collect, such as blood, tissues, urine, hair, *etc*. The policy could also indicate the quantity of each type of specimen that will be collected. For example, an HBGRD could indicate to participants that they will be asked to provide sixty millilitres (i.e., 4 tablespoons) of blood through standard blood collection, that the participant's DNA and plasma will be extracted from the sample in order to evaluate the different components and elements in their blood, such as glucose levels and haemoglobin.

50. The HBGRD's policy may also explain the methods that will be used to obtain the specimens. The methods for obtaining the specimens should aim to balance the need to obtain the most useful specimen with the risk for the participant. The HBGRD should also consider methods for obtaining specimens that minimise the risk of any invasive procedures. As well, the HBGRD may consider putting in place insurance to cover participant's damages that may arise independent of professional negligence.

51. The HBGRD may decide to not collect or maintain certain data, to not perform certain tests or to not allow certain types of analyses. The HBGRD should have a clearly articulated policy about which specific types of data will not be collected and which specific types of tests will not be performed. For example, where applicable, the HBGRD could indicate that it will not carry out tests nor collect information about paternity, HIV/AIDS, or the use of illicit substances.

52. An HBGRD releasing human biological materials and data should have a clearly articulated policy as to whether and how the results of analyses of such materials (e.g., genotypic data) should be returned to the HBGRD and how access to such results for further research will be managed, particularly if the results can be linked to other information about the participant. The policy should include the standard of quality applicable for incorporation of results into the HBGRD.

53. Different cultural and religious groups may have different attitudes towards biological material, and these may change over time. HBGRDs should take these into account, where they are known, and consider whether any steps should be taken to ensure such views are respected. Some groups regard certain types of biological material as having a special status, particularly where it is removed post mortem, and as deserving of special treatment *e.g.,* in terms of the method of its handling. Although this is most likely to be addressed during the consent process, there may be circumstances where this is not the case (*e.g.* in the case of existing collections).

54. HBGRDs can make an important contribution to the advancement of knowledge by participating in international endeavours and collaborations. One of the challenges facing international collaboration is establishing internationally-accepted technological standards and norms. Some efforts are underway to develop international standards to facilitate the linkage of datasets and the interoperability of systems so as to foster research and the sharing of data and materials. However, in many areas there is no international body responsible for establishing standards and/or there is no agreement among HBGRDs on commonly-accepted standards. For instance, for several types of data there is no international agreement on preferred format. Working with other initiatives, HBGRDs could seek to develop and/or adopt widely-accepted standards that would be useful for international collaboration.

6. Protection of Human Biological Materials and Data

55. This Recommendation specifies that the HBGRD should be established, governed, managed, and operated and discontinued so as to prevent the inappropriate or unauthorised access to or use of participant's human biological materials, personal data and/or information. The protection of human biological materials, data and information may be achieved through a variety of approaches and mechanisms, and often through the use of combined approaches. Some examples include: coding and encryption of human biological materials and data; anonymisation of samples and data; limiting access to the collection of human biological materials and data; implementation and maintenance of security measures to block unauthorised access; data enclaves; honest broker systems, *etc*. In the event that human biological materials and data are collected by various partners, then each partner holding these could use their own code with none of them holding the totality of the codes.

56. To ensure that researchers are not inadvertently provided access to identifying or potentially identifying data, the HBGRD can, for example, permit the querying of its databases only by HBGRD staff who return aggregated results to the researchers or by permitting researchers to query only certain aspects of the data held by the HBGRD. The HBGRD should also ensure that only properly authorised staff have access to identifying or potentially identifying information and that they access such data or information only where strictly necessary. The operators of the HBGRD should ensure that the staff respect their obligations to protect the confidentiality of the data and information.

57. Anonymisation is intended to prevent participant re-identification. Anonymisation involves the deletion of the coding key(s) linking the data and samples to a given participant's identifiers and as such provides additional confidentiality and privacy protection over coded data and samples. However, as anonymised samples and data are not traceable back to the participant, it is not possible to undertake actions such as sample withdrawal, or the return of individual results, even at the participant's request. The HBGRD should consider the implications of anonymisation as use of anonymised data and samples also does not allow, for example, clinical monitoring, participant follow-up or the addition of new data from the participant.

58. Honest broker systems involve independent third parties who are responsible for ensuring the separation of identifying information from other data. An honest broker may be, for example, a data protection authority. Data enclaves involve the use of a secure or controlled access environment, including databases, servers, networks or websites. They allow the HBGRD or a third party to physically and electronically control and monitor the use of the HBGRD's database(s) by external users to ensure it complies with the terms of access and is in conformity with the participant's consent.

59. The HBGRD should have a clearly articulated policy on the duration of storage of the human biological materials, data and information. The determination of how long the human biological materials, the data and information may be stored will vary according to the nature and potential uses of the specimens or data.

7. Access

60. The operators of the HBGRD need to ensure that access to and uses of human biological material and data are in line with those described in the research protocols, consistent with the participant's informed consent and respect the privacy of the participant and confidentiality of the human biological materials and data.

61. The HBGRD should provide information to the participant about the types of research that may be carried out using its resources. The HBGRD may also provide information about whether human biological materials and data will be made available for research pursuing commercial purposes or research carried out beyond national borders. The operators of the HBGRD need to ensure that data access requests and data distribution are consistent with the informed consent provided by the participant.

62. The HBGRD should provide to researchers human biological materials and data that are coded or anonymised. However, in exceptional circumstances, it may be in the participant's interest that the researcher has access to non-coded or non-anonymised materials or data. For example, this may be the case for research involving rare diseases.

63. This Recommendation sets out that the HBGRD should not grant access to or disclose participants' human biological materials or data to third parties for non-research purposes, except when required by law. For example, the operators of the HBGRD should not make available participants' human biological materials or data to third parties such as insurers, employers, law enforcement agencies or other civil-law agencies, for non-research purposes.

64. Participants should not be directly contacted by researchers who have accessed human biological materials and data from the HBGRD. In exceptional circumstances, contact between researchers and participants may be appropriate. Where the HBGRD contemplates that it will allow contact between researchers and participants, it should develop a policy that sets out the exceptional circumstances under which such contact will be permitted, the justification for such a request, the manner in which the contact will be carried out and should inform the participant of this policy. For example, the HBGRD's policy

could set out that access to participants will only be allowed with the written approval from the participant and from a research ethics committee.

65. In establishing criteria for prioritising access applications, the HBGRD can consider, for example, the objectives and feasibility of the proposed study, the appropriateness of the study design, and an assessment of the qualifications of the researcher to carry out the proposed research. The HBGRD may also want to ensure that the proposed uses are scientifically and ethically appropriate and consistent with applicable policies, frameworks and legislation. The HBGRD should have their access policies readily available for participants and third parties to ensure transparency.

66. Depending on the nature of the resource, the data/sample provider and the end user, access agreements (including data access and material transfer agreements) may address some or all of the following:

- What is to be provided (specification of data and materials, format and timing of release);
- What the data and materials provided can be used for (this is often limited to a specific project), and what they can't be used for (this may be everything other than the specified project, or something more specific, *e.g.* data linkage);
- The credentials of the end user;
- Fees (or royalties) payable;
- Arrangements concerning intellectual property rights (*e.g.* whether or not IP rights are asserted by the provider over existing or future IP, or any licences sought by them to future IPR);
- Requirement to return research findings to the resource owner to enrich the resource;
- Requirement to publish research findings and/or to disseminate them more generally, and to acknowledge the resource in publications;
- Requirement to act in accordance with participants' consent, and any procedures in the event of withdrawal of consent;
- Requirement to act in accordance with relevant legal and regulatory requirements, and obtain ethical approval (where applicable);
- Requirement to preserve confidentiality, and/or maintain anonymisation (and not attempt to re-identify or re-contact participants);
- Limits on (prohibition of or additional safeguards required for) transfer of data or materials to third parties, including cross-border;
- Limits on (prohibition of) certain uses of materials or data;
- Disclaimers of responsibility for data/ sample quality;
- Return or disposal of residual samples at the end of a project;

- Termination (*e.g.* for default);

67. The HBGRD may adopt stratified policies in regards to access to its resources or to the payment and amount of fees. These policies may be based on a number of criteria, including for instance the background or affiliation of the researcher. The HBGRD should ensure that these policies are applied in a fair, transparent manner and that they do not have the effect of inhibiting research.

68. The transfer of human biological materials and data outside the geographical jurisdiction where they were collected raises numerous complex issues. While most jurisdictions will have applicable legislation, regulation and policy, there may still be lacunae and more specific legalisation, regulation and policy may be required. The HBGRD and researchers requesting access should develop a material transfer agreement or other agreements for such purposes.

69. Where human biological materials are physically released to third parties by the HBGRD, consideration should be given to the implications for the custodianship of any data derived from the analysis of such material that relates directly to participants (e.g. genotype data derived from DNA), particularly where such data can be linked to significant amounts of phenotypic data about the same participant. Such issues should be addressed in the material transfer agreement which governs the release of human biological materials and data from the HBGRD to the researchers. The HBGRD should ensure that its governance mechanism is able to deal with problematic situations pertaining to data derived from the analysis of human biological materials and other information.

70. The HBGRD should provide the quantity of materials and data consistent with that required for the research to be carried out. The HBGRD should request information from the researcher on whether the quantities provided were sufficient and that there was no excess materials or data.

8. Qualification, Education and Training

71. Professionals employed by the HBGRD should possess the qualifications, education, training and experience appropriate for carrying out their professional activities. Personnel should be competent to ensure the quality of the human biological materials and data collected, stored and made accessible, as well as to ensure the ethical and legal use of the HBGRD's resources. Management should ensure that all personnel understand the nature of their responsibilities, whatever their function in the HBGRD. Depending on the responsibilities of a staff member, training can cover developments in regards to areas such as human genetics, ethics, informatics, law, management, as well as methods for collecting, preserving and storing human biological materials and data.

72. Since protecting the privacy of participants and the confidentiality of human biological materials and data is significant, personnel should receive training in regards to their obligations of confidentiality, particularly in regards to requests for access. The HBGRD's personnel should sign agreements that set out their duties to protect the privacy of participants and the confidentiality of data and human biological materials.

73. Some of the HBGRD's personnel may have to contact participants or communicate with the public. It may be useful for such personnel to be provided with specific training in such areas. This training could cover, for example, ways in which to address particularly sensitive issues for the community with whom they will need to communicate.

74. Appropriately educated and trained management and personnel is important for the effective and efficient operation and management of the HBGRD. The education programme of the HBGRD could draw on the education programmes of other institutions. As part of an educational programme, the HBGRD's

staff may participate in the development of other HBGRDs and may contribute in the development of international standards. It may also be desirable that the scientific/research community consider establishing an education program/system for educating and training personnel involved in HBGRDs.

9. Custodianship, Benefit-Sharing and Intellectual Property

75. The HBGRD should have a clear policy on who will retain rights over human biological materials and data, and on the nature of these rights, which may differ from jurisdiction to jurisdiction. Where the HBGRD intends to retain certain rights, it should inform the participant. The participant should be provided, in an understandable manner, with information on the nature of the rights that the HBGRD will retain and its consequences. In situations where the participant retains any rights, these should also be explained in an understandable manner.

76. Over time, benefits will arise from the establishment of HBGRDs. An HBGRD's benefit-sharing policy may refer to any benefits for the general public and for the specific participants. Benefits may include, but are not limited to, contributions to the advancement of science, the development of new diagnostic and therapeutic tools or products, or capacity-building, whether in OECD Members or non-Members. Benefits resulting from the HBGRD's activities and their applications should be shared as much as possible with participants, communities and society as a whole.

77. In recognition that the sharing of knowledge is one of the most important benefits to be derived from HBGRDs, its operators should endeavour to foster the exchange of information, technology and research through various means including: technology transfer, material transfer, licensing, joint development activities, *etc*. The *OECD Recommendation on the Licensing of Genetic Inventions* (2006) provides guidance to ensure that licensing and transferring agreements, as well as joint development activities, are carried out in a balanced manner and are based on economically rational practices that help eliminate high transaction costs and that serve the interests of society.

78. Where the HBGRD has been developed with input and contributions from researchers from resource-poor settings, it may also be appropriate for the initiators of the HBGRD and the users of the resources to identify ways in which the contributors can be supported (e.g. through the exchange of knowledge or know-how to develop research capacity in such settings) and benefits can be shared with the contributors.

79. The HBGRD should develop a detailed policy of whether or not it intends to commercialise any resources, such as the human biological materials (e.g., specimens, samples), data, information, the database(s), etc. It is important that this information be communicated to the participant during the informed consent process. This policy should also explicitly set out whether participants will derive any benefits from the commercialisation.

80. The HBGRD should also develop a clear policy on any intellectual property rights that may arise, either directly or indirectly, from the HBGRD. For example, the policy may set out to whom these rights accrue, and who will ensure their protection or enforcement, if necessary. Similarly, there may be IP rights that arise pursuant to the research that is carried out using the human biological materials and data obtained from the HBGRD. For example, the policy could explain that any IP rights arising from the research belong to the researchers or their employers.

81. This Recommendation sets out that researchers should acknowledge in their publications and presentations, the HBGRD whose resources they have used or relied on. It would be useful for the HBGRD to develop a policy providing specific guidance on the manner in which such an acknowledgement should be indicated.

10. Discontinuation of the HBGRD and Disposal of Materials and Data

82. Some HBGRDs may have a determined end date and should plan for how the human biological materials, data and information will be handled at that point in time. In addition, an HBGRD should also develop a plan for unexpected discontinuation, such as if its funding were terminated, or if it no longer serves a scientific valuable purpose. This policy should include detailed plans for the appropriate disposition or destruction of the human biological materials, data and information.

83. The HBGRD should develop plans for the appropriate transfer, disposition and destruction of human biological materials and data where it is no longer scientifically valuable or financially viable. The HBGRD should have policies and procedures in place for ensuring appropriate disposal of potentially bio-hazardous materials.

84. At the point of its discontinuation, the HBGRD should ensure the destruction of specimens and samples under its control, which may be more straight-forward than ensuring the destruction of specimens, samples and data that have been provided to third parties. While the HBGRD should make every effort possible to retrieve and destroy all such specimens and samples, there may be circumstances where this is not feasible (*e.g.,* if pooled samples are prepared or cells lines have been developed and disseminated anonymously).

85. The destruction of all data may also be quite difficult given that "back-up" files may cover a lengthy period (for example, 20 years). The HBGRD should destroy all information and data that it holds in accordance with the protocol, the participant's informed consent, as well as legislation and regulation, including that applicable to the protection of the participant's privacy. While the HBGRD should make every effort possible to retrieve and destroy all of the data, there may be circumstances where this is not feasible.

86. Where a scientific valuable HBGRD may be discontinued for financial reasons, its operators should consider the transfer of its resources to another entity or HBGRD. In the case that a transfer is being considered, prior to the transfer, the operators should ensure that the recipient has in place equivalent policies, governance structure, equipment and systems, and staff.

87. Different cultural and religious groups may have different attitudes to biological material, which can change over time. Some groups may regard certain types of biological material as having a special status and as deserving of special treatment *e.g.* in terms of the method of its disposal. Although this is most likely to be addressed during the consent process, it will also be an important consideration at the point of disposal of the human biological materials. The HBGRD should take these into account, where they are known, and consider how to respect those views. For example, some cultural or religious groups may follow traditional practices in the disposal or destruction of human biological materials.

GLOSSARY

The following definitions are provided only for information purposes. Some of these definitions are drawn from other documents and do not represent an effort by the OECD to agree on interpretations of these definitions or develop new ones.

Anonymised/ Anonymisation: Anonymised data and samples are initially single or double coded but where the link between the subjects' identifiers and the unique code(s) is subsequently deleted. Once the link has been deleted it is no longer possible to trace the data and samples back to individual subjects through the coding key(s). Anonymisation is intended to prevent subject re-identification. As anonymised samples and associated data are not traceable back to the subject, it is not possible to undertake actions such as sample withdrawal, or the return of individual results, even at the subject's request. The use of anonymised data and samples does not allow for clinical monitoring, subject follow-up or the addition of new data from the subject. The deletion of the coding key(s) linking the data and samples to a given subject's identifiers provides additional confidentiality and privacy protection over coded data and samples, as it prevents subject re-identification through the use of the coding key(s).

Assent: This term is used in the context of a child participant in research. Even though a child may not be considered legally competent to consent to participate in research, the child may be considered competent to give his/her assent, that is – his/her opinion on whether he/she wishes to participate in the research.

Associated Information: personal, clinical, biochemical and phenotypic information about the participant.

Coded: where data and samples are labelled with at least one specific code and do not carry any personal identifiers.

End-User: a health care practitioner, scientist, or laboratory personnel who performs an appropriate procedure, test or archival function for the specimen.

Governance: the processes and structures that an entity uses to set its objectives/goals, appoint the management whose responsibility it is to achieve these goals and to oversee management in its pursuit of these goals. Governance mechanisms are also needed to put in place internal controls and risk management systems. Management is accountable to the governance bodies that in turn are usually/should be accountable to those who have appointed them.

Human Biological Material: includes specimens, samples and aliquots of the original material, and their fractionated components.

Identifying information: information that may lead to the identification of the participant from whom the human biological material, data and associated information are obtained.

Informed consent: A process by which information concerning the intended research is provided to the participant or participant's substitute decision-maker with an opportunity for them to ask questions, after which specific approval is documented.

Management: comprises directing and controlling a group of one or more people for the purpose of coordinating and harmonizing that group towards accomplishing a goal. Management often encompasses the deployment of human resources, as well as financial, technological and natural resources. Management is responsible for achieving the objectives/goals set for the organisation and is given considerable leeway to undertake this task. While this may be operationally efficient, there is a possibility that management might act only in their own interests, hence the need for governance mechanisms.

Material Transfer Agreement: generally signed between a provider and a recipient, is used to document the transfer of materials, with or without information, either to an entity (*i.e.,* the recipient) and/or away from an entity (*i.e.*, the provider) subject to a number of terms and conditions.

Operators: the researchers, governmental entities and/or organisations involved in setting up and operating the HBGRD, and including the initiators of the HBGRD.

Oversight: is based on the notion that there is usually a difference between setting policy and objectives for an entity and overseeing or monitoring how these are being executed or put into operation.

Participant: Individual from whom biological materials, data and information are obtained.

Private entity: may cover for-profit entities but may also cover legal entities not publicly held or traded.

Private-Public Partnership (PPP): is a cooperative venture between the public and private sectors, built on the expertise of each partner and involves the allocation of resources, risks and rewards.

Processing: includes procurement, collection, labelling, registration, storage, tracking, retrieval, transfer, use and destruction

Research Ethics Committee (REC): is a local authority that evaluates research projects involving human beings, including genetic research. The primary function of a REC is to protect the welfare and rights of human participants in research. Depending on the jurisdiction, these may also be referred to as Ethics Review Board (ERB) or Institutional Review Board (IRB).

Sample: a single unit containing material derived from one specimen.

Specimen: a specific tissue, blood sample, urine sample, *etc*. obtained from a single participant at a specific time.