



Recommendation of the Council on Human Biobanks and Genetic Research Databases

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Date(s)

Adopted on 22/10/2009

Background Information

The Recommendation on Human Biobanks and Genetic Research Databases was adopted by the OECD Council on 22 October 2009 on the proposal of the Committee for Scientific and Technological Policy. 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.

THE COUNCIL,

HAVING REGARD to Article 5 b) 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 co-operation, 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 identifying 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.

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- **Declarations:** OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.
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- **Arrangement, Understanding and Others:** several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.