

Monitoring of the “Recommendation of the Council on
Human Biobanks and Genetic Research Databases”
[OECD/LEGAL/0375]

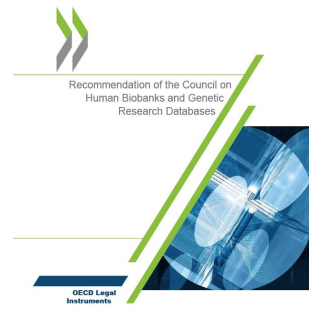
OECD, Hermann Garden



Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375]

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. All substantive OECD legal instruments, whether in force or abrogated, are listed in the online [Compendium of OECD Legal Instruments](#). They are presented in five categories:

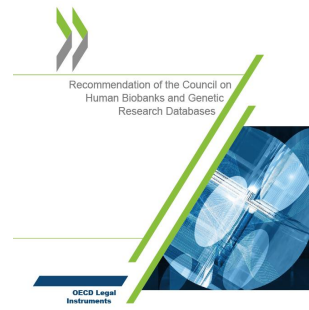
- Decisions: ...
- **Recommendations:** OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.
- Declarations: ...
- International Agreements: ...
- Arrangement, Understanding and Others: ...



The goal of many biobanks is to maximise the use of data in order to optimise scientific, economic and social value.

Recent advances in technologies, for example, population genomics, artificial intelligence, and cloud computing represent important opportunities for biobanks and health innovation.

But in exploring these opportunities, important challenges must also be navigated: data is the primary currency of value in this field, rising questions around consent, privacy, access, and building and sustaining scientific, economic and social value of biobanks.



Biobanks have played a pivotal role to monitor, better understand, and fight the COVID-19.

They have given researchers a head-start on collecting and sharing of high-quality data.

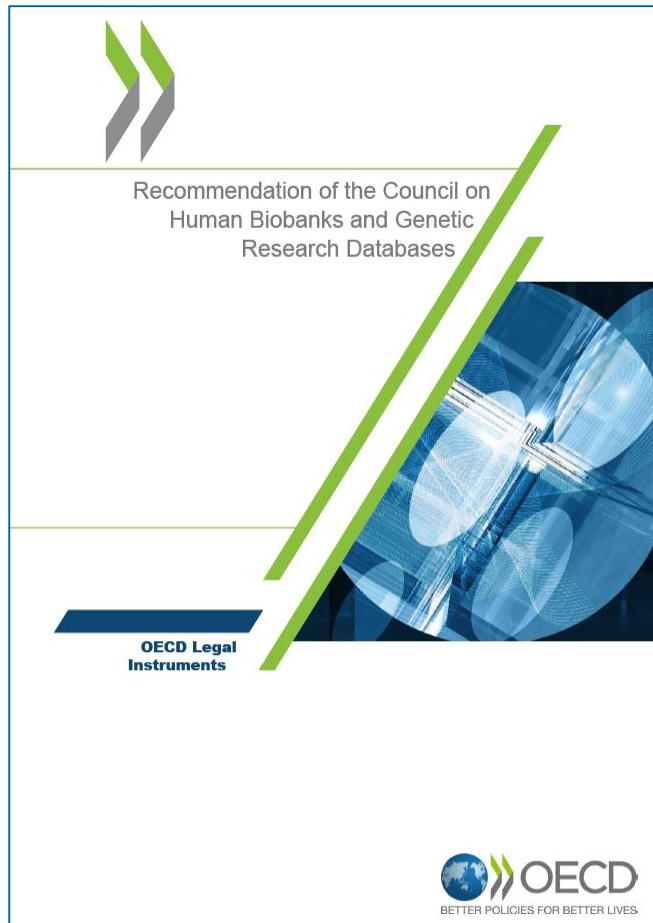
Biobanks are crucial in the run towards a COVID-19 vaccine and treatment.

For example:

- The UK Biobank has already completed recruitment of 20 000 biobank participants to collect blood samples and help undertake urgent research into the spread of the virus and COVID-19.
- The BBMRI-ERIC, a European research infrastructure for biobanking network of 600+ biobanks, provides key services, such as the efficient and high-quality storage of samples in clinical and research settings, and the guidance and standards for targeted identification, collection and conservation of important samples.



Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375]



- Recommendation adopted by the OECD Council on 22 October 2009.
- Recommendation applies to HBGRDs 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
 - b) extensive associated information.
- RECOGNISING that human biobanks and genetic research databases may provide **platforms** for broad international collaboration.



Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375]



OECD Legal Instruments



GARDEN, Hermann

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FR



OECD/LEGAL/0375

Adopted on: 22/10/2009

Text

Annex

Background information

Committee(s)

Date(s)/Reference(s)

Related instrument(s)

Implementation

Adherents

Download/Print Booklet

Share Link

Recommendation of the Council on Human Biobanks and Genetic Research Databases

In force Recommendation Science and Technology

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.



Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375]



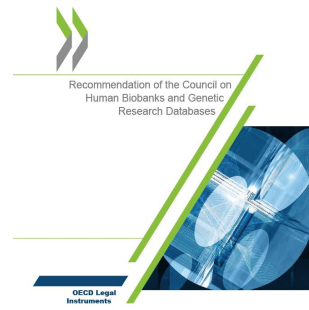
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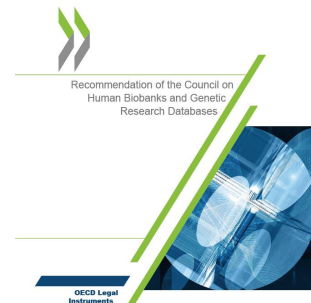
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Scope

Principles and Best Practices

1. General Elements
2. Establishment of HBGRDs
3. Governance, Management, and Oversight
4. Terms of Participation
5. Contents of HBGRDs
6. Protection of Human Biological Materials and Data
7. Access
8. Qualifications, Education and Training
9. Custodianship, Benefit-sharing and Intellectual Property
10. Discontinuation of the HBGRD and Disposal of Materials and Data



Scope

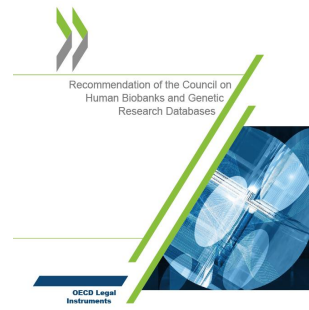
Principles and Best Practices

1. General Elements

Principle 1D: “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.”



Monitoring of Recommendation of the Council on Human Biobanks and Genetic Research Databases



Scope

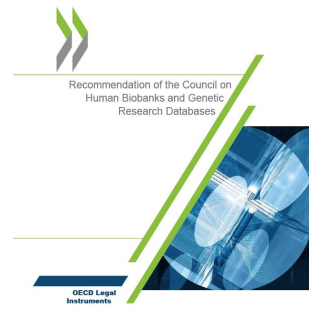
Principles and Best Practices

1. General Elements
2. Establishment of HBGRDs

Principle 2C: “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.”



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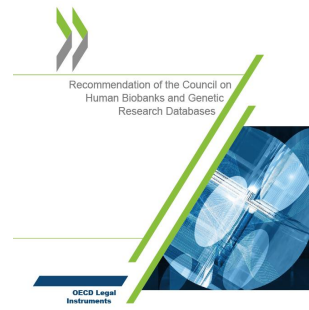


Scope

Principles and Best Practices

1. General Elements
2. Establishment of HBGRDs
3. Governance, Management, and Oversight
4. Terms of Participation

Principle 4B: “Prior, free and informed consent should be obtained from each participant.”



Scope

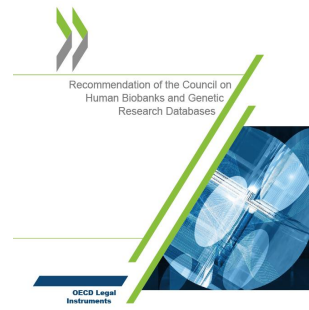
Principles and Best Practices

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6. Protection of Human Biological Materials and Data
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Principle 7F: “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..”



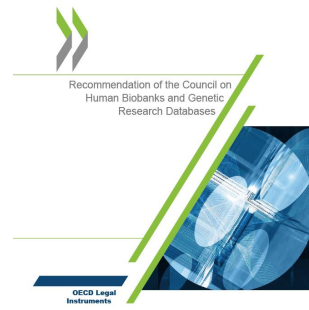
Monitoring of Recommendation of the Council on Human Biobanks and Genetic Research Databases



The Working Party on Biotechnology, Nanotechnology, and Converging Technologies (BNCT), reporting to CSTP, carried out a project on the monitoring of the Recommendation 2016-2019.

The questionnaire was divided into four sections:

1. Dissemination and awareness
2. Establishment of human biobanks and genetic research databases
3. Law, regulation and policy
4. Policy impact and continued relevance.

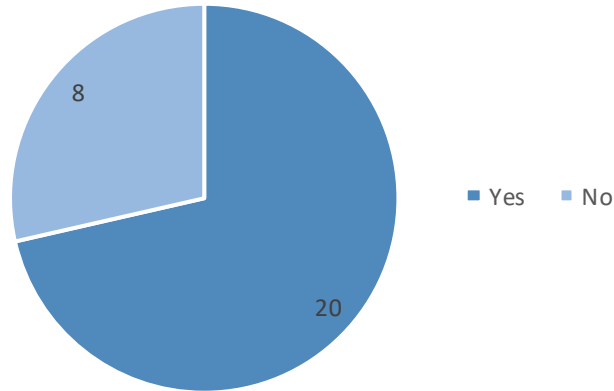
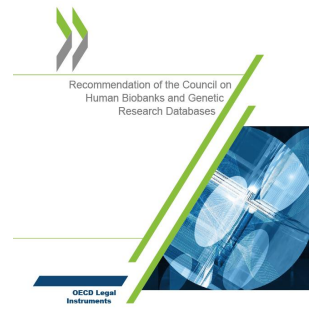


28 respondents to questionnaires (2016, 2019)

- Australia
- Austria
- Belgium
- Canada
- Chile
- Czech Republic
- EC
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Israel
- Italy
- Korea
- Latvia
- Lithuania
- Mexico
- Netherlands
- Norway
- Poland
- Portugal
- Sweden
- Switzerland
- Turkey
- UK
- USA



Monitoring of Recommendation of the Council on Human Biobanks and Genetic Research Databases

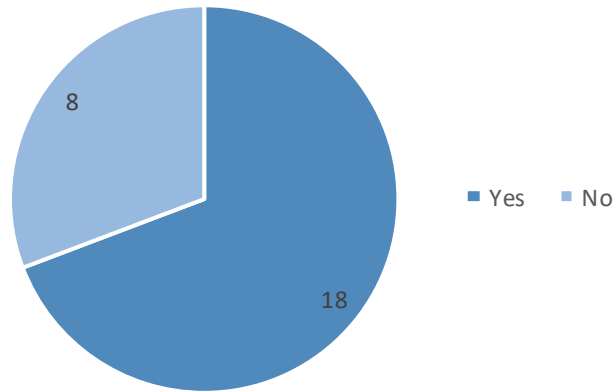
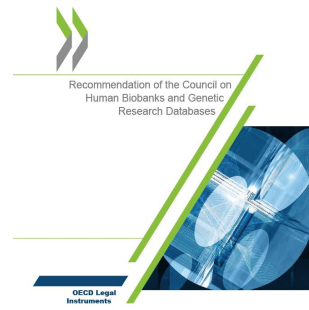


Question: “Are any large-scale HBGRDs (i.e. including data from at least 10 000 individuals) currently being managed within your country?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



Monitoring of Recommendation of the Council on Human Biobanks and Genetic Research Databases

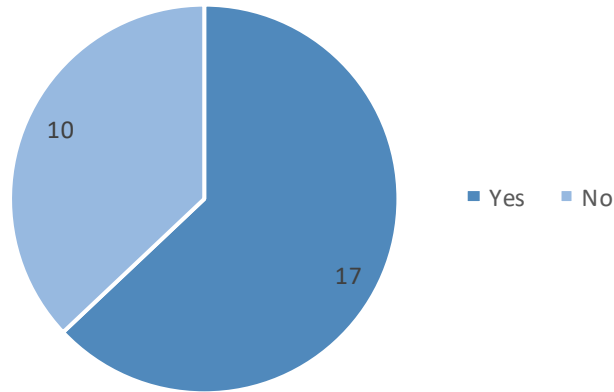
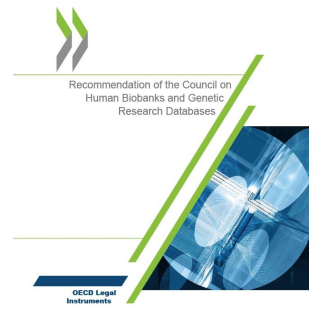


Question: “In your country has the establishment of new HBGRDs since 2009 followed the relevant principles and best practices contained in the Recommendation?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



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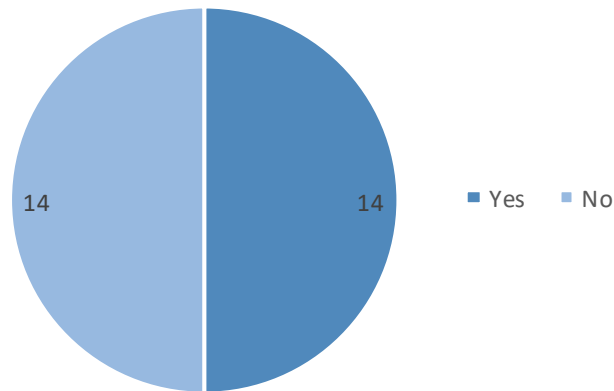
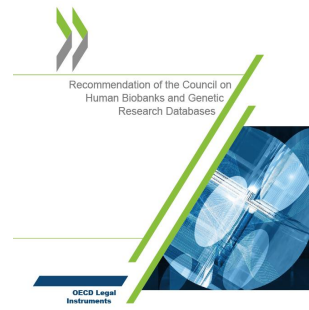


Question: “Are you aware of plans to develop any new HBGRDs containing data from participants who reside in your country, either to be managed within your country or elsewhere?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



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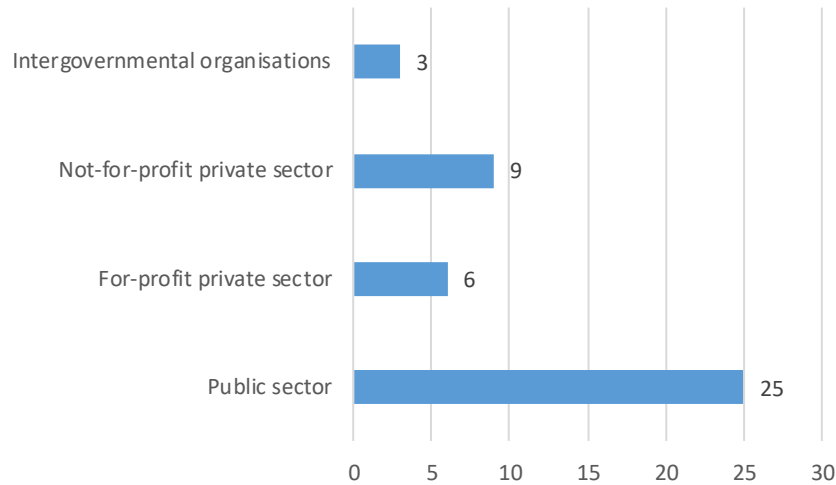
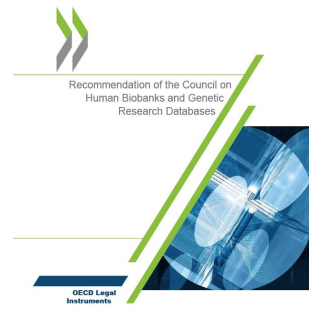


Question: “In your country, is funding from governments and government agencies for the creation or administration of an HBGRD conditional upon the principles and best practices contained in the Recommendation being followed?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



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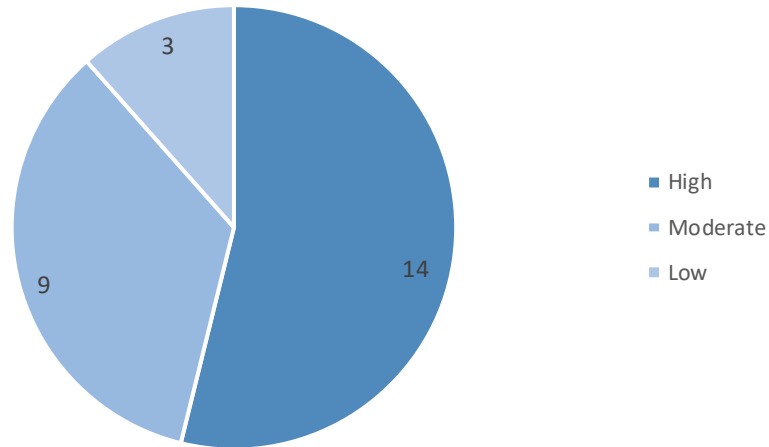
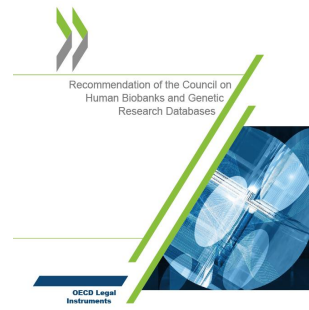


Question: “If an HBGRD has been established in your country, who is responsible for its management?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



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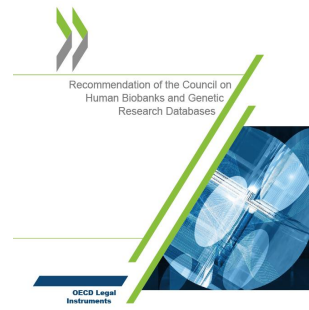


Question: “From the point of view of your country, do you consider the Recommendation to be relevant?”

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



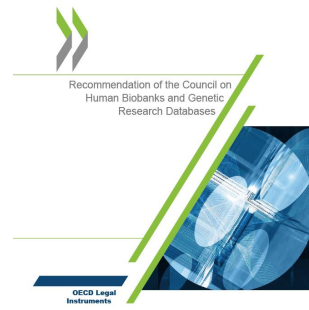
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Question: “From the point of view of your country, do you consider that there is a need for the Recommendation to be revised?”

- 10 respondents did not provide an answer.
- 5 respondents stated that they do not see an immediate need for a revision of the Recommendation.
- 8 respondents noted that the Recommendation should be revised, and/or provided concrete technical and policy examples that could imply a need for its revision.

Source: questionnaires to Adherents and the EC (2016, 2019) on the implementation of the Recommendation of the Council on Human Biobanks and Genetic Research Databases [OECD/LEGAL/0375].



Conclusions

- The Recommendation has proven highly relevant across Adherents. However, ten years on from its adoption by the Council in 2009, some Adherents identified areas where the Recommendation may not be up-to-date and may need revision to ensure continued relevance and alignment with relevant international standards.
- The BNCT and CSTP's conclusion was that they would review the Recommendation's continued relevance and implementation more closely as part of the BNCT PWB 2021-22.