図１　サンプルテンプレート画面

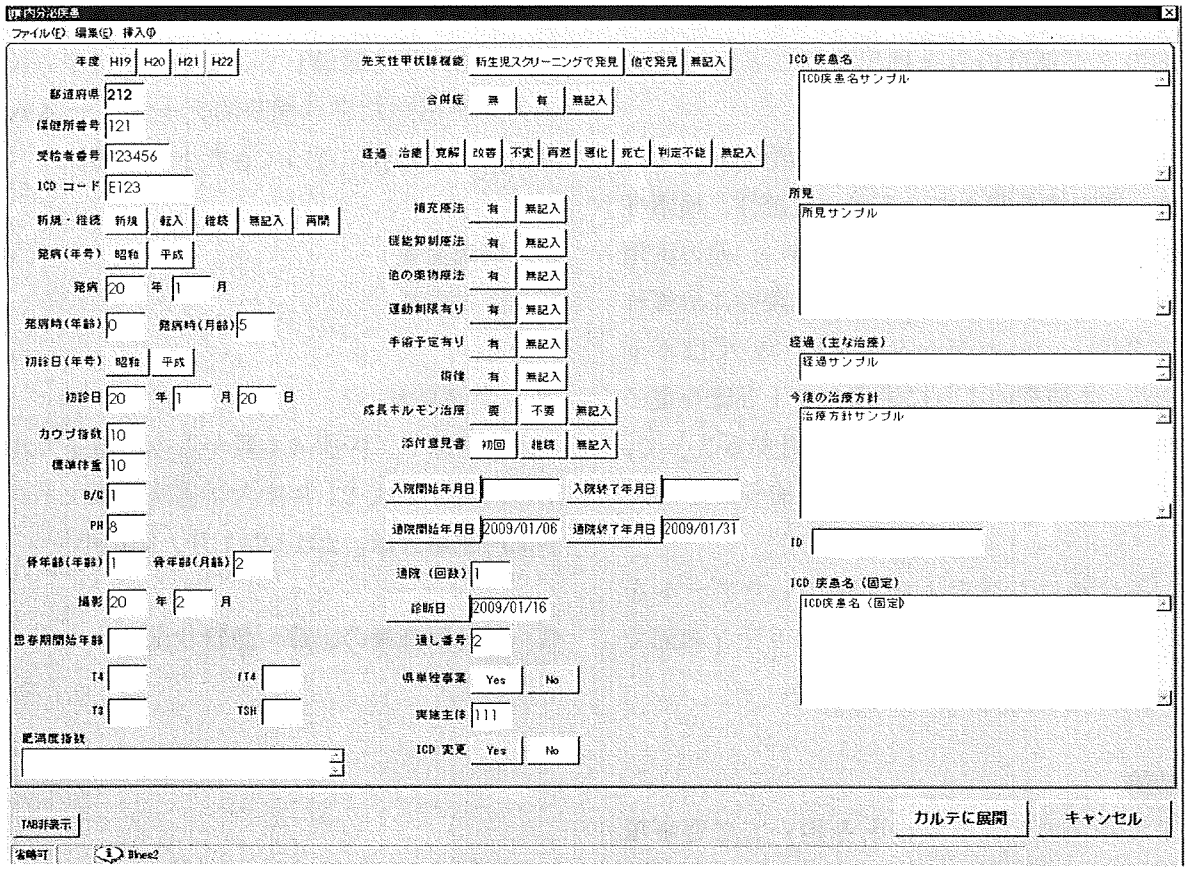

図２　サンプルテンプレートのカルテ展開画面

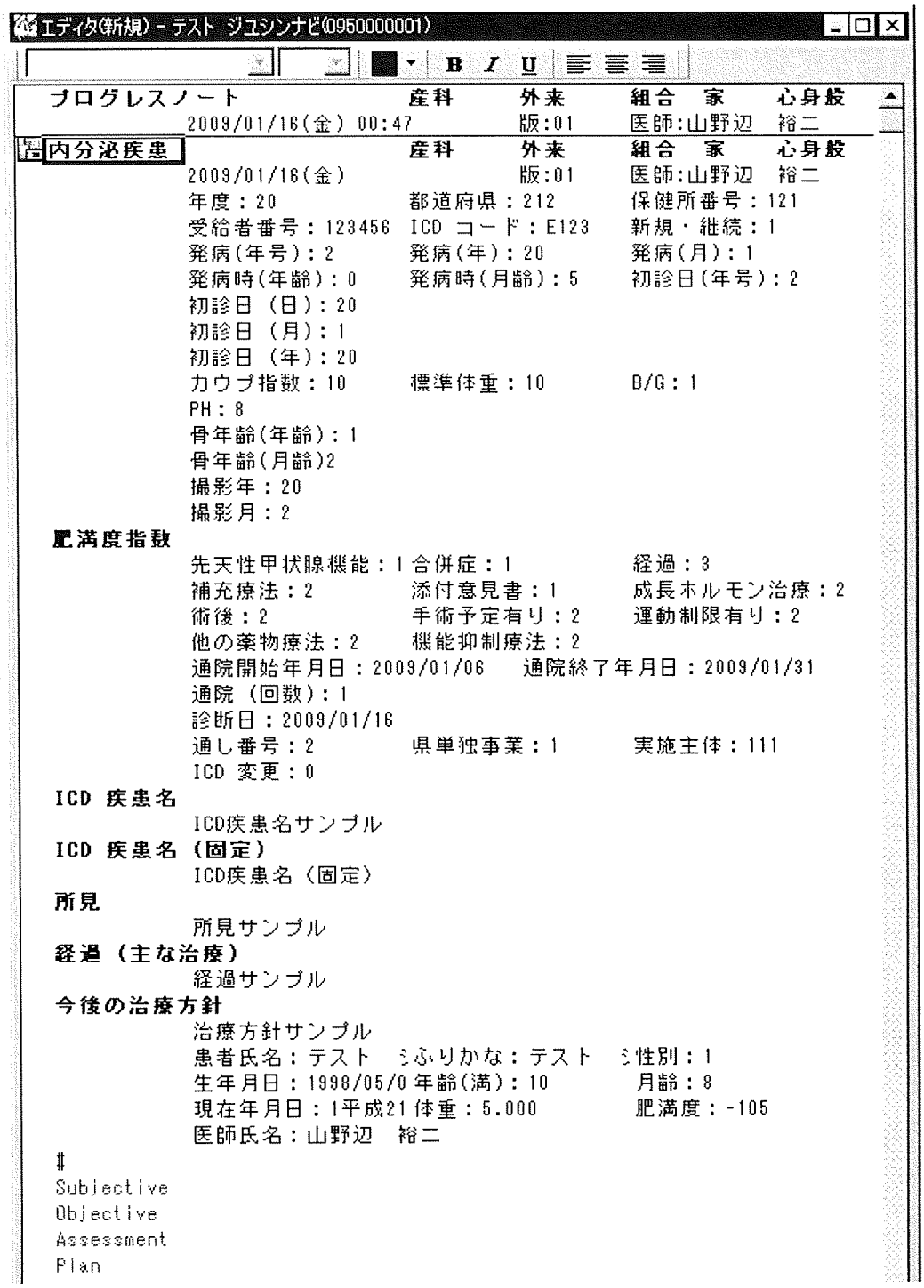

図３　サンプルテンプレートの後利用システムによる抽出画面

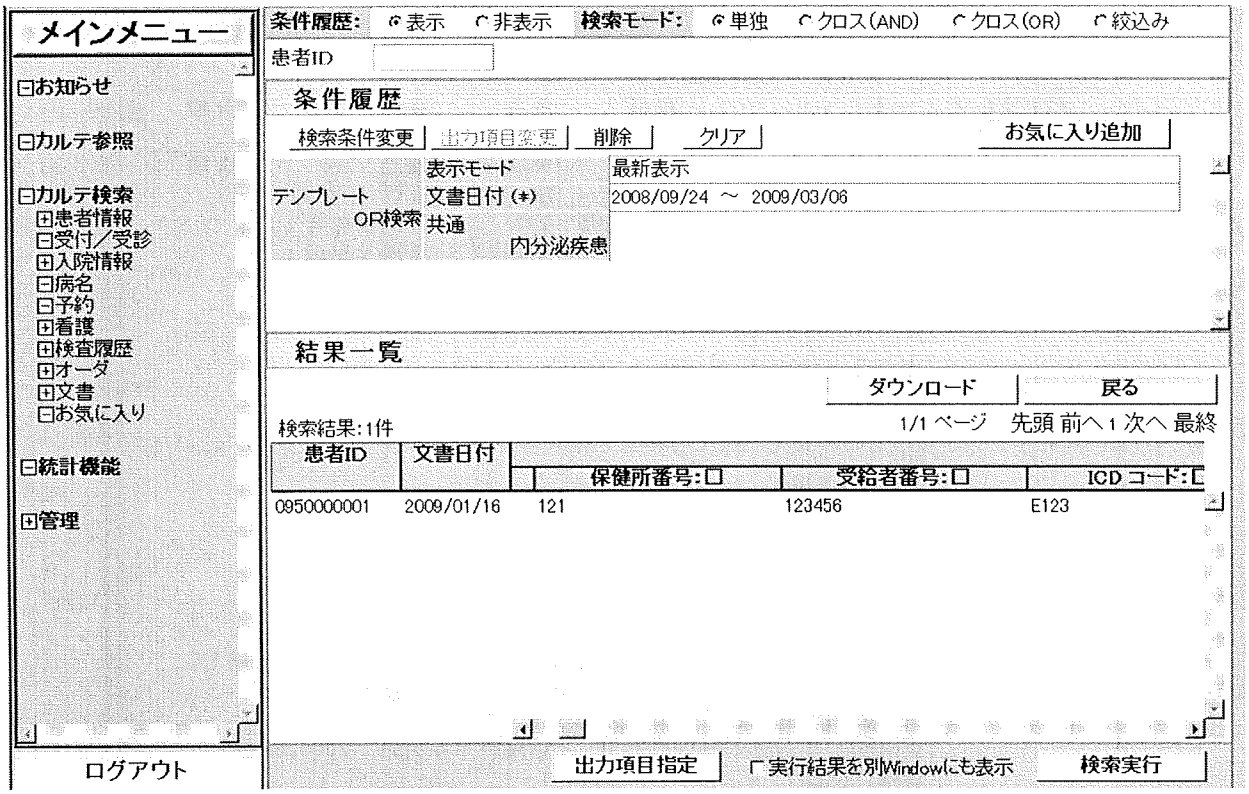

表１　サンプルテンプレートのソースコード抜粋

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      TITLE="内分泌疾患"
      MAKEAUTHOR="NAKAZATO Takashi"
      MAKEDATE="2009/11/15"
      UPDATEDATE="2009/01/16 0:05:22"
      VERSION="1.08"
      OUTBACKCOLOR="#00FFFFFF">
<INDEX NO="0"
      CATEGORY="B">
</HEAD>
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      TOP="0"
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      HEIGHT="13450">
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      BACKCOLOR="#00C0C0C0"
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      TOP="0"
      WIDTH="19000"
      HEIGHT="12170">
<PAGE >
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      NAME="GROUP1"
      FORECOLOR="#00000000"
      BACKCOLOR="#00C0C0C0"
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      WIDTH="5430"
      HEIGHT="12000"
      OUTFORECOLOR="#00000000">
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      NAME="GROUP9"
      FORECOLOR="#00000000"
      BACKCOLOR="#00C0C0C0"
      FRAME="False"
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      HEIGHT="450"
      OUTFORECOLOR="#00000000">
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      FORECOLOR="#00000000"
      BACKCOLOR="#00C0C0C0"
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      FONTSIZE="10"
      ALIGNMENT="RIGHT"
      OUTPUT="0"
      LEFT="0"
      TOP="98"
      WIDTH="1470"
      HEIGHT="255"
      TABINDEX="15"
      OUTFORECOLOR="#00000000"
      OUTBR="BEFORE"
      OUTFONTNAME="ＭＳ ゴシック">
<TEXTBOX NAME="Nendo"
      ELEMENT="Nendo"
      FORECOLOR="#00000000"
      BACKCOLOR="#00FFFFFF"
      FONTNAME="Century Gothic"
      FONTBOLD="True"
      IMEMODE="03"
      BEFORESTRING="年度："
      OUTPUT="-5"
```

```
        VISIBLE="False"
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        HEIGHT="450"
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        OUTFONTNAME="ＭＳ ゴシック">
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        TOP="0"
        WIDTH="530"
        HEIGHT="450"
        TABINDEX="17"
        OUTFORECOLOR="#00000000">
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        FORECOLOR="#00000000"
        BACKCOLOR="#00CFCFCF"
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        FONTSIZE="10"
        OUTPUT="0"
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        TOP="0"
        WIDTH="530"
        HEIGHT="450"
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        OUTFORECOLOR="#00000000">

 (中略)

</GROUP>
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        FORECOLOR="#00000000"
        BACKCOLOR="#00C0C0C0"
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        ALIGNMENT="RIGHT"
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        TOP="648"
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        HEIGHT="255"
        TABINDEX="0"
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        OUTBR="BEFORE"
        OUTFONTNAME="ＭＳ ゴシック">
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        HEIGHT="450"
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        OUTFONTNAME="ＭＳ ゴシック">
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        FORECOLOR="#00000000"
        BACKCOLOR="#00C0C0C0"
        FONTNAME="ＭＳ ゴシック"
        FONTSIZE="10"
        ALIGNMENT="RIGHT"
```

```
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        OUTFONTNAME="ＭＳ ゴシック">
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        IMEMODE="03"
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        OUTPUT="-5"
        LEFT="1530"
        TOP="1050"
        WIDTH="660"
        HEIGHT="450"
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        OUTFONTNAME="ＭＳ ゴシック">

 (中略)

<SCRIPT>
<!--
Sub Form_OnLoad()
'
FORM1.top = "1200"
FORM1.left = "0"
TAB1.top = "0"
TAB1.left = "0"

If Nendo.text = "19" Then
        Btn_Nendo1.backcolor = "&HFFFF00"
End If
If Nendo.text = "20" Then
        Btn_Nendo2.backcolor = "&HFFFF00"
End If

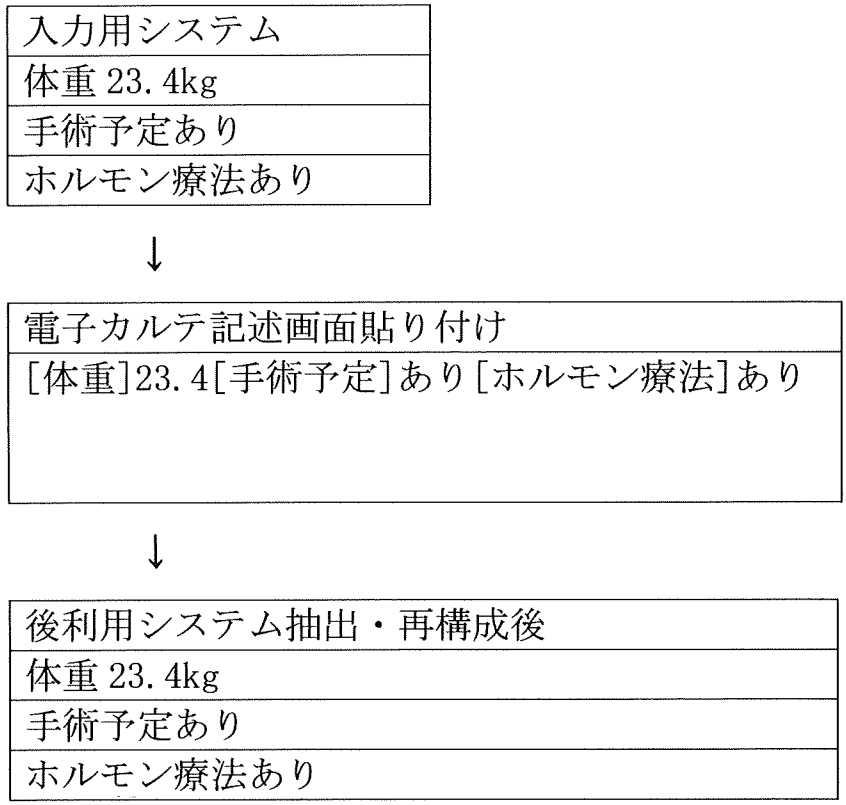
 (中略)

End Sub
Sub Nendo_OnChange()
If Nendo.text = "0" Then
                Nendo.text = ""
        End If
End Sub
Sub Btn_Nendo1_OnClick()
Btn_Nendo1.backcolor = "&HFFFF00"
        Btn_Nendo2.backcolor = "&HCFCFCF"
        Btn_Nendo3.backcolor = "&HCFCFCF"
        Btn_Nendo4.backcolor = "&HCFCFCF"
        Nendo.text = "19"
End Sub

 (中略)

-->
</SCRIPT>
</FORM>
</BODY>
</XTML>
```

図４　記述画面貼り付けと再構成の例



平成20、21年度厚生労働科学研究費補助金（子ども家庭総合研究事業）
分担研究報告書

分担研究課題：新生児マススクリーニング検査済み乾燥濾紙血液検体の保管と目的外使用に関する研究

経済協力開発機構（ＯＥＣＤ）による「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」について

研究要旨：経済協力開発機構（Organisation for Economic Co-operation and Development、ＯＥＣＤ）による勧告は法的拘束力を持たないが、メンバー国がその勧告を完全に実施するために最善を尽くすことが期待されている。ヒトの医学的情報のデータベースに関連するＯＥＣＤ勧告としては、平成21年10月22日に開催された理事会において「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」が採択されている。本研究班の課題遂行にあたっては同ガイドラインの普及と履行が必要であるため、その日本語訳の作成と研究報告書への掲載の許可をＯＥＣＤ東京センターを通して申請したが、財団法人バイオインダストリー協会（Japan Bioindustry Association、ＪＢＡ）がＯＥＣＤ本部の許可を得てＪＢＡ訳を作成、先行公開したことから、ＪＢＡの了解を得て同訳を資料として掲載した。

研究協力者
原田正平　　国立成育医療センター研究所室長
分担研究者
芳野　信　　久留米大学医学部小児科教授

Ａ．研究目的

先行研究である厚生労働科学研究費補助金（子ども家庭総合研究事業）「安全・安心な母子保健医療提供体制整備のための総合研究『子どもの病気に関する包括的データベース（難治性疾患に関する疫学研究データベース等を含む）の構築とその利用に関する研究』」の平成19年度分担研究として「経済協力開発機構での個人情報研究用データベースに関するガイドライン作成状況調査」（同平成19年度総括・分担研究報告書、p.49～77）を報告しており、その後の経済協力開発機構（Organisation for Economic Co-operation and Development、ＯＥＣＤ）におけるHuman Genetic Research Databases（ＨＧＲＤｓ）（個人遺伝情報研究用データベース）に関する取組みについて調査研究を行った。

Ｂ．研究方法

ＯＥＣＤのバイオテクノロジーに関する主要組織のうち、Committee for Scientific and Technological Policy（ＣＳＴＰ）の下部組織であるバイオテクノロジー作業部会（Working Party on Biotechnology、ＷＰＢ）がＨＧＲＤｓに関して取り組んできている。研究協力者（原田）は医学・医療に関わるデータベース構築の専門家（Expert Group on Human Genetic Research Databases）としてその活動に関わり、ＷＰＢの担当者である、ＯＥＣＤ・Biotechnology Divisionの Christina SAMPOGNA 氏及びＯＥＣＤ日本政府代表部の姫野泰啓書記官との電子メールでのやり取りにより情報を入手した。

またＯＥＣＤのバイオインダストリーに関する活動との連携を日本国内で行っている財団法

人バイオインダストリー協会（Japan Bioindustry Association、ＪＢＡ）事業推進部長の薮崎義康氏とも情報交換を行った。

「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤ勧告草案」（Draft Recommendation for Human Biobanks and Genetic Research Databases）については、厚生労働省大臣官房国際課国際企画室国際経済機関係長（ＯＥＣＤ等担当）中山佳保里氏より情報提供を受けた。

（倫理面への配慮）

本研究は、患者および患者検体を研究対象とするものではなく、また、直接、診療情報・個人情報を扱うものではないため、倫理面での問題は無いものと判断される。

Ｃ．研究結果

１．ＯＥＣＤパリ本部における専門家会議

「ヒトバイオバンクおよび遺伝情報研究用データベースに関するガイドライン草案」（Draft Guidelines for Human Biobanks and Genetic Research Databases）に関する専門家会議が平成20年９月24～26日にＯＥＣＤパリ本部で開催された。当初は同年７月中に開催予定で、研究協力者（原田）が出席予定であったが日程変更のため出席できず、姫野泰啓書記官から会議の内容について情報提供を受けた。

２．ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤ勧告草案

パリ本部での会議後、ＷＰＢがさらに検討を進め、平成21年４月に「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤ勧告草案」（Draft Recommendation for Human Biobanks and Genetic Research Databases）が提示された。その情報をＪＢＡの薮崎義康氏及び厚生労働省の中山佳保里国際経済機関係長より入手し、本研究班及び日本マス・スクリーニング学会等の関係者と内容について検討を加え、薮崎義康氏を通してＯＥＣＤに意見を送った。

３．「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」

前述のＯＥＣＤ勧告草案は、最終的に「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」（OECD Guidelines on Human Biobanks and Genetic Research Databases）として平成21年10月22日の理事会で採択された。

ＯＥＣＤ勧告は法的拘束力を持たないが、メンバー国がその勧告を完全に実施するために最善を尽くすことが期待されており、本研究班の課題遂行にあたっては同ガイドラインの普及と履行が必要であるため、その日本語訳の作成と研究報告書への掲載の許可をＯＥＣＤ東京センターを通して申請した。

ＪＢＡの薮崎義康氏からガイドライン（英語版）を入手し翻訳の準備を進めていたところ、その後、ＪＢＡがＯＥＣＤ本部の許可を得てＪＢＡ訳を作成、ホームページ上に先行公開したことから、ＪＢＡの了解を得て同訳を本研究報告書に資料として掲載することとした。

・ＯＥＣＤサイト上の英語版アドレス
Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)
http://www.oecd.org/dataoecd/41/47/44054609.pdf
・ＪＢＡ日本語版アドレス
http://www.jba.or.jp/report/international/document/pdf/HBGRD%20Guidelines%20jp_JBA201003.pdf

Ｄ．考察

「経済協力開発機構での個人情報研究用データベースに関するガイドライン作成状況調査」（同平成19年度総括・分担研究報告書、p.49～77）以後の国際的なガイドライン作成状況調査の結果、「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」（OECD Guidelines on Human Biobanks and Genetic Research Databases）に関する最新情報

を入手し、その日本語訳を紹介した。

平成 19 年度以降のわが国における検査済み濾紙血の取り扱いについての議論は、本研究班と構成労働科学研究費補助金による「タンデムマス等の新技術を導入した新しい新生児マススクリーニング体制の確立に関する研究」研究班においてなされているが、国際的な取組みに関する情報提供は十分とは言えないことから、ＯＥＣＤガイドラインの普及啓発を図り、同ガイドラインを遵守した上での、検査済み濾紙血の保管と目的外使用に関するわが国のガイドライン作成が望ましいと考えられた。

Ｅ．結論

「ヒトのバイオバンクおよび遺伝学研究用データベースに関するＯＥＣＤガイドライン」（OECD Guidelines on Human Biobanks and Genetic Research Databases）に関する最新情報を入手し、その日本語訳を紹介した。

Ｆ．健康危険情報

該当なし

Ｇ．研究発表

発表なし

Ｈ．知的財産権の出願・登録状況

該当なし

OECD Guidelines on Human Biobanks and Genetic Research Databases

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The OECD is a unique forum where the governments of 30 democracies work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD member countries are: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities takes part in the work of the OECD.

OECD Publishing disseminates widely the results of the Organisation's statistics gathering and research on economic, social and environmental issues, as well as the conventions, guidelines and standards agreed by its members.

Also available in French: *Lignes directrices de l'OCDE sur les biobanques et bases de données de recherche en génétique humaine*

Corrigenda to OECD publications may be found on line at: *www.oecd.org/publishing/corrigenda*.

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Introduction

This OECD *Recommendation on Human Biobanks and Genetic Research Databases* ("Recommendation") aims to provide guidance for the establishment, governance, management, operation, access, use and discontinuation of human biobanks and genetic research databases ("HBGRD"), 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). This 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 is not intended to exhaustively cover all aspects of HBGRDs. For example, 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] set out further complementary quality assurance and technical aspects for the acquisition, maintenance and provision of high-quality biological materials in a secure manner.

1. OECD (2007), *OECD Best Practice Guidelines for Biological Resource Centres*, published on the responsibility of the Secretary-General.

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 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

This *Recommendation on Human Biobanks and Genetic Research Databases* was adopted by the OECD Council on 22 October 2009.[2] This Recommendation, and the Guidelines ("Guidelines") that it sets out, are 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 and its Guidelines 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.

Part I

GUIDELINES ON HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

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 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.