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# International normative perspectives on the return of individual research results and incidental findings in genomic biobanks

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Managers of genomic biobanks constantly face ethical and legal challenges ranging from issues associated with the informed consent process to procedural concerns related to access by researchers. Yet, with the availability of next-generation sequencing technologies, one topic is emerging as the focus of ongoing debate: the return of individual research results and incidental findings to participants. This article examines this topic from an international perspective, where policies and guidelines discussing the matter in the context of genomic biobanks and genomic research are analyzed and commented. This approach aims to highlight the shortcomings of these international norms, mainly the danger arising from both the therapeutic misconception and the conflation of research results with incidental findings. This article suggests some elements to consider in order to complement available guidance at the international level.

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**Key Words:** biobanks; general research results; genomic research; incidental findings; individual research results; international norms

Genomic biobanks have been identified as "vital research tools in the drive to uncover the consequences of human health and disease."[1] These organized collections of human biological material and associated data[2] have even been described as one of the top 10 ideas changing the world.[3] With scientists recognizing that common diseases result from a multitude of interactions between genetic variation, lifestyle behaviors, and the environment, there has been a rise in the number of biobanks in the past decades, especially in large-scale genomic studies (over 10,000 individuals), which aim to produce aggregate findings derived from the data and samples of groups of persons.[4] The collection of data and samples and their analysis in the context of biobanks have traditionally led to debates about the return of individual research results (IRRs) to participants.[5] Although some biobanks limit feedback to general results (sometimes called "aggregate results"),[6] others that recruit through physicians may return individual findings to research participants.[7] For the purposes of this text, IRRs are results discovered during the course of a research project—and within its objectives—that concern an individual participant and have potential health or reproductive importance.[8]

With next-generation sequencing technology producing vast amounts of data, the debate has become more complex due to the ensuing increase in incidental findings (IFs) in research.[9] IFs are defined as findings concerning a research participant that have potential health or reproductive importance and are discovered during the course of research but are outside the objectives of the project.[10] The rise of data-intensive science stemming from the use of high-throughput technology has led to a debate on the pertinence of returning IRRs and IFs in genomic biobanks.[11–13] Although most of these debates are jurisdiction-specific, how is the issue of the return of IRRs and IFs reflected in international norms? What trends, if any, are discernable? The term "international" refers to laws, guidelines, and policies emanating from non-US countries and international organizations. Analyzing the issue of return of IRRs and IFs from an international perspective will serve to highlight current trends as well as the factors influencing possible future change.

## METHODOLOGY AND RESULTS

The international documents retrieved and referenced in this text were collected using the PopGen Module (http://www.popgen.info) of the HumGen International Database (http://www.humgen.org), a database of international, national, and regional guidelines and policies specific to human genetic research. The PopGen module is a specialized database composed of laws, guidelines, policies, and literature addressing the legal and ethical issues in biobanks generally and population biobanks more specifically. For the purpose of our research and in order to focus only on pertinent documents, the keywords "biobanks" and "communication of results" were used. Keywords such as "research result" or "incidental findings" were not available. All organizations were selected, and no limitations were set as to jurisdiction. This provided a large selection of documents. Only English documents dating from 1985 to 2011 (the default date restriction) were queried. This search resulted in 149 results.

US documents were removed from the list of documents retrieved, which reduced the number of results to 125. A thorough analysis of the remaining documents further narrowed the number of laws, policies, and guidelines pertinent to the

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return of IRRs and IFs to 15. This small number was expected, given that the term "communication of results" covers a wide array of feedback procedures and communication is not limited to research results or IFs. Moreover, many of these documents mention IFs or research results but do not provide guidance. The final list (**Table 1**) includes both laws and guidelines. Laws are binding, whereas guidelines are generally nonbinding but may be considered professional norms.[14]

## THERAPEUTIC MISCONCEPTION

Therapeutic misconception[15] occurs when a "research subject … inaccurately attributes therapeutic intent to research procedures."[15] It has been argued that alluding to the possible future disclosure of any IRRs and IFs promotes the therapeutic misconception. Indeed, the Singapore Bioethics Advisory Committee's 2002 *Human Tissue Research Report*[16] maintains that "… donors should not expect any personal or direct benefit from the donation of tissue, including information of any medical condition or predisposition or likelihood of such discovered in the course of research on the sample. Likewise, researchers and tissue bankers should not be under an obligation to disclose such information to the donors, unless they have agreed to do so in advance of the donation."[16]

The Singapore Bioethics Advisory Committee reiterates this stance in its 2005 document, titled *Ethical, Legal and Social Issues in Genetic Testing and Genetic Research*.[17] It posits that since "human genetics research enhances our understanding of the genetic basis of disease and how genetic and environmental factors influence one's health,"[17] the main goal is not to offer research participants or their families "specific information about their genetic status or health."[17] This "no-return" policy is not new to the biobanking field and is largely followed by large-scale, longitudinal population biobanks that are mainly epidemiological in nature.[18–22] Yet large-scale biobanks do provide their participants with feedback at assessment—which is provided as a matter of course and should not be confused with eventual IRRs, and more importantly, should not be considered equivalent to a medical checkup.[23]

**Table 1** List of international documents retrieved and referenced

| Title of document | Organization(s) | Ethics norm | Legislation |
|---|---|---|---|
| 1. Biobanks for Research, 2004 | German National Ethics Council | X | |
| 2. Ethical, Legal and Social Issues in Genetic Testing and Genetic Research, 2005 | Singapore Bioethics Advisory Committee | X | |
| 3. Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights, 2004 | World Health Organization: European Partnership on Patients' Rights and Citizens' Empowerment | X | |
| 4. Guidelines for Genetic Biobanks, 2004 | Italian Society of Human Genetics | X | |
| 5. Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs), 2009 | Organization for Economic Co-operation and Development | X | |
| 6. Guidelines for Human Biobanks, Genetic Research Databases and Associated Data, 2010 | Australian Office of Population Health Genomics—Public Health Division | X | |
| 7. Human Biobank Management Act, 2010 | Government of Taiwan | | X |
| 8. Human Biobanks for Research, 2010 | German National Ethics Council | X | |
| 9. Human Genes Research Act, 2000 | Government of Estonia | | X |
| 10. Human Tissue Research, 2002 | Singapore Bioethics Advisory Committee | X | |
| 11. International Ethical Guidelines for Epidemiological Studies, 2009 | Council for International Organizations of Medical Science | X | |
| 12. Joint Statement on the Process of Informed Consent for Genetic Research, 2008 | Canadian College of Medical Geneticists and Canadian Association of Genetic Counselors | X | |
| 13. Law 14/2007 of 3 July on Biomedical Research, 2007 | Government of Spain | | X |
| 14. Medical Technology: Health Surveys and Biobanking, 2004 | Norwegian University of Science and Technology | X | |
| 15. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2010 | Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada | X | |

In 12 of these 15 documents (all except 5, 6, and 11), two main trends were discerned: concern with the issue of therapeutic misconception, and the conflation of different types of results and findings. The remaining three documents are addressed in the discussion on Elements to Consider in order to improve and complement current international guidance.

That being said, it could be argued that the risk of therapeutic misconception engendered by return of results can be lessened if limited to disclosure of findings in exceptional cases where they are analytically valid, clinically significant, and medically actionable.[23] It is policies that mandate broader and imprecise obligations that constitute a greater risk. Witness the 2010 Canadian *Tri-Council Policy Statement*: *Ethical Conduct for Research Involving Humans*,[24] which states that "researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research."[24] In this text, material IFs are defined as having "significant welfare implications for the participant, whether health-related, psychological or social."[24] Return of these findings is described as an ethical "obligation." The statement does, however, encourage researchers who "are unsure of how to interpret findings or uncertain whether findings are material"[24] to consult with colleagues or refer to standards in their discipline. There could be several practical limitations to such a broad approach in the biobanking field, especially with the presence of privacy and confidentiality clauses in access agreements signed by researchers wishing to use biobanks.[25] Faced with an open-ended ethical obligation, researchers might be inclined in cases of doubt to systematically disclose findings. If so, rather than reflecting an exceptional situation, the disclosure of findings may well become the rule in cases of uncertainty, hence indirectly promoting the therapeutic misconception.

## THE CONFLATION OF RESEARCH RESULTS AND INCIDENTAL FINDINGS

Another visible trend in some of the international documents reviewed was the tendency to conflate various notions, such as (i) general research results with IRRs, (ii) the return of IRRs with IFs, and (iii) the return of IRRs and IFs with the legal duty to rescue.

### General research results versus IRRs

General research results and individual results are distinct, as are as well the modalities and conditions for their return.[23] As mentioned earlier, IRRs concern an individual participant and general research results concern a group of persons. Whereas general results are largely returned through newsletters and websites,[26] IRRs are returned per the policies of the biobanks as reflected in their informed consent forms and information brochures.[27]

Yet, while differences between these two types of results are obvious, some international norms conflate the two. One example of such confusion can be found in the Italian Society of Human Genetics' 2004 *Guidelines for Genetic Biobanks*,[28] which state that the research participant "should have the possibility to take separate decisions regarding whether: to wish/not wish to be informed about the results or diagnostic possibilities deriving from continuing research."[28] It is not clear whether the term "results" refers to general or IRRs. The issues associated with the return of individual as opposed to general results are not the same, and conflating the two can lead the research participants to expect future notice of both types of results—an expectation that could sometimes turn out to be groundless. That being said, this lack of clarity could be the result of a modest translation of this document from Italian by the country's Society of Human Genetics.

Along the same lines, the opinion of the German National Ethics Council's 2004 *Biobanks for Research*[29] specifies that it would involve unacceptable effort and expense to inform donors of "all results of the research."[29] Although later discussing "personal results,"[29] the document is not consistent in differentiating between general and IRRs. However, the German council's 2010 opinion on *Human Biobanks for Research* clearly specifies "individual research results"[30] in its text, which lists the reporting of such results as an occasion "for the donor to be contacted again in the future."[30]

### IRRs versus IFs

The difference between IRRs and IFs ultimately relates to the objectives associated with the research project in question. Nonetheless, many international norms do not explicitly distinguish between them. An interesting example is Estonia's 2001 *Human Genes Research Act*,[31] which states that gene donors might not always want "data on hereditary characteristics and genetic risks obtained as a result of genetic research."[31] This Act uses the word "risks," which could emanate from IRRs or IFs. The Norwegian University of Science and Technology's 2004 *Medical Technology: Health Surveys and Biobanking*[32] uses a similar term when it specifies that "some individuals could possibly benefit by being contacted when unexpected genetic risks for future disease were discovered."[32]

In 2008, the Canadian College of Medical Geneticists and Canadian Association of Genetic Counsellors adopted a *Joint Statement on the Process of Informed Consent for Genetic Research*.[33] This document states that if individual results are to be disclosed, then participants should be made aware that "unexpected results" could be obtained.[33] It is unclear whether this joint statement refers to IRRs or IFs more specifically, or even both.

The same could be said of Taiwan's 2010 *Human Biobank Management Act*,[34] one of the few Asian laws on biobanks. The Act discusses the need for the research participants to be made aware of "any possible impacts of the genetic information derived from the biological specimens on the participant, and his/her relatives or an ethnic group."[34] Here again, the term "genetic information" is broad and it is unclear whether this refers to IRRs or to IFs.

Although the conditions for returning IFs and IRRs may be similar,[8] an important difference lies in the expertise of the researchers handling them. In the case of research results, the researcher is usually competent to interpret them. The same cannot be said for IFs, which are not only largely clinical in nature, but could also fall outside the particular field of expertise of the researcher who discovered them. Echoing a similar concern in the Therapeutic Misconception section, a conflation between IRRs and IFs could create arduous responsibilities

for researchers and prompt some of them to return potentially important health information that may be discovered—although originally unexpected—for fear of liability.[14,35]

### Return of IRRs and IFs versus legal duty to rescue

The duty to rescue is a tradition found in many civil law jurisdictions and often carries penal sanctions. Generally, this duty is characterized as an obligation to provide assistance to an individual whose physical integrity is in peril.[36] In other words, there needs to be a situation where an identifiable individual is faced with immediate danger. Although not explicitly addressing the duty to rescue, the World Health Organization's European Partnership on Patients' Rights and Citizens' Empowerment's 2004 report[37] generally reflects the legal stance in Europe. It states that because "research includes matters of unknown future import, sometimes unexpected findings can be generated";[37] and when "an immediate and clear benefit to identifiable individuals can be achieved … [which] will avert or minimize significant harm to the relevant individuals,"[37] such findings should be returned. Another example comes from the Spanish 2007 Law on Biomedical Research, where the participant's right "not to know" about IFs is affirmed.[38] This law allows a close family member or a representative to be informed of IFs if this will avoid a serious damage to the health of the participants or that of their biological family.[38]

Although some authors have reconciled the notion of return of findings with an ethical duty to rescue,[39] this article posits that the legal duty to rescue is not a solid basis for a duty to return research results and IFs. Currently, five criteria for return dominate the debate on the return of IRRs and IFs:

1. "The findings are analytically valid;
2. Returning them to the donor comports with applicable law …;
3. The donor has been offered the option of consenting to return of individual findings … and has opted to receive them;
4. The findings reveal an established and substantial risk of (a) a serious health condition, or (b) a serious condition of reproductive importance …; and
5. The findings are actionable … ."[8]

It is conceivable that situations giving rise to a duty to rescue could satisfy these conditions, but that will not always be the case. One of the issues here is participants' right not to know. Unless explicitly mentioned—as in the Spanish biomedical research law—the element of consent and the right not to know are generally not at the forefront of decisions based on a duty to rescue. As mentioned earlier, what characterizes the duty to rescue is the seriousness and urgency of the situation. Rarely is genetic information "urgent." Moreover, what happens when participants have clearly consented not to receive IRRs or IFs? Using the concept of a duty to rescue in this case could be problematic, as it may ignore the participant's decision not to know. In an effort to provide consistent and harmonized guidance to researchers for the return of IRRs and IFs, the concept of the duty to rescue also falls short because it is not a legal obligation in all jurisdictions.[23]

Finally, another potential difficulty in using the concept of duty to rescue as a basis for the return of IRRs and IFs is the practical limitations associated with the nature of some biobanks. In large-scale, longitudinal population studies—where samples and data are collected and stored for future unspecified research, for example—it will be difficult to apply the urgency criterion once the data and samples are stored, given that discovering findings that satisfy the requirement of a legal duty to rescue is hypothetical and could stretch over time.

## UNTYING THE GORDIAN KNOT: ELEMENTS TO CONSIDER

Our comparative review of international normative guidance provides an interesting perspective that complements the analysis of issues in specific jurisdictions. As biobanking becomes more international, such a review is necessary. That being said, it is clear from the sections on Therapeutic Misconception and The Conflation of Research Results and Incidental Findings that the existing international norms pertinent to the return of IRRs and IFs are not consistent. They use ambiguous terminology and conflate different concepts. Creating a lexicon covering IRRs and IFs has been proposed.[40] It is necessary, however, that such a lexicon be adopted or adapted by international organizations through a mechanism similar to the International Conference on Harmonization.[41] Such a guidance document could include clear definitions of terms such as IFs, return of results, and clinical utility. This lexicon, if disseminated internationally, would provide much needed consistency in international norms and could reduce ambiguity and contradictions.

Moreover, it is important for any international guidelines on the matter to provide recommendations on the decision-making process leading to the return of IRRs and IFs, similar to the one proposed by the Working Group recommendations in this issue[8] and the 2010 National Cancer Institute Workshop on the Release of Research Results to Participants in Biospecimen Studies.[27] Indeed, future guidelines should include practical considerations for establishing analytical validity, assessing the seriousness of the risk, and concretizing actionability, while recognizing the different types of studies involved, a point we will clarify in the following.

That being said, any future international guidance document should uphold the discretion of researchers, as evident in documents such as the Council for International Organizations of Medical Sciences' 2009 *International Ethical Guidelines for Epidemiological Studies,*[42] the 2009 Organization for Economic Co-operation and Development *Guidelines on Human Biobanks and Genetic Research Databases*[43] and the Australian Office of Population Health Genomics' 2010 *Guidelines for Human Biobanks, Genetic Research Databases and Associated Data.*[44] While offering practical guidance on establishing analytical validity, and on the seriousness of risk and actionability, some discretion should be provided to researchers to determine

whether findings satisfy these conditions. Due to the potential scientific uncertainty of some findings,[45] such an approach would provide researchers with much needed professional leverage and avoid both stringent and open-ended obligations.

Finally, when one scrutinizes the scope of the international guidance available on the return of research results and IFs, it becomes clear that they are not homogeneous: some provide guidance for research at large; others are specific to tissue biobanking or genetic research. Differences are therefore understandable. We echo calls for distinguishing different contexts as concerns the return of findings to participants, based on the nature of the study in question.[46] In fact, although it is important to remain consistent with the general provisions existing in the majority of laws, regulations, policies, and guidelines, homogeneous approaches to the micromanagement of IRRs and IFs at the international level risk harming the integrity, credibility, and transparency of research.[25] For example, imposing the same modalities on the return of IRRs and IFs that are currently applicable in clinical trials on the broader infrastructure resource mission of population biobanks could undermine their longitudinal design to say nothing of the altruistic nature of the contribution of a citizen of a given country. This could inadvertently create unrealistic participant expectations and limitless, undefined duties for researchers.

## CONCLUSION

We discern two trends from our analysis. In a culture of heightened attention to IRRs and IFs, lack of specificity in obligations promotes professional confusion as well as the therapeutic misconception. Second, the tendency to confuse notions, such as general versus individual results, research results versus IFs, and the return of findings versus the duty to rescue, slows progress. Three key innovations are needed to address the elements to consider identified in the section on Untying the Gordian Knot: Elements to Consider. First, it is important to encourage endeavors that aim to provide a clear set of definitions related to the return of IRRs and IFs at the international level. This will allow for much needed consistency in international norms and will reduce ambiguity and contradictions. Second, clear practical guidance establishing the principal conditions for the return of findings, such as analytical validity, seriousness of the risk, and actionability must also be offered at the international level. This will create an important and consistent approach for researchers working in international biobanking initiatives across various jurisdictions. Finally, approaches to IRRs and IFs will need to reflect the types of biobanks and their contexts as well as the nature of the participation in question. Indeed, when proposing norms for the return of IRRs and IFs, the key will be to provide simple criteria that do not cover all possible situations but instead distinguish between the different research objectives and contexts. The Public Population Project in Genomics and Society provides a recent example of this.[47] At a time when it is perceived as increasingly difficult to establish the scientific certainty of genomic findings—where "distinctive cultures with respect to interpreting and reporting results"[48] exist—specificity, clarity, and transparency in policy will provide proper guidance that can bolster the trust of participants who altruistically contribute their data and samples for research.[25]

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## DISCLOSURE

The authors declare no conflict of interest.

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