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Research ethics review for the use of anonymized samples and data: A systematic review of normative documents

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ABSTRACT

While the anonymization of biological samples and data may help protect participant privacy, there is still debate over whether this alone is a sufficient safeguard to ensure the ethical conduct of research. The purpose of this systematic review is to examine whether the review of an ethics committee is necessary in the context of anonymized research, and what the considerations in said ethics review would be. The review of normative documents issued by both national and international level organizations reveals a growing concern over the ability of anonymization procedures to prevent against reidentification. This is particularly true in the context of genomic research where genetic material's uniquely identifying nature along with advances in technology have complicated previous standards of identifiability. Even where individual identities may not be identifiable, there is the risk of group harm that may not be protected by anonymization alone. We conclude that the majority of normative documents support that the review of an ethics committee is necessary to address the concerns associated with the use of anonymized samples and data for research.

KEYWORDS

Ethics review; normative documents; research ethics; systematic review

Introduction

Human biological samples and data collected in the clinical and research context present an invaluable resource for research. To protect participants from privacy risks that may arise as a result of the use of identifiable samples and data, research materials may be anonymized or irreversibly de-identified (Rothstein 2010). This is a process by which all identifying information connected with the materials is removed and destroyed (Phillips and Knoppers 2016). While in this document we will use the term "anonymized" to refer to this level of identifiability, it is important to note the inconsistency in terminology throughout the normative documents and literature on this topic. Notably, some normative documents use the term "de-identified"

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instead, particularly when the identifying information is irreversibly removed from the samples and data (Phillips and Knoppers 2016).

Anonymized samples and data could be used both prospectively and retrospectively in research (Junod and Elger 2010; Tassé et al. 2010). Depending on the applicable laws and policies, in prospective use of samples and data, a specific or a broad consent for various research purposes might be obtained from the research participants. In contrast, a retrospective use of existing samples and data (legacy samples and databases) may occur in the absence of consent from the individuals for a "secondary use," unless a re-consenting of research participants is required. To date, the discussions related to adequate models and requirements of consent in retrospective or prospective use of anonymized samples and data have received widespread attention. However, what are the ethical considerations on research use of anonymized samples and data beyond consent issues? What safeguards might be necessary to ensure that participants' interests are respected?

A need for adopting adequate safeguards for research participants is stressed in the view of privacy concerns associated with using anonymized samples and data. Such concerns are in part a result of technological advances that have called into question what is considered identifiable. These developments may contribute to concerns regarding re-identification, although it remains unclear how significant this risk may be (Rodriguez et al. 2013). Determining the privacy concerns has also been further complicated as the ethical considerations shift from approaches that are purely individualistic towards a more holistic perspective that takes into account community-level and familial interests (Robinson et al. 2016). To what degree group risks are or are not mitigated by anonymization is yet to be determined. It should be noted that the abovementioned concerns are further heightened in the view of increasing use of biological samples for genomic research, which generates sensitive health and non-health related information about the individuals and their family members. To date, re-identifiability of genomic data has been showed by a number of studies, resulting in massive discussions about the best policies for protection of individuals in research (Church et al. 2009; Gymrek et al. 2013; Homer et al. 2008).

With these concerns in mind, in this review we wanted to examine the differing recommendations on whether or not ethics committee review should be required for the research use of anonymized samples and data, and what would be the considerations when conducting an ethics review. This remains a contentious and ever-developing debate in both the scientific community and the general public due to the concerns regarding privacy that potentially come into conflict with the importance of scientific advancement. While much has been written in the literature about the potential ethical concerns of using anonymized samples and data (Eriksson and Helgesson 2005; Fullerton and Lee 2011), no study specifically analyzed normative documents (including

guidelines and position papers) on the need of ethics committee review in this particular context. Moreover, considering the increasing international sharing of samples and data for research purposes, studying the areas of agreement and disagreement among included international and national normative documents addressing similar topics is timely and needed. We hope that our systematic review will contribute to a better understanding of the ethical concerns regarding the research use of anonymized samples and data.

Methods

We performed a systematic search of the databases Pubmed, Web of Science, and Google Scholar. After pilot testing various search strings, we derived the following string that resulted in the highest number of relevant results: [(policies OR guidelines OR reports) AND (samples or data) AND "research use"]. In order to ensure the comprehensiveness of our search, we performed a general Google search so as not to exclude documents not published as papers and not included in the other databases. To supplement our search yield, we utilized the snowballing method by referring to the reference section of the retrieved documents in order to find additional sources. Additionally, we referred to the websites of various ethics committees, which were listed in the website of World Health Organization (WHO). Searches were carried out by two researchers (AP and MS) between May 16, 2017 and July 6, 2017. AP performed an initial review of the titles and abstracts to determine which documents would be included. Any uncertainty or doubt about the inclusion or exclusion of a particular document was discussed in depth by the other authors (Figure 1).

Only normative documents released in or after the year 2000 were included. Because of the dynamic nature of issues surrounding anonymized research, we excluded documents released before 2000 so as to ensure the relevance of included documents. For the purpose of this study, normative documents are defined as documents issued by national or international authorities in the form of guidelines, position papers, reports, and best practice documents, in order to determine a course of action and streamline a process in the view of pertinent ethical considerations. All included documents were in English and were released by national or international level organizations. On a content level, we limited our inclusion criteria to documents that addressed the issues related to the ethics committee review of research using anonymized samples and data. In total, 22 normative documents met our inclusion criteria, issued by International, European, or national authorities from countries including Australia, Canada, Ethiopia, India, Ireland, New Zealand, U.K., and the United States (Table 1).

In order to analyze the data, we used an inductive approach. In doing so, from the included documents we extracted quotes (text fragments)

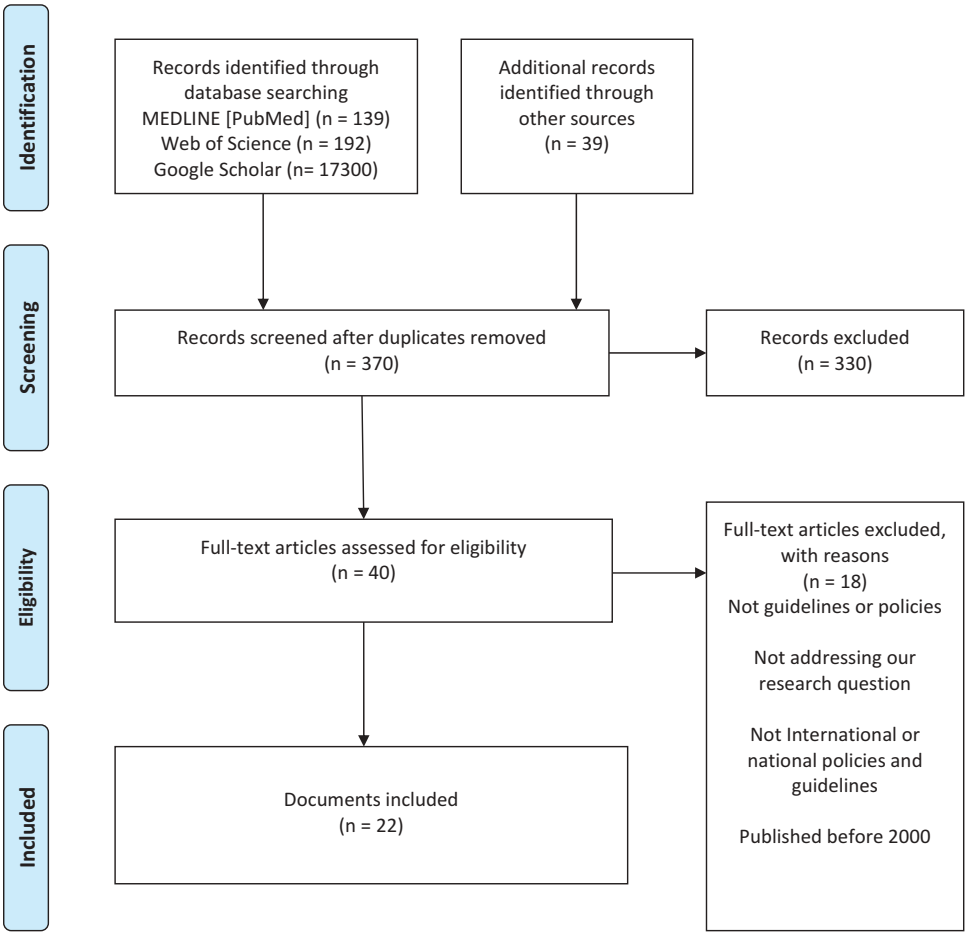

Figure 1. PRISMA flow diagram.

relevant to our specific research question regarding the requirement of obtaining ethics approvals for anonymized samples and data and the related considerations. We excluded the quotes that solely discussed the issues related to consent requirements in general. From the selected quotes, we extracted the core elements related to our research question which we then developed into codes. This process of developing the codes was first conducted independently and then discussed and confirmed by all the authors.

Results

The way in which anonymization has been defined and used varies among the reviewed normative documents. The majority of the documents required obtaining ethics approval for use of anonymized samples and data in

Table 1. The list of included normative documents in the review.

Region	Author	Title	Year
National (UK)	Human Tissue Authority	Code of Practice and Standards	(2017)
International	World Medical Association	WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks	(2016)
International	The Council for International Organizations of Medical Sciences (CIOMS)	International Ethical Guidelines for Health-related Research Involving Humans	(2016)
Europe	Council of Europe	Recommendation of the Committee of Ministers to member States on research on biological materials of human origin	(2016)
International	Global Alliance for Genomics and Health	Privacy and Security Policy	(2015)
National (Australia)	National Health and Medical Research Council	National Statement on Ethical Conduct in Human Research	(2015)
National (USA)	National Institutes of Health (NIH)	Guidance on Consent for the Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy	(2015)
Europe	eTRIKS	Code of Practice on Secondary Use of Medical Data in Scientific Research Projects	(2014)
National (Ethiopia)	FDRE Ministry of Science and Technology	National Research Ethics Review Guideline	(2014)
National (Canada)	Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Science and Humanities Research Council of Canada	Tri-Council Policy Statement Ethical Conduct for Research Involving Humans	(2014)
National (USA)	NIH	Genomic Data Sharing Policy	(2014)
National (UK)	Medical Research Council	Human Tissue and Biological Sample for Use in Research: Operational and Ethical Guidelines	(2014)
National (New Zealand)	Ministry of Health	Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes	(2007)
National (India)	Indian Council of Medical Research	Ethical Guidelines for Biomedical Research on Human Participants	(2006)
National (Canada)	Canadian Institutes of Health Research	CIHR Best Practices for Protecting Privacy in Health Research	(2005)
National (Ireland)	Irish Council for Bioethics	Human Biological Material: Recommendations for Collection Use and Storage in Research	(2005)
International	World Health Organization (WHO)	Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights	(2004)
International	UNESCO	International Declaration on Human Genetic Data	(2004)
Europe	European Council	25 Recommendations on the ethical, legal and social implications of genetic testing	(2004)
Europe	European Society of Human Genetics	Data Storage and DNA Banking for biomedical research: Technical, social and ethical issues	(2003)
Europe	Council of Europe Steering Committee on Bioethics (CDBI)	Proposal for an Instrument on the Use of Archived Human Biological Materials in Biomedical Research	(2002)
National (USA)	National Bioethics Advisory Commission	Research Involving Human Biological Materials: Ethical Issues and Policy Guidance	(2000)

research. Privacy and re-identification risks were identified throughout the normative documents as a concern regarding the research use of anonymized samples and data. While the normative documents are largely unified in their concern over this issue, they remain divided on whether anonymization *alone* sufficiently protects participants against this potential harm or whether additional safeguards are necessary. Concerns regarding inadequate anonymization procedures and protections, re-identification, heightened risks associated with genomic research, and the potential inability of anonymization to protect groups have motivated several normative documents to require at least some degree of ethics committee oversight in the context of research use of anonymized materials.

Defining anonymization

A disparity between the definitions of anonymization provided by the various normative documents has been observed. Some normative documents make a clear distinction between the levels of identifiability. The Global Alliance for Genomics and Health (2015) Privacy and Security Policy defines anonymized material as material that "is likely no longer identifiable to anyone." Anonymous material on the other hand "never was identifiable." The Canadian Tri-Council Policy Statement (TCPS) also explicitly acknowledges this distinction with the claim that "Anonymous information and human biological materials are distinct from those that have been coded, and also from those that have been anonymized" (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada 2014).

Other normative documents do not explicitly distinguish between anonymous and anonymized materials. The eTRIKS (European Translational Information and Knowledge Management Services) Consortium (2014) Code of Practice on Secondary Use of Medical Data in Scientific Research Projects defines anonymization as the "process of removing all elements allowing the identification of an individual person (i.e., of rendering data anonymous)." This lack of distinction is also exhibited in their definition of anonymized data "which was identifiable when collected but which are not identifiable anymore (have been rendered anonymous)." The Ethiopian National Research Ethics Review Guideline makes no distinction between these two levels of privacy and provides one definition for "anonymous/anonymized" material (FDRE Ministry of Science and Technology 2014).

Requirement of obtaining ethics approvals

A strong support for obtaining ethics approvals for using anonymized samples and data is witnessed in the majority of included normative documents.

In 25 Recommendations on the Ethical, Legal, and Social Implications of Genetic Testing, the European Council (2004) recommends that all Member States "ensure that approval by a competent review committee is obtained before research is undertaken." This recommendation applies "regardless of the purpose of the collection and the level of anonymity." The Ethiopian National Research Ethics Review Guideline (FDRE Ministry of Science and Technology 2014) also states that "secondary use … may be done only on anonymized samples and after getting prior approval by the Institutional Review Boards (IRB)."

Although it is a minority view, some advisory bodies maintain that ethics board approval is not required for the use of anonymized samples and data. For example, in Research Involving Human Biological Materials: Ethical Issues and Policy Guidelines, the American National Bioethics Advisory Commission (NBAC) (2000) stated "if the tissues are not identifiable as to an individual tissue source, the research protocol can be exempted from IRB review." The reasoning for this argument is based in the claim that the oversight and restrictions on the use of materials should be proportionate to the amount of risk involved. In the case of anonymized materials, some normative documents have argued that the risks are low enough that they do not warrant the additional safeguard of ethics committee approval. Although ultimately the Council for International Organizations of Medical Sciences (CIOMS) (2016) International Ethical Guidelines for Health-related Research Involving Humans recommends for the necessity of obtaining ethics approvals, it does support the reasoning premise used by the NBAC (2000) that "because the data or specimens are not personally identifiable, the risks to those individuals are no greater than minimal."

Ethical considerations for ethics committee review

Assessment of protection measures

One element of the research protocol for which several normative documents have recommended that there be ethics review is for the confirmation that sufficient security measures are in place such that materials can truly be classified as anonymized. Recommendations of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2016) state that "non-identifiability should be verified by an appropriate review procedure." In the document on Instrument on the Use of Archived Human Biological Materials in Biomedical Research, the Council of Europe (2002) reiterates that "in the case of unlinked anonymized research, anonymity shall be confirmed by a review procedure." The Canadian TCPS has a similar recommendation. The World Health Organization (WHO) (2004) report on Genetic Databases: Assessing the Benefits and the Impact on

Human and Patient Rights also advises that "privacy measures must be transparent and subject to ethical approval by a suitable body." The WHO report elaborates that it is the duty of ethical approval committees "to assess and review the adequacy of security provisions of the data held on the database for the protection of privacy." Additionally, the Indian Council of Medical Research (2006) Ethical Guidelines for Biomedical Research on Human Research recommends that "every request for secondary use shall be examined by the Institutional Ethical Committee to ensure that … provisions for ensuring anonymity of the samples for secondary use are stated."

Re-identification and high-risk studies

Some normative documents maintain that it may not be sufficient for an ethics committee to merely affirm anonymization of samples and data. One argument in favor of a higher degree of oversight has to do with concerns over whether anonymization procedures (even ones reviewed by an ethics committee) can sufficiently protect participants to such a degree that no further oversight of research is necessary.

As it is indicated by eTRIKS guideline (2004), the issue of potential re-identification is of particular concern in genetic and genomic studies because "DNA is a key that allows to uniquely and permanently identify a person." The identifying nature of genetic material makes anonymization difficult to define and ensure in this context. Furthermore, as TCPS (Canadian Institutes of Health Research et al. 2004) stresses, "rapid technological advances facilitate identification of information and make it harder to achieve anonymity." The National Institutes of Health (NIH) (2014) Genomic Data Sharing Policy elaborates, "because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks." For these reasons, several normative documents have challenged whether anonymization alone (i.e., without ethics committee oversight) is a sufficient safeguard of participant interests. The eTRIKS guideline, for instance, argues against anonymization being used to waive the need for an ethics review safeguard. Instead, eTRIKS (2014) recommends that the safeguards applicable to personal data "shall apply even if related [genetic] data have been anonymised."

Group concerns

Anonymization has also been criticized in the normative documents for offering only a limited scope of protection. While it may protect individual level interests, some normative documents question whether it would guard

sufficiently against group level concerns such as stigmatization and discrimination. This is because even if personally identifying information has been removed, it may still be possible to identify a group to which the participant belongs. "Material can be anonymous with respect to an individual's identity but may not be anonymous with respect to classes of individuals," as TCPS (Canadian Institutes of Health Research et al. 2014) states. For this reason, in Recommendations for Collection Use and Storage in Research, the Irish Council for Bioethics (2005) recommends that "a Research Ethics Committee should review all research protocols seeking to use anonymous archival biological material in order to safeguard the rights of groups and communities." With regards to group concerns, the TCPS points out the often limited view on identifiability for materials that "may involve identification of groups, even though the human biological materials are non-identifiable at an individual level." The TCPS (Canadian Institutes of Health Research et al. 2014) goes on to state: "Researchers and REBs should be aware of, and guard against, threats to individual privacy and autonomy that arise from re-identification risks, as well as risks to groups, particularly where sensitive research findings will be linked to specific groups." Even the NBAC (2000), which allows for an exemption of anonymized research from ethical review, recommends that in the case of materials originating from a particular group where "the research is attempting to associate specific genetic traits with these groups, full IRB review … should be utilized prior to the protocol's commencement."

Discussion

In this systematic review, we examined national and international normative documents regarding the need for ethics committee approval for the use of anonymized samples and data in research. Our goal was to identify and contextualize the ethical factors motivating the recommendations on this issue.

First, it was important to clarify what we meant by the term anonymized. This proved to be a significant obstacle due to the lack of unification between the terminology and definitions of levels of identifiability. While some normative documents specifically delineate anonymous as being markedly distinct from anonymized (Canadian Institutes of Health Research et al. 2014), other normative documents did not use term "anonymized" but rather only used the term "anonymous" (FDRE Ministry of Science and Technology 2014). A further complication occurred due to the inconsistencies in terminology, when normative documents referred only to "de-identified" materials. While some policies such as the Global Alliance's *Privacy and Security Policy* lists (irreversibly) de-identified as being synonymous with anonymization, it is unclear whether all normative documents abide by the similar method of classification that would make these two terms, and subsequently their corresponding recommendations,

interchangeable. Arguably, the current ambiguity in the normative documents left institutions and researchers "without a framework for their deliberations and decisions" (de Vries, Munung et al. 2017). This inconsistency in the terminology surrounding identifiability has also been observed and critiqued in the literature and has led to a call for the "harmonization of terminology" (Phillips and Knoppers 2016).

An important factor in this lack of clarity in definitions is a result of technological advances that in principle allow for the re-identifiability of the samples and data. According to the Canadian TCPS, this has made it "more difficult to categorize human biological materials as anonymous or anonymized" due to the fact that it is now "harder to achieve anonymity." This means that the definition of identifiability (and conversely non-identifiability) is evolving. In the case of genetic research for example, it may be possible to re-identify materials due to the uniquely identifiable nature of DNA and genomic data. This has motivated some in the literature to argue that genomic research with anonymized samples be regulated by the provisions made for human subjects research, including review by an ethics committee, even though this is not required by all pertinent regulations—for example, under the Revised Common Rule in the U.S. (Lynch and Meyer 2017); McGuire and Gibbs 2006). This view is reiterated by a NIH policy, which states as follows:

> The federal regulations do not require IRB oversight for projects that use de-identified biospecimens, although IRBs have the prerogative to develop more stringent policies than the regulations require. Given the potential sensitivity of research in this domain, we recommend that all projects undergo IRB review and approval. In addition, the federal regulations do not adequately address potential harms or wrongs to racial or ethnic groups that may occur through the use of specimens that are individually de-identified but retain demographic information that associate them with racial or ethnic groups. IRBs should be alert to potential group harms or wrongs in this context. (National Institutes of Health 2015)

Furthermore, even if anonymization could be guaranteed, it may still be limited in the sense that it may only protect individuals while neglecting community level concerns (Rothstein 2010). It has been argued that normative documents for anonymized research should be careful of "focusing narrowly on risks related to individual identifiability" (Fullerton and Lee 2011). It would likely be difficult for researchers to fully assess the complex issues regarding group concerns that require an understanding of the participant population. In the example of the Arizona State University researchers working with Havasupai biospecimens, it became clear that insufficient consideration was given to the interests of the tribe (Sterling 2011). Despite the fact that the materials were anonymized, it still presented a risk to the already stigmatized population due to the researches' focus on sensitive issues regarding inbreeding, mental illness, and origin studies that went against

Havasupai traditional beliefs. Although tribal members had given their broad consent, many felt that this should not have been treated as an unlimited consent without safeguards of their interests (Tsosie 2007). As subject populations can be diverse and have many different, complex kinds of vulnerability, the review of an ethics committee would be an important additional safeguard of participant interests.

Despite the identified concerns associated with anonymization in the reviewed normative documents, a 2015 study conducted by Goldenberg et al. indicated that many IRBs view anonymization as a sufficient safeguard of participant interests, and "consider studies using anonymized biospecimens to be no greater than minimal risk" (Goldenberg et al. 2015). In practice, however, the studied IRBs adopted various approaches concerning the requirement of ethics review for anonymized samples and data: "For anonymized data, a majority (61%) of Administrative Directors said their IRBs would usually or always require a researcher to submit his or her study for an initial review, while 39% said that their IRBs would never, rarely, or sometimes require this practice"(Goldenberg et al. 2015). We believe the underlying reasons for the observed disparity between the normative documents and the practices of ethics committees should be further studied in the future.

Conclusion

Across the normative documents and literature, we observed a lack of clarity with regards to not only terminology regarding levels identifiability, but also conflicting standards over what is required for materials to be considered "anonymized." We recommend that there be further harmonization of these concepts in order to facilitate discussion and to ensure that participants' samples and data are protected. These conversations and normative documents must be responsive to technological developments that may challenge prior conceptions of anonymization and identifiability.

Normative documents must also take into account risks that extend beyond individual participants and into their respective communities. Respecting participants' interests and their communities requires more than removing the identifying information from their materials. As this becomes increasingly clear and concerns over re-identifiability grow, ethics committee reviews should be attentive to a wide range of identified considerations when reviewing research use of anonymized samples and data.

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