



# Ethical considerations for Forensic Genetic Frequency databases: First Report conception and development

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## ABSTRACT

The Forensic Databases Advisory Board (FDAB), an independent board that assists the International Society for Forensic Genetics (ISFG), has presented a First Report on ethical aspects of the following Forensic Genetic Frequency Databases (FGFD): EMPOP, STRidER and YHRD. The FDAB designed an ethical framework to evaluate the content of these FGFD, and the factors to be considered for retention and acceptance of submissions. The FDAB framework proposes to categorize submissions according to the risk of having contravened the universal ethical principles outlined by international organizations, and the guidelines adopted by the ISFG. The report has been open to discussion by the scientific community since 2023. Herein we present the conception and development of the First Report along with a summary of its content, with consideration of the feedback received.

## 1. Introduction

### 1.1. The FDAB

The Forensic Databases Advisory Board (FDAB) is an independent advisory board convened in January 2022 to provide evidence-based ethical advice to the International Society for Forensic Genetics (ISFG) and, consequently, to the Forensic Genetic Frequency Databases (FGFD). The primary objective of the FDAB is to outline a methodology to evaluate the compliance of sampled population data contained in non-commercial FGFD with defined ethical guidelines for current and future submissions, as well as legacy data. Presently, these FGFD hosted and maintained by European institutions comprise the Y-chromosome Haplotype Reference Database (YHRD) [1,2], the EDNAP Mitochondrial DNA Population Database (EMPOP) [3], and the STRs for Identity ENFSI Reference Database (STRidER) [4].<sup>1</sup> In its report ([5] and Appendix), the FDAB presented an ethical framework aimed at identifying relevant

questions for evaluating the alignment of data within the FGFD with this framework. This encompassed considerations such as data privacy, informed consent, and data sensitivity. The report was made accessible to the forensic community, inviting feedback from March 1st to August 1st, 2023. This approach extended to a subsequent workshop on May 18th, 2023, inviting comments and discussions on the report. Valuable contributions from the workshop, along with received feedback, were incorporated into the last version of the report, ensuring a comprehensive and collaborative perspective. The following paper offers an overview of the FDAB's First Report, focusing on the composition, contributions, access, control, and utilization of the FGFD. While acknowledging the need for more in-depth discussions on informed consent alternatives and the impact of including datasets of minorities and vulnerable groups, the paper will address ethical challenges associated with the FGFD. It will outline core elements for a proposed ethical framework to evaluate legacy, contemporary, and future contributions and consider factors related to the retention and acceptance of

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<sup>1</sup> While some of the considerations outlined herein may also be relevant to other types of genetic databases, for the purposes of this paper only the three FGFD, namely the YHRD, EMPOP and STRidER, were specifically reviewed.

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submitted data to these databases.

### 1.2. Ethical challenges of Forensic Genetic Frequency Databases

The FGFDs like EMPOP, STRidER or YHRD serve the purpose of providing reliable frequencies of DNA profiles in different human populations. These frequencies are necessary to correctly evaluate matches between DNA profiles established from crime scene samples and DNA profiles from persons of interest to the investigation. They are also necessary for the probability assessment of different hypotheses of filiation based on DNA results, e.g., in paternity tests or the identification of human remains. The FGFDs do not include personal metadata like names, birthdays, or addresses, but they include the population group from which the profiles are derived. The critical aspects of the FGFD contents have been identified as:

#### 1.2.1. Validity of practices in the data acquisition process

In this section we discussed the variety of participants and submitters: the genetic data in the FGFD have been collected from several sources of biological material including voluntary participants and submitted mostly but not exclusively by academic contributors.

#### 1.2.2. Data sensitivity and identifiability

Even if the identification of individuals is not the purpose of FGFD, and the risk of re-identification from database entries is expected to be rather low, suitable measures to prevent inappropriate identification attempts should still be taken. It is also important to know what the consequences of a successful re-identification attempt could be for the individuals concerned. A closer look at the type of genetic data in terms of sensitivity and potential for re-identification is therefore necessary.

In its Report ([5] and Appendix), the FDAB outlined the sensitivity and potential for re-identification of the data held on EMPOP, STRidER and YHRD. While no risks, both in terms of re-identification and data sensitivity could be identified for the aggregated autosomal allele frequency data held on STRidER, a more nuanced view is necessary for the haplotypes held on EMPOP on YHRD. Most of the data held on EMPOP and YHRD is already available in the public space through the original study publications. However, both the EMPOP and YHRD databases provide search functions for haplotypes that facilitate the finding of certain study populations.

Additional information may potentially be retrieved from the original publications that describe those study populations. This information, if combined with entries from other databases where other genetic data from the same individuals have been submitted, could potentially lead to a re-identification or the disclosure of more sensitive information attributable to a certain entry.

The potential for re-identification of an individual with a particular haplotype also depends on the design of the original study from which the haplotypes originated. Sufficient de-identification procedures should be undertaken by researchers responsible for population genetic studies and those measures need to be monitored vigilantly.

Data sharing and possibilities for data linkage will most likely increase in the future. It is therefore essential that database curators keep an eye on technical developments in the field and react promptly to any emerging threats to privacy.

#### 1.2.3. Consent and vulnerable groups

Special attention must be given to ethical requirements concerning the incorporation of datasets from minorities and vulnerable populations. According to the guidelines set forth in the report of the International Bioethics Committee of UNESCO (IBC) [6], vulnerability in genetic research is not easily defined but frequently revolves around fundamental principles such as human dignity, human rights, and freedoms. Social vulnerability, stemming from social, political, and environmental determinants, is complex and affects individuals and communities by interfering with self-determination and increasing

exposure to risks through social exclusion.

Both YHRD [1,2] and EMPOP include datasets from vulnerable populations, such as Roma people and Native Americans [7]. Concerns have been raised about the submission of haplotypes from minority groups, like Uyghurs and Roma people, to publicly accessible databases like YHRD, indicating potential lapses in obtaining proper informed consent [7–11]. The use of ethically unsound practices in collecting information from these vulnerable groups has resulted in the retraction of several papers in forensic sciences and other disciplines from peer-reviewed journals [12–17].

It is noteworthy that certain minority organizations may require group consent prior to individual consent, emphasizing the need for a more nuanced approach to consent in genetic research involving vulnerable populations, e.g. [18–20]. Researchers in forensic genetics should seek explicit agreement from self-organized vulnerable population groups through their representatives for retaining datasets in databases. The decision to retain information on vulnerable groups should consider the benefits to these groups, ideally involving them in the assessment process.

In evaluating the vulnerability of study populations, genetic database curators should establish a checkpoint process. This process should entail submitters declaring the content of their submissions, conducting supplementary checks for widely recognized minority groups, and providing users with the ability to report concerns regarding datasets involving minorities or vulnerable groups directly on the database websites. Continuous monitoring of re-identification thresholds and strict adherence to privacy regulations are crucial. This ensures that sensitive datasets undergo controlled access or a similar privacy protection mechanism, in line with the requirements mandated by privacy laws and international declarations on human rights.

## 2. Methodology

Once assembled, the first order of business for the FDAB was to clarify the mandate for its first assessment. Following discussions with the IFSG, we agreed our assessment should bear on the ethical criteria and outline procedures for international forensic genetic frequency databases to process data responsibly. Given the advisory and voluntary nature of our relationship with the IFSG, we excluded both carrying out a formal legal assessment of the responsibility of the IFSG, or the FGFD databases, and determining their data privacy obligations from our mandate. Our assessment followed a classical social science research methodology that was mostly, but not solely, based on documentary research. The following steps were followed:

### 2.1. Assessment of the FGFD databases: STRidER, EMPOP and YHRD

The objective of this first step was to document the types of data hosted and data governance processes followed by each of the FGFD databases. This information gathering process focused on some of the more controversial aspects identified in the genetic databases ethics and policy literature: nature of the data hosted, requirements for data submitters, requirements for data users, data transfer agreements, security/privacy mechanisms etc. The information was gathered through a careful search on the website of each database, supplemented by phone conversations with the database administrators as needed.

### 2.2. Documents' review

We then carried out complementary reviews of (a) the scholarly literature, (b) the websites of key international organizations (ex. UNESCO, HUGO, WMA, CIOMS, etc.) involved in the ethics of medical research or the ethics of forensics. Keywords used for the literature review were terms generally associated with the controversial aspects identified in step one above. Given that this was not intended to be a legal review, we excluded transnational and national laws and

regulations from our results. To avoid bias towards any specific national approach to database governance, we prioritized using internationally recognized policies and standards rather than favoring a particular national perspective. We are aware of the different experiences and viewpoints that indigenous population groups may have on providing samples and data to an international database. While our advisory group did not include any indigenous member, we did make efforts to consider their views as expressed in documents such as the CARE principles for Indigenous Data Governance (Collective Benefit, Authority to Control, Responsibility, and Ethics) [21] and OCAP (Ownership, Control, Access, and Possession) principles for data collection [22].

### 2.3. Development of the draft report

Using the information collected through step one and two and following discussions within our multidisciplinary group, we put together an initial draft of our report sent to key members of IFSG and administrators of FGD databases for comments. This last step was meant to avoid any factual inaccuracy in our report and no significant change was made to the content and findings following their response. At this point, we felt that we had a Working Draft of sufficient quality that could be shared broadly with all stakeholders for comments.

### 2.4. Consultation and workshop validation

The Working Draft was openly accessible on the ISFG website, with an invitation to the community to provide comments, from March 1st to May 30th, 2023 that was extended until August 1st, 2023. To promote our work and solicit more comments to our Working Draft we organized a half day workshop that took place on the morning of May 18th, 2023 the context of the 12th Haploid Markers Conference. The meeting was well attended by over 80 delegates from the forensic genetics' community. After presenting the key elements of our report, a significant portion of time was allocated to engaging in an open discussion with the delegates, allowing them to raise questions of their choice.

All comments communicated to us in the context of the online consultation and the in-person workshop, were considered for the development of the final report that was made openly available on January 30, 2024.

## 3. A risk assessment strategy

The FDAB designed a strategy for an ethics risk assessment of the FGDs content. The critical factors previously identified were then assessed based on the prevailing universal principles and guidelines at that time. Given the evolving nature of the universal principles and adopted guidelines, the data contributions to the FGD were categorized in temporal categories. The contrasted information served as a foundation to define the degrees of risk of the submissions to the FGD.

### 3.1. Temporal categories of data submissions

The FDAB proposes adopting temporal categories to data samples collected, classifying the data in terms of risk (low-medium-high), with regard to the risk of infringement of ethical principles, the risk or re-identification as well as the source and provider of data/samples. These categorizations were informed by, amongst other international standards, the *Declaration of Helsinki* (1964 [23], 1975 [6], and later updates), the *UNESCO Universal Declaration on the Human Genome and Human Rights (1997)* [25] and the guidelines adopted by the forensic genetics' community (2010 and 2020) [26,27].

#### 3.1.1. Data from samples collected pre-1964

These data come from samples collected prior to the establishment of generalized ethical principles in the *Declaration of Helsinki: ethical principles for medical research involving human subjects* [23]. Removal of the

dataset could still be warranted if misconduct upon sample collection or data generation is reasonably suspected.

#### 3.1.2. Data from samples collected between 1964 and 1997

The *Declaration of Helsinki* first established the principles of free informed consent and 1975 amendments added a requirement of approval by an ethics review committee [24]. While the principles outlined by the *Declaration of Helsinki* were already well recognized in the biomedical field by 1997, no comparable framework for human genetics existed.

Even though it can be assumed that most samples collected in this period were collected with consent, the practice of including statements of consent and approval by ethics boards in publications was not widely established. In addition, a substantial proportion of samples from this period appear to have been re-purposed for genotyping with current forensic markers [28].

#### 3.1.3. Data from samples collected between 1997 and 2009

These samples were mostly collected with the specific purpose of forensic statistics applications after the 1997 *UNESCO Universal Declaration on the Human Genome and Human Rights* [25] and before the publication of the first explicit ethical guidelines in a forensic genetics journal [26]. This period can be considered as a transition phase for bioethics in forensic genetics.

A review of database entries revealed that a considerable proportion of samples collected in this period only refer to informed consent or compliance with the *Declaration of Helsinki*, with no explicit reference to a Research Ethics Review Board (RERB).

Vague or imprecise statements regarding informed consent may indicate a high-risk that the sample collection or data acquisition did not follow ethics requirements. Missing statements regarding ethics board approval should be classified as medium risk.

#### 3.1.4. Data from samples collected between 2010 and 2020

These samples were collected at a point in time when standardized national and international regulations, and explicit journal submission guidance [26]) were well known. However, enforcement of ethical practices remained poor during this period [29]. Submissions with incomplete statements or records, such as consent alone, no ethics committee approval, or no explanation of why ethics committee approval is not necessary, and submissions with no tangible record of consent, such as an oral communication, should be considered high-risk.

#### 3.1.5. Contemporary and future population studies

Samples collected from 2021 onwards are regulated by the Guidelines and Recommendations published in 2020 in the journals *Forensic Science International: Genetics* and in *Forensic Science International: Reports* [27]. These guidelines require that records of the informed consent and of the approval by ethics boards be disclosed, the code or number of the approved revision should be provided, as well as an indication of the date of collection, or alternatively, a disclosure of a waiver or justification for non-adherence.

### 3.2. A risk-assessment approach

Identifying entries that potentially violate universally accepted ethical principles, standard ethical practices, and specific guidelines may necessitate a comprehensive analysis. A careful case-by-case analysis considering the benefits of data retention against their associated ethical risks should include the evaluation of additional factors. The risk factors and assessment criteria include but are not necessarily limited to:

- Scientific value.
- Data submitters.
- Lack of RERB.
- Source of biological material.
- Study design.

**Table 1**  
Scheme for assessment of risk according to ethics compliance

Samples' temporal categories	Ethics practices		Risk Assessment
<i>Period</i>	<i>Informed Consent</i>	<i>Ethics Board/s</i>	
Prior to 1997	No consensus reached by the FDAB		
1997-2010	No	No	High
	Yes	No	Medium
	No*	Yes	Medium
	Yes	Yes	Low
2010-2020	No	No	High
	Yes	No	High
	No*	Yes	High
	Yes	Yes	Low

\*Unless waived by an Research Ethics Review Board these cases are categorized at risk.

- Vulnerability status.

### 3.3. Recommendations for medium to high-risk cases

If entries are determined to have medium to high risk, they may be excluded from the databases. However, in cases where the samples have high value, it is possible to seek a retrospective waiver or approval if the collection process did not violate ethical principles.

It is crucial to prioritize engagement with organized minorities and vulnerable groups to obtain retrospective approval for retaining data in the reference databases. This step should be considered highly valuable in the overall process [Table 1](#).

### 3.4. Further recommendations

Regular assessment of the FGFD in various evolving areas of interest is recommended. These areas include the need for transparency on traceability in sample collection and law enforcement access requests, the establishment of consistent ethical processes worldwide granting human dignity and promoting trust in genetics. Additionally, there should be vigilance regarding function creep of the consent scope to unrelated purposes for donors, particularly in commercial or law enforcement use. Database managers should also monitor re-identifiability thresholds and employ applicable techniques for the data types hosted on their database. Lastly, there is a need for improved accountability, including clearer professional guidelines for sharing genetic data in the forensic field internationally.

## 4. Conclusion

While the core purpose of the FGFD is to promote justice and protect human society, it is important to consider the potential infringement of individual human rights and research ethics norms in the collection, retention, and disclosure of individual genetic data. This report aims to strike a balance between these complex interests by ensuring ethical principles are followed while acknowledging the important purpose of the FGFD. However, deeper discussions are needed on informed consent alternatives, the impact of including datasets of minorities and

vulnerable groups, privacy and identifiability risks, and other relevant considerations for data hosted on the FGFD. Such challenges require a broader ethical and privacy assessment approach involving professionals and diverse stakeholders, as well as external audits. By addressing past and current issues, this article lays the foundation for handling future challenges, and advocates for a continuous monitoring and adaptation to ongoing and emerging ethical and social issues.

### CRediT authorship contribution statement

**M. E. D'Amato:** Conceptualization, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Y. Joly:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **V. Lynch:** Conceptualization, Investigation, Methodology, Writing – original draft, Writing – review & editing. **H. Machado:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **N. Scudder:** Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **M. Zieger:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing.

### Declaration of Competing Interest

The authors declare no competing interests.

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### Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.fsigen.2024.103053](https://doi.org/10.1016/j.fsigen.2024.103053).

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