



## Research paper

## Consent process for US-based family reference DNA samples

Sara H. Katsanis<sup>a,\*</sup>, Lindsey Snyder<sup>a</sup>, Kelly Arnholt<sup>b</sup>, Amy Z. Mundorff<sup>b</sup><sup>a</sup> Duke Initiative for Science and Society, Duke University, Durham, NC 27710, USA<sup>b</sup> Anthropology, University of Tennessee, Knoxville, TN 37996, USA

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## ABSTRACT

DNA collection from family members of the missing is a tenet for missing persons' and mass fatality investigations. Procedures for consenting family members are disparate, depending on the context supporting the reason for sample collection. While guidelines and best practices have been developed for handling mass fatalities and for identification of the missing, these guidelines do not address standard consent practices for living family members of potential victims. We examined the relevant U.S. laws, international guidelines and best practices, sampled consent forms currently used for DNA collection of family members, and drafted model language for a consent form to communicate the required and recommended information. We modeled the consent form on biobank consenting practices and tested the consent language among students and the general population for constructive feedback and readability. We also asked respondents to consider the options for DNA collection and either hypothetically agree or disagree. The model language presented here highlights information important to relay in consent processes and can serve as a foundation for future consent practices in mass fatalities and missing persons' investigations.

## 1. Introduction

DNA is the most reliable method for demonstrating biological kinship for identification of deceased persons. In times of mass disaster, conflict or for individual missing person cases, DNA samples from families of the missing may be collected to identify the deceased. Over the past couple decades, disaster victim identification (DVI) operations have led to development of international DNA collection standards and recommendations, including best practices for processing DNA and the need for written consent for collection of family reference samples [1]. Still, the consent procedures differ greatly depending on the context of the incident and the scope of involvement of government and law enforcement. Moreover, the international nature of many contexts for family reference sample (FRS) collection necessitates clear guidance on processes and parameters for protection of data to be shared across borders. The U.S.-based DNA collection programs are some of the earliest models for DVI and missing persons' investigations, and hence a good starting place for examination of consent processes for FRS collection.

Collection of DNA for forensic purposes is governed under jurisdiction-specific protections. In most contexts, DNA collection to investigate missing persons' cases is entrusted to authorities under the assumption that the case may be a homicide, human rights violation or other crime. Law enforcement and medicolegal personnel adhere to the

standard chain of custody as part of any criminal, missing person or disaster investigation. To maintain legal authority of what could become a criminal case, U.S.-based missing persons' cases are entered into the National Missing and Unidentified System (NamUs) and DNA profiles are funneled toward the national missing persons database operated through the COmbined DNA Index System (CODIS), which is managed by U.S. Federal Bureau of Investigation and subject to specific legal standards [2]. Some nongovernmental organizations (NGOs) have argued that the criminal justice system for missing persons' investigations excludes certain populations, such as missing migrants [3]. Continuing migration crises across the Mediterranean Sea [4] and at the U.S.-Mexico border [3,5] require ongoing collection of DNA from families of the missing. In these cases, the family members may be fearful of government authorities and even non-governmental representatives. Conversely, while historic cases of missing persons, like disappearances due to conflict, usually follow similar practices as law enforcement, they may be managed in cooperation with academic or private organizations as discrete projects.

Whether a victim is missing due to conflict or disaster, identification of their remains often depends on DNA comparisons with related family members. The voluntary provision of DNA samples from living biological relatives involves some form of donor consent. Standardization of an informed consent process has not been developed since most of the scenarios are case-based (e.g., a particular missing person), jurisdiction-

\* Corresponding author.

E-mail addresses: [sara.katsanis@duke.edu](mailto:sara.katsanis@duke.edu) (S.H. Katsanis), [lindsey.snyder@duke.edu](mailto:lindsey.snyder@duke.edu) (L. Snyder), [karnholt@vols.utk.edu](mailto:karnholt@vols.utk.edu) (K. Arnholt), [amundorff@utk.edu](mailto:amundorff@utk.edu) (A.Z. Mundorff).

based, and/or context specific (e.g., an airplane crash). The disparate practices for consenting donors involve varying degrees of information provision and little two-way communication between investigators and the participants. In some cases, consent involves mere willingness of a participant to be swabbed, and in other cases, consent is a part of a multi-hour intake process for a case report. Documentation during consent processes also vary in level of detail and content of information collected from donors, ranging from name and relationship with victim, to full family pedigrees drafted by individuals trained in genetics. The disparity in documentation may reflect whether DNA samples are collected solely by law enforcement or in conjunction with other types of personnel [6].

The American Bar Association (ABA) Standards on DNA Evidence describe the need for obtaining consent from the person who is the source of the sample, stating that law enforcement would not have access to or otherwise be able to obtain the collection without the persons' consent. These standards also apply in law enforcement contexts, noting the right to be informed on the reason for the request and the right to refuse the request [7]. Internationally, multiple organizations' involvement in efforts to identify victims of conflict, military war dead [8], and mass fatalities [9] has resulted in the collection of thousands of DNA samples from relatives of the missing. Best practice recommendations emerged following major incidents that relied upon DNA collection for victim identification, noting common themes regarding important processes such as chain of custody, integrity of samples, and commonality of DNA markers. Mass fatality identification processes were enhanced following the identification efforts of the World Trade Center attacks [10], with the immediate aim to improve accuracy and transparency [11–13], including development of an informed consent process for family members [14]. Practices now incorporate inclusion of genetics professionals in the identification processes [15] and provision of family support services [16]. Acquiring consent from WTC victim family members for identifications, in particular, were challenging given the lack of advanced coordination in place and the magnitude of the disaster [17]. The innovative work of the Kinship and Data Analysis Panel (KADAP), an advisory team assembled following the disaster to develop consistent guidelines, eventually improved the processes tremendously [11]. Nevertheless, the lessons learned in one context – the WTC disaster – were challenging to translate to later events including Hurricane Katrina and the Southeast Asian tsunami [18]. Some recommendations are specific to the organization responsible for identifications. INTERPOL for example, notes that the consent form should specify the possibility of international data sharing [19]. International Committee of the Red Cross (ICRC) includes exceptions in their best practices that personal data may be disclosed if “required by a substantial public interest or for the protection of the vital interests of the person concerned” [20]. The ICRC also notes in their recommendations that the person collecting consent should do so in layman's terms and in an understandable manner [21].

Still today, the numerous DVI guidelines [9] thoroughly address the science and practicalities of identification, but ethical aspects related to the family members providing genetic information are largely unaccounted for. One un-reconciled difference among current recommendations is whether or not to disclose genetic information (e.g., misattributed parentage) revealed through testing, either to the donor or the potentially affected kin. The ICRC argues that “access to personal data should be granted to the individual to whom the data relate” [21]. This policy resonates with the principle right to access personal information held by government authorities in order to question the accuracy of the information. Yet academics have argued that some genetic information about biological relationships can be dangerous and that the right to not know information should supersede this right to access data, particularly when that data could be damaging to family dynamics, or put a person at risk of violence [22]. For instance, misattributed paternity may put a woman or child at risk of abuse when the fact of non-paternity brings supposed shame upon a family, even in

cases of rape or incest.

Protection of genetic information has long been a priority in medicine and law enforcement. Bioethical guidelines for participation of research subjects were developed following the release of the Belmont Report in 1978 [23]. The protection policies and guidelines, developed since the report's publication, encompass many aspects of research risks including but not limited to protection of biological and genetic information. One of the mandates following the report's release implemented the process of informed consent to ensure a person's participation in research is with full knowledge and understanding, freely and without coercion or duress [24]. Provision of biological specimens for research is included as research. United Nations Educational, Scientific and Cultural Organization (UNESCO) proposed additional measures to protect genetic data collected for research from misuse, including data from governmental authorities [25]. The use of, sharing of, and access to voluntarily provide genetic information is a topic of much discussion since the completion of the human genome sequence in health applications [26,27].

Samples collected for forensic purposes in the U.S. are not ordinarily considered research, but are instead protected from misuse by the various state laws, and sharing of data at the federal level is governed under the Privacy Act of 1974 (5 U.S.C. §552) [28]. The Privacy Act is limited in its scope, excluding non-residents and with no provisions for persons who may be considered belonging to a vulnerable population. The Privacy Act does require that the agencies collecting information inform each individual of the intended uses, the authority under which it is collected, and what the effects may be on the person (See §3(e)(3)). In the context of DNA collection, the Privacy Act notice for the National DNA Index System (NDIS) from 1996 (61 FR 37495) requires consent for retention and disposal of DNA records outside of judicial or criminal justice authority [29]. In the missing persons context in particular, the NDIS protocol requires consent to document the voluntariness of the collected FRS [2]. The mechanism of consent, however, is not proscribed.

While FRS collection for missing persons is not research per se, the families of the missing may be of populations considered “vulnerable” under research contexts governed under the Common Rule (45 CFR 46) [30,31], which typically encompasses groups that are perceived to lack the capacity to consent fully and/or that are at risk of exploitation (e.g., children, pregnant women, and prisoners) [32,33]. Recent updates to the Common Rule have expanded this definition to include individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons [34]. Not covered under this definition are populations that have been historically excluded and socially disadvantaged persons [35].

In the contexts of FRS collection, the vulnerability of a person may include these definitions, and indeed the missing person may be from a socially excluded population (e.g., homeless, immigrants, refugees, sex workers, youth) [33]. But also importantly, collecting FRS from a person who has a missing loved one places the donor at risk of coercion. In an emergency scenario, like the loss of a loved one, the comprehension of risk is secondary to the urgency to do whatever is possible to locate the family member. With that mindset, a person under duress at the time the agreement is presented may not fully comprehend informed consent. In this way, the family members of a missing person should be considered a group vulnerable to coercion by authorities. Standard practices in FRS collection acknowledge this coercion risk and recognize that trust between the agent collecting the sample and the family member is vital [9]. Moreover, the criminal justice purpose of FRS collection in mass fatalities and missing persons' cases overlaps with the humanitarian nature of the identification of the deceased, necessitating an examination of the privacy protections of the family members. Therefore, we argue that the bioethical principles of informed consent in research contexts ought to be applied in FRS provision.

One best practices analysis for missing migrants' investigations

suggested that the collection of FRS in the U.S. might be subject to the Common Rule since DNA is collected and then compared within databases in a manner in which the person is identifiable [36]. Since the collection of DNA for missing persons' investigations is not a research activity for generalizable knowledge, we do not believe that the Common Rule normally applies to FRS. However, if the samples may be used for future unspecified research or for research and development, then these protections may be warranted. In any case, the principles of protection refined through the Common Rule and consent practices for biomedical research are similarly applicable to the collection of voluntary samples for missing persons' identifications. Moreover, the requisite for trust between the parties (i.e., collecting agent and family member) necessitates a formal, controlled exchange as well as an ongoing engagement to allow contributors to change their minds [37].

We sought to model draft language for consent processes that would be applicable across many missing persons' contexts to standardize consent processes for FRS collection. We requested consent documents for example language from several groups collecting FRS for non-criminal purposes. We analyzed the elements in the provided consent documents, noting best practice language and the relevant U.S. legal requirements. We then modeled our consent form language on the Beskow et al. proposed short consent form for biobanking, adapting the form flow and example language for a missing persons' context [38]. Finally, we piloted this form with two populations for feedback on the language readability and documented their hypothetical willingness to provide a FRS.

## 2. Materials and methods

### 2.1. Example consent documents and analysis

We collected consent documents from organizations and projects collecting DNA as part of a missing persons or missing migrants project. We analyzed the current best practice and guidance documents for mention of FRS collection, to document recommendations for consenting relatives of the missing. We broke down the consent documents and cross-referenced them by legal requirements and best practices. We applied the U.S. Privacy Act of 1974 and the Privacy Act notice for the National DNA Index System (NDIS) from 1996 to our analysis to document requirements for NDIS inclusion [28,29].

### 2.2. Draft model consent language development and pilot

We organized the existing consent elements into themes and systematically arranged them to reflect a biobank consent form [38]. We added language where requirements or best practices were not reflected in the existing example consent documents. To improve the readability, we modified the language of the example forms to simplify terminology. We authored a separate Frequently Asked Questions (FAQ) document to provide detailed information on relevant concepts. As in the Beskow, et al. biobanking example, we used plain language to clearly convey each topic [38]. After devising the resulting model consent form, we recruited undergraduate student volunteers at Duke University and The University of Tennessee, Knoxville to pilot the form (under Duke University IRB review). Students were invited to participate via email and were asked to complete a survey designed and distributed using Qualtrics software (Qualtrics, LLC, Provo, UT) to provide quantitative and qualitative feedback. All participants were asked to rate on a Likert scale on whether each section was clear. Participants were asked to provide feedback on the clarity of the language. Qualitative data from the comment-based feedback was reviewed by two investigators independently, and analyzed for themes. The investigators developed a new version addressing each comment. The second version was then piloted to a general population for quantitative feedback on readability and agreement. Data was compared between the two pilots as to whether participants indicated willingness to consent to the

options provided. Quantitative data was tabulated and statistical analysis assessed using Qualtrics software and Microsoft Excel (Redmond, WA) tools.

Finally, input was requested of experts from organizations collecting FRS. Expert responses received at each stage were integrated into the drafted language to ensure accuracy of information, including after the second pilot.

## 3. Results

### 3.1. Identification of relevant guidelines

The two primary U.S. laws pertaining to DNA collection were analyzed for applicability to non-criminals and family members of the missing. The Privacy Act of 1974 (5 U.S.C. §552a) [28] establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies. This Act is the law that mandates protection of donors to the national DNA database and governs the privacy protections. When CODIS was established, the federal government published standards of the database to comply with the Privacy Act. These published standards are codified in the Privacy Act Notice for the National DNA Index System (61 FR 37495) [29].

In addition, published guidelines, best practices, and recommendations on missing persons and DVI were reviewed for content related to collection of DNA from family members of the missing. Because there are no specific standards for FRS collection, we explored the published recommendations that touch upon the topic. Resources included two guides to best practices for identification of human remains in armed conflicts by the International Committee of the Red Cross (ICRC) [20,21], guidelines from the International Criminal Police Organization (INTERPOL) for DVI [39] and best practices for the uses of DNA for the identification of missing persons and human remains; [19] guidelines for mass fatality DNA identifications developed by American Association of Blood Banks (AABB) [13]; and a report from the Binational Migration Institute (BNI) on best practices for processing remains found along the U.S.-Mexico Border [36]. Table 1 outlines the compliance standards from these recommendations and laws for the consent form content developed. A complete breakdown of the consent form and relevant compliance standards is available in the Supplementary data file as Appendix A in Supplementary material.

### 3.2. Comparison of example consent documents

Example consent documents were provided by several stakeholders. Some of the provided documents were not relevant to the study and were excluded from analysis. Several of the supplied consent form documents (see Table 2) contained elements for general intake of missing persons' reports and were not specific for DNA collection. Documents were analyzed only for the aspects related to the FRS collection (not, for instance, the anthropology and demographic intake sections). Most documents described the purpose, the permitted (or limited) use of supplied personal data, as well as a description of the confidentiality protections. The law enforcement based documents (Forms A-D) mentioned the potential use of DNA profiles for quality control and population statistics. The NGO documents differed broadly, with one (Form H) describing the risks of genetic information and sample loss, the duration of the record retention, and the opportunity to withdraw from participation, and others (Forms E-G) with no discussion on the risks of participating. The CODIS contributing documents (Forms A, B, & D) all described the Privacy Act protections including the plan to destroy the personal data once an association has been made. None of the forms noted the limitation of the Privacy Act of 1974 to U.S. citizens and legal residents.

**Table 1**  
US-based laws, guidelines and best practices for consent to collect family reference samples.

CONSENT TOPIC	U.S. LAWS		GUIDELINES and RECOMMENDATIONS			
	Privacy Act of 1974	61 FR 37495	ICRC 2009	AABB 2010	INTERPOL 2015	BNI 2015
Purpose						
Description			+	+		
Benefits			+			
Capacity to consent	+			+	+	+
Procedures			+			
Voluntariness						
Alternatives			+			
Participant records access			+			
Secondary uses				+		
Withdrawal			+			
Retention of samples/data		+				
Destruction of samples/data		+	+	+		+
Risks						
Sample collection						
Genetic information				+		
Sample loss				+		
Confidentiality						
De-identification for research		+	+	+		+
Limit of use	+	+	+			+
CODIS protections	+	+				
Record review		+				
Nondisclosure	+		+			+
Privacy Act limitations						
Costs						
Reporting						
Official reports	+			+		
Report sharing			+		+	
Family notification	+		+			
Contact information			+			

+ = The content was specifically mentioned.

### 3.3. Proposed model language

We propose U.S.-based model language for a consent form for FRS collection (see Exhibit 1 for the final version of the model consent form and Appendix A in Supplementary material for annotations on each element describing the original source of the language and relevant compliance). The model language is designed to be used by law enforcement agencies or private organizations, and further refined to the specifics of the organization. The form is structured to mimic a biomedical research consent form and is modifiable for the context of the collection intents for an organization. The consent form references a Frequently Asked Questions (FAQs) on DNA for Missing Persons document at several points. The FAQs supplement the consent form with definitions and detailed descriptions of the risks and protections (see Exhibit 2 for the final version of the FAQs document).

The consent form for FRS collection is structured into twelve sections.

#### 3.3.1. Purposes

The Privacy Act requires that agencies obtain consent to use records pertaining to an individual for another purpose, which means the agency must first describe the purpose of the information being collected. To fully consent, a participant should be informed on all purposes of the collection, which may require a separate document to describe the process. The ICRC recommends that DNA be collected only for a “clearly identified and specific purpose” (pg. 43, [21]). The ICMP uses such an “information sheet,” which we modified to generalize for our model language. The Privacy Act references use of a parent or legal guardian to act on behalf of a minor or an incompetent individual; [28] as such, we added a provision to note the potential use of a legally authorized representative. In addition, the AABB notes that provisions should be considered for persons who cannot read or write or who require interpretation (pg. 9, [13]).

#### 3.3.2. Benefits

A clear description can help define why a person may want to participate and counter any actual or perceived risks. The ICRC recommends that benefits be described (pg. 43, [21]).

#### 3.3.3. Procedures

A general description of the steps involved and the specific procedures that a participant will undergo is standard for research participation consent. The ICRC recommends that the consent process include a description of how the identification process will work (pg. 43, [21]). The AABB further suggests obtaining specific authorization to collect data for population statistics (pg. 18, [13]). The ICMP example form describes the use of data for validation purposes. We added a detailed description of the step-by-step process that a family member may experience, modeling our language on Beskow et al. [38].

#### 3.3.4. Voluntariness

Another tenet of informed consent in research is the voluntariness of participation. The voluntary provision of FRS can help guide a missing persons' investigation and may be one part of demonstrating trust between the family and the investigator. The ICRC notes specifically in their best practices that relatives should be informed that participation is voluntary (pg. 43, [21]). Given that some family members may fear government authorities or law enforcement for provision of a DNA sample, we added consent elements for databases that may be operated through law enforcement or through a private organization.

#### 3.3.5. Withdrawal

The ICRC also recommends that participants be informed that “they can withdraw from the programme if they later change their minds, and that they do not need to provide any reason for their withdrawal” (pg. 43, [21]). Such a policy is consistent with biomedical research consent but unusual in the missing persons' processes.

**Table 2**  
Consent document content from sampled organizations.

CONSENT TOPIC	US LE <sup>a</sup>				US NGO <sup>b</sup>	Non-US NGO <sup>c</sup>		
	A	B	C <sup>d</sup>	D	E	F	G	H
Purpose								
Description	+	+	+	+	+	+	+	+
Benefits	-	-	-	-	-	-	-	+
Capacity to consent	-	-	-	-	-	-	-	-
Procedures	-	-	+	-	-	-	-	-
Voluntariness								+
Alternatives	+	+	+	+	-	-	-	-
Participant records access	-	-	-	-	-	-	-	+
Secondary uses	-	+	-	+	-	-	-	+
Withdrawal	-	-	+	-	-	-	-	+
Retention of samples/data	-	-	+	-	-	-	-	+
Destruction of samples/data	+	+	+	+	-	-	-	-
Risks								
Sample collection	-	-	+	-	-	-	-	+
Genetic information	-	-	+	-	-	-	-	+
Sample loss	-	-	-	-	-	-	-	+
Confidentiality								
De-identification for research	-	+	+	+	-	-	-	-
Limit of use	+	+	+	-	-	+	-	+
CODIS protections	+	+	NA	-	NA	NA	NA	NA
Record review	-	-	+	-	-	-	-	+
Nondisclosure	+	+	+	+	-	-	-	+
Privacy Act limitations	-	-	-	-	-	NA	NA	NA
Costs	-	-	-	-	-	-	-	-
Reporting								
Official reports	+	-	NA	-	-	-	-	+
Report sharing	+	-	-	-	+	+	-	+
Family notification	+	-	+	-	-	-	-	-
Contact information	+	+	+	+	-	-	+	-

+ = The content was specifically mentioned; - = the topic was not mentioned; NA = not applicable.

<sup>a</sup> US law enforcement forms provided are either for general missing persons DNA submission in criminal investigations for a national database inclusion (forms A, B, & D) or for consent to research in a government-based pilot program (form C).

<sup>b</sup> US non-governmental organization form is designed for a missing migrant report; this organization in some cases partners with law enforcement (LE) agencies for DNA collection.

<sup>c</sup> Non-US non-governmental organization includes either a broad intake form for filing a missing persons' report (form H) or a missing migrant report (forms F & G); form F & G organizations in some cases partner with LE agencies for DNA collection.

<sup>d</sup> Form C is IRB reviewed for research.

### 3.3.6. Duration

The NDIS privacy regulations (61 FR 37495) [29] require the destruction of records that are “no longer permitted or appropriate for retention in NDIS,” which might include FRS for missing persons' investigations. However, these guidelines are not clear, stating on the one hand that sample retention of FRS is not permitted once an identification has been made; on the other hand, NDIS allows that DNA records be retained as long as they are permitted either by consent or by law. In any case, with voluntary provision of FRS, standard language to specify the duration and disposition of samples and profiles is an important part of informed consent.

### 3.3.7. Risks

Unlike biomedical research requirements, the description of risks to the participant is not required by law, but is tantamount in bioethical principles for informed consent, allowing a potential participant to weigh the pros and cons of participation. Risks to a family member potentially include pain or discomfort if a blood sample is taken, sample loss, and inadvertent disclosure of personal or genetic information. Importantly, genetic tests can reveal information that is private or unknown to the family. One recurring challenge in consenting for genetic analysis is that not all future risks and benefits are known at the time of the consent [31]. Relaying these risks in standard and in understandable language is essential for informed consent.

### 3.3.8. Confidentiality

As stated in the NDIS manual, Standard 11 of the FBI's Quality Assurance Standards requires “confidentiality for reports, case files, DNA records and databases, unless otherwise provided by Federal or State law” (pg. 30, [2]). Safeguards for confidentiality include: (a) the limited use of any provided information or data resulting from a DNA sample to missing persons' investigations; (b) nondisclosure of information and data except where required by law; and (c) processes to de-identify samples and data for database comparison purposes. The Privacy Act of 1974 only applies to collection of information by federal entities of U.S. citizens and legal permanent residents, so cannot be evoked by nonresident aliens or foreign citizens. Since DNA may be collected by law enforcement from family members outside the U.S. or undocumented residents, we thought it important to note this on a consent form. Furthermore, the Privacy Act would not apply to DNA collected outside of a U.S. government agency for a private database.

### 3.3.9. Costs

While costs normally are not the responsibility of the family member providing a reference sample, we added this element to clarify for potential participants the potential costs that may be accrued in some cases.

### 3.3.10. Reporting

In the U.S., a death certificate confirming the identity of an unidentified person can be issued only by a medicolegal authority of each jurisdiction (such as the Medical Examiner or Coroner) (pg. 59, [2]). For this reason, we added an element that notes the limitations for organizations collecting DNA for private databases to be able to report to families without confirming first through the legal authorities. The Privacy Act requires that authorities “make reasonable efforts to serve notice on an individual when any record on such individual is made available to any person under compulsory legal process when such process becomes a matter of public record” [28]. In missing persons' cases, authorities are obligated to “make reasonable efforts” to notify relatives of the missing person of the association since it will become public record on a death certificate. In some cases the jurisdiction may withhold information if the family member is under suspicion of a crime associated with the identification. The ICRC suggests that the family members be consented as to “how they will receive information during the identification programme,” implying a need to describe the reporting process at the time of FRS collection (pg. 43, [21]).

### 3.3.11. Contact information

The ICRC recommends that participants be “given contact details in case they want to ask questions or withdraw from the programme” (pg. 43, [21]).

### 3.3.12. Acknowledgment

We used opt-in language to permit a participant the flexibility to select aspects for which they would agree to participate.

## 3.4. Preliminary field testing for readability

Of the 141 students starting the survey of the first version of the consent documents, 93 participants completed the survey, for a 66% completion rate. Qualitative data from all responses informed trends in adjusting the language for the second versions; only the 93 completed responses were used for readability and option selection analysis. We received 197 responses in the general population pilot of the altered language. Participants in both rounds indicated satisfaction with the readability of the language. In the first versions pilot, participants provided 123 comments that we reviewed; 56 of these comments resulted in language adjustments to the consent form and/or FAQs. Complexity of the language following revision increased in the second versions (see Table 3). Nevertheless, participants in both surveys

**Table 3**  
Readability of Model Consent Language.

CHARACTERISTIC	MEASURE	RESULT			
		1st Version		2nd Version	
		Consent	FAQs	Consent	FAQs
Readability	Flesch-Kincaid grade level	11.6	11.9	12	12
	Flesch reading ease	45.1	41.5	42.2	39.5
	Passive sentences	33%	41%	32%	43%
Complexity	Sentences per paragraph	1.7	4.1	1.8	4.3
	Words per sentence	18.7	18.7	19.5	19.2
	Characters per word	4.9	5.1	5	5.1
	Length				
Length	Characters	9870	6039	11,583	7298
	Words	1976	1157	2286	1400
	Sentences	100	62	111	73
	Paragraphs	67	15	69	17
	Pages	5	3	6	3

Statistics calculated using tools available in Microsoft Word for Mac 2011 (Version 14.7.2, Redmond, WA). Readability tests are based on the average number of syllables per word and words per sentence. The Flesch Reading Ease test rates text on a 100-point scale; the higher the score, the easier to understand. The Flesch-Kincaid Grade Level test rates text on a U.S. school grade level.

indicated that the sections were clear and sufficient to make their selections (see Fig. 1). In response to the feedback on the first survey, we separated the permission to share DNA profiles in other countries with private laboratories versus law enforcement units into two questions on the second survey.

3.5. Preliminary field testing for agreement

Participants in both pilots were invited to agree (or disagree) to the hypothetical provision of consent as though providing a FRS for a missing persons database. Table 4 describes the outcomes of the participants’ willingness to agree to various aspects of the consent and Fig. 2 demonstrates the differences in choices. Overall students in the first survey were more likely to agree to the options than the general population in the second survey. The greatest differences were found in the respondents’ willingness to share their DNA profiles with other countries, both for law enforcement (students’ survey 1–77% vs. general population survey 2–60%, *P* value = 0.004) and private laboratories (students’ survey 1–72% vs. general population survey 2–44%, *P* value = 0.000). Among the general population respondents, this finding was reflected in the breakdown by education levels. Of the respondents with a high school education or less, 50% were willing to authorize sharing their DNA profile with a law enforcement laboratory in another country compared to 65% of college-educated respondents (*P* value = 0.0477). Conversely, high school graduates and college-educated respondents were similarly willing to authorize sharing their DNA profile with a private laboratory in another country (43% and 44.5% respectively; not significant with a *P* value = 0.873). Responses in this category indicate minor differences for this question in whites versus non-whites (law enforcement – 63.1% vs. 44.8%, *P* value = 0.0628; private – 42.9% vs. 51.7%, *P* value = 0.379). While some statistically significant differences were seen in white students versus non-white students for these choices, the significances did not hold in the larger general population survey. No other statistically significant differences were noted among other demographic factors for either survey.

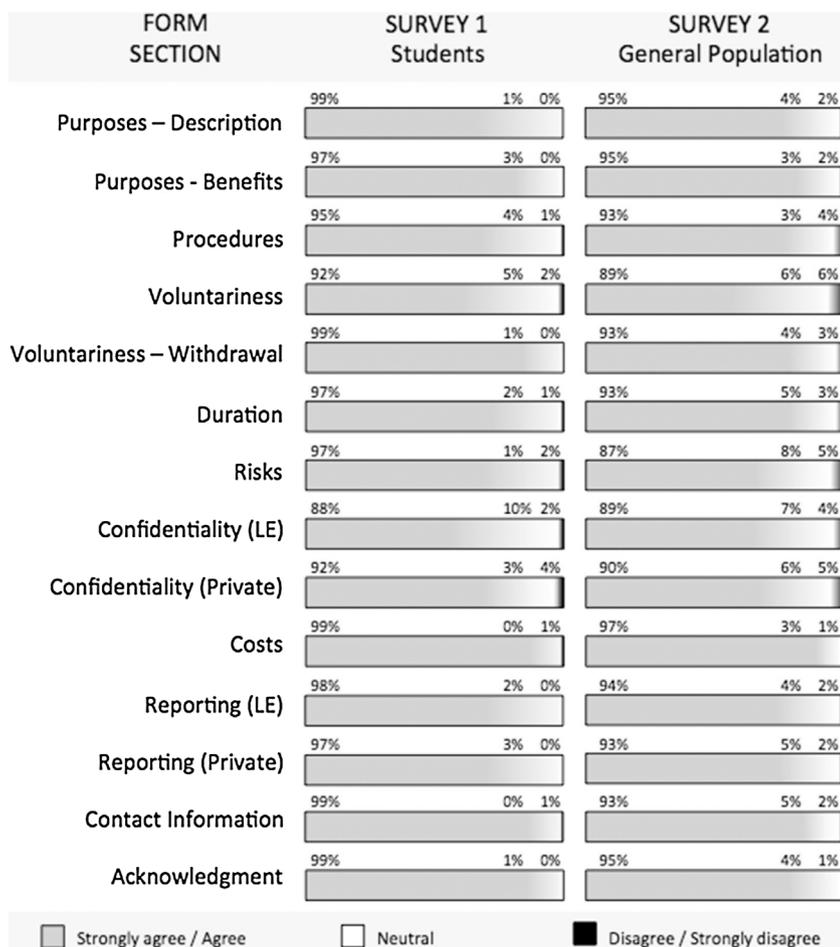


Fig. 1. Participant reaction to model language. Participants were asked to rate their overall satisfaction with the clarity of each section of the consent form on a 5-point Likert scale of strongly agree (SA), agree (A), neither agree nor disagree (N), disagree (D), strongly disagree (SD). In the first survey, no participant selected “strongly disagree” for any section. In this figure, the gray bar is weighted from left to right, SA – SD. The black portions of each bar indicate the proportion disagreeing and the white portions of each bar indicate the proportion of neutral responses.

**Table 4**  
Ordinal regression results comparing strength of agreement to participate between students and general population sample sets.

CONSENT STATEMENT	RESPONSES (%)		P value
	Students N = 97	General population N = 197	
I authorize the AGENCY/ORGANIZATION listed above to collect my DNA sample for the purpose of identifying my missing family member. I authorize my DNA profile to be entered into the Relatives of Missing Persons Index of the Combined DNA Index System (CODIS), and searched against the Unidentified Persons Index of CODIS. CODIS is maintained by the FBI under authority of Title 42, United States Code, Section 14132.	91 (98%) 88 (95%)	182 (92%) 172 (87%)	0.064 0.056
I authorize my DNA profile to be entered into the DNA DATABASE listed above to be compared with DNA profiles from unidentified persons in this database. I authorize my DNA profile to be shared with law enforcement missing persons databases in other countries. I authorize my DNA profile to be shared with databases in other countries. <sup>a</sup>	89 (96%) 72 (77%)	171 (87%) 119 (60%)	0.020 0.004
I authorize my DNA profile to be shared with private missing persons databases in other countries.	67 (72%)	87 (44%)	< 0.001
I authorize the use of my DNA profile in an anonymous population database. The database will not contain any of my personal information, and the DNA profile cannot be associated with me as the donor.	86 (92%)	161 (82%)	0.016
NOT ASKED	-	157 (80%)	-

<sup>a</sup> Provided options: law enforcement only, private only, neither, or both.

#### 4. Discussion

The FRS consent form elements and language resulting from this study may be applicable for developing consistent processes and guidelines governing the collection of DNA following a mass fatality or in missing persons' casework. The language we developed was found to be generally acceptable by the majority of respondents, with minor feedback from both pilot surveys. Student feedback informed changes that were implemented prior to fielding the form to the general population. These changes may have added complexity to the form, which subsequently may have affected the general population's reaction to the language and willingness to participate, hypothetically. Nevertheless, both the students and the general population were satisfied with the readability of the information in the form.

Our hypothetical pilots revealed some differences in respondents' willingness to participate in the FRS collection. The individual respondents in this research scenario are not under emotional duress due to a missing loved one, nor are they under pressure to participate, so the figures presented here likely are far below the realistic numbers expected from an actual mass fatality or a missing person's case. However, the trends are informative for planning informed consent and indicate which topics may require additional protections and reassurance to optimize participation, depending on the context of the scenario necessitating FRS collection.

Interestingly, student respondents seemed to be more lenient with authorizing the use of their DNA than the general population, perhaps since most were white and college-educated, or perhaps because of their age and lack of real-world context or experience. In our limited population (97 respondents) we noted a relative difference between white and non-white students in willingness to participate; further exploration of the race differences will be essential for future engagement of non-white populations in FRS collection. Of note, in the general population survey, white respondents were more likely to trust law enforcement organizations in other countries than private organizations, while non-whites trusted private agencies more than law enforcement. For both scenarios, the option of sharing DNA profiles with either organization in other countries resulted in less agreement and in numerous comments questioning the reasons for sharing. Significant work is necessary to ensure that consent is truly informed and complete when considering the sharing of genetic profiles across borders with either type of organization. It is clear from these data that respondents have differences in trust between a private organization and a law enforcement agency, so teasing out these differences and what information is necessary to communicate with participants will be important to document.

In our review of existing processes, we noted a few key differences. With one exception (the NGO providing form H has the most comprehensive informed consent process), the NGO forms were sparse in information pertinent to collection and retention of a DNA sample. These forms, however, were broadly designed for collection of a vast amount of ante-mortem information beyond DNA, so were not inadequate for their intended purpose. In most instances, these organizations did not have a specific intake form for private DNA collection; however, in some cases they partner with law enforcement organizations.

One difference in policy noted between the supplied forms and review of guidelines is how to handle incidental findings and participant access to information. Some organizations recommend that family member participants have access to relevant information in their cases, with little guidance on how to define relevance [21]. Other organizations consider unfettered return of genetic information an ethical risk, especially when misattributed parenthood could be revealed [1]. In developing informed consent processes, clarifying the policies of the organizations in charge and justifying the reasoning for these policies is important for participants' full understanding of their own risks and risks to their extended families.

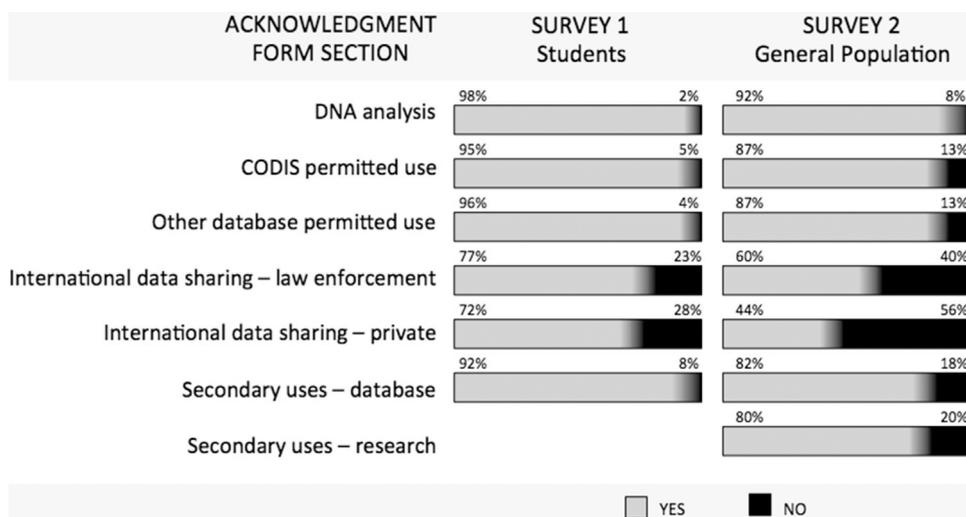


Fig. 2. Participant hypothetical agreement to consent. Participants were asked to agree or not agree to provide a DNA sample, under the mock circumstance that a family member is missing. In this figure, the gray bar is weighted from left to right, YES – NO, with the gray indicating willingness to consent and the black portions of each bar indicating the proportion not agreeing to consent.

## 5. Conclusion

The elements we devised build upon a plethora of guidelines and existing consent forms and processes, with a modest attempt to simplify and streamline information into laymen terms. Existing programs and processes already follow much of what we recommend here. Every organization must consider the legal and institutional standards that apply to their cases, the processes specific to their logistical workflow, and the cultural differences among the populations with which they work. The language developed here is not intended to be complete or stand-alone, but rather to be foundational recommendations for the scope of information important to relay to family members providing DNA samples and suggestions for wording for a complete informed consent process. Further, consent of an individual person to provide a DNA sample should not be the end of their engagement with the organization. It is important that continuing engagement (potentially a rolling consent in some cases) as outlined in a consent form allows participants to be a part of the process, to withdraw permissions, or to ask questions of the organizations administering their data. Most family members approached for providing a DNA sample will be under duress and at risk of coercion, which places the prospective participants in a vulnerable situation. They may not understand or fully comprehend the selections they have made or even remember the information provided at the time of consent [37]. Information provided must be written, detailed, and include contact information for future inquiries, and signed consent agreements should be provided to the participant for future reference. Further, some populations may be more vulnerable than others, for instance family members of missing migrants, homeless persons, children, or teenagers. These populations should be considered vulnerable and future pilots of informed consent processes are essential for determining how information is comprehended and participants' concerns with processes.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.fsigen.2017.10.011>.

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