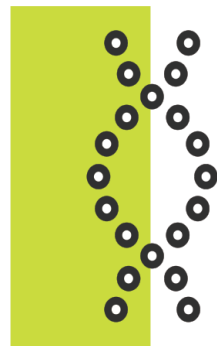
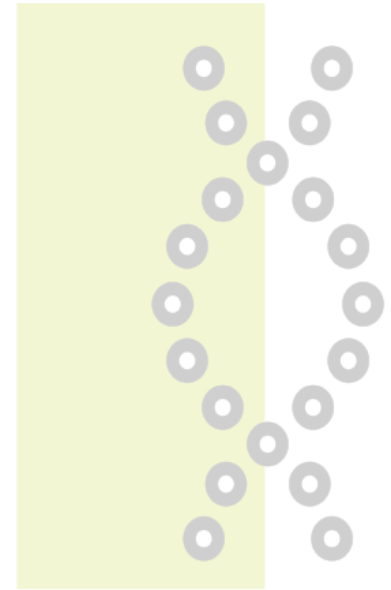
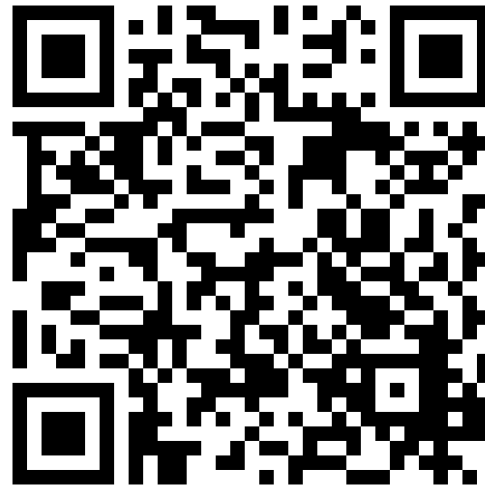


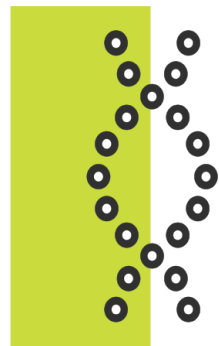
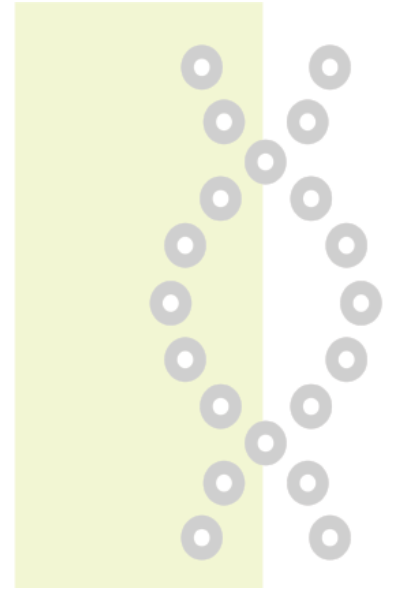
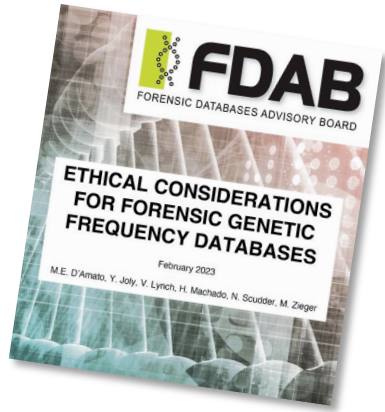
Program:



FDAB

FORENSIC DATABASES ADVISORY BOARD

Full Report:

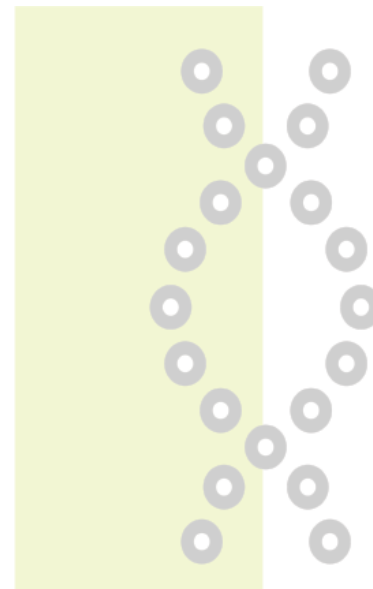


FDAB

FORENSIC DATABASES ADVISORY BOARD



Dr Vanessa Lynch
DNA for Africa, GTH–GA, South Africa



ETHICAL CONSIDERATIONS FOR FORENSIC GENETIC FREQUENCY DATABASES

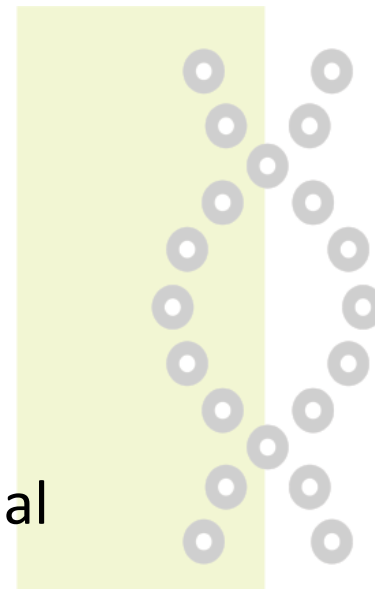
OVERVIEW OF THE FIRST REPORT
BY THE FDAB

Budapest, Hungary 18 May 2023

DISCLAIMER: In undertaking this ethical assessment, neither the FDAB nor its members are providing legal advice. The observations and commentary of this group must be interpreted with due regard to legislation applicable in each country.

Overview of the Report

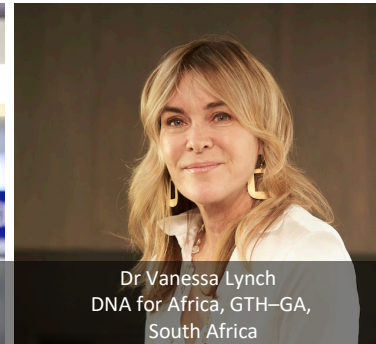
- Mandate and Objectives
- FGFD – the data held and their mandate
- Methods, Legal Frameworks and International Guidelines
- Legacy Data
- Vulnerable Populations
- Risk Assessment
- Conclusion



BOARD MEMBERS

ABOUT US

- Independent* advisory board
- Established January 2022
- Provide evidence-based ethical advice to ISFG

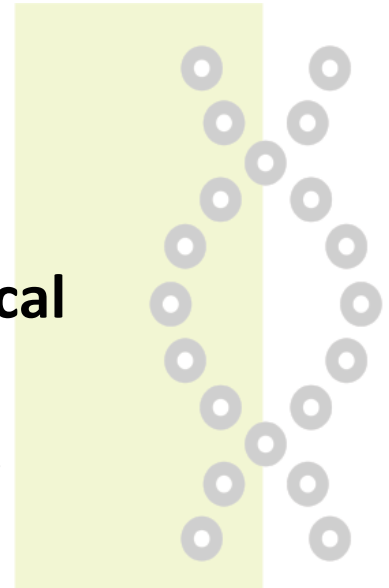


*None of the members of the FDAB have financial or other arrangements with the ISFG that would constitute a conflict of interest to report.



Our Mandate

- Provide ISFG with a **framework to assess the ethical implications of hosting data from a variety of population groups on the FGFD** [Forensic Genetic Frequency Databases*]
- Discuss the **ethical challenges** raised in respect of the FGFD
- Define the **ethical criteria and outline the processes** for FGFD to be curated, maintained, accessed and utilized by the forensic community

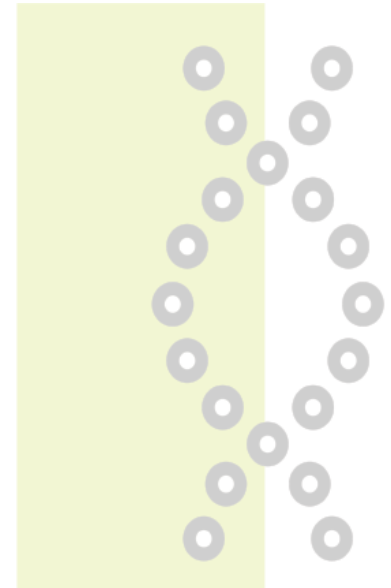


*NOTE: only the non-commercial, European based YHRD, EMPOP and STRidER genetic frequency databases were reviewed for the purposes of this report

Objectives:

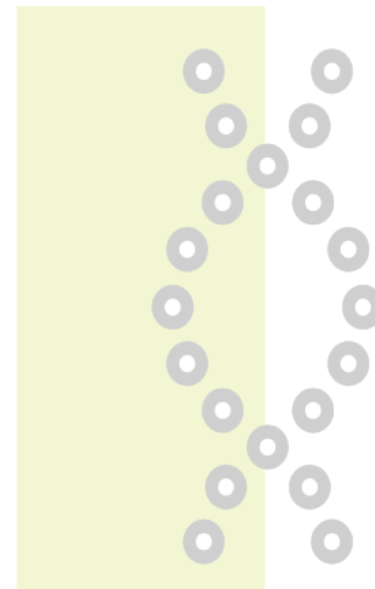
First Report of the FDAB

- **PRESENT an overview**
 - of the **composition, contributions, access, control** and **utilization** of the various FGFD
- **OUTLINE a methodology**
 - to **evaluate the compliance** of sampled population data in the FGFD
- **SUBMIT guidelines**
 - to **identify** and **assess the ethical conformity** of data residing on the FGFD (eg. data privacy, informed consent, sensitivity of data)
- **PROPOSE an ethical framework**
 - for the evaluation of legacy, contemporary and future contributions to the FGFD incl. retention practices and acceptance of data submitted to the FGFD.



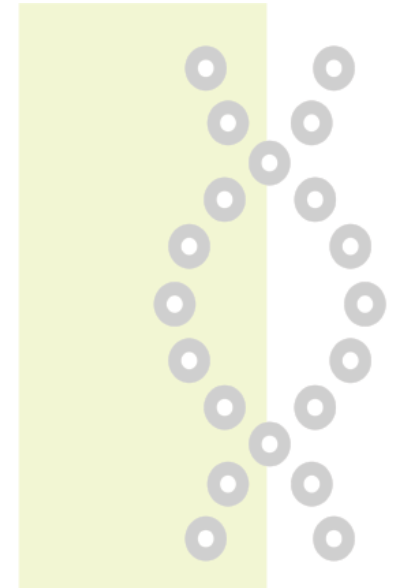


Dr Martin Zieger
Universität Bern, Switzerland



FGFDs - Purpose

- **Provide frequencies** of alleles or allele combinations (haplotypes) for:
 - Weight of evidence estimation
 - Kinship probability calculations
- **Quality control** of published datasets
 - FSI:Genetics, FSI:Reports, Int J Leg Med

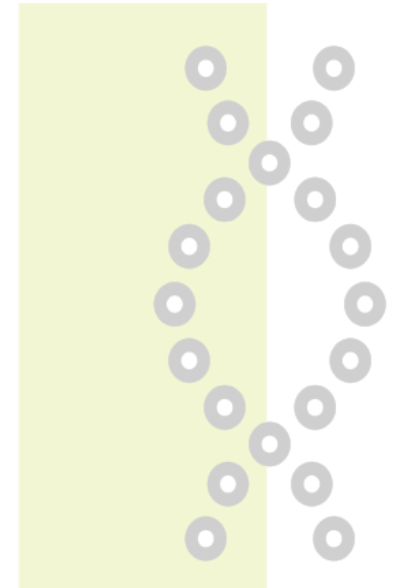


FGFDs - Structure

- **Genetic data without personal identifiers**
 - Grouped according to geography and linguistics
 - References to original studies

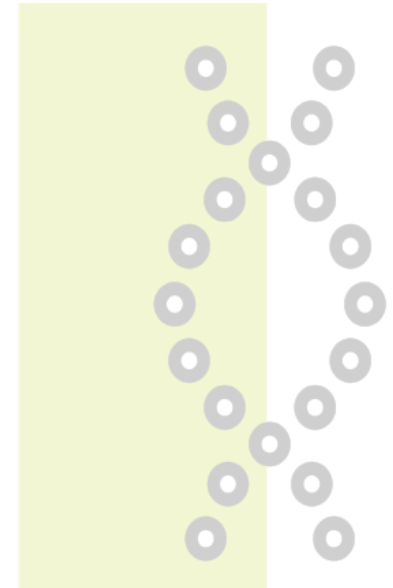
STRidER

- **Access**
 - Registration not required
- **Data type**
 - Autosomal STRs from ~10'000 individuals
- **Identifiability**
 - Impossible: Uncoupled, aggregated allele frequencies
- **Sensitivity (contained information)**
 - Very low (potential roles in gene expression)



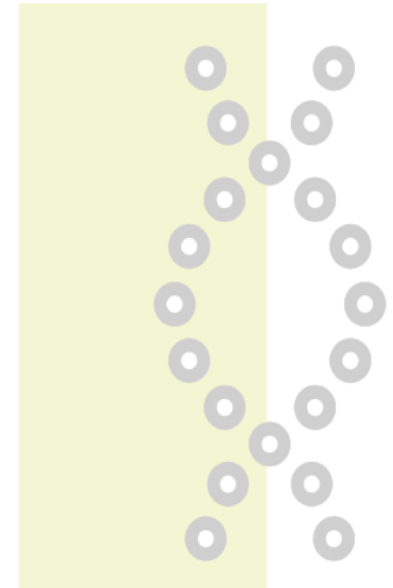
YHRD

- **Access**
 - Registration not required
- **Data type**
 - Y-STR haplotypes from ~350'000 individuals
 - Information on Y-SNPs (not searchable)
- **Identifiability**
 - Depending on original population study
 - (No. of markers, pseudo-/anonymisation, storage, study group)
 - Potential kinship inferences
- **Sensitivity**
 - Little medical information (infertility)



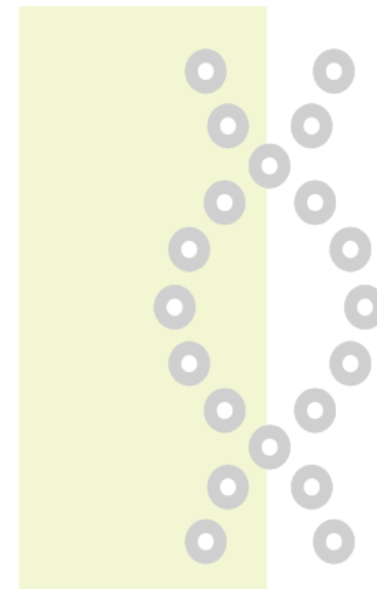
EMPOP

- **Access**
 - Registration required
- **Data type**
 - mtDNA sequences from ~50'000 individuals
 - Control region or full mitogenome (~9%)
- **Identifiability**
 - Depending on original population study
 - (CR or full mtDNA, pseudo-/anonymisation, storage, study group)
 - Potential kinship inferences (less than Y-STR)
- **Sensitivity**
 - Full mitogenomes carry medical information.



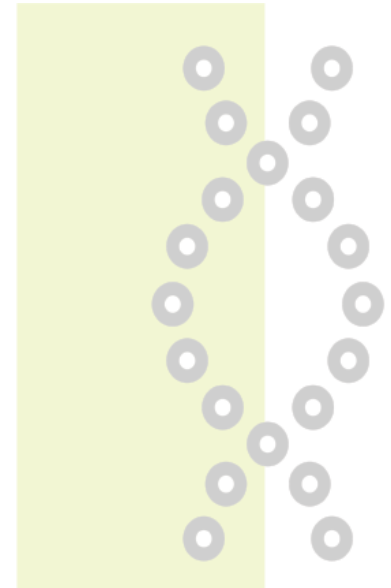
Data on FGFDs

- **Currently considered anonymized**
 - No personal metadata registered
 - Very little potential for re-identification
 - Large efforts needed (e.g., warrants)
- **Caution is advised**
 - Identification potential depends on the design of the original population study.
 - Increased data sharing in science
 - Increasing data linkage capacities
 - Data from the same individuals on different databases



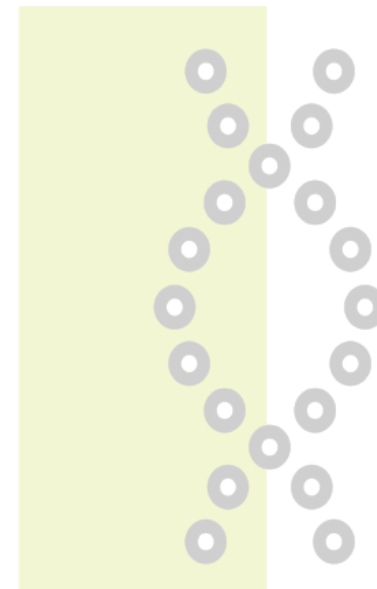


Prof. Yann Joly
McGill University, Canada



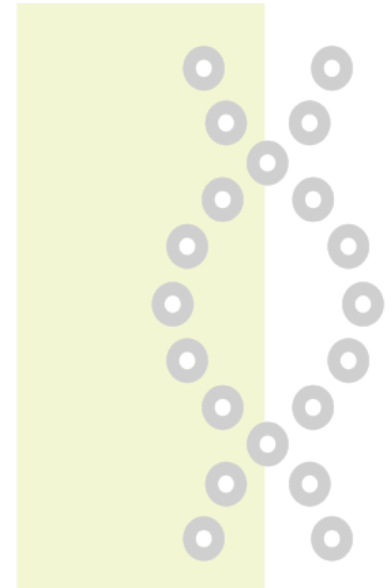
Methods

- **Literature review** (focus on group harm, privacy, ethics & consent issues associated with forensic genetic frequency databases (FGFD)).
- **Assessment of FGFD:** STRidER, EMPOP and YHRD.
- Identification of **applicable ethical principles**.
- Proposition of an **assessment strategy**.



Key ethical principles for research on human biological materials

- **Consent:** informed consent must be obtained prior to sample/data collection and sharing. Data subjects should be informed that it is for broad international sharing of their data.
- **IRB/ethics committee review:** depending on the data privacy safeguards applied, in some jurisdiction, IRB/ethics committee's approval is required for data sharing.
- **Privacy:** duty to reasonably protect identifiable or potentially identifiable personal data from data subjects. Legal and ethical requirements may apply differently depending on data privacy safeguards.

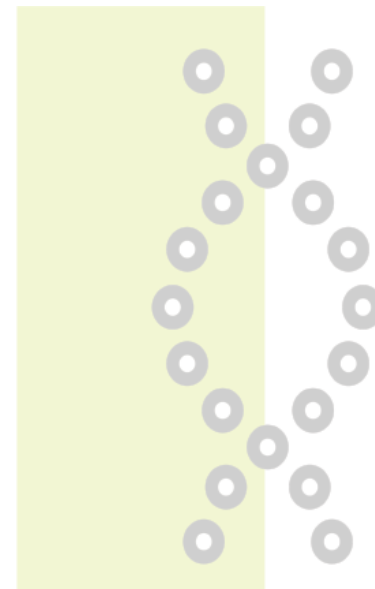


Key ethical principles for research on human biological materials

- **Non-discrimination:** prevent discrimination based on genetic characteristics, that are intended to infringe or have the effect of infringing human rights, fundamental freedoms, and human dignity.

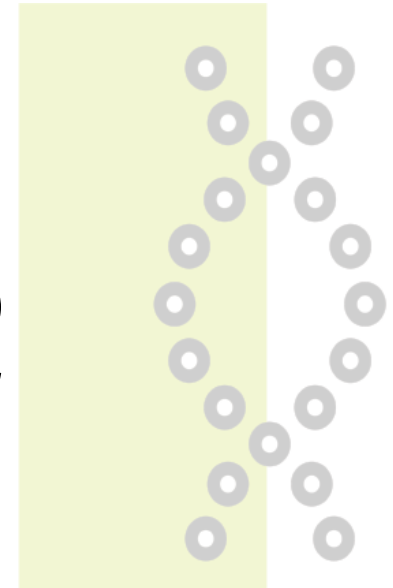
Ethical guidelines

- **Activity:** collection of DNA samples and data for future storage in a forensic open repository (could be used for a range of purpose including research).
- **Limitation:** we did not look at the GDPR, or at any other regional or national privacy legislation. Only internationally recognized ethics and governance texts were considered – not a legal assessment.
- **Date of adoption of each was a key consideration:** we cannot retrospectively apply ethical principles to events that happened before such principles were recognized by the international community.



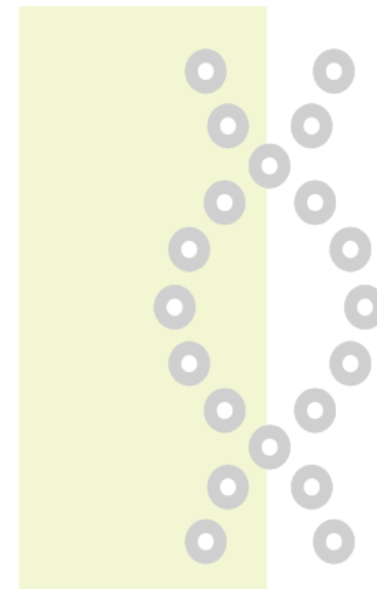
Ethical guidelines

- *Nuremberg Code 1947 (USGPO 1946-49)*
- *Declaration of Helsinki (WMA 1964 & subsequent versions)*
- *CIOMS Ethical Guidelines for Biomedical Research Involving Human Subjects (1993)*
- *HUGO, Statement on the Principled Conduct of Genetics (1995)*
- *HUGO, Statement on DNA Sampling: Control and Access (1998)*
- *UN, Universal Declaration on the Human Genome and Human Rights (1997)*
- *UN, International Declaration on Human Genetic Data (2003)*
- *ESHG, Data storage and DNA banking for biomedical research: technical, social and ethical issues (2003)*
- *FSI, Publication of population data for forensic purposes (2010)*
- *FSI, Ethical publication of research on genetics and genomics of biological material: guidelines and recommendations (2020)*



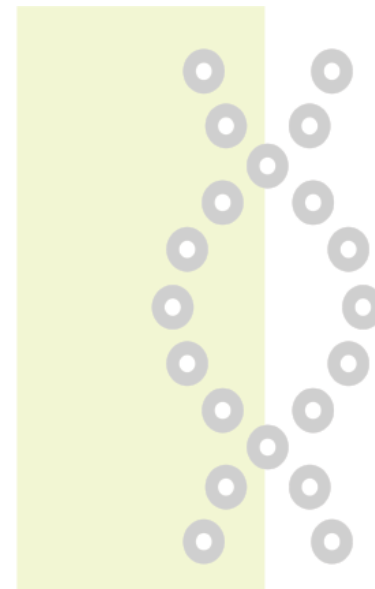
Ethical guidelines (key findings)

- Requirement for **informed consent** for ‘medical experimentation’ was recognized internationally in 1947 (Nuremberg Code) and reinforced by the *Declaration of Helsinki* in 1964.
 - Unclear whether this requirement applied to samples/data collected from human subjects for broad future use. This was clarified by HUGO in 1995 (and Helsinki in 2000).
- Requirement for **ethical review** appeared in Helsinki, in 1975 (same limitation as above) and, in the context of genetics, was introduced by the Universal Declaration on the *Human Genome and Human Rights* (1997).



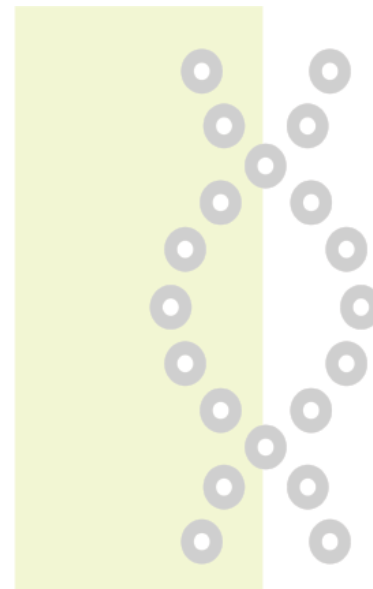
Ethical guidelines (key findings)

- In addition to these ethical requirements, it is possible that there existed additional **national legal requirements** on topics such as research, consent and privacy.
- **Privacy requirements** evolved on a spectrum: the right to privacy has been recognized for a long time, but sensitivity of samples/data has increased with our capacity to re-identify individuals and gather more information from said samples/data.
- Requirements may not have been widely known by the forensic community prior to 2010.



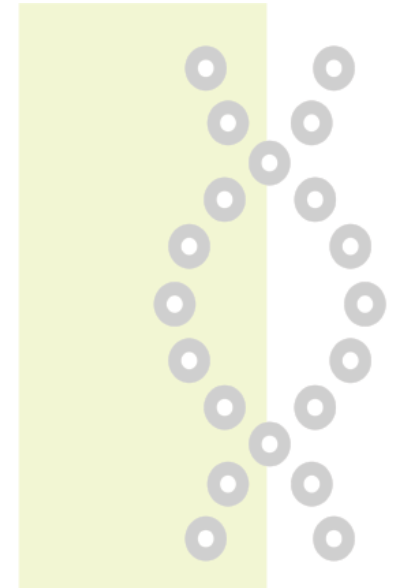


Adj. Assoc. Prof. Nathan Scudder
Univ. of Technology Sydney, Australia



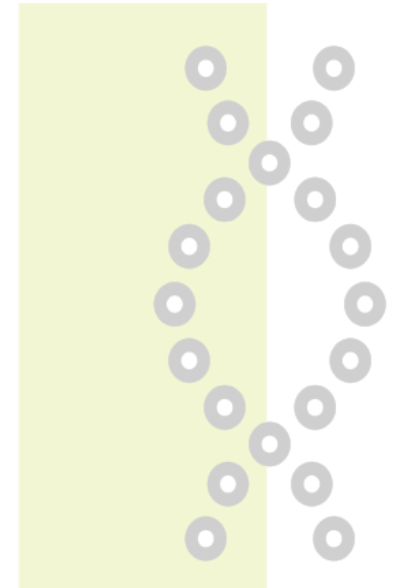
Legacy Samples

- **How to define**
 - German Research Foundation guidelines: defining a legacy sample as more than ten years old.
 - Latest *Forensic Science International: Genetics* guidelines (2020) suggest a more granular breakdown/assessment.



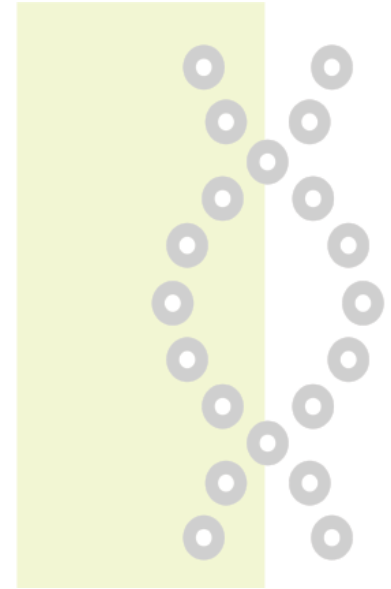
Legacy Samples

- **Conceptualising Legacy Samples**
 - Risk of infringement of ethical principles
 - Risk of re-identification
 - Source of samples
 - Provider of samples



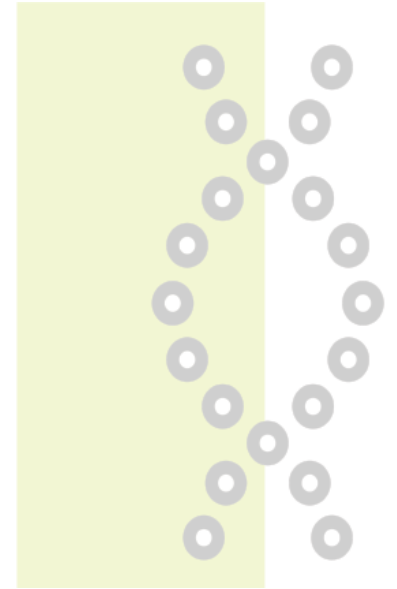
Samples collected pre-1964

- Collected prior to **Declaration of Helsinki** (Ethical Principles for Medical Research Involving Human Subjects)
- Re-identification risk may be lower
- Retrospective risk assessment may be unnecessary, although known misconduct could still necessitate removal



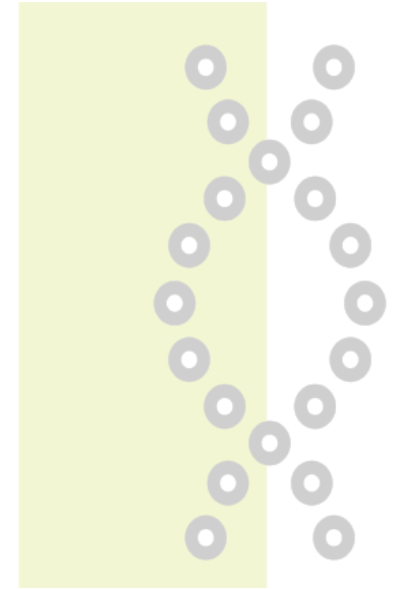
Samples collected 1964-1997

- **Declaration of Helsinki** in effect, but no universal framework for non-medical research
- Statements of consent and ethics boards not widely established
- Likely 're-purposed' samples for FGFD



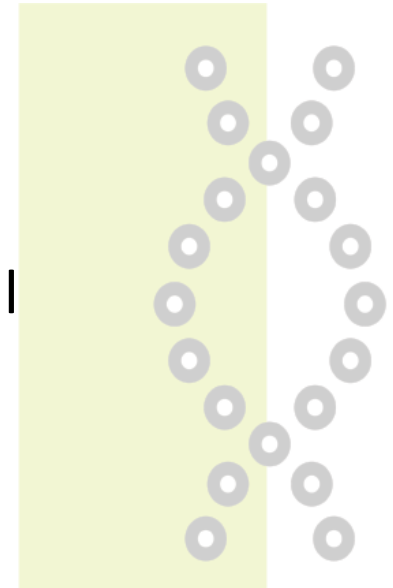
Samples collected 1997-2009

- New international agreements
 - 1997 **UNESCO Universal Declaration on the Human Genome and Human Rights** (non-binding)
 - 1999 **Oviedo Convention of the Council of Europe** (binding in 29 ratified states)
- Form of consent may be vague and Ethics Boards may not be universal.



Samples collected 2010-2020

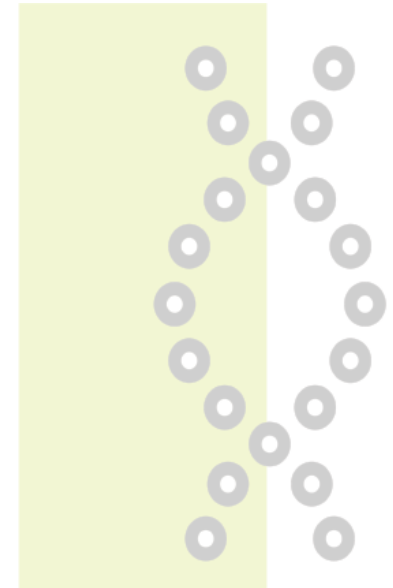
- Consent and Ethics Board requirements were well known, but potentially not well enforced.
- Incomplete records or lack of Ethics Board documentation may indicate high risk



Other considerations

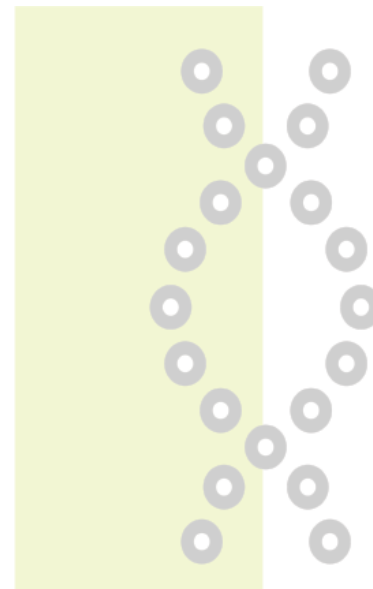
- Samples from **non-academic contributors**
 - Samples mandated by legislation
- UNESCO Universal Declaration on the Human Genome and Human Rights (1997):

“limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights”



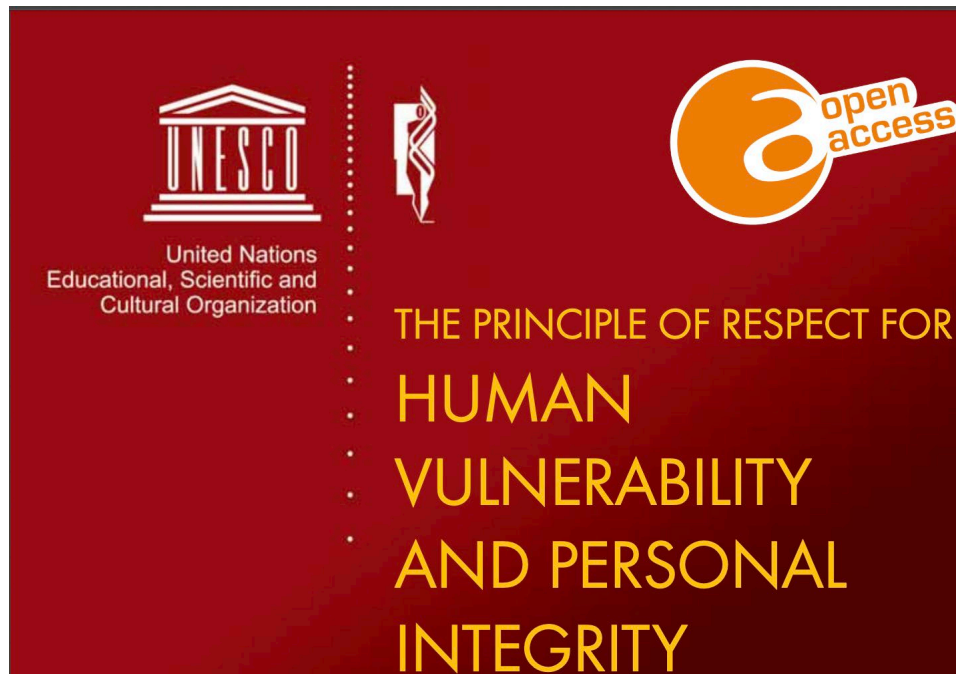


Prof. Helena Machado
University of Minho, Portugal



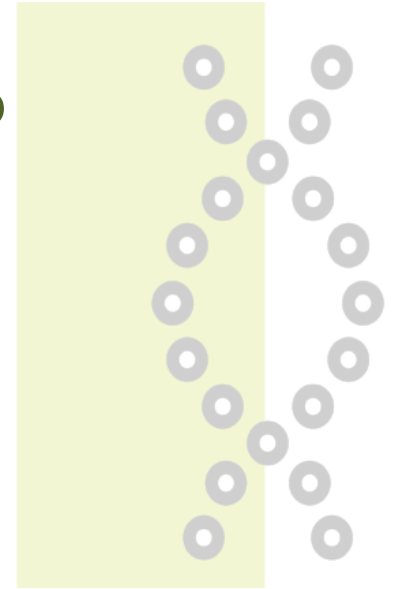
Vulnerable populations and minorities

- **The Principle of Respect for Human Vulnerability and Personal Integrity: report of the International Bioethics Committee of UNESCO (IBC)**



What are vulnerable populations?

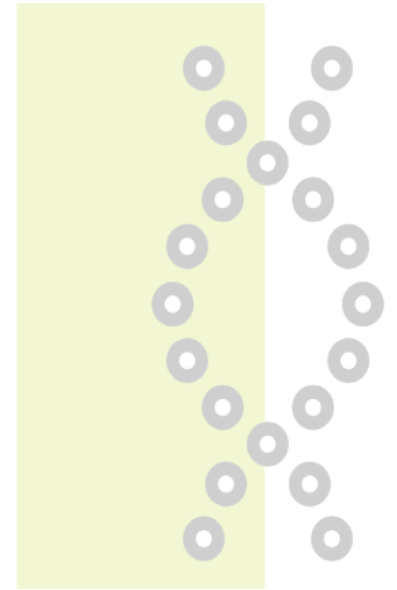
- To define vulnerability in general is risky
- Human rights, human dignity, and fundamental freedoms are at stake
- Examples: ethnic minorities tracked by the criminal justice system, populations historically subjected to data extraction...



Minorities

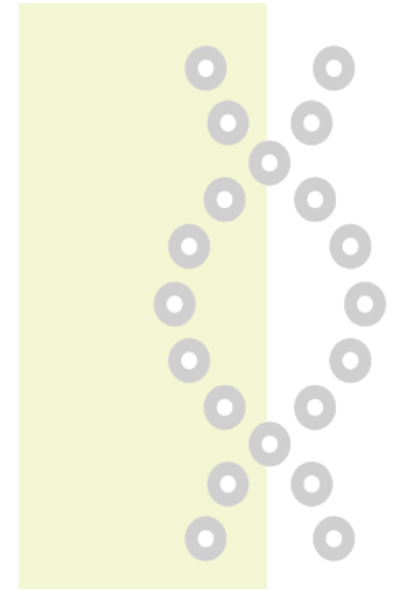
- **Francesco Capotorti definition (1977)**

“A group numerically inferior to the rest of the population of a State, in a non-dominant position, whose members - being nationals of the State – possess ethnic, religious or linguistic characteristics differing from those of the rest of the population and show, if only implicitly, a sense of solidarity, directed towards preserving their culture, traditions, religion or language.”



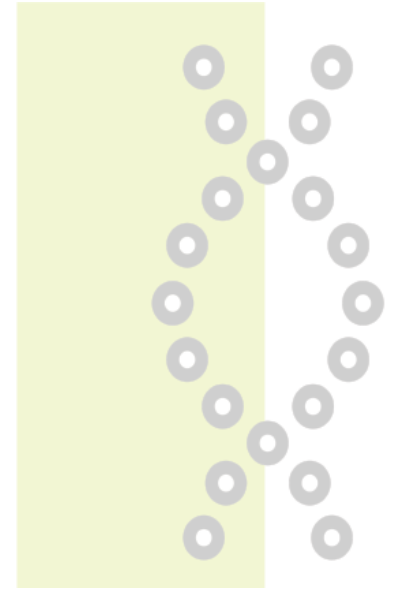
How to evaluate vulnerability?

- **Typical vulnerable categories of individuals** are children, patients, people subject to discrimination, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, etc.
- **Information to be provided for ethics clearance:**
 - a) Type of vulnerability
 - b) Details of the recruitment and informed consent procedures
 - c) Procedures to ensure donors of samples are not subject to any form of coercion and undue inducement





Prof. M. Eugenia D'Amato
Univ. of the Western Cape, South Africa



Risk Assessment Criteria

1. SCIENTIFIC VALUE

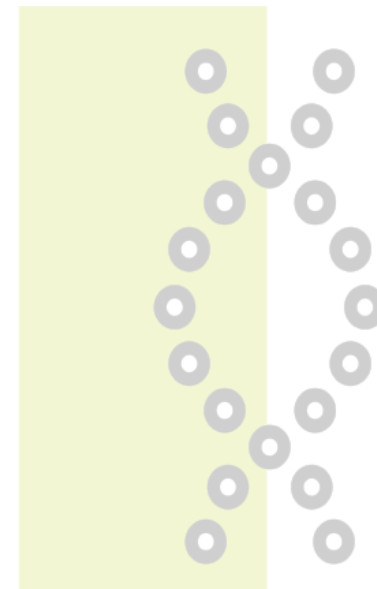
- Representative data / scarce data

2. DATA SUBMITTER

- Academic
- Non-academic direct submissions
 - Law enforcement
 - Private sector

3. ETHICS BOARD REVIEW STATUS

- National / Institutional RB approvals
- Informed Consent



Risk Assessment Criteria

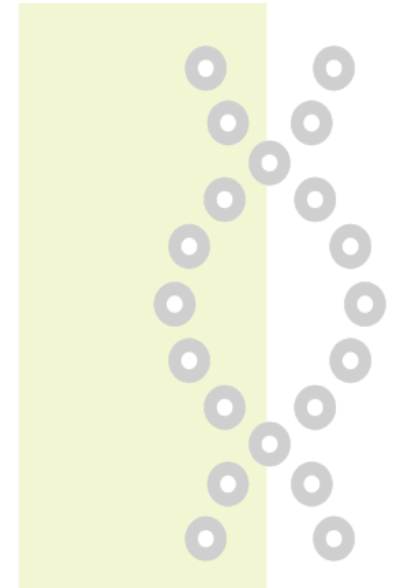
4. SOURCE OF BIOMATERIAL

- Voluntary participants
- Biobanks
- Undefined

5. STUDY DESIGN

- Identifiability
- Poor pseudonymization
- Data linkage
- Poor privacy rights

6. VULNERABILITY STATUS



Risk Assessment by Criteria and period

No Risk

Concern

Non-Ethical Concern

| | <i>Risk criteria</i> | | | | | | |
|---------------|----------------------|----------------------|------------------|----------------------|--------------------------|-------------------------|-----------------|
| Period | Consent | Board | Submitter | Source | Data availability | Scientific value | Minority |
| 0000-1964 | YES | YES | Academic | Voluntary donors | Published | Sound | YES |
| 1965-1975 | NO | NO | Commercial | Biobanks | Databased unrestricted | Poor | NO |
| 1975-1997 | NA | Incomplete statement | Law enforcement | Detainees, prisoners | Databased restricted | Obsolete | Unknown |
| 1998-2010 | Waived | NA | Unknown | Unknown | Direct submission | Unknown | |
| 2011-2020 | | Waived | | Other | | | |
| 2021-present | | | | | | | |

[Link to interactive table](https://uwcacza-my.sharepoint.com/:x:/g/personal/medamato_uwc_ac_za/ETqd-rlIJ2lFotGJz02a_WEBfpmXhaXdrQpJQEQ6oiwm1g?e=TH4UW2)

https://uwcacza-my.sharepoint.com/:x:/g/personal/medamato_uwc_ac_za/ETqd-rlIJ2lFotGJz02a_WEBfpmXhaXdrQpJQEQ6oiwm1g?e=TH4UW2



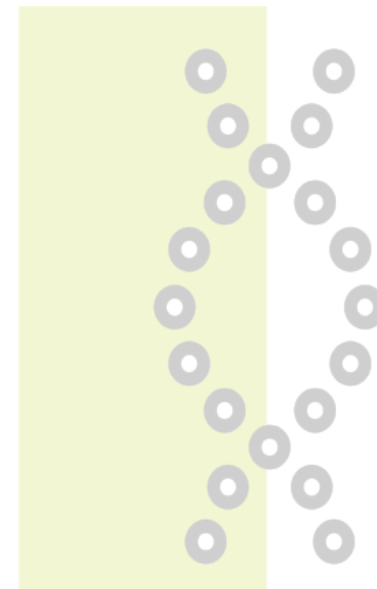
Recommendations

RISK SAMPLES

- Retention – retrospective waivers
- Discard

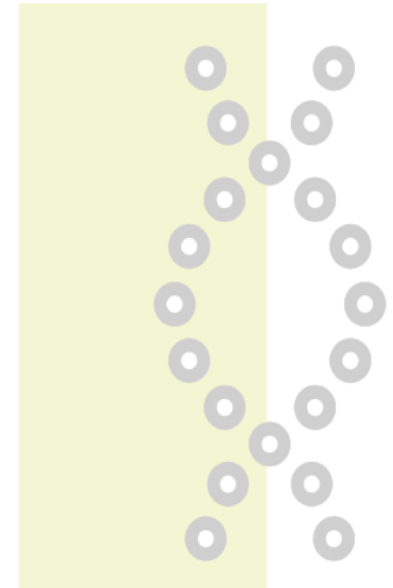
ADDITIONAL CONSIDERATIONS

- Registration of database users/Access criteria/TOU
- Disclosure of contributors-entry
- Assessment of vulnerability
- Examples of consent forms
- BGA: alert
- Transparency about data governance/ access criteria
- Audits
- ISFG support for curators
- Periodic reports from curators



Periodic Ethics Assessments

- Transparency: access, ethics approvals
- Consistency in ethical processes globally
- Consents and function creep, Identifiability
- Accountability deficits

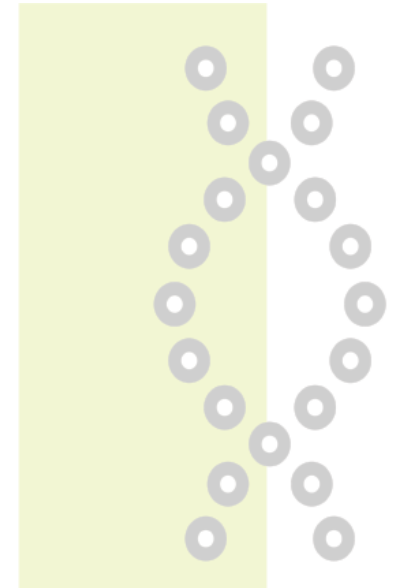


CONCLUSIONS

- **Balance benefits vs risks**

Promotion of justice
Public interests

Human rights
Ethical principles
in research

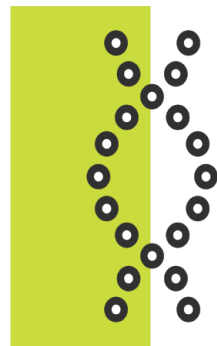
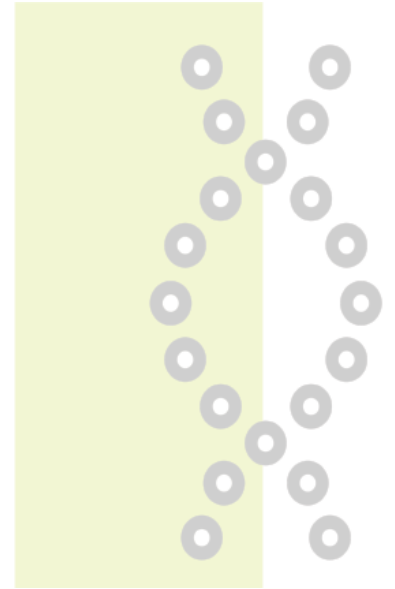
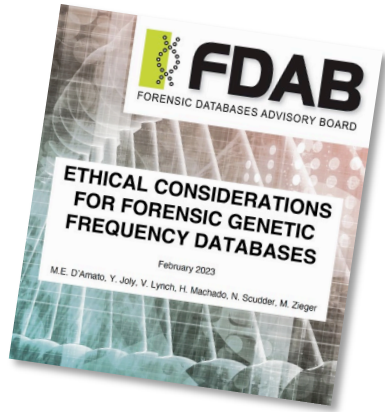


- **Further debate on**

- Acceptable forms of consent
- Societal issues, public interest, impact on minorities, novel technologies

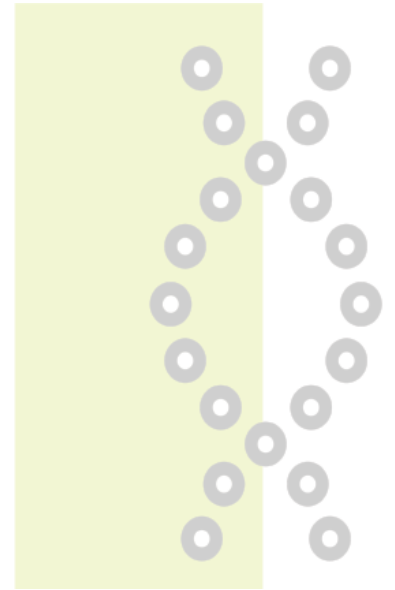
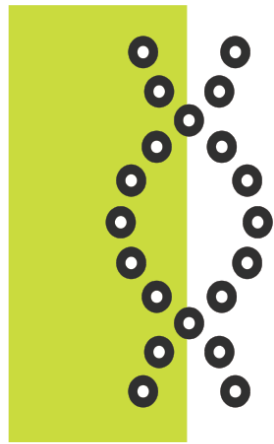
This report constitutes a foundation for further debate on current and emerging ethical challenges on the FGFD

Full Report:



FDAB

FORENSIC DATABASES ADVISORY BOARD



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