



Ethical Issues in Biobanking

Nordic Biobank Conference 2022

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Conflict of Interests

- **No conflicts to disclose**

Biobanks

- Allow researchers access to material & data from large numbers of people.
- Support many types of studies:
 - Genetics of disease
 - Biomarker discovery
 - Drug discovery
 - Personalized medicine
 - Emerging infectious disease
- An important resource in medical research!



So why do Biobanks Create Unique Ethical Challenges?

- Truly informed consent difficult
 - Single specimen may be used for multiple studies & stored for long time
- Protection of privacy very important
 - Large amounts of private health data from many people collected
 - Genetic information
 - Return of results
- Trust hard to achieve
 - Transparency
 - Data/specimen sharing
 - Financial interests & equal access to benefits



Gronowski. *Clin Chem* 2019;65:1497-1507

Foundation for Medical Ethics

Nuremburg Trials

NORDIC Biobank
Conference



Evolution of Modern Medical Ethics

1947

Nuremburg
Code

Set of ethical principles for
human research

Nuremburg Code-1946

- voluntary, well-informed, consent of subject.
- experiment aims at **positive results** for society that cannot be procured in another way.
- based on previous knowledge that **justifies the experiment**.
- avoids unnecessary physical and mental suffering and injuries.
- should **not be conducted** if risk of death or disabling injury.
- risks should be in **proportion** to expected benefits.
- adequately **protect the subjects** against the experiment's risks.
- staff must be fully trained and **scientifically qualified**.
- subjects must be free to quit the experiment at any point.
- **staff must stop** when continuation would be dangerous.



Evolution of Modern Medical Ethics

1947

Nuremburg
Code

Set of ethical principles for
human research

1948

Declaration
Geneva

Physician's oath intended as a revision of the
Hippocratic Oath

Declaration of Geneva-1948

At the time of being admitted as a member of the medical profession:

I solemnly pledge

to consecrate my life to the service of humanity;

I will give

to my teachers the respect and gratitude that is their due;

I will practice

my profession with conscience and dignity;

The health of my patient

will be my first consideration;

I will respect

the secrets that are confided in me, even after the patient has died;

I will maintain

by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues

will be my sisters and brothers;

I will not permit

considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

I will maintain

the utmost respect for human life;

I will not use

my medical knowledge to violate human rights and civil liberties, even under threat;

I make these promises

solemnly, freely and upon my honour.

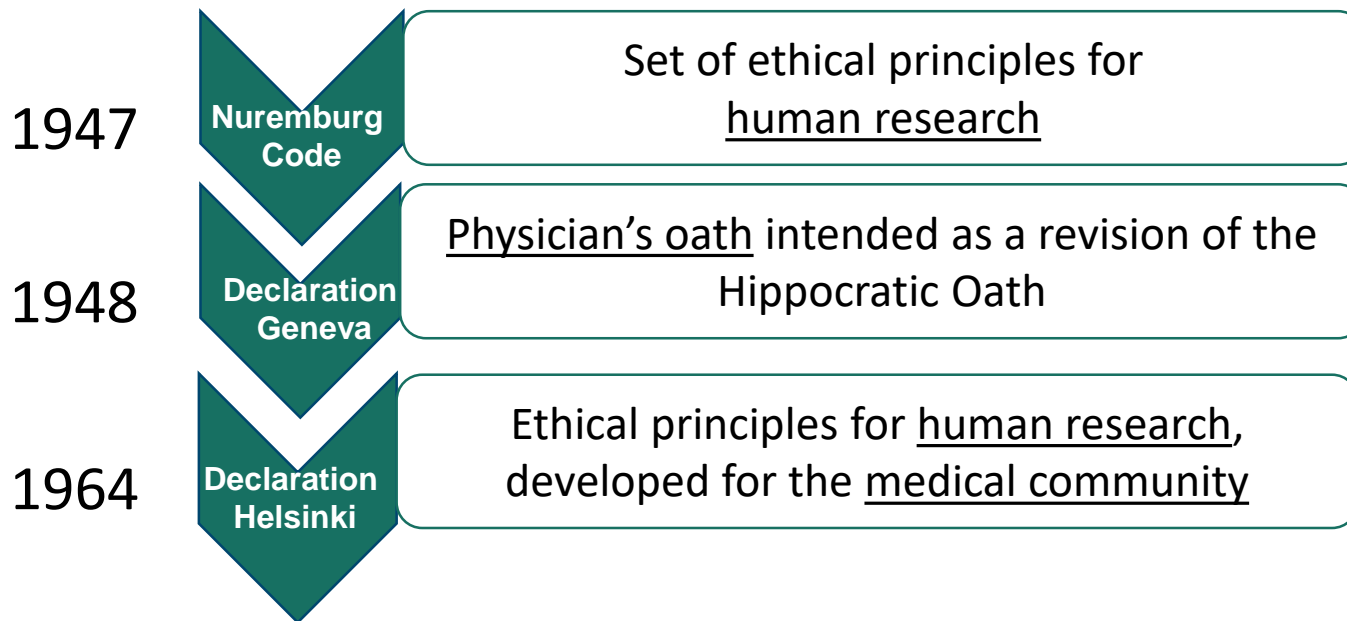
Justice

Do good

Respect for Persons

Do no harm

Evolution of Modern Medical Ethics



Declaration of Helsinki-1964

- The **well being of the subject** prevails over the interests of science and society
- **Consent** should be in writing
- Introduced the concept of **oversight** by an independent committee
- Use caution if participant is in **dependent relationship** with researcher
- Limited use of **placebo**
- Greater **access to benefit**



Fundamentals of Biomedical Ethics

Respect for Persons:

Protecting the autonomy of all people & treating them with respect & allowing for informed consent. Researchers must be truthful. No deception.

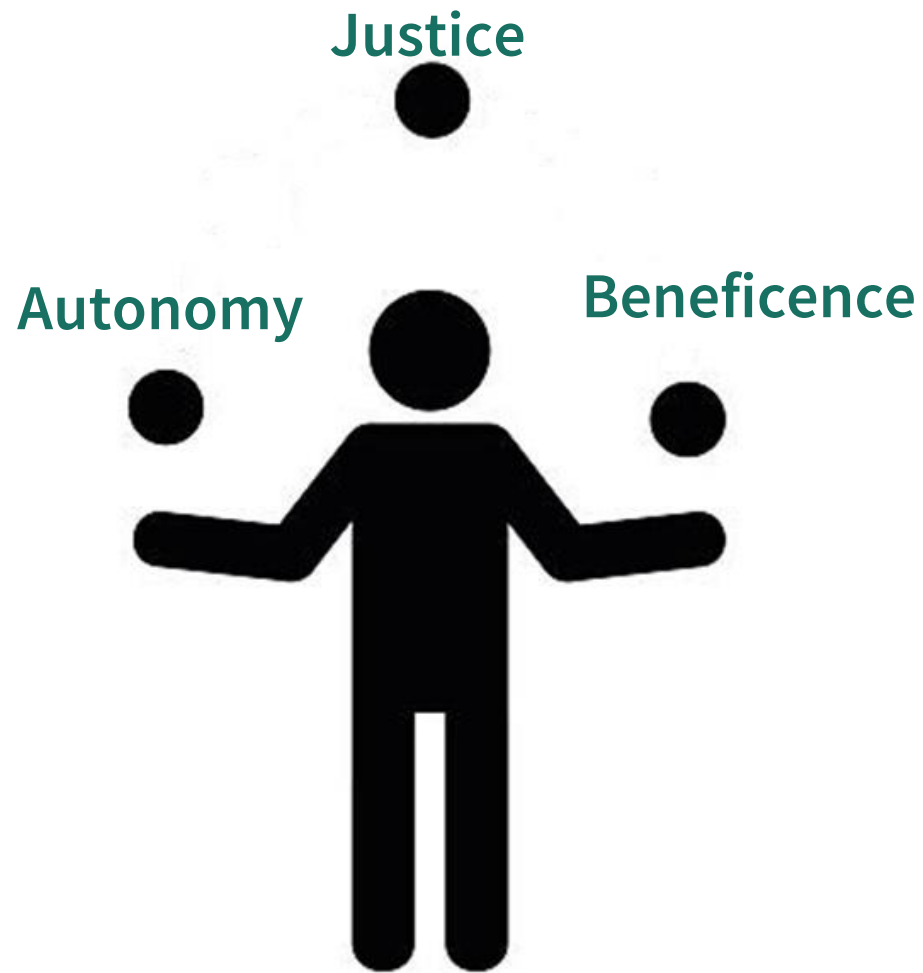
Beneficence:

Doing good. Maximizing benefits & minimizing risks to the research subjects.

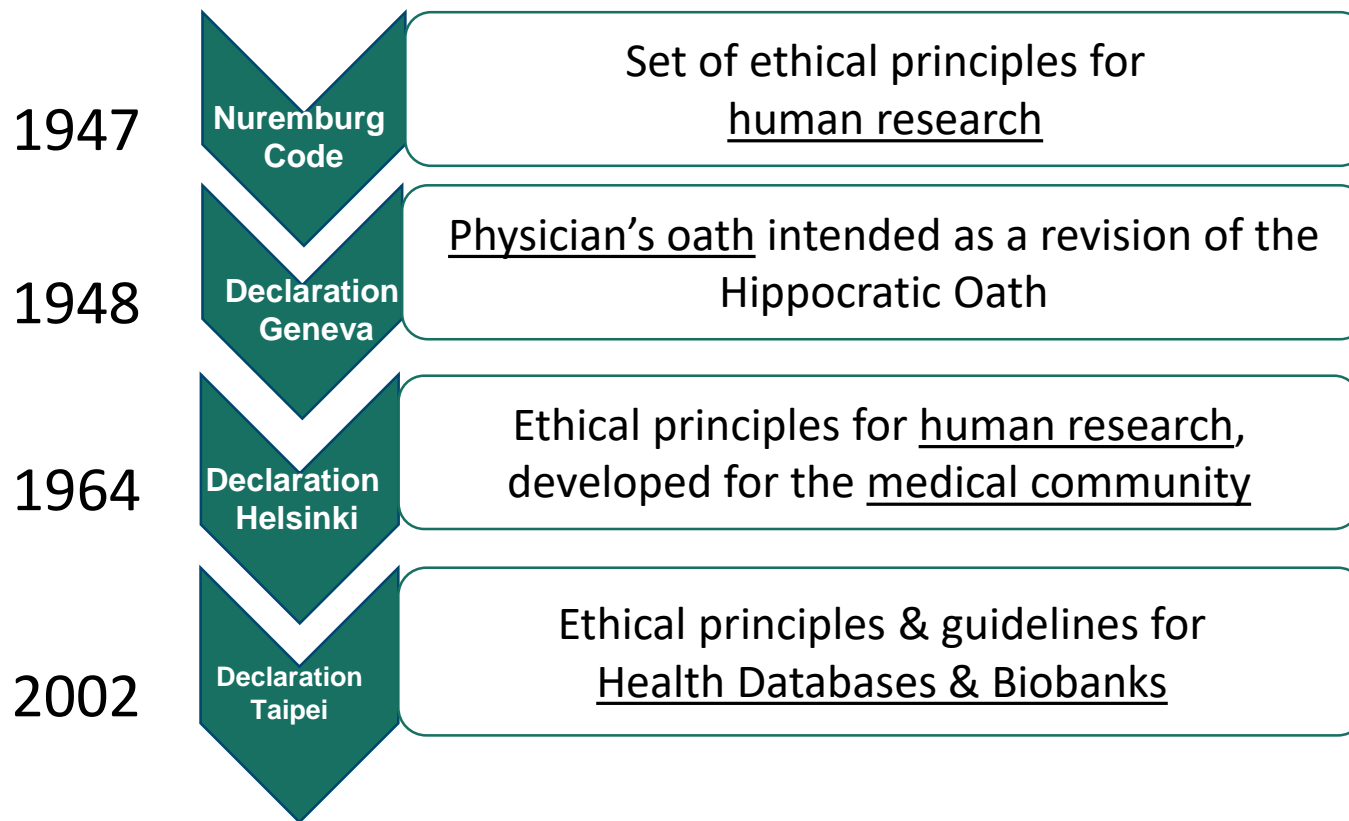
Non-maleficence = Do no harm

Justice:

Fair distribution of costs & benefits to subjects equally.



Evolution of Modern Medical Ethics

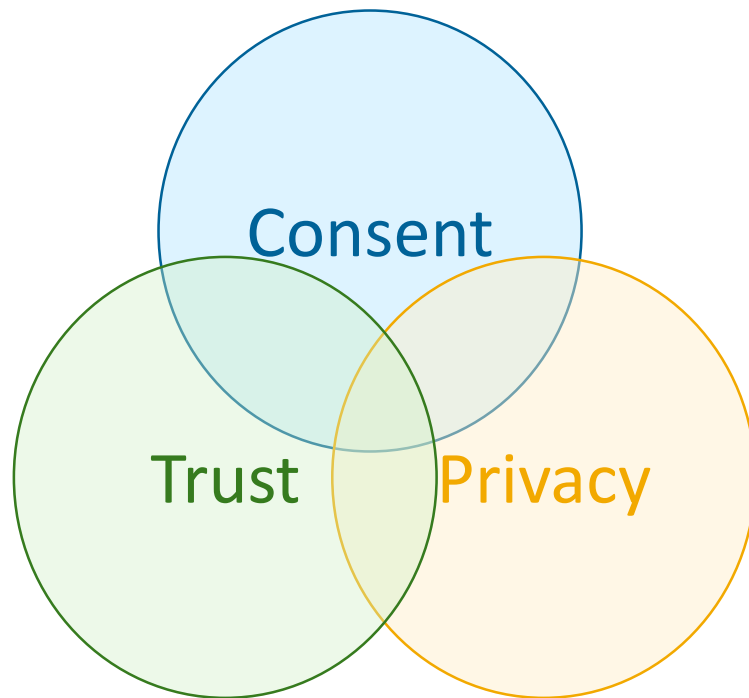


Declaration of Taipei-2002

- Defines health data bases and biobanks
- Importance of data privacy & confidentiality
- Consent must be voluntary & explain purpose, risks, incidental findings, how data is being used & right to withdraw
- Must use an oversight committee
- Elements of governance such as security, specimen/data disposal, transfer of materials

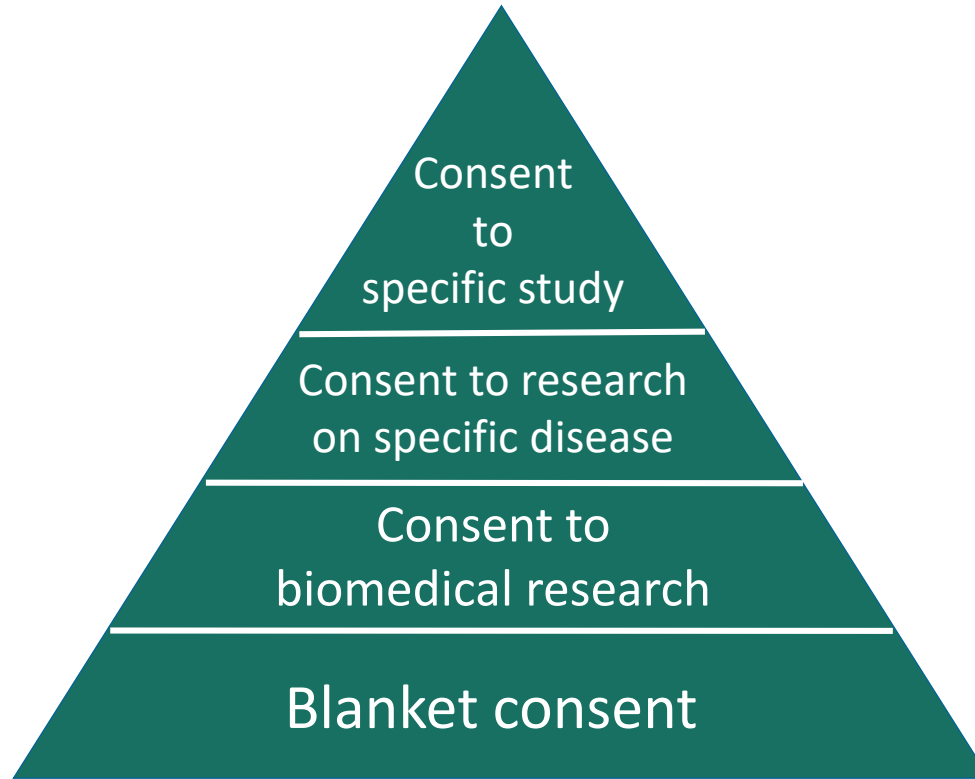


Outline



Consent

Continuum of Consent



More specific &
more autonomy



Less
specific &
less
autonomy

Consent only valid if individuals have been adequately informed about:

- Purpose of the Biobank;
- Risks & burdens associated with collection, storage & use of material;
- Type of material to be collected;
- Procedures for return of results including incidental findings;
- The rules of access to the Biobank;
- How privacy is protected;
- The governance arrangements;
- If material made non-identifiable, individual may not be able to know what is done with their material & may not have the option of withdrawing consent;
- Commercial use, benefit sharing, intellectual property issues & transfer of material.

<https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>

Havasupai Tribe v. Arizona State University

Native American tribe donated specimens for diabetes research. Specimens were used for studies on schizophrenia, alcoholism & other.

Settled out of court. Arizona regents to pay \$700,000 to tribe, and return blood specimens.

The New York Times

U.S.

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH
POLITICS EDUCATION BAY AREA CHICAGO

Indian Tribe Wins Fight to Limit Research of Its DNA



Jim Wilson/The New York Times

Edmond Tilousi, 56, who can climb the eight miles to the rim of the Grand Canyon in three hours.
[More Photos »](#)

By AMY HARMON

Published: April 21, 2010

Privacy

Genetic Data

- Genetic information may be possible to identify donor & relatives
 - In 2008, geneticists showed that they could easily identify individuals within pooled, anonymized data sets if they had a small amount of identified genetic information for reference.
- Confidentiality cannot be fully guaranteed despite all efforts
- Full confidentiality should never be promised

N. Homer *et al.* PLoS Genet 4, e1000167; 2008

Golden State Killer Caught Using Family DNA

2018, genealogy website used to arrest suspect in the Golden State killer case.

Case had gone cold, although law enforcement had reliable DNA sequence of the suspect.

Police uploaded DNA sequence to a commercially available on-line genealogy website that compares people's genetic information to trace relatives.

Match with family members led police to identify & arrest a suspect.

Resulted in ethical hailstorm about the privacy of genetic material & informed consent.

The ethics of catching criminals using their family's DNA

A high-profile arrest in California shows how the long arm of the law can now extend into DNA databases to check for relatives.



<https://www.nature.com/articles/d41586-018-05029-9>

Return of Results

- **Individual research result**-finding with potential health or reproductive importance discovered as part of *the study's aims*.
- **Incidental finding**-finding with potential health or reproductive importance discovered during research but *beyond the aims of the study*.
- Biobanks complex due to:
 - Large number of results (lots of patients, lots of data)
 - Results generated over long period of time (hard to reach patients)
 - “Actionable” results unclear
 - Research labs often not same standards for reporting as clinical lab

Wolf SM et al. *Genet Med* 2012;14:361-84
 Brothers KB. *Personalized Medicine* 2011;8:71-9

Tens of thousands of Icelanders contributed DNA & medical records.

Never explicitly consented to be notified of personal health risks that scientists might discover.

Later, deCODE decided they wanted to warn women with BRCA mutations.

Courts said No.
Subjects have a “right not to know”.

The Right Not to Know: When Ignorance Is Bliss but Deadly



<https://pulitzercenter.org/stories/right-not-know-when-ignorance-bliss-deadly>

Trust

Governance & Public Trust

- Who owns & finances the biobank?
 - University
 - Government
 - Industry
- Who has access to the specimens and data?
- How will specimens/data be used?



Must include the following elements:

- Arrangements for:
 - Length of time material stored;
 - Disposal & destruction of material;
 - How material will be documented & traceable;
 - How the material will be dealt with if change of ownership;
 - Obtaining appropriate consent;
 - Protecting dignity, autonomy, privacy & preventing discrimination;
 - Criteria concerning access to & sharing of material;
 - Persons responsible for governance;
 - Security measures to prevent unauthorized access;
 - Procedures for re-contacting participants;
 - Procedures for addressing enquiries & complaints.

<https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>

Ownership & Commercialization

- Who can profit from specimens?
- Who has to pay for specimens?
- Should subjects be paid if researcher makes money?
- General principle that subjects have no property rights to their specimens (*res nullis*, 'no one's thing')
- In a few cases this has been challenged

TUESDAY, MAR 7, 2000 11:00 AM CST

Who owns your DNA?

Genetic research that can save lives is often stymied by biotech companies' greedy patent claims.

BY ARTHUR ALLEN



TOPICS: HEALTH



For years, the parents of children suffering from an implacable genetic disorder called Canavan disease dutifully packed off their blood and tissue samples to Dr. Reuben Matalon, a researcher at Miami Children's Hospital. These shipments were an altruistic, volunteer effort by a devastated group of people — their own children were dead or dying, but they hoped to prevent the births of more children

Families of Children with Canavan Disease donated specimens to understand molecular basis of the disease.

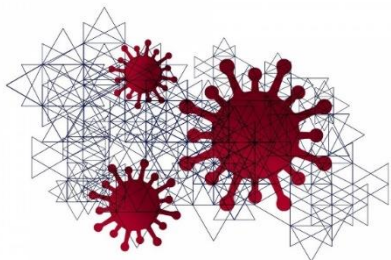
Gene was found & genetic test developed.

Families sued after learning University licensed test.

Subjects have no property right to tissue as they voluntarily donated for medical research.

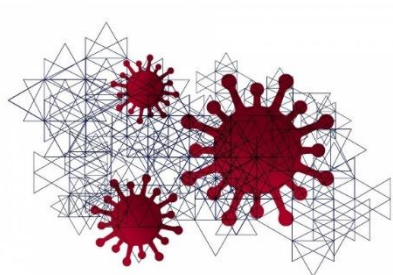
Biobanking During a Pandemic

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Biobanking During a Pandemic

Biobanking Ethics

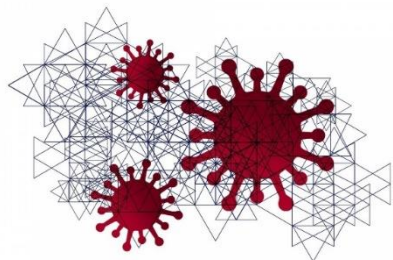


☐ Informed consent

☐ Autonomy

☐ Right to refuse

Biobanking During a Pandemic



Biobanking Ethics



☐ Informed consent

☐ Autonomy

☐ Right to refuse

Public Health Ethics



☐ Social responsibility

☐ Need to be inclusive

☐ Consent waived



Ethical Paradox



Unauthorized appropriation of resources from farming/indigenous communities by individuals or institutions seeking exclusive control of patents or intellectual property.

Biopiracy



2007

H5N1

Indonesia refused to share samples with WHO unless assured access to vaccine

Argued when low-income countries share material with WHO high income countries profit

Singh S. *J Med Ethics* 2022;48:466-71

Biopiracy



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2014

Ebola

50,000 specimens collected in West Africa

Shipped to labs around world without state authorization or consent

Singh S. *J Med Ethics* 2022;48:466-71

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2020

COVID-19

South Africa Participated in AstraZeneca vaccine trial

Paid double the price per dose compared with other European countries

Singh S. *J Med Ethics* 2022;48:466-71

Summary

In order to uphold principles of ethics, biobanks should:

- 1) Abide by all national/local laws
- 2) Follow guidance from Declaration of Taipei
- 3) Obtain informed consent
- 4) Protect privacy
- 5) Establish trust!

Thank you!

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NORDIC Biobank Conference

Gothenburg, Sweden



Theme: Current trends and challenges in the Nordic countries

A unique opportunity to meet representatives in the area of human biobanking as well as other scientific experts from healthcare, academia, and industry.

Webbpage and registration: nbc.biobanksverige.se

The Nordic Biobank Conference 2022 is jointly organized by the Nordic countries, comprised of Denmark, Finland, Iceland, Norway and Sweden.