KMA 대한의사협회 KOREAN MEDICAL ASSOCIATION

WMA

WMA Expert meeting on **Health Databases** and **Biobanks**

Ethical Considerations on **Biobanks**

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Janus serumbank

Janus serumbank inneholder blodprøver fra 317 000 nordmenn. Janusbanken, som er forbeholdt kreftforskning, er unik i verdenssammenheng med hensyn til størrelse og antall.

Janus serumbank er en populasjonsbasert biobank forbeholdt kreftforskning. Materialet er samlet inn i perioden 1972-2004 og er lagret ved minus 25 grader celsius. Prøvene kommer fra 317 000 personer som har deltatt i helseundersøkelser i Norge og fra blodgivere i Oslo og omegn. I dag samles det kun inn prøver fra tidligere Janusgivere som har utviklet kreft.

JANUS serumbank

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Process in Biobanking

Biomaterial

Cells
Tissues
Blood
DNA/RNA
Wastes

\+

Information

Ethical Issues

Collection

- **Independent Collection** for Biobanking vs Banking
  Leftover or Surplus Specimens after Diagnostic or Clinical Procedures
- Sample Archiving for
  1. **Project**-based
  2. **Disease**-specific
  3. **Population**-based

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Different Issues from Traditional Research

- Past research focused on drugs, biological products and devices
- Recent research uses stored biological specimens with genetic tests, which are stored at biobank
- There must be caution to protect the confidentiality, privacy and safety of the subjects

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WMA Declaration on Ethical Considerations regarding Health Databases & Biobanks

- **Biobank research gives rise to new ethical challenges**
  - Samples collected with sensitive personal information, especially genetic
  - Technical Development in Genetic Testing

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Main Controversies Related to Biobank

- What kind of consent is needed/In what case, consent can be waived?
- How to protect the confidentiality and whether or not disclose the data to subjects
- Assessment of the risk of the test to the subject
  - What is the risk to a subject and what is the minimal risk to waive consent?

4 Kinds of Specimen

	Prospective	Retrospective
Anonymous Anonymized	Level of consent form	What to do securely anonymize?
Identifiable Identified	Cannot be used without IRB permission	Reconsent needed

Level of **Anonymity**

- Anonymous
- Anonymized
- Identifiable
- Identified

Pseudoanonymization

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WMA Declaration

11. The collection, storage and/or reuse of data and biological material from individuals capable of giving informed consent must be **voluntary** in accordance with the Declaration of Helsinki. If the data and biological material are collected **for a given research project**, the **specific, free and informed consent** of the participants must be obtained.

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Informed Consent

1. **Voluntary** consent
2. **Well-informed** and understand the purpose of research with its expected benefits and risks, before obtaining consents
3. **Withdrawal** of consents

The details of future research could not be known at the time when the consent is obtained for banking biomaterial

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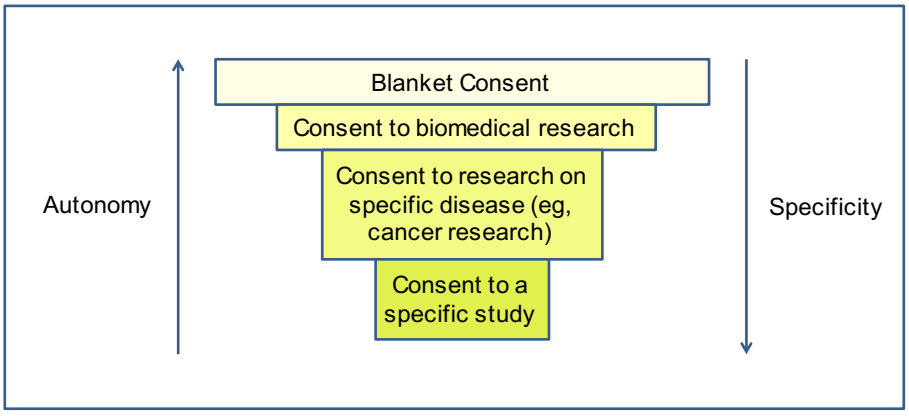
Level of Consent Procedures



Less restriction on the types of consent allowed implies increased respect for autonomy.

Broad Consent

1. Research must be **of great importance**.
2. A **maximum protection of privacy** must be guaranteed to participants.
3. They must be allowed anytime to **withdraw** the consent.
4. Every future research should be approved by an **ethical review board**.

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Re-Contact & Re-Consent

- To get additional or new consent for every future research question or technology can be **very impractical**, **time consuming**, **expensive**, and even **confusing** (or harassing or worrying) to the participants.

Broad consent has an advantage

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WMA Declaration

12. If the data and biological material are stored in a Health Database or a Biobank for **multiple and indefinite uses**, it is only ethically acceptable for the individuals to give consent if they have been adequately informed about:

a. the purpose of the Health Database or Biobank,
b. the nature of the data or material to be collected,
c. the rules of access to the Health Database or Biobank,
d. the governance arrangements,
e. the means that will be used to protect the confidentiality of their information,
f. the procedure regarding incidental findings,
g. the potential decision to anonymise data, and in case of irreversible anonymization, the fact that the individual will not be able to know what is done with their data and biological material, nor will they have the option of withdrawing their consent.
h. their fundamental rights and safeguards established in this Declaration, and
i. when applicable, intellectual property issues and the transfer of data to third countries.

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Waiver of Consent

- If they are **fully anonymized**
- For large collections of human samples collected for diagnostic or clinical purposes
  - "**Leftover** or **Surplus**" Specimens
- Must be approved by an Ethical Review Board (ERB)

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Genetic Testing

- Risk for family pressure; family involuntarily involved to genetic testing
- Privacy of the family revealed
- Giving access to test result; debated/ autonomy centered view vs beneficence centered view

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Autonomy vs Beneficence

- Autonomy centered view; volunteers should be given test results and they can do whatever they wish with information
- Beneficence centered view; volunteers should be given results only when the data are validated and clinical utility is established

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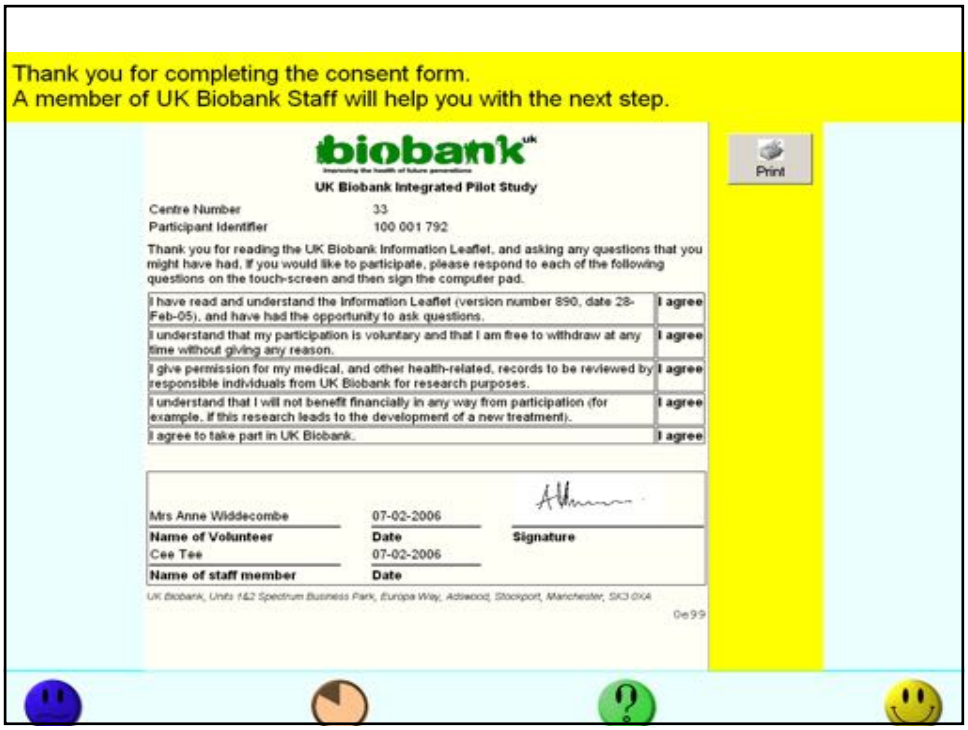

UK Biobank Consent Form (part 1)

I have read and understand the Information Leaflet, and have had the opportunity to ask questions.
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
I understand that I may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this is optional.
I give permission for access to my medical and other health-related records, and for long-term storage and use of this and other information about me, for health-related research purposes (even after my incapacity or death).

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UK Biobank Consent Form (part 2)

I give permission for long-term storage and use of my blood and urine samples for health-related research purposes (even after my incapacity or death), and relinquish all rights to these samples which I am donating to UK Biobank.
I understand that none of my results will be given to me (except for some measurements during this visit) and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment)
I agree to take part in UK Biobank.

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Conclusions

- There happens special need in ethical consideration for biobank.
- WMA declaration is timely in meeting new needs
- There remains many areas that should be clearly defined such as level of consent, re-consent, retrospective data, and access to the data by the subject