Biobank & Bio-PIN
Anonymous material and data, 2-way communication

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INTRES.CO
The Bio-PIN: a concept to improve biobanking

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Bio-PIN could cut biobanking risks

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Content

1. Introduction
2. Biobanking problems + Bio-PIN solutions
3. Bio-PIN technology + procedures
4. Alternative?
5. Advantages + Disadvantages
6. Conclusions + Application
About advantages of the Bio-PIN for:

- Participants (patients / donors)
- Biobankers
- Researchers

A new PET

Privacy Enhancing Technology
About potential effects of the Bio-PIN on:

1. Registering / Managing samples & data
2. Laws / regulations & Ethics
3. Informed consent procedures
4. Privacy protection
5. Public trust / engagement
6. International harmonization / exchange
What is a Biobank?

A facility for:

• storage and release of biomaterial samples
  - material to retrieve data
  - material to use in therapy

• storage and release of data related to the material
  - data retrieved from the material:
    ▪ diagnostic, prognostic data
    ▪ research data (e.g. for pharma)
  - data from the donor of the material:
    ▪ medical history, lifestyle, environment, demographics, genealogy
Types of samples / data in a biobank

- **Not-anonymous**
  - Identified: Stored with identity data
  - Coded: Stored with code
- **Anonymous**
  - Stored without identity data
Biobanking problems 1

- Building a ‘local’ statistically significant collection of biomaterial samples and data can take decades.
  - Especially for diseases with low prevalence and incidence.
  - Especially for multi-factorial diseases.

➢ International collaboration is necessary!
Biobanking problems 2

• In many countries for “identified” or “coded” samples & data each new use requires a new signed consent.

• For “identified” or “coded” samples & data special security measures have to be taken.

• Laws / regulations differ between countries.

• Differences in definitions between US and EU.
Laws & Regulations

• For use of anonymous samples & data in most countries simpler regulations apply.

No privacy to be protected!

Should samples & data be anonymous?
Anonymity has disadvantages

• No messages from biobank to patient / donor.
  - No new research proposal
  - No request for more data / material
  - No unexpected finds

• No messages from patient / donor to biobank.
  - No objection to new research
  - No reply to requests
  - No requests for results / deletion (opt out)
Choices & Problems

• Identified / coded samples
  ➢ Privacy risks
  ➢ Regulatory burdens
  ➢ International differences
  or

• Anonymous samples
  ➢ No privacy risks
  ➢ No communication
  ➢ Less valuable collection
Solution?

• Can one build an anonymous system without the disadvantages?

  Yes!

• Replace identity data with the Bio-PIN.

  ➢ Samples & data become anonymous.
  ➢ Features of non-anonymous system remain.

  ♦ A person’s name has no biomedical meaning.

  In research it is not needed.
Biological PIN code

The Bio-PIN is based on a distinguishing biological characteristic (DBC), e.g. a set of SNPs.

Biobanking card

Bio-PIN system

Chip with ‘locked’ Bio-PIN

+ Security code to unlock the Bio-PIN
Bio-PIN linking prevented

SNPs lab

Individual

Bio-PIN facility

SNPs set

>99 kByte

Bio-PIN

Bar code

< 55 Bytes
Set of SNPs

• Does not contain identity data:
  Name, birth date, birth place, address.

• Does not contain gene data:
  Eye / hair / skin color etc.

• Does not contain medical data:
  Diagnostic / prognostic etc.
Bio-PIN properties

• The **Bio-PIN** cannot be linked back to the SNPs.
  ➢ The **Bio-PIN** is **not** linkable to an individual.
  ➢ The **Bio-PIN** cannot be linked to a name.

• The **Bio-PIN** gives maximum privacy protection.
Biobanking with the Bio-PIN

Donor / patient

Biobank

Website

DBC* laboratory

Research laboratory

Other biobanks

Data users

Bio-PIN facility

Hospital

A = Anonymous

& = Exchange

* = Distinguishing Biological Characteristic

A = Sample

= Data

= A number

= Bio-PIN

A = Anonymous

& = Exchange

* = Distinguishing Biological Characteristic
Is a random number an alternative?

• Dangers:
  - Patient / donor loses number.
  - Biobank loses number.
  - Mistakes / fraud (no proof).

• Impossibilities:
  - No combination of different samples.
  - No combination of different data sets.
Sample / data labeling with the bio-PIN

Locked Bio-PIN

Card reader

Hospital computer

Bio-PIN system

Bio-PIN

Biobanking card

Security code e.g. 123456

Locked Bio-PIN

Bio-PIN system

Bio-PIN label

Bio-PIN

Sample

Data

Biobank
Bio-PIN advantages for biobanks

+ Maximum privacy protection
+ No privacy costs, no regulatory burden
+ Ambiguity in identity data is not an issue
+ Enhanced donor trust and engagement
+ If lost, the Bio-PIN can be re-determined
+ Flexible biobanking system
+ Combination of samples / data of one person
+ Easier international sample / data sharing
Bio-PIN advantages for biobanks

+ All advantages of anonymous samples / data (like less regulatory burden and costs, plus enhanced security and data protection).

+ All possibilities of a system with identified samples / data can be utilized, except knowing the identity.
Bio-PIN disadvantages for biobanks

- Identity of participants is not known
- Biobank has to wait for participants
- Differences in speed of participation
- Potential (temporary) bias in data

➢ The disadvantages are not worse than for systems with participants approached via letters and/or telephone, part of whom will not respond.
Bio-PIN advantages for participants

+ Maximum privacy protection

+ Safety (unalienable) & Sustainability (once)

+ All rights protected:
  - The rights to be informed / ‘not to know’
  - The rights to object / opt out
  - The rights to request / correct / add data
  - No necessity to give ‘broad’ / blanket consent

+ Strengthened autonomy

+ Electronic personal health record possible
Bio-PIN disadvantage for participants

- Losing the Bio-PIN leads to costs
Electronic Personal Health Record: a contact stimulus for participants

Biobanking card

Bio-PIN system

Biobank slogan:
“Use your biobank account to invest in Health!”

Amplifying loop

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Conclusions

• The Bio-PIN system offers:
  - Maximum protection of patient / donor rights.
  - Maximum possibilities for biobanks / researchers.

• The Bio-PIN system is superior to systems with a code that is a random number.

• The Bio-PIN system leads to a whole new way of biobanking, involving ethical, legal and societal aspects.
International Bio-PIN application

Biobank1  Biobank2  Biobank3  IBR

Lab-A  Lab-B

Bio-PIN facility

= Samples
= Data
= DBC
= Bio-PIN

Anonymous  International Bio-PIN Registry
Distinguishing Biological Characteristic
Referee:

“The proposal offered by the authors seems to be extremely elegant and feasible and deserves to be seriously taken into consideration.”