Basic Structure of Ethics Governance of Biobank

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** The view expressed in this presentation is strictly my personal one, and not necessarily represent the opinion of the Japan Medical Association.*

Characteristics of Biobank - Need of new ethical structure =Governance

- Large scale collections (population based)
- Collection and storage of human materials together with personal information
- Samples stored anonymous but linked
- Multiple use
- Genomic information analyzed

Questions concerning establishment and management

- Concern of the general public : consensus
- Anonymized but linked samples and data
- Recruitment
- New type of consent
- Confidentiality management
- Other ethical issues

Concern of the general public

- Biobank with genetic/genomic database consists of personal information that may reveal the privacy of each participants as well as groups and communities.
- A large scale biobank should be initiated or established in consultation with the general public of the nation or of the population as well as other stakeholders.

  (potential participants, representatives of the population/community or focus groups, patients groups, industry, State, researchers' community)
- The extent of consultation will vary following the nature, purpose, size and risks and sensitivity of the data and the access.
- Methods of consultations are diverse.
- Importance should be given to build up a consensus to establishment of a biobank

Recruitment

Recruitment of participants of a large scale is a heavy task.

1) Understanding and Support of the public

Long process from public announcement of the project, through public informing meetings and consultations, to informed consent procedure.

2) Assurance of free will

Pressure of the community

(family, local community, state)

Prohibition of economic or social incentives

commercialization of human body and parts

Consent

Traditional informed consent procedure is inapplicable.

New type of consent is necessary

"One sample, for multiple purpose, stored for a long time, anonymized but linked, and sometimes periodically re-collected"

⇒"Linked anonymisation"

Purposes of research using collected samples are not defined and necessarily multiple.

"Broad Consent"(?)

The donor should be let understand what is a biobank, and how samples and information are stored and used.

The weight of importance shifts to the confifdentiality.

Withdrawal

- Graduation of withdrawal should be considered.

  consent – collection – during storage/before use – during use (research) – before publication – after publication

- After each stage, the effect of withdrawal will be gradually limited.

  disposal of samples : all, remaining, or made unlinked and not disposed

  erasure of data : all, part (kinds of data)

Linked anonymisation

- Samples and data should be kept anonymous.
- However, the connection is indispensable between the donor and the samples and the data.

  Follow the evolution of the donor's health/disease

  Revise the evaluation and the meaning of the samples and data with new scientific developments
- Double randamised anonymisation is universally recommended and recognised.
- Linkage to a specific participant necessary for adding the samples and the data of the person concerned. Continuous sampling and data collecting from the same person is a key element for a biobank.

System for confidentiality management

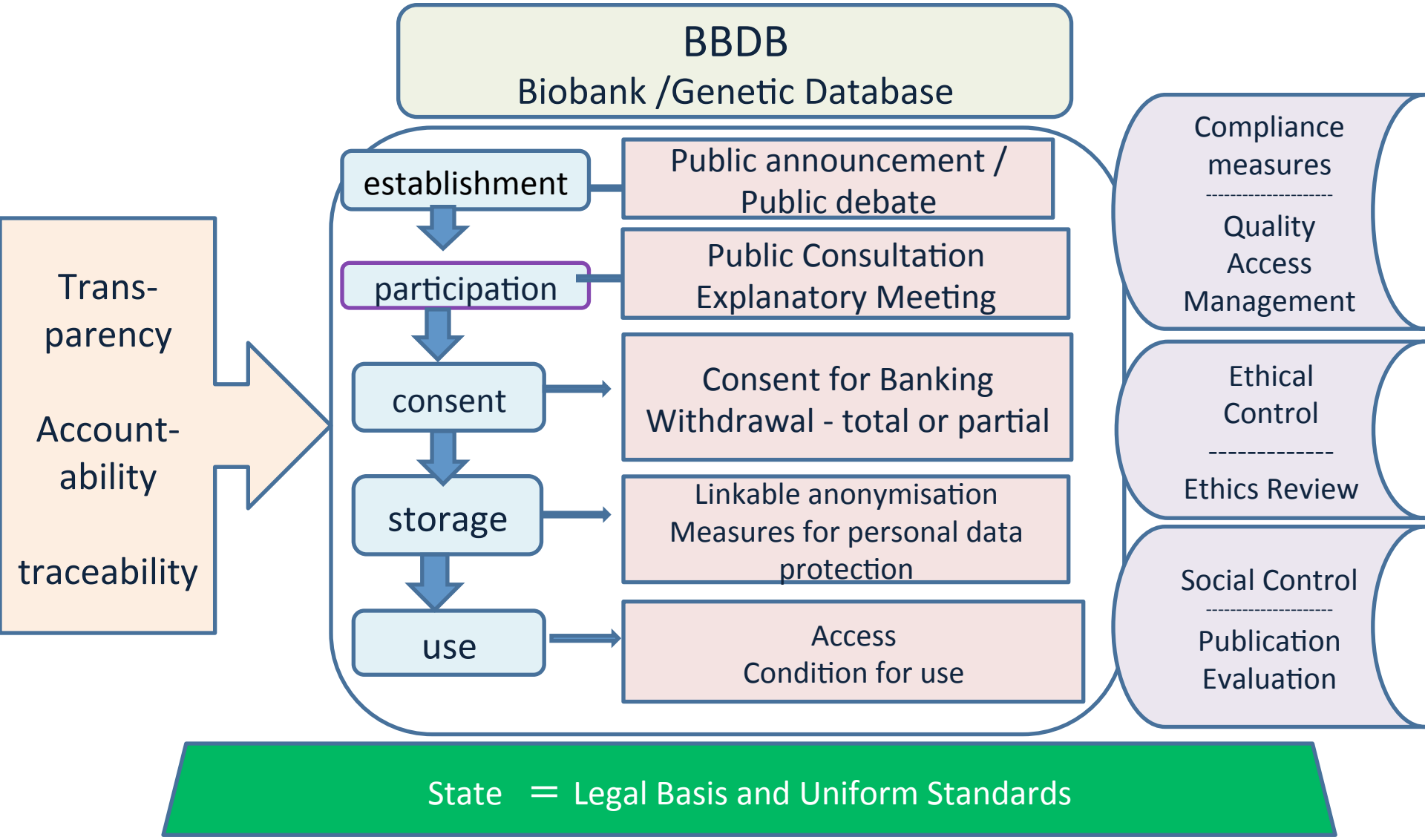
- Measures of confidentiality protection should be clearly built.
  Security of stored samples, security of the data
- Custody of Code Registry
  Designation of custodian of personal information
  (identifiers, link between donor - personal data/information)
  Duty of non-divulgation of information
  Strictly protected data management (ex: stand-alone PC setting)
- Access limitation to the personal information
  Limited access to personal information stored in the bank
  Special authorization
  Degree of access limitation may be proportionate of the purpose
  The user (researchers and doctors) may only use personal information which is deemed indispensable for a specific research or application.

Need of Regulatory Regime

- For the efficient use of the sample and the data stored in the biobank, a regulatory regime should be established relating to the purpose of use, intellectual property rights, management of the whole biobank, etc..

Basic Structure of Ethics Governance of Biobank

- Triple principle
  Transparency, accountability and traceability
- Three levels of control mechanism
  Compliance control
    quality control
    access control
    management control
  Ethical control : Ethical review committee
  “Public control” : public reporting and evaluation
- Need of national standard
  Quality of the data
  Degree of confidentiality protection



Governance of Biobank and Database

For DoH revision

Should DoH include provisions on biobank?

The current stage of development of medical research requires some articles on biobank, whether or not mentioning “biobank”.

A) If “biobank” should be mentioned,

difficulty = definition

B) If we remain providing only articles regarding the issues at each stages of biobank process without mentioning “biobank”, this efficient tool of research may be confused with other procedures, and such will not be for the protection and interest of the participants/patients.

Possible solution

Mention “biobank, but leave regulatory framework to each country’s laws and regulations. Soon or later, a kind of universal standards will be established, in order to facilitate the flow of the qualified data.


Merci.
Thank you.
ありがとうございました。