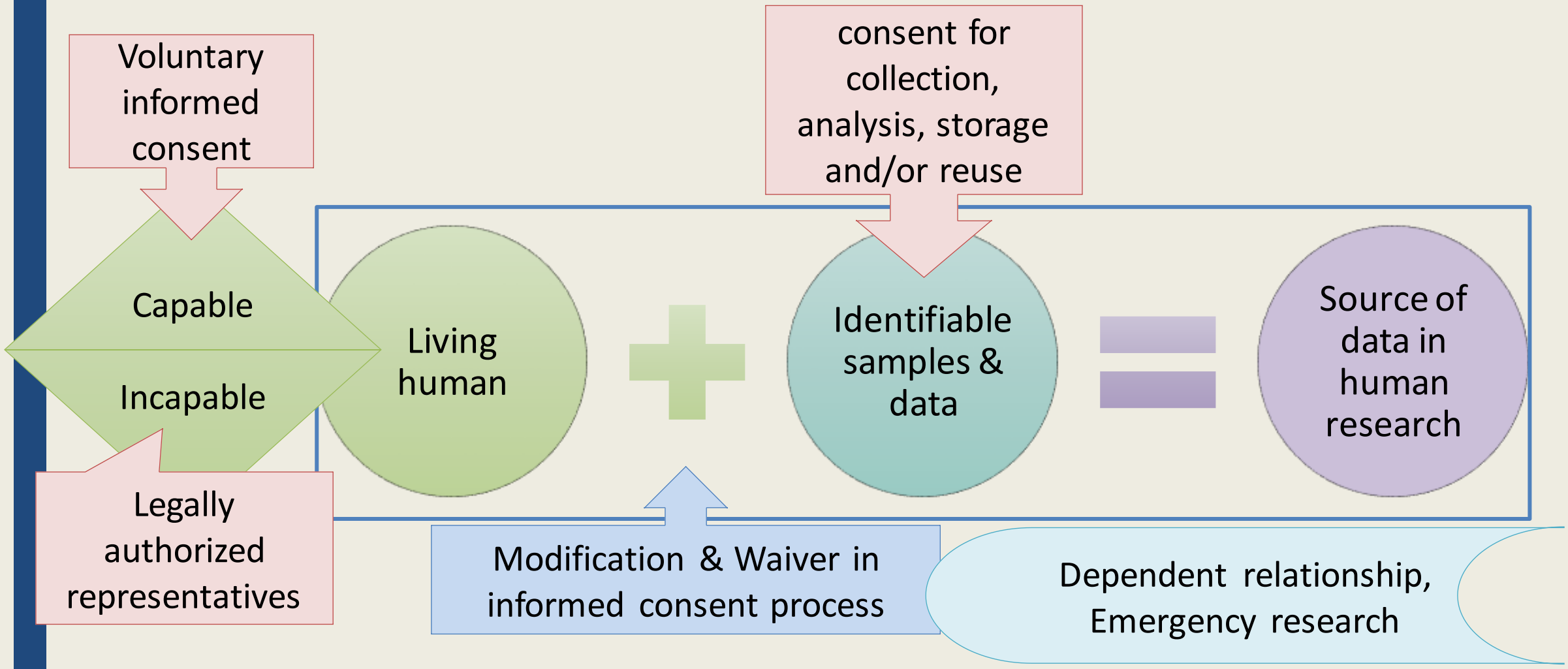
GUIDELINE 11: COLLECTION, STORAGE AND USE OF *BIOLOGICAL MATERIALS AND RELATED DATA*

GUIDELINE 12: COLLECTION, STORAGE AND USE OF *DATA IN HEALTH-RELATED* RESEARCH

Council for International Organizations of Medical Sciences (CIOMS) 2016

Human research & informed consent process

Declaration of Helsinki



Human biological materials may include:

Biobank = the collection of stored biological materials and associated data
- large population biobanks and
- small bio-repositories of bio-specimens in laboratories.

tissues, organs,
blood, plasma, serum,
DNA, RNA, proteins, cells,
skin, hair, nail clippings,
urine, saliva, or other bodily fluids.

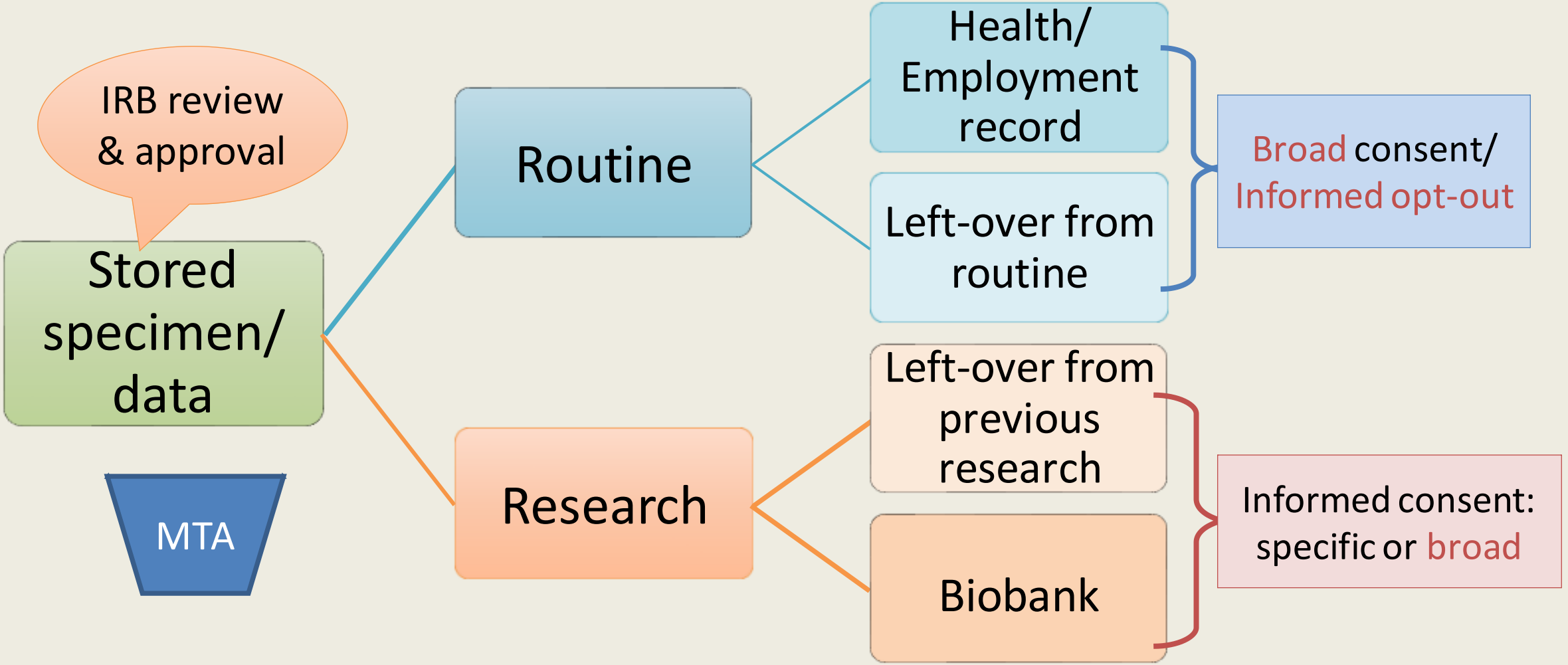
- mostly come from patients following diagnostic or therapeutic procedures,
- autopsy specimens,
- donations of organs or tissue from living or dead humans, or
- bodily wastes or abandoned tissue.

Medieval Latin phrase meaning
"having changed what needs to be changed" or
"once the necessary changes have been made"

This *mutatis mutandis* should also apply where the research uses samples and data from deceased individuals.

Guideline 11: Collection, storage and use of biological materials and related data

- When biological materials and related data, such as health or employment records, are collected and stored, institutions must have a *governance system to obtain authorization for future use* of these materials in research.
- When specimens are collected for research purposes, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained
- When human biological materials are left over after clinical diagnosis or treatment (so-called "residual tissue") and are stored for future research, a specific or broad informed consent may be used or may be substituted by an informed opt-out procedure.


IRB review & approval
Stored specimen/ data
MTA
Routine
Research
Health/ Employment record
Left-over from routine
Broad consent/ Informed opt-out
Left-over from previous research
Biobank
Informed consent: specific or broad

Stored left over biospecimen after clinical diagnosis or treatment (so-called residual tissue) for future research

Consent

An informed opt-out procedure

Broad consent

-the range of future uses

-the conditions and duration of storage;

-who will manage access to the materials;

-the foreseeable uses of the materials,

-the intended goal of such use, whether only for research, basic or applied, or also for commercial purposes,

-the possibility of unsolicited findings and how they will be dealt with.

- **An informed opt-out procedure** = the material is stored and used for research unless the person from whom it originates explicitly objects
- The informed opt-out procedure has to fulfill the following conditions:

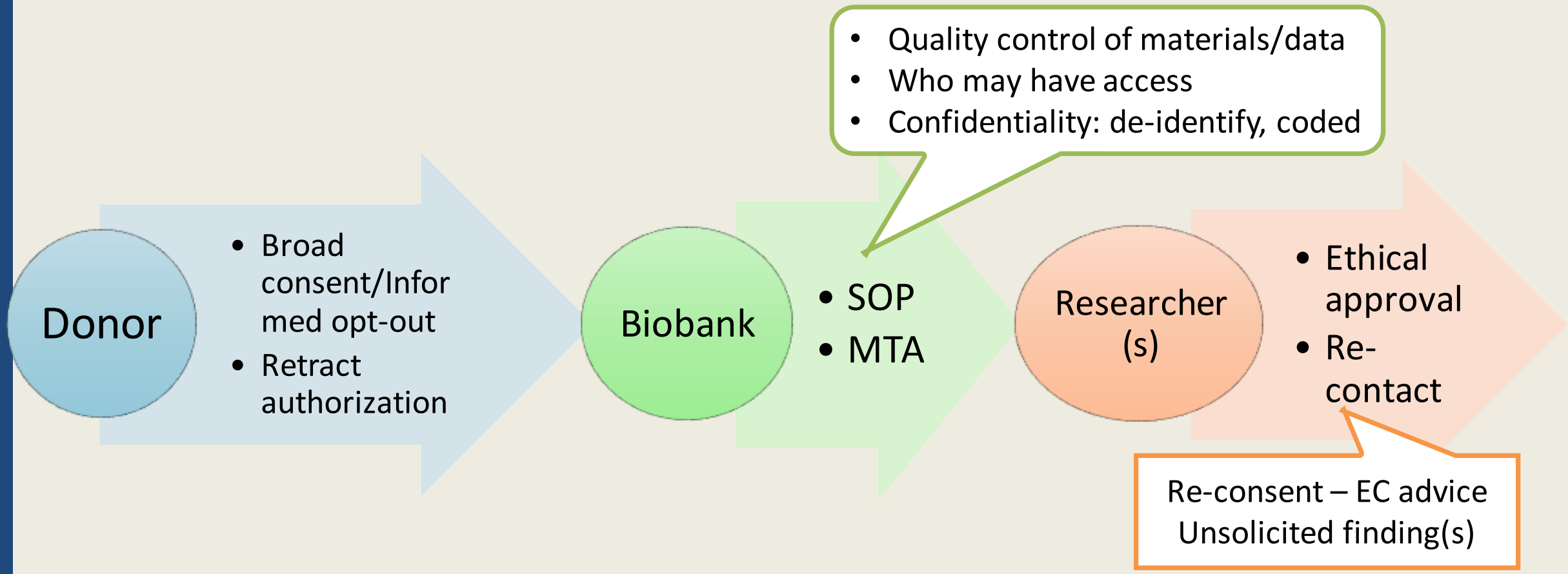
1) patients need to be aware of its existence;

2) sufficient information needs to be provided;

3) patients need to be told that they can withdraw their data; and

4) a genuine possibility to object has to be offered.

Biobank governance structure



Research ethics committees and biobanks

The protocol for **every** study using stored human biological materials and related data must be submitted to a research ethics committee,

- ensure that the proposed use of the materials falls within the scope specifically agreed to by the donor – broad informed consent for future research.
- If the proposed use falls outside the authorized scope of research → re-consent
- IRB may waive the requirement of individual informed consent for research with historical materials – the 3 conditions were met

1. the research would not be feasible or practicable to carry out without the waiver;
2. the research has important social value; and
3. the research poses no more than minimal risks to participants or to the group to which the participant belongs.

Confidentiality

- Biobanks must arrange to protect the confidentiality of such information by, for example,
  - *providing only anonymized or coded data to researchers and*
  - *limiting access of the material of third parties*.
- When researchers use coded materials obtained from biobanks in later studies, the key to the code must remain with the custodian of the biobank.
- It should be acknowledged that the possibility of complete anonymization is becoming increasingly illusory as the possibility of cross matching large datasets improves.

Return of results and disclosure of (un)solicited findings

- Tiered consent, meaning the possibility of obtaining packages or subsets of information, gives donors a range of choices and allows them to choose some options to give them greater control over the use of their biological materials.
- the 3 guiding principles for return of results need to be followed:
  1. *results must have analytical validity,*
  2. *clinical significance and*
  3. *actionability to qualify for being returned:*
- life-saving information and data of immediate clinical utility involving a significant health problem must be offered for disclosure,
- information of uncertain scientific validity or clinical significance would not qualify for communication to the participant.

Guideline 11: Collection, storage and use of biological materials and related data

- The transfer of biological materials must be covered by a **Material Transfer Agreement (MTA).**
- Biological materials and related data should only be collected and stored in collaboration with local health authorities.
- The governance structure of such collection should have representation of the original setting.
- If the specimen and data are stored outside the original setting, there should be provisions to return all materials to that setting and share possible results and benefits.

Material Transfer Agreement

- Ensure that the biological materials are documented in such a way that they can be retrieved.
  - *The range and duration of use and*
  - *What needs to happen at the end of the period of use*
  - *All responsibilities concerning these elements*
- An MTA is also needed in multinational research projects in which one entity collects samples from persons in all participating countries and stores them in a single biobank.

Ethical review and approval should be obtained for the taking and/or use of human tissue samples in research, except

- where samples will be used for evaluation or assessment of established diagnostic devices or in-vitro diagnostic kits then destroyed (performance assessment);
- where material is used in a program for systematic monitoring/evaluation of a project, service or facility to ensure that standards of quality are being met (Quality assurance);

Ethical review and approval should be obtained for the taking and/or use of human tissue samples in research, except

- where the tissue sample is being used in research laboratories as a reagent – e.g. as a source of feeder cells for maintenance of cell lines or clones, or substrate for growth of virus stocks (i.e. no knowledge is being derived from the tissue itself);
- where the tissue is an established in-house or commercially available cell line

The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body

1. Specifically identified relevant material

This includes material such as bodies, organs and tissues, consisting largely or entirely of cells, and clearly identifiable.

2. Processed material

As a result of the process – to leave it always either cellular or acellular

Note that if the process used to separate plasma is intended to generate platelet-poor or platelet-rich plasma (as opposed to platelet-free), then there may still be cells within the plasma, making it relevant material.

The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body

3. **Bodily waste products** (including excretions and secretions) should normally be regarded as relevant material

4. **Cell deposits and tissue sections on microscope slides**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