

Best practices and ethical considerations to publish in Allergy

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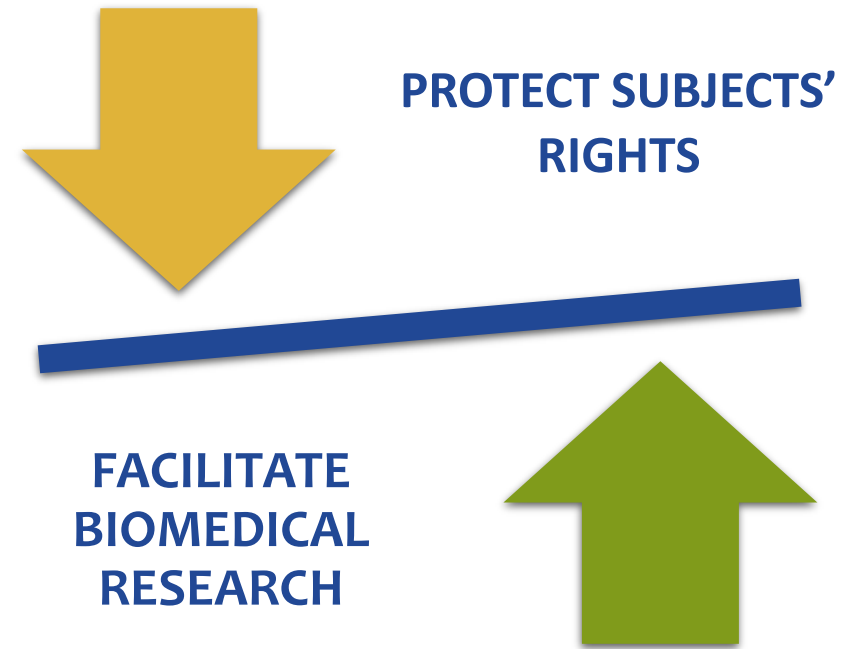


PRINCIPLES OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Research involving human subjects is always associated with a certain degree of health risk.

The decision to undertake a study should be based on a positive risk/benefit assessment.

The potential benefit must be justifiable.



PRINCIPLES OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

RIGHT OF AUTONOMY



1. Aware: purpose, benefits/risks.
2. Accept to participate.
3. Right to withdraw.

RIGHT OF CONFIDENTIALITY



1. Coding of personal data.
2. Safety of databases.
3. Registry in a public agency.

PRINCIPLES OF BIOMEDICAL RESEARCH IN EUROPEAN STATES

European Member States should:

Protect the dignity and privacy of all participants

Protect the health, interest and well-being of every human being

Ensure confidentiality of private life and other rights and fundamental freedoms that could be affected by the research activity.

All of these rights should be ensured in agreement with the precautionary principle.



WORKFLOW OF BIOMEDICAL RESEARCH INVOLVING HUMANS



CHALLENGES FACED BY ETHICAL COMMITTEES/BOARDS

- Great diversity of research studies beyond clinical trials and human studies
- Not every aspect is regulated in legal documents
- Need to reflect on the specific features of the study and to be rigorous
- Assessing the risk and benefit ratio
- Need to keep a proper balance between the individual and society



PRINCIPLES OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

- Patient participation must be done on a voluntary basis.
- The authors must ensure that the study has been conducted according to the corresponding national legislation, in addition to the Declaration of Helsinki (General Assembly, Fortaleza, Brazil, 2013 and the subsequent updates). This point should be stated in the manuscript.
- The authors are responsible for applying for ethical approval to the corresponding national or regional board. In order to be published, research studies must count on ethical approval. This aspect should be specified in the manuscript.



HUMAN STUDIES: samples

- The biological samples and subjects' personal and clinical data must be kept confidential and treated according to the relevant international and national regulations (e.g. Belmont Report). In European studies, the EU Regulation 2016/679 applies. All members of the research team are responsible for ensuring confidentiality.
- The biological samples must be stored in a Biobank, following the standard operating procedures approved by the competent bodies. The Biobank should be officially recognized by the corresponding regional and national authorities.
- All study individuals (patients and controls) must provide signed informed consent in order to store the samples at the Biobank. This document is not necessarily the same one that the patient signed to participate in the study.



HUMAN STUDIES: samples

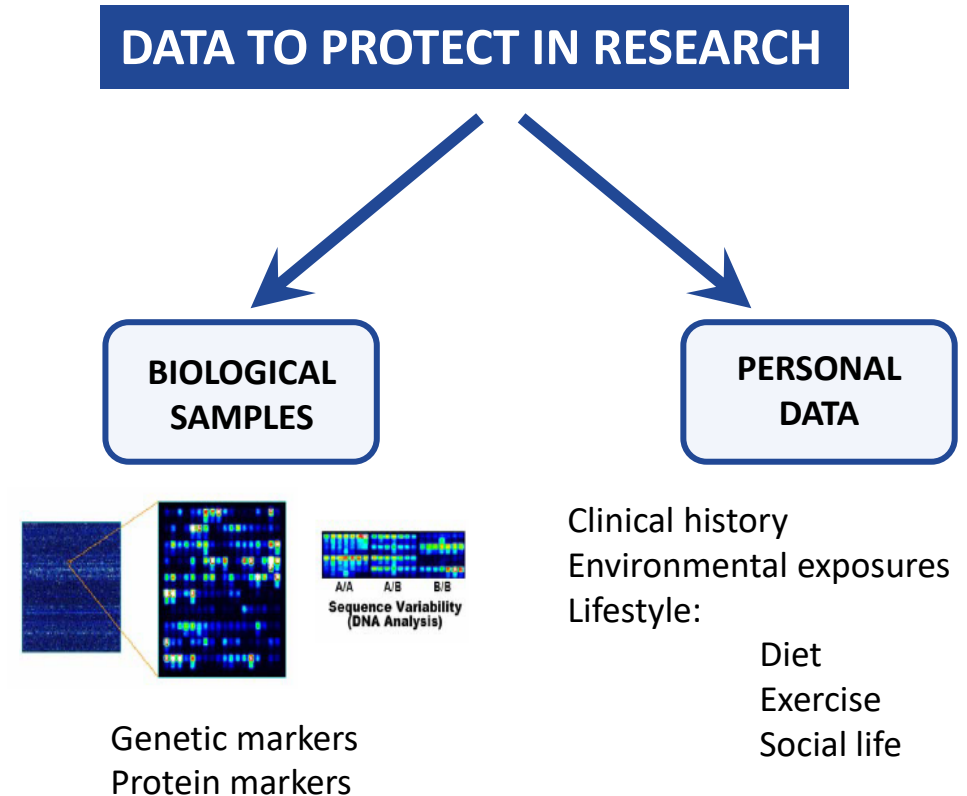
- The inclusion criteria of patients in the study should be unbiased and non-discriminatory.
- In some European states, financial gain for participating in research studies is prohibited.
- The data collected is confidential and should not be released as public information.

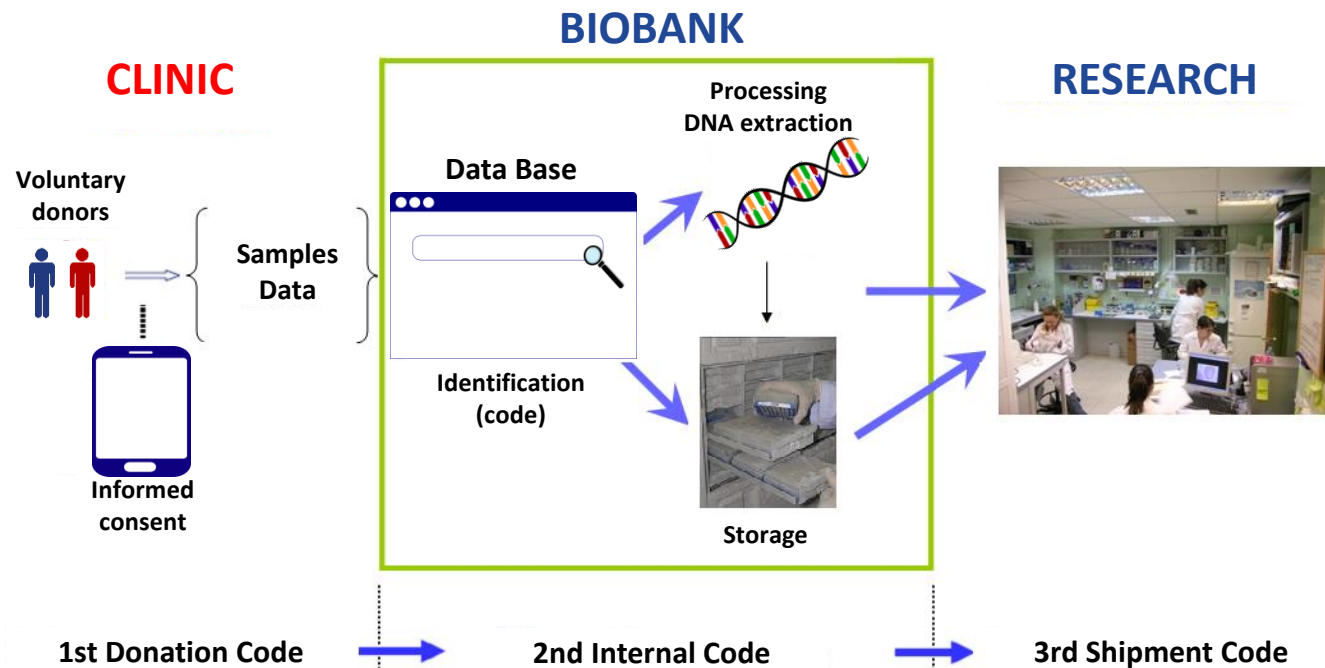


HUMAN STUDIES: samples

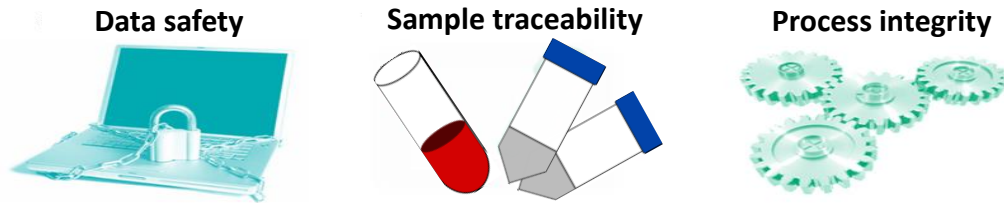
Samples must be collected **after** the donor has signed **informed consent**. The donor has the right to **withdraw** consent for participating in the study.

Biological samples will be stored only for the **purposes specified prior to collection**, unless the donor has provided explicit consent for further use.





PROCEDURE FOR QUALITY MANAGEMENT



HUMAN STUDIES: clinical trials

- Clinical trials are subject to the same requirements in terms of need for signed informed consent for both the study and the Biobank. The trial must be conducted according to the Guidelines for Good Clinical Practice, in addition to the Declaration of Helsinki. All clinical researchers participating in the trial must be appropriately trained in the procedures of good clinical practices.
- In addition to the approval from the corresponding Local Ethics Committee, clinical trials must obtain approval from the competent national or regional Drug Agency.
- Clinical trials should be recorded in an appropriate registry (e.g. clinicaltrials.gov)



HUMAN STUDIES: clinical trials

The clinical trial should be undertaken only when there is **no alternative therapy with an efficacy comparable to the one expected for the investigational drug.**

The clinical trial must not delay or deprive the participants from the medical procedures (either preventive, diagnostic or therapeutic) required to improve or restore their health.

The participants assigned to control groups must receive health care based on preventive, diagnostic and therapeutic procedures of proven usefulness.

The use of placebo is only accepted for cases where there is no treatment of proven efficacy or when its discontinuation is not associated with an unacceptable risk for the patient.



ANIMAL STUDIES: principles

European Directive: the main objective is to establish measures to protect animals used for scientific or educational purposes.

- Research studies involving animals must be guided by the three “R” principle: *replace* (consider alternative options to answer the research question), *reduce* (consider limiting the number of animals) and *refine* (minimize the risk of suffering and improve animal welfare).
- Animal studies require approval by the competent Animal Care and Use Committee. Animals should be handled according to the approved protocol for the corresponding study. This aspect should be specified in the manuscript.



Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.
<http://data.europa.eu/eli/dir/2010/63/2019-06-26>

ANIMAL STUDIES



Scientific purposes where the use of animals is ethically acceptable

- Basic research
- Translational or applied research with any of the following aims:
 - The avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants.
 - The assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants.
 - The welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes
- Development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products.
- Protection of the natural environment in the interests of the health or welfare of human beings or animals.
- Research aimed at preservation of the species.
- Higher education, or training for the acquisition, maintenance or improvement of vocational skills.
- Forensic inquiries.

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