CODE OF GOOD SCIENTIFIC PRACTICES

IDIBAPS-HOSPITAL CLÍNIC BARCELONA RESEARCH FOUNDATION

Preamble

December 2024

In 2012, Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (hereinafter, 'IDIBAPS') drafted the first edition of its Code of Good Scientific Practices to promote ethical standards and good scientific practice in its research. The purpose of this document was to provide the institution's research community and staff with a set of rules and recommendations to improve the quality of their research practices and define an ethical framework for conduct.

It was revised and updated in 2019, including IDIBAPS' and its research staff's commitment to the principles of good practices laid out in the Human Resources Strategy for Researchers (HRS4R). This was integrated into the institutional strategic plan and IDIBAPS was awarded the recognition of HR Excellence in Research. Granted by the European Commission, this award promotes strategies to achieve the principles and requirements described in the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[1], which specify the research community's and research institutions' roles and responsibilities when conducting research and managing human resource issues. The Ombuds Committee was also set up to mediate conflicts between members of the research community.

This year's revised edition is aimed at clarifying and improving understanding of the code, as well as including new requirements and recommendations on good practices in scientific research. One of the main new features of this update is how the content has been restructured, as it is now split into two main parts: (1) regulations, commitments and recommendations and (2) protocols and committees. This new structure makes for a more fluid reading experience, providing the information faster and more efficiently. New sections and information have been added in accordance with the recent update of The European Code of Conduct for Research Integrity, published by ALLEA (2023). Recommendations on the use of artificial intelligence in research and institutional affiliations are now included and the new Good Practices Committee and the Ethics Mailbox reporting system are also covered. Overall, regulations in force have been reviewed, ensuring that all the code's content is aligned with the current legal framework. This careful attention paid to regulations bolsters IDIBAPS' commitment to transparency and responsibility in its scientific research and practice.

Like the previous version of this document, this update adheres to the CERCA Code of Conduct (2019) (link in Catalan). Issued by CERCA, the institution representing Catalan research centres, this document outlines the general principles and requirements that define the responsibilities and rights of both the research community and related organisations, as well as the new update of the CERCA Code of Conduct (2025). As a member of CERCA, IDIBAPS follows the CERCA Code of Conduct.

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[1] In 2023, both documents were updated and merged into the European Charter for Researchers.

First edition: July 2012

This document was first drafted by the following working group members: Lluís Mont (coordinator), Anna Bosch, Xavier Carné, Begoña Gómez, Margarida Jansa, Belen Nadal, Neus Riba and Antoni Trilla. All enjoyed the support of the following people, whose collaboration is gratefully acknowledged: Albert Barberà, Gemma Llaverias, Teresa Peña and Neus Portella.

Second edition: May 2019

At the request of the IDIBAPS Strategy Directorate, the document was updated by a committee created ad hoc by Lluís Mont (coordinator), Cristina Fillat, Eduard Guasch, Guillem Masdeu, Gemma Pascual, Aina Rodríguez and Joan Serratosa, with the collaboration of Sandra Piquer.

This document reflects and is based on the research situation and the legal framework in force in May 2019, updating the previous document released in July 2012. The IDIBAPS Code of Good Scientific Practices is a living document that will be updated depending on the changes that take place or at the request of IDIBAPS' management. This is expected to happen once every one to three years.

Third edition: December 2024

The Strategy Directorate of IDIBAPS and the Directorate of Hospital Clinic have agreed to adopt this Code of Good Scientific Practice for personnel conducting research within these institutions. This document was updated in 2024 by an ad hoc committee composed by Michela Bertero, Maria Fatjó, Eduard Guasch, Guillem Masdeu, Lluís Mont, Anna Novials, Sandra Piquer, Montserrat Rigol, Aina Rodríguez and Paula Samsó, with the collaboration of Daniel Arbós and Teresa Lloret.

This document reflects and is based on the research situation and the legal framework in force in September 2024, updating the previous document released in May 2019. The IDIBAPS Code of Good Scientific Practices is a living document that will be updated depending on the changes that take place or at the request of IDIBAPS' management. We can expect this to happen once every three to five years.

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1. Introduction: integrity in scientific research

Scientific research is defined as an activity producing knowledge through systematic study, observation and experimentation. In biomedical research, the subject of study is human health. IDIBAPS's primary objective is to significantly help to improve people's health and quality of life through high-impact research that enables more effective translation of scientific advancements into the prevention and treatment of health issues.

This document lays out the fundamental principles that guide research integrity, as stipulated in the Code of Conduct issued by the CERCA institution. Integrity refers to the research community's basic responsibility to formulate the principles of its research, define criteria for proper research behaviour, maximise the quality, reliability and solidity of its research and its findings and respond appropriately to threats or violations of good research practices. IDIBAPS' promotion of these principles and their adoption by the research community are crucial for ensuring reliable and high-quality research for society, whilst safeguarding the credibility of the research system and its findings. The following sections detail these principles and explain how they must be followed. Furthermore, this document discusses how to manage any infringement of the established principles or breach of scientific integrity.

The personal commitment to good scientific practices and to upholding ethical standards, which is inseparable from the CERCA Code of Conduct, requires all scientific and technical staff of each affiliated CERCA research centre to comply with the entire Code of Good Scientific Practices.

2. Regulations, commitments and recommendations

A. Related to scientific practice

2.1. Main regulatory requirements in scientific practice

The purpose of biomedical research is to gain understanding of the biological mechanisms, aetiology, pathophysiology and progression of diseases, and to develop and enhance preventive, diagnostic and therapeutic interventions.

All research activities conducted in the research institute must respect fundamental ethical principles, as well as Spanish legislation, relevant European Union legislation and standards, international conventions and agreements and the opinions of the European Group for Ethics and Protection of Animals. Spanish national and local committees that judge the ethical aspects of planned experiments must give their explicit consent before any experiment and/or project begins.

Research on human beings, biological data and samples

1. Research staff working with human subjects, human data and human biological samples must be trained in the standards of good clinical practice. This training meets the international ethical and scientific quality requirements for designing, conducting, registering and reporting studies involving human subjects, as well as the regulations that safeguard the rights, safety and wellbeing of study participants in accordance with the principles of the Declaration of Helsinki (in its most recently revised version) and the credibility of the clinical research results.
2. Any research protocol that involves the participation of healthy or ill volunteers, requires clinical or non-clinical information or involves human biological samples must:
    - Be drafted, submitted to and approved by the Clinical Research Ethics Committee (CEIm, link in Catalan)[2], which evaluates aspects related to the importance, methodology and ethics of each particular project.
    - Consider the bioethical principles[3] and ethical considerations of health databases and Biobanks[4], in addition to the legislation in force in Spain[5], as well as the regulations applicable according to the type of study (see Figure 1 for more details on specific regulations).
3. The collection, processing and/or preservation of human biological samples will comply with what is specifically provided for in current Spanish legislation[6]. The privacy and right to informational autonomy of the subjects from whom the samples originate must be guaranteed.
4. The collection, processing and/or preservation of biological material of human embryonic origin must also have the corresponding permit from the Spanish Ministry of Health, prior approval from the relevant CEIm[7].
5. Human biological samples collected for conducting biomedical research that are preserved beyond work on a specific project that falls outside the organisational scope of the Biobank must belong to a research line collection that must be registered in the Registro Nacional de Biobancos (National Biobank Registry) of Instituto de Salud Carlos III[8]. The HCB-IDIBAPS

[2] Royal Decree 1090/2015, of 4 December.
[3] Declaration of Helsinki.
[4] Declaration of Taipei.
[5] Law 41/2002, of 14 November; Law 14/2007, of 3 July, on Biomedical Research; Decree 406/2006 of 24 October 2006; Royal Decree 1527/2010, of 15 November.
[6] According to Law 14/2007 on Biomedical Research.
[7] Royal Decree 1716/2011, of 18 November.
[8] According to Law 14/2007 on Biomedical Research and Royal Decree 1716/2011.

Biobank is responsible for processing the registration of all the institution's collections[9]. To register a collection, please contact the Biobank Coordination Department.

6. The use of institutional computer files or the creation of databases with information related to individuals and research purposes must guarantee the confidentiality of the data therein and must be subject to the approval of the CEIm. It must also comply with current data protection legislation[10] [11] [12].

Research with laboratory animals

1. Any research protocol involving animals must always be approved by the relevant Animal Experimentation Ethics Committee (CEEA)[13] and subsequently by the Government of Catalonia (Generalitat). The CEEA relevant to IDIBAPS is the University of Barcelona (link in Catalan).
2. The protocols for maintaining, caring for and working with laboratory animals must be followed in accordance with current legislation[14].
3. Work with laboratory animals must follow the 3R rule: Replacement (use of animals solely when no other biological system can be used), Reduction (restriction of the number of animals used to the bare minimum) and Refinement (use of appropriate experimental procedures ensuring that the animals suffer as little as possible).
4. Staff working with laboratory animals must be duly trained and accredited in accordance with current regulations[15].
5. IDIBAPS has an Animal Welfare Officer whose main duties are to supervise the wellbeing and health status of laboratory animals and to advise to prevent pain, suffering, distress and prolonged harm to animals at all times, in keeping with the 3R principle and the guidelines of current regulations[16].
6. As an institution that signed the Transparency Agreement on the Use of Animals in Scientific Experimentation of the Confederation of Scientific Societies of Spain (COSCE) and as a member of the European Animal Research Association (EARA), IDIBAPS and its staff members who work with laboratory animals are committed to:
    - Explaining clearly when, how and why they use animals in research.
    - Providing adequate information to the media and the general public about the conditions under which research that requires the use of animal models is conducted.
    - Promoting initiatives that produce more knowledge and understanding in society about the use of animals in research.
    - Reporting annually on progress and sharing experiences in this area.

Induction sessions on animal research have been held for research staff who conduct experiments with animals since September 2018. The purpose of these sessions is to inform the staff of the different

[9] Royal Decree 1716/2011, of 18 November.
[10] See: '2.4. Registration and conservation of biological material data and samples'.
[11] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016; Decree 29/1995, of 10 January; Law 23/1998, of 30 December; Law 12/1989, of 9 May.
[12] Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights.
[13] Law 6/2013, of 11 June, amending Law 32/2007, of 7 November; Royal Decree 1201/2005, of 10 October, repealed by Royal Decree 53/2013, of 1 February; Decree 214/1997, of 30 July; Order ECC/566/2015, of 20 March.
[14] Law 6/2013 of 11 June, amending Law 32/2007 of 7 November; Royal Decree 1201/2005 of 10 October, repealed by Royal Decree 53/2013 of 1 February; Decree 214/1997 of 30 July; Order ECC/566/2015 of 20 March.
[15] See the legislative and regulatory references in the section 'Research with laboratory animals'.
[16] Directive 2010/63/EU, RD53/2013, Decree 214/1997.

steps to take before carrying out procedures with animals, reviewing the rules and legal terms of animal welfare and health and their impact on research.

Good laboratory practices and biosafety

Studies intended for non-clinical health or environmental safety testing, whose results must be submitted to the competent regulatory authorities, will be conducted according to the principles of good laboratory practices and in compliance with applicable regulations[17].

However, in terms of biosafety, IDIBAPS manages several research rooms where its groups can pursue their research activity, so all laboratory areas have both room rules[18] and use and maintenance data sheets for the equipment shared at the institution. These data sheets also describe how to process the chemical and biological waste generated and provide information on classifying and labelling substances and mixtures in accordance with current regulations[19]. Users are notified of all this informative documentation when they are hired.

Moreover, the company specialised in collecting, transporting, processing and disposing of waste periodically holds sessions to instruct the staff working in the laboratories in proper waste handling procedures. All laboratories have waste rooms where full containers are removed by the waste management staff each day and replaced with empty containers.

IDIBAPS' LSB-2[20] and LSB-3[21] cultivation rooms have a specific operating protocol with a section indicating the use and maintenance data sheets for the equipment located there. These rooms have registers where users must enter notes on the maintenance and possible incidents affecting the equipment.

IDIBAPS' radioactive facility is a category 2 (IRA-3029) room authorised for working with non-encapsulated radioactive sources, located on the lower level (floor -1) of the Esther Koplowitz Centre (CEK) building. This room provides a documented procedure for how to process the waste generated, known to all users of the room.

The Biosafety Committee was created in 2012 to evaluate and ensure the safety of all experimental activity carried out in IDIBAPS' facilities and terminate any that do not comply with the biosafety principles established by legal and internal regulations. This committee also promotes training and informative activities related to biosafety at IDIBAPS.

The duties of the Biosafety Committee are to:

- Participate in advising, identifying, reviewing and approving facilities and activities related to the export/import, release into the environment, contained use, production, transport, marketing, storage, destruction and/or elimination of biological agents, regardless of whether or not they are genetically modified, as well as derivatives and products containing the same, whilst verifying the degree of compliance with current regulations.

[17] Royal Decree 664/1997, developed in the Technical guide for assessing and preventing risks related to exposure to biological agents of 2014 (link in Catalan). It has recently been adapted to technical progress with Orders TES/1287/2021 and TES/1180/2020; Law 31/1995; RD 39/1997; Royal Decree 486/1997; Royal Decree 374/2001; Royal Decree 178/2004 (Royal Decree 367/2010); Royal Decree 773/1997; DIRECTIVE 2009/41/EC of the European Parliament and of the Council; Decree 27/99.

[18] These documents include standard data sheets for cold rooms, centrifuge rooms, freezers, histology, PCR, pre-PCR, microscopy, electrophoresis and work.

[19] Regulation 1272/2008.

[20] Notification number: A/ES/I-13(CEK) and A/ES/14/I-07(CELLEX).

[21] Notification number A/ES/13/I-11.

- Evaluate facilities and activities that require authorisation before notifying the competent authorities.
- Advise on compliance with the legal and internal regulations in force in IDIBAPS' activities and facilities.
- Approve IDIBAPS' Biosafety Manual and general biosafety procedures at the institution.
- Promote initiatives, procedures and action to effectively protect human health, biological diversity and the environment within the scope of IDIBAPS and to propose improvements to conditions or the rectification of pending biosafety issues when necessary.
- Notify the competent authorities of any spill, contamination or serious accident involving biohazardous material.
- Evaluate the safety of any new experimental activity carried out in IDIBAPS' facilities.
- Terminate any activity that violates the biosafety principles set out in legal and internal regulations.
- Promote training and informative activities related to biosafety within the scope of IDIBAPS.
- Protect the intellectual property rights and/or confidentiality of data and information provided to the Committee as required.

IDIBAPS recently drafted its Manual of Sustainable Good Practices, which is available to all research staff. Though it is not a regulatory requirement, it includes a set of recommendations that IDIBAPS advises its research staff to follow. You can read it here.

Personal protection and occupational hazards

1. IDIBAPS schedules training sessions on occupational risk prevention for new staff members. The Human Resources Department is in charge of notifying them of these sessions and enforcing attendance. They are held for both research and administrative staff.
2. In the event of an accident and/or biological or chemical incident, all laboratories have informative posters and action protocols located next to or inside cabinets containing personal protective equipment (PPE).
3. All facilities managed by IDIBAPS have a safety plan in case of emergency. The CEK building has a self-protection plan (PAU) and the CELLEX building uses a plan drawn up according to the self-protection criteria of the Faculty of Medicine of the Campus Clínic.
4. All staff working in facilities managed by IDIBAPS are informed of the action plan in case of emergency. Leaflets have been prepared and distributed in different languages and informative posters are found throughout the facilities.
5. Drills are conducted annually in the CEK and CELLEX buildings and in the Neurological Tissue Bank platform in accordance with Civil Protection Regulations. The 7 Tesla and 3 Tesla MRI facilities and the CRES experimental operating room, which are located in the Hospital Clínic building, hold at least two partial drills per year. Drills are conducted every four years in the rest of IDIBAPS' centres.
6. People designated to participate in first response teams during an emergency are trained in their duties and in fire extinguishing activities at least once every four years.

2.2. Considerations and approval for research projects

Before they begin, all research and innovation projects must be previously formulated in a written research protocol.

Regarding all research protocols and projects:

1. Before starting all research and innovation projects must be approved by the competent authorities in accordance with Figure 1, with the principal investigator being responsible for securing approval and ensuring that all regulatory requirements are met. Each project must be approved specifically.
2. Once approved, the competent authorities must be notified of any change or modification made to the project, requesting approval of the change in question.
3. All research protocols must include a description of the background, the specific objectives, the methodology to be used, the work plan and expected timetable, the resources available and needed and the participating team.
4. Research protocols must include the sex/gender variable in the formulation of scientific questions, the design of the study, the methodology and analysis and the interpretation and dissemination of the results. Our institution has released a list of ten recommendations to do this, called the PROGENDERS decalogue. Researchers can also view this document issued by the European Commission on gender equality.
5. To achieve a more inclusive research protocol, and for all studies or trials using human participation, we recommend that the researchers consider other variables such as age, culture, religion, ethnicity, geographical location and/or social class.
6. Research projects are covered by IDIBAPS' general insurance policy. If necessary, as is the case with most clinical trials, a special policy must also be taken out in accordance with current regulations and the opinion of the CEIm. The insurance policy will be paid for by the funder of the study/trial and the person responsible for the initiative (promoter) will manage it. In some cases, such as studies/trials with promoters located in other countries, specific insurance may be necessary for activities carried out at IDIBAPS' facilities.

Certain types of approval and/or authorisation detailed in Figure 1 will be required, depending on the characteristics of the study. This is also explained in section 2.1. For more information on how to assess the degree of ethical compliance of your research and innovation projects, you can also read the following guide issued by the European Commission.

Figure 1. Approval necessary according to the research project:

	CEIm	AEMPS	Guarantee Commission (ISCIII[22])	Centre for Regenerative Medicine (CMR)[23]	CEEA	Specific regulations
RESEARCH IN HUMAN BEINGS OR WITH BIOLOGICAL SAMPLES OF HUMAN ORIGIN						
Observational studies	✓					
Studies with post-authorisation medication	✓					
Observational epidemiological studies	✓					
Clinical trial with medication	✓	✓				✓[24]

[22] Instituto de Salud Carlos III.
[23] Acting as a benchmark regional clinical research ethics committee as established in Royal Decree 406/2006.
[24] Royal Decree 1090/2015, of 4 December.

Clinical trial without medication	✓					
Clinical trial involving embryonic cells and derived cell lines	✓	✓	✓	✓		
Advanced therapies clinical trial	✓	✓				✓[25]
Studies with EC marked medical devices[26]	✓					
Studies with non-EC marked medical devices	✓	✓				✓[27]
Studies with samples of human origin or derived cell lines (including GMOs)	✓					✓[28]
Studies with embryonic samples or derived cell lines	✓		✓			
Studies using personal data	✓					✓[29]
RESEARCH WITH LABORATORY ANIMALS AND OTHER STUDIES						
Studies with animal experimentation (including GMOs)					✓	✓[30]
Studies with samples of animal origin or derived cell lines (including GMOs)					✓[31]	✓[32]

2.3. Informed consent: participants and biological samples

As a general rule, people may only participate in any study and biological samples and personal data may only be collected for purposes of biomedical research when the donor/participant has given his or her informed consent. **Informed consent** is the written expression of free and conscious will, validly issued by a person in full use of their faculties or by their authorised representative.

[25] Royal Decree 477/2014.
[26] EC refers to a type of labelling approved by the EU that demonstrates that the manufacturer has evaluated the product and deems that it complies with the EU's safety, health and environmental protection requirements. For more information, see this link.
[27] Regulation EU 2017/745 on regulating studies with medical devices and Regulation and EU 2017/746 on in-vitro diagnostic medical devices.
[28] For activities related to Genetically Modified Organisms (GMOs), researchers must notify and request authorisation from the competent authority, which depending on the funding of the project is either the Interministerial Council on GMOs (CIOMG) or the Catalan Biosafety Commission. Before the activity can be authorised, the facility where it is to be carried out must be authorised.
[29] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.
[30] See footnote 23.
[31] CEEA authorisation is only required when animal samples are obtained as part of the project.
[32] See footnote 23.

1. Consent must be granted freely after the potential participant/donor has been informed about the consequences and possible risks that their participation/donation may pose to their health, about the project and its objectives and about their rights and the implications for their health and privacy, and after they have asked all the questions, they deem necessary.
2. All this information will be provided in writing to the potential participant/donor or legal representative before they grant their consent in a specific information sheet for each clinical or research trial. The language used to express the informed consent must be concise, understandable and limited but sufficient in length.
3. The written documentation is supplementary to the verbal explanation that the researcher must provide, taking bioethical values into account, and must be sufficient for the participant/donor to give their consent in an informed and voluntary way.
4. The information sheet and the informed consent form must be approved by the CEIm.
5. The research staff must ensure that the donor understands that donations of biological material are used for research purposes and not therapeutic ones.
6. The complementary bioethical principle of beneficence must be applied to participants who are legal minors or who lack cognitive autonomy to make decisions, informing relatives or legal representatives and requesting their consent. People with limited autonomy and minors will participate in decision-making to the extent possible according to their age and capacity. Minors may give consent starting from the age of 12. Research staff must be aware that the criteria for legal adulthood may vary depending on the type of project[33].
7. Participants in a biomedical research project may revoke their consent at any time without affecting their participation. They have the right to be informed of their genetic and other personal data according to the terms in which they expressed their wishes.
8. The lack of consent may be an exceptional circumstance and must be approved by the CEIm, in accordance with the criteria and conditions established by the corresponding regulations. These criteria can be found in the CEIm's Protocol of Criteria for the Exceptional Use of Samples, on the CEIm webpage.
9. Along with the content and legal requirements, it is recommended that the information sheets and informed consent forms consider the minimum requirements for preparing written material aimed at patients: adapted content, typographic clarity, linguistic clarity and prior testing of the material. The Spanish Agency for Medicines and Health Products (AEMPS) has drafted a guide (link in Spanish) for their proper preparation, including several recommendations.
10. In any event, the information sheet and consent form must contain:
    - The purpose of the research or clinical trial.
    - The methodology for obtaining the sample, if applicable.
    - The expected benefits for the patient and/or society.
    - Possible inconveniences linked to donating and taking the sample, including the possibility of being contacted later to obtain new data or samples.
    - The identity of the person responsible for the research or the Biobank and contact details.
    - The name of the CEIm that approved the study.
    - The right to revoke consent.

[33] For example, the age of legal adulthood is 18 for clinical trials, whilst in projects regulated by the Biomedical Research Law (LIB), it is 16 years. If a minor participates in trials or projects regulated by the LIB, a parent or guardian must sign to grant the minor's express and tacit consent.

- The location where the analysis will be conducted and the destination of the sample once the research is completed (destruction, deposit in a Biobank, collection for a research line or use in another project with prior request for new consent).
- The right to know the genetic data taken from the analysis of the samples.
- A guarantee of confidentiality.
- A warning about the possibility that information may be communicated to the donor about their health, as well as the donor's right to decide whether or not to receive such information.
- A warning about the potential implications of the information that may be obtained for their family members.
- A guarantee of the voluntary nature of the donation.
- The name and contact information of the Data Protection Officer (DPD).

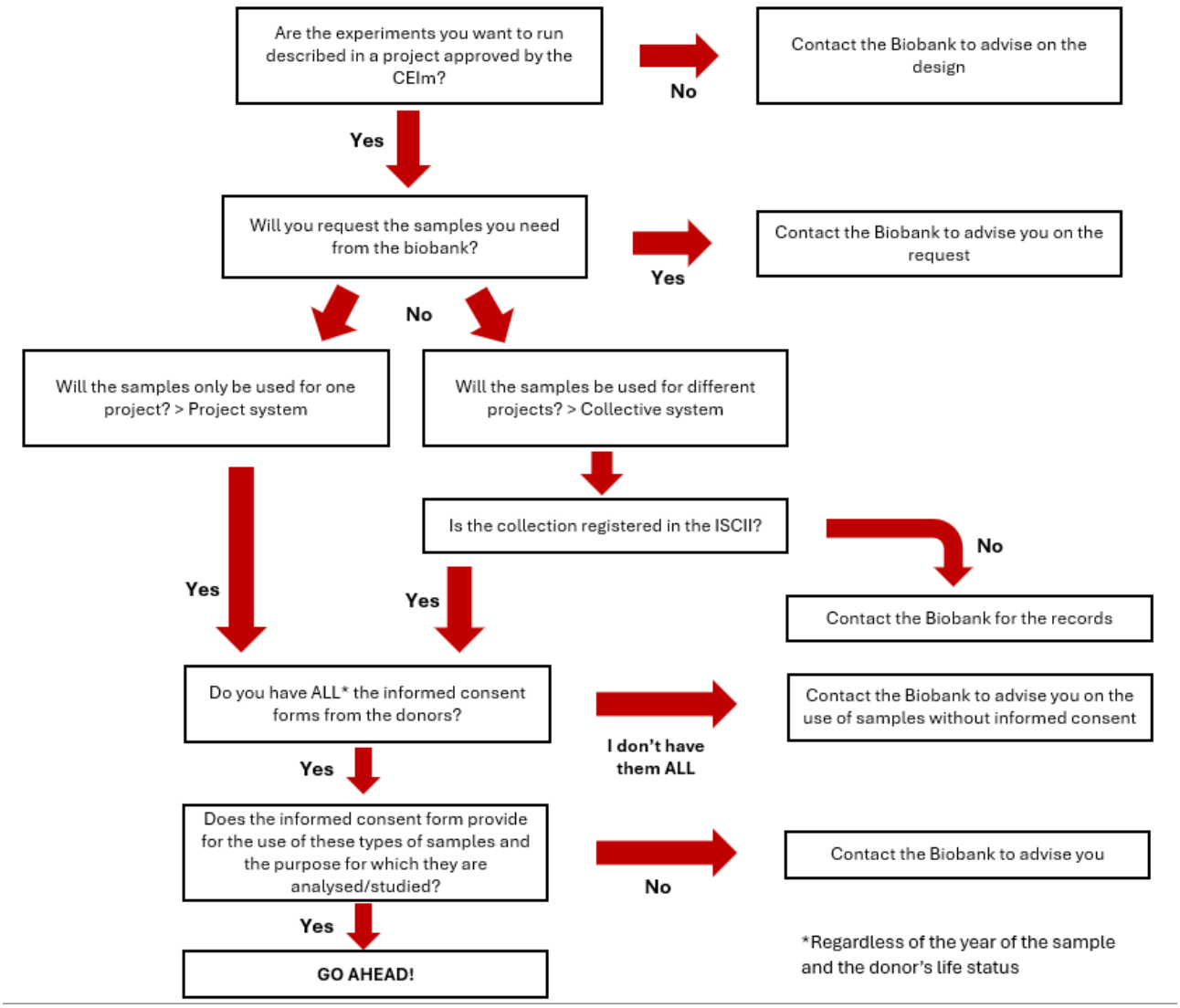
The documents and templates of the CEIm of Hospital Clínic Barcelona are available at this link (link in Catalan).

11. Depending on the research being conducted or the origin of the sample, the information sheet and informed consent document must indicate other aspects:
    - For **clinical trials**, it must specify:
        - The methodology used.
        - The treatment that may be administered, with reference to a placebo, if applicable.
        - Alternative treatments available.
        - The form of financial compensation, if any, and provided that this is not an inducement, and treatment in case of harm or injury associated with their participation in the trial, as stated in the Medicines Law.
        - The researcher in charge of the project must inform the participant, clear up all doubts, answer all questions and explain how they can be contacted in case of emergency.
    - **Research projects, except clinical trials.** In these cases, it is advisable to include a section where the donor can impose restrictions on the use of the samples, if they so desire. It is particularly necessary to determine what will be done with the sample once the research project is completed, since consent must be obtained. The methodology used to analyse the samples must also be indicated.
    - **Genetic studies included in research projects and/or clinical trials.** An information sheet and a specific informed consent form must be prepared for genetic studies that involve taking, processing and/or conserving biological samples, guaranteeing the subject's privacy and right to informational autonomy. The subject's consent may provide for the sample to be used for other projects related to the one initially proposed. The consent must be renewed whenever the biological samples are intended to be used for purposes other than those intended at the time of donation, with the corresponding permission requested from each participant.
    - **Storage of biological samples in a Biobank.** IDIBAPS and Hospital Clínic Barcelona have a coordinated Biobank that provides a single and complete reference catalogue. According to Law 14/2007 on Biomedical Research and Royal Decree 1716/2011, which establishes the basic requirements for the authorisation and operation of Biobanks, a Biobank is a non-profit establishment that houses one or more collections of biological samples of human origin for biomedical research purposes, organised as a technical unit with criteria of quality, order and destination, regardless of whether it stores samples for other purposes.

Biological samples of human origin that are incorporated into the Biobank of Hospital Clínic and IDIBAPS may be used for any biomedical research, provided that the donor has consented to these terms. This will be the only case in which the consent form may be generic, without the need to specify the line of research or research project for which the samples will be used. Projects planning to use samples from the Biobank must be approved by the CEIm, the Biobank's External Scientific Committee and the scientific director of the platform. The Biobank staff will also provide advice to scientific or clinical staff interested in drafting consent forms for research projects or for making deposits in the Biobank.

- **Biological samples left over from extractions made for healthcare-related purposes.** In this case, consent for collection will not be necessary, as it is implied in the provision of care. However, the patient's consent must be obtained for using the sample, in the same terms as set out in the previous sections. If the samples are deposited in the Biobank, donors may generally consent to any research that has been approved by the Biobank's external committees. Otherwise, the donor must consent specifically to use in each specific project.
- **Biological samples of human embryonic origin.** These must be adapted to what is established in the Biomedical Research Law and the Commission of Guarantees for the Donation and Use of Human Cells and Tissues.
- **Biological samples from autopsies.** These samples may taken if the subject expressed that desire during their lifetime or if they did not expressly state their opposition to the same. Thus, it will be necessary to inquire into any prior instructions. If none are found, the subject's closest relatives and the professionals who attended them at the health centre will be consulted and a record will be made of any such consultations. The samples may only be used for research with prior approval from the CEIm.

Figure 2. Diagram of decisions on the use of human biological samples in relation to the Biobank.



2.4. Registration and conservation of biological material data and samples

General considerations

1. Each research protocol must include a system for collecting data, records and biological and derived material resulting from the research conducted, as well as the plan for storing, preserving and potentially sharing them.
2. All data resulting from research experiments or observations must be collected. This information must be recorded in databases, logbooks, clinical histories or data collection notebooks. The records will also include changes, errors, negative results, unexpected results and discordant results. The person who collects or observes them will always be identified.
3. For research in laboratories and in keeping with the indications of Good Laboratory Practices, the use of laboratory notebooks provided by IDIBAPS is mandatory. These are the only laboratory notebooks that IDIBAPS' research staff may use. Each user is responsible for the quality and veracity of the information contained. These notebooks are the property of the institution and must not leave the laboratory. The regulations regarding the use of these notebooks are detailed inside them.

Who owns the research protocols and records or databases?

1. In clinical trials with medicines, the protocol and data collection notebooks belong to the sponsor (whether private or an independent researcher). The principal investigator (PI) may not use the data obtained for their own benefit without the sponsor's consent. These conditions and the publication conditions must usually be specified in the study protocol. However, the PI must keep a copy of both the protocol and the data collection notebook in the study file. The original data and source documents (results of complementary examinations) will be kept by the PI in the clinical record. What a sponsor external to the institution will never possess are the data identifying the participants in a project[34].
2. In studies with external sponsors, all primary documentation (clinical histories, results of complementary examinations, databases, etc.) will be the property of the centre where the trial is conducted. The sponsor may ask the participants for their consent to store and preserve biological samples outside the institution.
3. In studies sponsored by IDIBAPS, the protocols, records, data collection notebooks, biological and derivative material obtained during the course of the project are the property of IDIBAPS, as established in the institutional intellectual property policy.
4. If the PI changes institutions, they will leave all original records and biological samples at IDIBAPS or at the appropriate institution, duly identified and at the expense of the researcher or person responsible. At the request of the IP leaving the institution, the CEIm and IDIBAPS management may consider providing the IP with a duly anonymised copy of the original records.

How and for how long should the original research data and records be preserved?

1. The PI is responsible for maintaining a Clinical and/or Laboratory Procedures Manual (called the Investigator's File in clinical trials with medicines), which details the procedures followed to ensure the traceability, veracity and inalterability of the data.
2. This Manual or Investigator's File must be safeguarded from loss, theft or accidental destruction. This means that it must be duly identified and stored somewhere with controlled

[34] See: Data confidentiality.

access. There must be a specific plan for making periodic backup copies of data recorded on electronic media.

3. The clinical records (which constitute the original document in clinical trials with medicines) must be archived in accordance with the regulations governing the clinical record and the conditions established by the centre where the patient is treated.
4. The PI is responsible for keeping the project documentation and the data obtained properly archived for the period necessary in each case, generally 10 years after the end of the project (10 years after the publication of the results), except when longer periods are required by law.
5. In clinical trials with medicines, the Investigator's File must be kept for 25 years after the end of the trial, or for a longer period if other applicable requirements so provide, such as if the trial is submitted as the basis for registering a particular medicine.

Data confidentiality

1. In no case should the data obtained from a research project contain information that may be used to identify the participants, except in the clinical history. All records derived from a research project must be identified with an individual code per patient that does not allow their identity to be known. The PI of the study at the centre will be the only person to keep a record of the codes associated with the patients' identifying data. Therefore, the data collection notebooks, data recording sheets and identification of biological samples will only contain this code.
2. The data must be processed (for a research project) in accordance with current regulations[35]. For more information, see the Manual of Good Practices for Data Protection (link in Catalan).
3. The data controller and the person in charge of data processing must take technical and organisational action to safeguard personal data and prevent their alteration, loss, processing or unauthorised access.
4. Those responsible for data processing and those who work in any phase of the data processing are bound to professional confidentiality regarding the data. This confidentiality requirement will remain in force even after the end of their relationship with the data controller.

Research data and open science

The registration, documentation, preservation and sharing of research data is also addressed in the institutional open science policy, which recommends the creation of data management plans for each project. It also recommends that research data be deposited in trusted repositories in accordance with FAIR principles[36] and accompanied by the attribution of Creative Commons licenses.

2.5. Artificial Intelligence in research

Research in artificial intelligence (AI) and research that uses AI-based tools requires consideration of the main challenges that this technology poses, related to the responsible development and use of autonomous systems, the consequences and social responsibility of this research and the use of data[37]. To face these challenges, it is recommended to adhere to the key principles of **reliability,**

[35] See the section on Legislative and regulatory references, with special attention paid to Additional Provision 17 regarding the use of health data in the field of research.
[36] FAIR Principles: Findable, Accessible, Interoperable and Reusable.
[37] For more information, see the EU Living Guidelines on the Responsible use of genAI.

honesty, respect and responsibility and to bear the following considerations in mind in projects involving AI:

- Due to the capacity of AI systems to make autonomous decisions despite human supervision, it is necessary to ensure that **fundamental human rights** are not compromised and to consider the possible or expected **impact** that their use may have on people, living beings and society.
- Research staff who conduct research in/with AI are **responsible** for the integrity of its content, including the results or other outputs in the framework of their research.
- The use of AI systems in research may raise doubts about the quality and reliability of its results. Therefore, researchers must ensure the maximum **transparency, traceability and ability to inspect this research**, taking a critical approach, applying quality controls and measures, promoting the use of open and publicly available data sources and ensuring open access to the results, promoting their **reproducibility**. Any action taken to ensure the **trust** of the research community and society in this research will be beneficial.
- AI tends to be a tool with intrinsic **biases**. This must be kept in mind when analysing conclusions obtained from it, reporting such biases transparently and trying to minimise them.
- A **data protection** breach is one of the primary risks when using AI systems. Thus, in addition to requesting informed consent for the use of personal data, researchers must take particular care to advise subjects on the degree of public access to the information, its sensitivity, the vulnerability of those potentially affected and the impact and consequences of the research.
- The **unpredictability** of AI systems must be acknowledged and explained accordingly. Researchers must also work to minimise it to the extent possible.
- When these tools are developed, their **environmental impact** must be borne in mind, with special emphasis placed on the energy consumption they require.
- With regard to **disseminating** the research, the research staff's deep and informed knowledge must be tapped to inform a balanced discussion on the risks and opportunities provided by AI. Members of **society** at large must also be invited to participate in discussions on research in/with AI to include their perspective, values and interests in the related decision-making to the extent possible, since they also bear the impact of this research.
- Whenever possible, research staff must stay informed about this rapidly evolving technology and the good practices of its use, in addition to taking advantage of the training opportunities offered.

B. Related to research environment

2.6. Research project management

The management of all aspects of research projects must follow the principles of transparency and responsibility. In addition to current legal regulations, it must also obey IDIBAPS' internal regulations.

Transparency

As a public sector foundation, IDIBAPS upholds standards of transparency following the Charter of Fundamental Rights of the European Union, the Spanish Law on Transparency, Access to Public Information and Good Governance and the Code of Principles and Recommended Conduct in Public Procurement of the Generalitat de Catalunya to promote transparency and integrity in public activity, ensuring access to information and establishing obligations of good governance.

Research staff must use research funds appropriately and consciously, according to the principles of effectiveness and efficiency, responsibility and proper management.

Moreover, research staff must ensure that IDIBAPS' public and professional reputation is not compromised by establishing research agreements with people or groups involved in illegal activities. Therefore, when considering conducting research for an external funder, the research staff should not get involved in projects that, to their knowledge (when negotiating and confirming the agreement), are financed with resources acquired irregularly.

Transparency and the priority of the public interest must be defended not only in research financed with public funds, but also in every partnership with other organisations or companies involving financial benefits.

Conflicts of interest

A conflict of interest is a situation in which financial or other interests may potentially compromise the professional judgment and objectivity of researchers in the design, development, evaluation or dissemination of research.

Conflicts of interest involve the use of someone's authority for personal, professional and/or financial gain, leading to bias and a loss of objectivity in research. For example, an academic conflict of interest could arise if someone interferes with the peer review process to extract some type of personal benefit or when the research is funded by an institution that may prefer a specific research outcome.

Conflicts of interest must be declared in any context in which they arise, such as in the publication or notification of research results, peer review, participation in evaluations, the management of cases of misconduct, among others.

IDIBAPS members must not accept donations or personal benefits linked to their work at IDIBAPS. Personal awards that recognise a research staff member's scientific career are considered exempt from this restriction.

Project management with external collaborators and/or organisations

The following considerations must be borne in mind when managing research projects with external actors:

1. **Transparency**. The general interest must always prevail in the exchange of information and knowledge between members of IDIBAPS and the industry or other organisations involved in any given research project. The basic condition to achieve this is that all agreements reached between the parties involved must be completely transparent. The representatives of the centres involved must approve the aforementioned agreements in advance and ensure that there are no abusive clauses that could affect the dissemination of knowledge and the authors' intellectual freedom. IDIBAPS will call on its legal services for advice whenever deemed necessary.
2. **Intellectual property rights**. All IDIBAPS research groups' contributions in technology or knowledge to projects led by external organisations must be documented in the agreements mutually agreed upon with the promoting organisations. The research group and/or individuals participating in the project must be clearly identified as members of IDIBAPS in the agreements, particularly concerning the conditions for publication and dissemination agreed upon with the promoter and/or the partners of the collaborative projects.
3. **Industrial property rights, spin-offs and/or patents**. In collaborative projects where the contribution of IDIBAPS members may result in industrial property rights, spin-offs and/or patents, the necessary agreements will be drawn up to share them with the promoters and/or partners. IDIBAPS' current Intellectual Property Rights (IPR) regulations and the Regulations on the creation of spin-offs will govern these issues. In case of doubt, researchers must seek advice from the Knowledge and Technology Transfer Department (KTT).
4. **Financial consideration protocols**. All financial agreements made between IDIBAPS researchers or research groups and external organisations will be documented in the corresponding contracts, agreements or donations, which will be made accessible to the competent IDIBAPS bodies and committees. These documents will detail all agreed financial compensation directly or indirectly related to the project. IDIBAPS research staff or research groups may not reach financial compensation agreements for the same project other than those detailed in these documents[38].

2.7. Supervising research staff in training

1. Each individual linked to a research project through a contract, grant, stay or internship aimed at acquiring some type of training (i.e., trainee) must be assigned at least one supervisor. They may also be assigned a mentor to guide them in their professional career, helping them to resolve challenges and/or conflicts or facilitate new connections and partnerships. These supervisory and mentoring roles can be performed by the same person or by different people. For more information on this section, see the European Charter for Researchers and the Marie Sklodowska-Curie actions guidelines on supervision.
2. The supervisor is responsible for the trainee's education. Therefore, the supervisor must have the right level of expertise and commitment to perform the role. The supervisor must ensure that the objectives set for the trainee are met by the agreed time and guide the trainee in their future professional career.
3. The number of trainees under a supervisor should be appropriate and compatible with their obligations and commitments. The supervisor is expected to perform to the highest quality standards.

[38] The contracts and agreements will be reviewed and signed through the Projects Management Department, except for patent license contracts, the transfer of industrial property rights, Material Transfer Agreements (MTAs) and Data Transfer Agreements (DTAs), which will be reviewed and processed through the KTT Office.

4. The supervisor must cultivate a constructive and positive relationship with the trainee, helping to provide an optimal environment for the transfer of knowledge and the successful pursuit of their professional career.
5. The trainee's responsibilities are determined by the supervisor's instructions and by the training programme to which they are assigned. Trainee researchers must pledge to make the most of the training opportunities provided by their supervisors and the institution.
6. The supervisor's responsibilities include: interacting personally on a regular basis with the trainee(s) under their charge, holding regular collegiate meetings to ensure that each trainee completes assigned projects and to monitor their progress, offering and facilitating participation in training and career development activities, ensuring all trainees' working conditions and preparation in terms of occupational risk prevention and informing them of key issues that are important to them. It is also the supervisor's responsibility to prevent trainees from getting involved in external tasks that could interfere with their own training.
7. The supervisor is responsible for ensuring that the trainee receives both general institutional information and information addressed to their specific profile. This is why they must ask the head of the research group (if this is not the same person) to notify the Scientific Coordination Department of the trainee's arrival at the institution.
8. If the trainee is a predoctoral (R1) researcher, the supervisor is expected to facilitate access and admission to a university doctoral programme. To the extent possible, the supervisor must also offer support in covering the programme's registration fee. As part of the programme, the supervisor will ensure that the trainee receives the annual monitoring commission from the university to monitor the development of the research project. The supervisor will also ensure that the trainee is informed of the regulations and procedures for writing their thesis, as well as any supporting tools, mobility grants, etc.. They will also need to facilitate the trainee's participation in the activities organised as part of the IDIBAPS PhD Programme[39].

For more information about this section, see the European Charter for Researchers and the Marie Sklodowska-Curie actions guidelines on supervision.

2.8. Publication, protection and dissemination of results

1. The results of all research projects must be disseminated in a scientific medium[40]. Research results must be shared or published in peer-reviewed scientific journals or other publication or communication platforms. Publication in journals with deficient peer-review systems, including those known as predatory journals, is not recommended. The publication of preprints (manuscripts without peer review) is considered a preliminary step before publication in other established media.
2. Failure to publish the results of a research project or any excessive delay in doing so may constitute a misappropriation of resources. The publication of results of studies in which people have participated is an ethical imperative.
3. Negative results or results different than those expected in a research project must also be published.
4. Duplicate publication or publications are considered malpractice.

[39] These activities include PhD Welcome Days, PhD Day and others. It is also important to promote active participation in the PhD Community, a self-managed association for pre-doctoral researchers, so they can interact with peers of similar profile and create a community.

[40] Law 14/2007, of 3 July, on Biomedical Research and the institutional open science policy.

5. When publishing, fragmenting the results obtained from a single research project or fragmenting a data set into different publications must be avoided. Fragmentation is only justified for reasons of extension.
6. Publications or communications must explicitly include:
    a. The institution(s) where the research was conducted as established in the Institutional Affiliation and Acknowledgements Policy.
    b. The ethics committees that approved and supervised the research protocol(s).
    c. Any details of subsidies, grants or financial sponsorships received.
    d. A declaration of possible conflicts of interest, real or perceived.
7. Before publishing the results of a research project in any medium, it is recommended that the researcher responsible for the project contact the Knowledge and Technology Transfer Department (KTT) and communicate their results to receive an analysis of their potential application and commercial interest. If the analysis is positive, the KTT may recommend that the researcher protect their results before publication.
8. It is not acceptable to communicate and disseminate the results of original research in non-scientific media (newspapers, television, radio, the Internet, social networks, etc.) before it has been peer-reviewed, meaning before it has been accepted for publication. Exceptionally, their disclosure may be justified for public health reasons. In this case, the authors will ensure that the results are reviewed in parallel.
9. The IDIBAPS Communication Department must be contacted before making any press release or announcement in the public media that disseminate the results of a research project. Bear in mind that many journals impose embargo rules on news derived from articles pending publication.
10. Any public statement must be derived from the original results of the research. Such disclosure must be made in a cautious tone and especially free of false expectations, as recommended by the Code of Ethics (*Codi Deontològic*; link in Catalan) of the *Col·legi Oficial de Metges de Barcelona*. Hasty or inaccurate public disclosure of the results of a research project in an incorrect, partial or biased way is an inappropriate ethical and scientific practice that can have serious consequences for the research staff and for the institution.
11. Open access ensures transparency, equity and the reuse of scientific knowledge whilst also contributing to its reproducibility and improving its impact and visibility. Consequently, open access to publications must be ensured, either through publication in open access journals or deposit in public repositories, as required by the institutional open science policy. This is the responsibility of the Scientific Coordination Department.

2.9. Authorship of research results

The authorship of research results does not depend on belonging to any particular profession or hierarchical position, but is determined by the **type of contribution** to research.

Authorship of research articles

According to the latest recommendations of the International Committee of Medical Journal Editors (ICMJE), one must meet (all) the following conditions to be considered an author:

- Contributed substantially to the conception or design of the study or to the collection, analysis or interpretation of the study data.
- Helped to write the draft or to critically review the work by contributing intellectual content.
- Accepted the final version of the work for publication.
- Assumes responsibility for ensuring that questions related to the accuracy or integrity of any part of the study are investigated and properly resolved.

According to these recommendations, authors must accept the final draft of original manuscripts in writing before they are submitted for registration or publication. In addition, mere participation in obtaining resources, collecting routine data or providing experimental subjects does not necessarily justify author status, though these efforts should be recognised in the acknowledgements section.

Generally, the **order** of the authors of scientific publications must be as follows:

- The first author is the one who made the greatest effort in the research and prepared the first draft of the article.
- The person who directs or has the final responsibility for the study is the last author.
- The remaining authors should appear in order of the importance of their contribution.
- The person in charge of correspondence is primarily responsible for the entire editorial process, as well as for any future communication arising from the publication of the work.

When two or more authors have expended the same effort and shared the main task of preparing the manuscript, they will both be considered first authors. Such a circumstance will be expressed explicitly in the publication. The same criterion can be applied in the case of the last author.

Authorship of other research results

The recommendations described above apply equally to the authorship of other publications (reviews, monographs, book chapters, posters, conference presentations, etc.) and to other research results such as data (datasets), software, code and research protocols.

Artificial intelligence and authorship

Artificial intelligence (AI) systems cannot meet the criteria for authorship, so they cannot be authors or co-authors. Authorship implies responsibility, which can only be required of human authors. Furthermore, as non-legal entities, AI systems cannot declare conflicts of interest or manage copyright or licensing agreements. Authors are fully responsible for the content of their manuscript, including those parts produced by an AI tool, and are consequently held responsible for any breach of publication ethics.

Following the principles of transparency and accountability, AI-based tools used to write a manuscript, to produce images or graphic elements appearing in the article or to perform any other task must be declared. This includes explaining which tool has been used and how in the publication process. It is the author's responsibility to assess whether to declare the use of tools with a minimal impact on the manuscript, such as those solely used for spell checking.

2.10. Institutional affiliation in research results

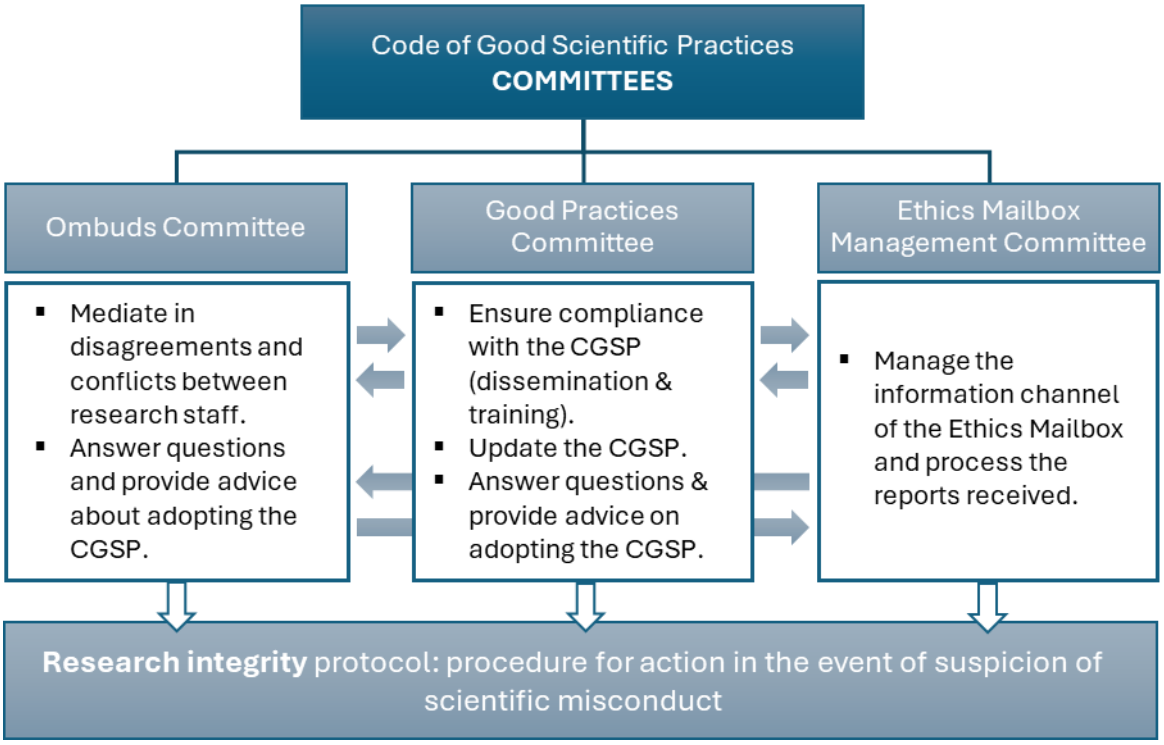
1. Authors of scientific works must declare the organisation(s) with which they were affiliated or formally (contractually or administratively) linked when they conducted their research. The first

and primary scientific affiliation of research works must be the organisation where the author did most of the reported research.

2. Institutional affiliations must be stated in any research result, including scientific publications, contributions to conferences and bibliometric databases.
3. It is the author's responsibility to declare their affiliations honestly and truthfully. An author's declaration of affiliations that do not correspond to any formal and documentable relationship with an institution, as well as affiliations with centres where the research was not carried out, may be considered fraudulent.
4. You may read the regulations on the use of IDIBAPS affiliation in the Institutional Affiliation and Acknowledgment Policy.
5. IDIBAPS researchers' multiple affiliations with consortium institutions (Hospital Clínic Barcelona, University of Barcelona, etc.) and/or non-consortium institutions imply the possibility of declaring multiple affiliations in their scientific work. Multiple affiliations are explicitly recognised in cases of partial affiliation with a different institution than the main one and must be declared in any output derived from the activity carried out during the period of partial affiliation. These cases include researchers affiliated with different institutions, but also situations such as sabbatical leave or cases in which part of the research is carried out in centres different from the one to which they are primarily linked, among other cases.
6. In addition to their main affiliation, an author may declare additional affiliations in a scientific work when each institution provided substantial support to the study. It should be remembered that a situation of multiple affiliations should be authorised and regulated by the institutions involved, within the framework of agreements or through specific permits.
7. When multiple affiliations are declared in a scientific work:
    - Each author's main affiliation must be the institution in which most of the work reported was conducted.
    - Equitable treatment must be respected in the order in which the affiliations are listed.
8. Researchers affiliated with IDIBAPS who acquire a new affiliation outside the consortium institutions are responsible for notifying the Scientific Coordination Department prior to formalising the affiliation. The new affiliation will require formalising an agreement or convention between IDIBAPS and the new institution that will regulate the declaration of institutional affiliations in the authorship of scientific works.

3. Protocols and committees

Figure 3. Summary of the committees related to the Code of Good Practices and their duties.



(CGSP: Code of Good Scientific Practice)

3.1. Research integrity protocol: procedure for action in the event of suspicion of scientific misconduct

Introduction

Research at IDIBAPS is conducted according to the principles of **honesty, responsibility, respect** and **reliability**, subscribes to the main international declarations and guidelines on research integrity and adheres to the principles defined in the European Code of Conduct for Research Integrity published by ALLEA (2023).

IDIBAPS assumes responsibility for establishing transparent procedures in the event of suspicion of scientific misconduct, to identify the nature of any possible scientific misconduct and resolve it appropriately. It also holds itself responsible for protecting people suspected of having committed misconduct until the facts are proven. These procedures are applicable to all staff members attached to IDIBAPS.

Scientific misconduct

Scientific misconduct or malpractice happens when false statements and/or assertions are made intentionally or as a result of gross negligence, or when intellectual property is infringed. In general, scientific misconduct is defined as a violation of what is established in this Code of Good Scientific Practices. Active participation in other researchers' misconduct, failure to report cases of misconduct committed by others and significant negligence in performing supervisory duties may also be considered misconduct. Unintentional errors or honest differences of opinion do not constitute misconduct.

The main activities that constitute research misconduct are:

- Fabrication: Inventing data and/or results and recording and/or publishing them as if they were real.
- Falsification**:** Manipulating materials, equipment, images and processes or changing, omitting or suppressing data without justification so they do not accurately represent the results of the research.
- Plagiarism: Appropriating the work, ideas, results or processes of other authors without authorisation or giving corresponding credit.

Other activities that involve a breach of good research practices, such as all those that affect the integrity of the research process or the research staff, also constitute misconduct. A list of these activities can be found in section 3 of the European Code of Conduct for Research Integrity published by ALLEA (2023).

Operational procedure for suspected scientific misconduct

The parties involved must pledge to maintain complete confidentiality at all stages of this procedure. This will be articulated by signing a confidentiality agreement. People responsible for assessing the case will also sign a declaration of absence of conflicts of interest.

Notifications of suspected misconduct may come from staff within the institution or from external sources and must be addressed to the management of the centre (director, general manager and strategy director) (direccio@recerca.clinic.cat). Alternatively, they may be addressed to the Good

Practices Committee (cbonespractiques@recerca.clinic.cat).

When a request for enquiry into suspected misconduct is received, the following steps will be taken:

Assessment of the allegations presented. This process entails checking whether the allegations made have enough credibility and may indicate any possible misconduct. At this stage, it will also be determined whether IDIBAPS is competent to launch the study of the case. IDIBAPS' **management** is responsible for conducting this initial assessment. Any members of management who are involved or have a conflict of interest in assessing the case must recuse themselves from the process. If the entire management is involved, the chair of the Scientific Advisory Board will appoint the commission that will conduct this initial assessment.

Preliminary investigation. This process involves collecting information and evidence to determine whether it is necessary to launch a formal investigation.

An **ad hoc commission** will be appointed by IDIBAPS' **management** (or, alternatively, by the chair of the Scientific Advisory Board) to follow the procedure. The process will begin with a meeting between the commission and the accused individual, who will have to explain the facts. The accused individual will be given a period to submit the information that allows for discrimination regarding the incriminating facts. After the commission has collected all the information, it will set a time to meet based on the complexity of the case, and decide whether to conclude the investigation because no misconduct has occurred or to proceed with a formal investigation. The commission will prepare a report that will be sent to both parties and to IDIBAPS' management.

Formal investigation. This process requires examining all the evidence in detail and either issuing recommendations and administering the appropriate punishment, if applicable, or closing the case and protecting the accused individual.

The **commission** will notify the accused individual of all the allegations for which they will be investigated and launch an investigation in which it must remain impartial. This will include the submission of evidence as required from the accused individual. The commission may also interview other actors or witnesses and may follow all proceedings deemed necessary to clarify the facts.

At the end of the process, a report will be drawn up that must be conclusive about whether or not scientific misconduct has occurred. This report must be ratified by IDIBAPS' director. The accuser may appeal the decision within 15 days of notification. If the investigation concludes that no scientific misconduct has taken place, it will be recommended to take actions so the accused individual's reputation can be restored, if appropriate. If the process concludes that scientific misconduct has taken place, the punishment deemed appropriate according to the type of offence will be administered and the different actors involved will be informed, including those external to the institution, if applicable. If other institutions are involved, they will be informed of IDIBAPS' decision and the necessary action will be taken regarding institutional relations with them.

Notification of CERCA. IDIBAPS' management promises to inform the institution CERCA that outstanding scientific misconduct has taken place and to notify the CERCA Ombudsperson of the details under strict confidentiality and respect for the people involved.

Action in case of misconduct

The action taken in confirmed cases of misconduct will greatly depend on each case and its context, and thereforewill be adapted to each situation. Below is a list of some possible consequences and punishments. This list is to be considered indicative rather than exhaustive or complete:

- Academic consequences, such as the withdrawal, correction or retraction of scientific publications or the revocation of academic degrees.
- Work-related consequences in accordance with applicable legislation, such as the disciplinary termination of a contract.
- Civil or criminal consequences as established in the respective applicable codes, such as the return of material or funds to the institution or research funders, the termination of access to IDIBAPS or consequences for infringement of copyright rights or falsification of documents.

3.2. IDIBAPS Research Ombuds Committee

Definition and composition

The IDIBAPS Research Ombuds Committee is an institutional committee mainly tasked with mediating potential conflicts and/or unresolved disagreements between members of the institution's research staff. It is independent of the governing bodies, impartial, formed by duly qualified professionals of high personal integrity and required to maintain discretion, anonymity and confidentiality in managing any consultation, mediating or performing any other task.

The Ombuds Committee is made up of four members of the IDIBAPS research and structure staff appointed by IDIBAPS' management every four years.

Duties

The duties of the Ombuds Committee are to:

- Act as a mediator in disagreements and conflicts between research staff members, primarily in matters related to the content of the Code of Good Scientific Practices, but also in any other scientific and/or personal matter that interferes with the professional activity of the staff involved. This includes possible conflicts between predoctoral (R1) or postdoctoral (R2) researchers and their supervisors.
- Answer any queries arising from the adoption of the Code of Good Scientific Practices by IDIBAPS' research staff. When appropriate, it must refer these cases and queries to other competent committees, teams or offices.

Operations

Correspondence with the Ombuds Committee can be sent to its email address: ombudscommittee@recerca.clinic.cat. Alternatively, the Ombuds Committee may receive correspondence through other mechanisms, such as the Ethics Mailbox, the Good Practices Committee or IDIBAPS' management.

The Ombuds Committee will assess whether there is any conflict of interest between any of its members and any of the parties involved in the conflict to be resolved. If so, IDIBAPS' management will be notified. The Ombuds Committee will also assess whether a case requires activating the research

integrity protocol in the event of suspicion of scientific misconduct, which is described in point 3.1 of this Code of Good Scientific Practices.

The Ombuds Committee will analyse the conflict by talking to the parties involved, and propose a solution. It will leave a written record of the description of the conflict and the solution adopted.

If the conflict persists or one of the parties does not agree with the proposed resolution and submits an allegation or plea, the Ombuds Committee must inform IDIBAPS' management.

Coordination with the CERCA Ombudsperson

After informing IDIBAPS' management, the IDIBAPS Ombuds Committee may refer the cases it deems appropriate to the CERCA Ombudsperson regarding disagreements between research staff members, conflicts and issues of integrity, scientific misconduct or breaches of the CERCA Code of Conduct, as stipulated in the Operating Regulations of the CERCA System Ombudsperson (link in Catalan).

3.3. Good Practices Committee

Definition and composition

The IDIBAPS Good Practices Committee is an institutional committee that coordinates all actions related to the development and implementation of the Code of Good Scientific Practices.

The Good Practices Committee is made up of members of the IDIBAPS research and structure staff who are specialists and/or in charge of the topics covered in the code and are appointed by IDIBAPS' management. Two members are responsible for coordinating the main actions of the committee.

Duties

The duties of the Good Practices Committee are to:

- Ensure compliance with the Code of Good Scientific Practices, taking action mainly aimed at disseminating them among the scientific community and promoting training in good research practices.
- Update the Code of Good Scientific Practices every three to five years at the request of IDIBAPS' management.
- Answer questions and/or queries arising from the adoption of the Code of Good Scientific Practices by IDIBAPS' research staff. When appropriate, it must refer these cases and queries to other competent committees, teams or offices.

Operations

- The duties described above will be performed at the request of IDIBAPS' management.
- Research staff members can communicate with the Good Practices Committee through the contact email address: cbonespractiques@recerca.clinic.cat or through the Ombuds Committee, the Ethics Mailbox or IDIBAPS' management.

3.4. Ethics Mailbox Management Committee

Definition

The Ethics Mailbox Management Committee is responsible for managing the Ethics Mailbox, a communication channel for all information related to events that may constitute a serious or very serious crime or administrative infraction in a work-related or professional context[41] at IDIBAPS, as well as infractions of IDIBAPS' internal regulations.

This committee reports organically and operationally to the director of IDIBAPS and is made up of people with management, financial management, human resources management and legal management positions at IDIBAPS.

Duties

The duties of the Ethics Mailbox Management Committee are to:

- Manage the internal information channel, adapting it if necessary, and process the communications received according to the applicable regulations.
- Ensure that whistleblowers do not suffer retaliation and provide advice in this regard.
- Periodically inform the director of IDIBAPS of the most important aspects related to the Internal Information System.
- Ensure the effectiveness of the legal guarantees for protecting whistleblowers.

Operations

This committee operates through the **Internal Information System**, a structure that includes the IDIBAPS Ethics Mailbox. Securely designed, established and managed, it enables and guarantees that all information received about possible serious or very serious criminal or administrative infractions can be dealt with effectively and processed appropriately, whilst always ensuring maximum confidentiality and establishing safeguards for the whistleblower's due protection. This Internal Information System does not change any existing protocols or disciplinary powers.

If desired, all correspondence with the Ethics Mailbox may be anonymous.

You can read the Ethics Mailbox Management Policy and Procedure here (link in Catalan). To access the Ethics Mailbox, follow this link.

[41] Following the provisions of State Law 2/2023, of 20 February, regulating the protection of people who report regulatory violations and the fight against corruption.

4. Important contact information

Animal Experimentation Ethics Committee (CEEA)	ceea@ccit.ub.edu
Clinical Research Ethics Committee (CEIm)	consultaceic@clinic.cat ceic@clinic.cat
Biosafety Committee	bioseguretat@recerca.clinic.cat
Good Practices Committee	cbonespractiques@recerca.clinic.cat
National Grants Department (pre-award)	otri@recerca.clinic.cat
Communication Department	idibaps.comunicacio@recerca.clinic.cat
Scientific Coordination Department	coordinacio.cientifica@recerca.clinic.cat
Biobank Coordination Department	Biobancs@recerca.clinic.cat
Office for Research Management, Contracts and Agreements (Legal Department)	fccontra@recerca.clinic.cat
Project Management Department (post-award)	projectes@recerca.clinic.cat
European and International Projects Department (pre-award)	ope@recerca.clinic.cat
Knowledge and Technology Transfer Department (KTT)	innova@recera.clinic.cat
Management	direccio@recerca.clinic.cat
Ombuds Committee	ombudscommittee@recerca.clinic.cat
Data Protection Officer	protecciodades@recerca.clinic.cat
Animal Welfare Officer	mrigol@recerca.clinic.cat

5. Bibliographic and reference documentation

Code of Conduct, CERCA (2018)
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6. Legislative and regulatory references

Main regulatory requirements in scientific practice

- **Research involving human beings**

Royal Decree 1090/2015, of 4 December, which regulates clinical trials with medicinal products, the Clinical Research Ethics Committees and the Spanish Clinical Studies Registry.

Law 41/2002, of 14 November, basic regulation of patient autonomy and rights and obligations in terms of clinical information and documentation.

Law 14/2007, of 3 July, on Biomedical Research. In the territorial scope of Catalonia, the only benchmark CEIm for these types of studies is the one attached to the Barcelona Centre for Regenerative Medicine (CMR), according to Decree 406/2006 of 24 October 2006, which regulates the requirements and accreditation procedures for clinical research ethics committees (DOGC) 26/10/20.

Royal Decree 1527/2010, of 15 November, which regulates the Commission for Guarantees for the Donation and Use of Human Cells and Tissues and the Research Project Registry.

Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for the authorisation and operation of Biobanks for the purpose of biomedical research and the processing of samples of human origin and regulates the operation and organisation of the National Biobank Registry for biomedical research.

Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use, which repeals Directive 2001/20/EC.

Royal Decree 957/2020, of 3 November, regulating observational studies with medicinal products for human use.

Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on health products, which amends Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and by which Directives 90/385/CEE and 93/42/CEE of the Council are repealed.

Royal Decree 192/2023, of 21 March, regulating health products.

- **Research involving animals**

Law 6/2013 of 11 June, amending Law 32/2007, of 7 November, on the care of animals, regarding their exploitation, transport, experimentation and slaughter.

Royal Decree 1201/2005, of 10 October, repealed by Royal Decree 53/2013, of 1 February, laying down the basic rules applicable to the protection of animals used in animal experimentation and other scientific purposes, including teaching.

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.

Decree 214/1997, of 30 July, regulating the use of animals for experimentation and other scientific purposes.

Order ECC/566/2015, of 20 March, which establishes the training requirements that must be met by staff who manage animals used, bred or supplied for experimental and other scientific purposes, including teaching.

- **Good laboratory practices**

Royal Decree 1369/2000, of 19 July, which modifies Royal Decree 822/1993, of 28 May, which establishes the principles of good laboratory practices and their application in the conduct of non-clinical studies on chemical substances and products.

Royal Decree 664/1997, of 12 May, on the protection of workers against risks related to exposure to biological agents during work. Developed in the Technical guide for assessing and preventing risks related to exposure to biologic agents of 2014. It has recently been adapted to technical progress with Orders TES/1287/2021 and TES/1180/2020.

Law 31/1995 of 8 November, on the Prevention of Occupational Risks.

Royal Decree 39/1997, of 17 January, which approves the Regulation of Prevention Services.

Royal Decree 486/1997, of 14 April, which establishes the minimum provisions for health and safety in the workplace.

Royal Decree 374/2001, of 6 April, on the protection of the health and safety of workers from the risks related to chemical agents at work.

Royal Decree 178/2004, of 30 January, which approves the General Regulation for the Development and Execution of Law 9/2003, of 25 April, which establishes the legal system for the contained use, voluntary release and marketing of genetically modified organisms.

Royal Decree 178/2004, of 30 January, which approves the General Regulation for the Development and Implementation of Law 9/2003, of 25 April, which establishes the legal system for the contained use, voluntary release and marketing of genetically modified organisms. BOE no. 27 of 31 January and subsequent amendments Royal Decree 367/2010.

Royal Decree 773/1997, of 30 May, on minimum safety provisions and relating to the use by workers of personal protective equipment. BOE no. 140 12/06/1997.

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms.

Decree 27/1999, of 9 February, on the management of sanitary waste.

Recording and preservation of data and samples of biological material

- **Data confidentiality**

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights, with special attention paid to Additional Provision 17 regarding the use of health data in the field of research.

Ley 14/2007, of 3 July, on Biomedical Research.