IR Sant Pau

Code of Good Research Practices

Version 5

Versions

Version	Date	Modification
1	12/05/2009	Drafting of the Code of Good Scientific Practice
2	14/07/2010	New logo and coding of documentation according to ISCIII criteria
3	26/10/2015	Points 3, 4, 5, 8, 9, 14 and 15 are added to version 2 of the document
4	20/04/2022	Code of Good Scientific Practice updated and name changed to IR Sant Pau Code of Good Practice in Research
5	26/07/2024	Updating with the new IR Sant Pau institutional logo. Incorporation of section 5.7. Use of Artificial Intelligence. Update of current legislation. Update of section 8.1 Biosafety, health and environment. Update of section 14.8 Communication, dissemination, and publication of results

Approvals

Written by:	Reviewed by:	Reviewed and approved by:			
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Institutions comprising IR SANT PAU Sant Pau

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www.santpau.cat

FUNDACIÓ INSTITUT DE RECERCA DE L'HOSPITAL DE LA SANTA CREU I SANT PAU
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https://fundaciosantpau.cat/

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AGÈNCIA DE SALUT PÚBLICA DE BARCELONA
https://www.aspb.cat/

BANC DE SANG I TEIXITS
www.bancsang.net

CENTRE COCHRANE IBEROAMERICÀ
www.cochrane.es

EQUIP D'ATENCIÓ PRIMÀRIA SARDENYA
www.eapsardenya.cat

UNIVERSITAT AUTÒNOMA DE BARCELONA (UAB)
www.uab.cat

Contents

Abbreviations

CBS: Biosafety Committee
CGPR-IR: IR Sant Pau Code of Good Practice in Research
CEEA: Ethics Committee for Animal Research
CEIm: Ethics Committee for Investigation with Medicinal Products
CIR: Research Integrity Committee
ESC: External Scientific Committee
GR: Research Groups
HR: Human Resources
HRS4R: Human Resources Strategy for Researchers
ICMJE: International Committee of Medical Journal Editors
IR Sant Pau: Research Institute Sant Pau
ISC: Internal Scientific Committee
eQRD: Electronic data collection notebook
OMG: Genetically modified organisms
QRD: Data collection notebook
RRI: Responsible Research & Innovation
R&I: Research and Innovation
SEA: Animal Experimentation Service

Introduction

In order to ensure excellence in scientific research within a culture of scientific integrity, the concept of **R**esponsible **R**esearch & **I**nnovation (**RRI**) is a crucial component. RRI is designed to strengthen links between the scientific community and stakeholders (civil society organisations, the educational and scientific community, policy decision-makers, and industry) to work closely together throughout the research and innovation process, thereby creating space for co-creation.

In this regard, the Research Institute of the *Hospital de la Santa Creu i Sant Pau* (IR Sant Pau), as a ***Ce**ntres de **R**ecerca de **Ca**talunya* (**CERCA**) center, adheres to the CERCA Institution's Code of Conduct (*Codi de conducta de la Institució CERCA*[1]**)** and follows the guidelines of the *European Charter for Researchers*[2] concerning the roles and responsibilities of research staff and institutions in the research process and human resources. IR Sant Pau is committed to following these guidelines in accordance with the HRS4R seal granted by the European Commission in 2015.

The IR Sant Pau **C**ode of **G**ood **P**ractice in **R**esearch (**CGPR-IR**) serves as a framework for self-regulating scientific practices. It establishes standards, recommendations, and commitments that must be observed by the scientific personnel affiliated with the Institution.

Its content is supplementary to the existing legal regulations in this area and has been designed and updated by the RRI unit, reviewed by the Internal Scientific Committee, and approved by the External Scientific Committee, the Scientific Management, and the Governing Board of IR Sant Pau.

[1] Codi de conducta CERCA, Institució CERCA, novembre 2018
[2] The European Charter for Researchers, European Commission, march 2005

1. OBJECTIVES AND SCOPE OF THE DOCUMENT

The objective of this Code is to establish guidelines for the conduct of scientific activities at IR Sant Pau. The CBPR-IR is a collective regulatory instrument that must be adhered to, reviewed, and updated periodically to ensure its applicability and relevance.

The CBPR-IR applies to all research personnel, including trainees, technical staff, and support staff, regardless of their type of affiliation with IR Sant Pau or the nature of their contract. It also applies to individuals external to the institution who conduct scientific activities at IR Sant Pau. Its content is applicable to all research projects managed by the Research Institute of Sant Pau.

Therefore, the CBPR-IR is integrated into the employment, affiliation, or collaboration relationships of the entities within IR Sant Pau.

Although this code has been written in inclusive, non-sexist language, any gender-specific nouns should be understood as grammatical gender that is non-specific and inclusive.

2. DISSEMINATION, IMPLEMENTATION, AND MONITORING COMMITMENTS

Once this document has been approved by the Governing Board and the Board of Trustees of IR Sant Pau, as evidence of the adoption of its contents, the representative of each institution within IR Sant Pau, along with the Director of IR Sant Pau, will sign a copy of the final document and commit to its internal dissemination and implementation.

Additionally, the Director of IR Sant Pau, through its Institutional Communication unit, will ensure the dissemination of the CBPR via the intranet and publicly on the IR Sant Pau website (https://www.recercasantpau.cat/) for open access and consultation, and will ensure its internal application.

The Director of IR Sant Pau, through its HR unit, will provide a copy incorporated into the IR Sant Pau Welcome Manual to any new professional joining the center at the time of their entry.

3. GENERAL PRINCIPLES OF THE SCIENTIFIC PRACTICE AT THE IR SANT PAU

3.1. Values, mission and vision[3]

The key values of the Institute are as follows:

- ✓ Excellence
- ✓ Collaboration and multidisciplinary approach
- ✓ Transparency
- ✓ Efficiency
- ✓ Ethical and social commitment
- ✓ Responsibility
- ✓ Continuous improvement and innovation
- ✓ Flexibility and adaptability
- ✓ Transfer of knowledge

The IR Sant Pau mission and vision are set out in the *Strategic Plan for Research and Innovation.*

3.2. Basic rules governing scientific practice

Research at IR Sant Pau is organized around Research Groups (GR), and all personnel involved in research activities must adhere to the principles of rigor, honesty, responsibility, transparency, and confidentiality, as established in the *European Charter for Researchers* [4], while promoting cooperative work and collaboration between groups.

Additionally, the policies of IR Sant Pau in this area follow the guidelines set out in the Science Law, *Llei de la Ciència*, 09/22 de 21 de desembre[5].

[3] The values, mission and vision are the current in the Strategic Plan referenced on the date of approval of this document.
[4] Carta Europea del Investigador, Comissió Europea, març 2005
[5] Llei de la Ciència, 09/22 de 21 de desembre

3.3. Adhesion to the CERCA Code of Conduct

Since 2011, the IR Sant Pau has been a center within the CERCA system of Catalonia, and in November 2018, it signed its adherence to the CERCA Institution's Code of Conduct (*Codi de Conducta de la Institució CERCA*[6]), thereby adopting its ten principles.

3.4. RRI

IR Sant Pau has a RRI Plan aimed at aligning the process and outcomes of our research and innovation with the values, needs, and expectations of European society, taking into account criteria such as ethics, sustainability, and social relevance.

4. RESEARCH ORGANIZATION

The organization of research at IR Sant Pau is outlined in the Internal Rules of Procedure (*Reglament de règim intern*) and Shared Scientific Project.

The research groups and other research structures at IR Sant Pau must have at least one person responsible for leading and representing them publicly. For research groups, this leader must hold a doctoral degree and is responsible for fostering a work environment that promotes knowledge exchange and allows staff to develop their skills and expertise. They must also encourage cooperation with other research teams to facilitate the exchange of ideas and stimulate new collaborations.

Research groups and other research structures at IR Sant Pau must have a well-documented organizational structure that specifies the responsibilities of each member in research activities, including those of trainee researchers.

4.1. Monitoring research trainees

The priority tasks for trainee personnel must be those related to their training and should be clearly defined. They are responsible for completing the tasks assigned by

[6] Codi de conducta CERCA, Institució CERCA, novembre 2018

their designated supervisor according to the planned schedule, in order to achieve the set objectives.

Trainee research personnel have all the rights provided for under the *Estatut de l'estudiant*[7].

4.2. Assignment of a supervisor

Any individual affiliated with the institution for training as a researcher (undergraduate, postgraduate, master's, doctoral students, or others) will be assigned a supervisor. This supervisor, who will act as the primary point of reference for the trainee researcher, must hold a doctoral degree and possess documented research experience.

4.3. Responsibilities of supervisors

The supervisor will be directly responsible for:

- The education of the trainee, acting as a mentor and guide with the goal of meeting their full training expectations, appropriate to the initial objectives and within the expected timeframe, by providing the best possible conditions for their future scientific development.
- Considering both teaching and research activities in the training of doctoral students.
- Meeting regularly with trainees to monitor and supervise the completion of tasks, and to discuss new publications or relevant information related to ongoing research.
- Be responsive to the trainee, especially to ensure that the trainee is not asked to perform tasks unrelated to the planned training programme.
- Ensure that the trainee's working conditions are appropriate and comply with the CGPR-IR Sant Pau.

[7] Estatuto del estudiante Universitario, diciembre 2010

4.4. Limitations on the number of trainees per supervisor

The maximum number of trainees per supervisor must be compatible with the supervisor's other obligations and commitments, and consistent with the research group structure.

5. RESEARCH DEVELOPMENT

5.1. Research project planning

Project planning is an essential part of the research process. Accordingly, any research involving direct intervention with human subjects (data, materials, patients, healthy volunteers), experimental animals, embryonic material, other types of biological material, or any other research activities must be meticulously planned and detailed in a written document (protocol) prior to its execution.

Depending on the characteristics of the research project, it is essential to consider ethical, legal, and safety and health aspects. The project may require approval from relevant regulatory bodies concerning ethics or safety, such as the Animal Experimentation Ethics Committee (Comitè d'Ètica d'Experimentació Animal, **CEEA**), the Clinical Research Ethics Committee (Comitè d'Ètica d'Investigació amb medicaments, **CEIm**), the Joint Prevention Service (SPM), or the Biosafety Committee (Comitè de Bioseguretat, **CBS**). No project may proceed without obtaining the prior approval of the pertinent regulatory bodies.

5.2. Defining the research protocol

A research protocol is a document that provides a detailed description of the project, including the study aims, methods, and research question. The protocol should contain all of the following:

- Members of the research team (researchers, or principal investigator [PI] and collaborators)
- Introduction explaining the research subject

- Background information (or the *State-of-the-art*)
- Hypothesis
- Study objectives
- Study population (samples/data for the project)
- Methodology (design, sample measure, N calculation, statistical methodology, etc.) and study variables
- Expected impact
- Human and material resources needed to carry out the project
- Bibliographic references
- Budget
- Data management plan (data collection and safeguards)
- Risk management plan (if necessary)
- Statistical analysis (if necessary)
- Tasks planning and study schedule
- Participant Information Document and Informed Consent Form (in human studies)
- Publishing rights and financial agreements (when necessary)
- Insurance policy (when necessary)
- CEIm, CEEA, and/or CBS approval (depending on the study population)
- Authorisation from the relevant regulatory body (or bodies)

The principal investigator is the individual responsible for the project, assuming leadership and accountability for achieving its objectives. They are also responsible for the accuracy of the committed resources.

5.3. Development and monitoring of research projects

The project should follow the planned schedule. The methodology and results should be recorded in source documents (laboratory notebooks, CRF, eCRF, clinical history, medical records, working documents, or another documentary support).

5.4. Modification of the research project/protocol

Any modification requiring new procedures or changes in study variables, sample size, objectives, or the intended use of the resulting biological and/or chemical material for

purposes other than those described in the original protocol must be duly documented as a modification of the original project.

Modified protocols for research in humans, animals, or that involve biological material must adhere to established approval and authorisation procedures, regardless of whether the changes are considered significant or not.

5.5. Secret research

Secret research is not permitted. However, it is important to differentiate secret research from research whose dissemination is temporarily limited for reasons of competitiveness, patentability, or confidentiality.

5.6. Collaborative projects

When groups from different institutions participate in a research project, the scope and terms of the collaboration must be established in writing before starting the project.

The joint collaboration agreement must meet the usual requirements of a research agreement. In addition, this agreement shall: 1) clearly describe all aspects of the research plan expected to be carried out within the framework of the joint collaboration, 2) the criteria for updating studies, 3) the distribution of responsibilities, rights, and obligations of the participating groups and/or centres with regard to the results as well as storage and processing of data or samples; 4) a preliminary draft of how the results obtained will be presented and disseminated; 5) issues related to intellectual property; 6) rules for publishing results; and 7) any other potentially relevant issues, including possible commercial implications, financing, and conflict resolution.

5.7. Use of Artificial Intelligence

In order to use Artificial Intelligence (AI) tools, it is essential to be clear about the responsibilities of their use as well as the limitations of these tools. Researchers will be responsible for their scientific output, maintaining integrity and a critical view of AI-generated content while considering its limitations and biases. The AI system will not be considered an author, as authorship requires human responsibility. All content generated by AI must be reviewed, and the original source should always be cited to

avoid copyright issues and ensure that the content is appropriate and aligns with the principles of intellectual property.

It is essential to be transparent in its use and to appropriately cite which AI tools have been used and how, including the name of the AI, the version, and the influence it has had on the generated content. Additionally, researchers must be vigilant about privacy, confidentiality, and intellectual property rights, protecting sensitive information from misuse, especially when uploading data to online AI systems.

In any case, European regulations regarding harmonization of the use of AI[8] must be complied with.

6. RESEARCH PROJECTS INVOLVING WITH EXPERIMENTAL ANIMALS

Anyone involved in the project who works with experimental animals must receive the appropriate training as stipulated by the pertinent regulatory authority.

Research involving animals must be conducted out responsibly in accordance with all current laws and regulations (Referenced in Annex 1) and meet all ethical requirements in place at the registered centre (SEA).

Whenever possible, the use of alternatives to experimentation on live animals shall be encouraged, following the three "Rs" principle: 1) Replacement of animals with other methods, 2) Reduction in the number of animals used, and 3) Refining experiments on animals to prevent or minimise pain and suffering.

6.1. Ethics Committee for Animal Research (CEEA)

Research studies involving animals must first obtain approval from the CEEA and the competent authority.

[8] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024

7. HUMAN RESEARCH

Research projects involving human subjects (healthy volunteers or patients), or involving the collection of clinical data or biological samples, must follow the tenets of the *Declaration of Helsinki*[9] (last update, Fortaleza, Brasil 2013), and also comply with Spanish law (*Ley 14/2007 de 3 de julio de Investigación Biomédica*)[10] and *Ley 41/2002 sobre Autonomía del paciente*[11].

Clinical trials involving drugs or healthcare products must be conducted in accordance with the regulations of the European Union (*Regulation (UE) nº 536/2014 of 16 April 2014*)[12] and Spanish law (*RD 1090/2015*)[13], which regulate clinical trials involving medicinal products. Observational studies should be conducted in accordance with Spanish law *RD 957/2020*[14].

It is strongly recommended that all researchers involved in clinical trials receive training in Good Clinical Practice (GCP), which includes international ethical and scientific quality requirements for the design, conduct, recording and reporting of trials involving human subjects, ensuring the protection of rights, safety, and well-being of the subjects involved.

For research studies involving patients, all members of the research team who are not involved in treating patients must collaborate fully with the treating physician and avoid interfering in any way with the treatment.

In all cases, the health and well-being of the participants in research studies shall be prioritised to maximise benefits and minimise risks.

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[9] Declaration of Helsinki, Fortaleza, Brasil, Octubre 2013
[10] Ley 14/2007, de 3 de julio, de Investigación biomédica
[11] Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica.

[12] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/ec
[13] Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos.
[14] Real Decreto 957/2020, de 3 de noviembre, por el que se regulan los estudios observacionales con medicamentos de uso humano.

7.1. Research Ethics Committee

The evaluation of any research protocol in the IR that involves studies of any type involving human beings will never begin without the prior favourable opinion of the CEIm and the approval of the competent authority.

The evaluation of any research protocol in the IR, which requires the favourable opinion of a Research Ethics Committee (CEI), will be carried out in our institute by the CEIm of the Hospital de la Santa Creu i Sant Pau

Note that the other institutions that comprise the IR Sant Pau all have their own CEIm within their institution for the evaluation and authorisation of research protocols.

7.2. Informed consent

Prior to study enrolment, researchers shall clearly and transparently inform potential participants about the study aims and risks. The researchers must be available to answer any questions that potential participants may have. After the researcher have provided all relevant study-related information, subjects who agree to participate must first sign a written informed consent form provided by the researcher. This form must comply with all the current laws and regulations[15]. The informed consent form given the researcher the right to register, manage, process, and store data throughout the duration of the project.

This document must include contact details for the Data Protection Delegate of the corresponding institution at IR Sant Pau. In addition, it must clearly state that the participant has the option to enforce the following rights: access, rectification, deletion, limitations on data processing, portability, and opposition (withdrawal of consent), and the right to request a copy of the form.

[15] Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos.

7.3. Confidentiality and personal data protection

Research projects involving the collection and/or conservation of human biological samples must guarantee donor confidentiality and comply with all current legislation on the collection, storage, use, and disposal of biological samples.

Research projects involving the use of institutional information technology (IT) files or the creation of databases containing information on individuals must guarantee the participants data confidentiality. These files and databases are subject to current regulations for database registries.

All research projects at IR Sant Pau involving in human participants must comply with the following laws and regulations: *Regulation (EU) 2016/679 of the European Parliament* [16], the *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*[17] and *Ley 14 / 2007 de 3 de julio de Investigación Biomédica*[18].

8. OTHER RESEARCH

8.1. Biosafety

Any research project or procedure involving the manipulation of biological samples, organisms, or biological agents, including genetically modified ones, will never begin without the approval of the **Biosafety Committee (CBS).** The CBS will assess the risk of the experiment based on its intrinsic hazard and the characteristics of the infrastructures, work practices, and work equipment.

[16] 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, and repealing directive 95/46/EC (general data protection regulation)

[17] Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.

[18] Ley 14/2007, de 3 de julio, de Investigación biomédica.

8.1.1. Research with biological agents

Any research project involving the use or manipulation (deliberate or not) of biological agents, including genetically modified ones, must comply with *RD 664/1997*[19], concerning the protection of workers against risks related to exposure to biological agent during work.

8.1.2. Research with genetically modified organisms

Any research project involving genetically modified organisms must comply with Spanish law (*RD 178/2004*)[20], which approved the general regulation for the development and execution of the law (*Ley 9/2003 de 25 de Abril*)[21], which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms, and to request the mandatory ministerial and/or regional authorization.

8.1.3. Research involving embryonic source material

Research projects involving the collection, processing or conservation of human embryonic source material or functionally similar cells must first obtain approval from the CEIm. Then, the researchers must request a report from the competent authorities (Committee on Guarantees) for the donation and use of human tissues and cells in accordance with the following laws: *Ley 14/2007, de 3 de julio de Investigación Biomédica*[22] and *RD 1527/2010*[23]. Additionally, they must request favorable authorization from the CEIm.

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[19] Real Decreto 664/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes biológicos durante el trabajo.

[20] Real Decreto 178/2004, de 30 de enero, por el que se aprueba el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente

[21] Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente.

[22] Ley 14/2007, de 3 de julio, de Investigación biomédica.

[23] Real Decreto 1527/2010, de 15 de noviembre, por el que se regulan la Comisión de Garantías para la Donación y Utilización de Células y Tejidos Humanos y el Registro de Proyectos de Investigación

[24] DIRECTIVA 2004/10/CE DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 11 de febrero de 2004 sobre la aproximación de las disposiciones legales, reglamentarias y administrativas relativas a la aplicación de

8.2. Good laboratory practices

Non-clinical studies intended for health or environmental safety tests that may be reported to the regulatory authorities will be carried out in accordance with current legislation governing *good laboratory practices*[24].

9. RESEARCH PROJECTS FUNDED BY NON-PROFIT ORGANISATIONS

9.1. Transparency and general interest

The transfer or exchange of knowledge and technology with private entities must be done with complete transparency, ensuring that this transfer is in the public interest and that it complies with both Catalan *(Llei 19/2014 de transparència, accés a la informació pública i bon govern*[25]) and Spanish law, (Ley 19/2013, de 9 de diciembre [26], RD 919/2014[27] and *Proyecto de RD por el que se aprueba el reglamento de desarrollo de la ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno*[28])

9.2. Industrial and intellectual property rights

Researchers who contribute significantly to the design and execution of a research project must inform their institution and obtain advice on technology transfer. Agreements involving financial compensation and transfer or exchange of knowledge

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los principios de buenas prácticas de laboratorio y al control de su aplicación para las pruebas sobre las sustancias químicas

[25] Llei 19/2014 de transparència, accés a la informació pública i bon govern, desembre 2014
[26] Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno.
[27] Real Decreto 919/2014, de 31 de octubre, por el que se aprueba el Estatuto del Consejo de Transparencia y Buen Gobierno.
[28] Proyecto de Real Decreto XX/2015 por el que se aprueba el reglamento de desarrollo de la ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno

and technology with private entities must comply with all aspects relative to industrial property rights and, if necessary, intellectual property rights. These agreements must be accessible to the institutions, committees, and people with responsibility for such matters.

9.3. Dissemination of results

Researchers conducted externally-funded projects normally require access to confidential data from the sponsoring company or organisation. However, confidentiality agreements must not restrict the researchers' ability to publish new results, unless otherwise specified.

The results obtained through industry-sponsored research studies must be disseminated according to the terms agreed by the two parties to avoid bias in publications, to support transparency, and to ensure public benefit.

According to *current regulations*[29], the sponsor of the research project is required to disclose the results, whether positive or negative. However, the researchers may disclose the results obtained prior to receiving authorisation from the sponsor.

9.4. Conflict of interest

Conflicts of interest are common in many human activities and research is no exception. Conflicts may arise when a scientist's opinion of a given research project could potentially be influenced by secondary interests. It is the individual's responsibility to recognise situations in which conflicts of interest may exist in order to properly manage these, by directly declaring the existence of a possible conflict, avoiding the conflict altogether (if possible), or resolving the conflict appropriately in accordance with the policies of the contracting companies, assessment bodies, or publisher.

9.5. Research data protection

Any transfer of data or material must be regulated in a specific agreement for the defined object (eg: Material Transfer Agreement, Data Transfer Agreement), and always

[29] COMMISSION DECISION (EU) 2021/1240

following the legislation of the Reglament de protecció de dades[30] and the Ley orgánica de protección de datos y garantía de los derechos digitales[31].

10. RESEARCH FACILITIES

10.1. Equipment and facilities

All research facilities must be suitable for research work and must comply with all legal requirements. These facilities must be designed and built to ensure the safety of the people who work there and also the quality of the research results.

Equipment acquired by public funds must be labelled to indicate the source of the funds with an inventory number.

All facilities and equipment must receive regular maintenance and repair. When applicable, a verification and calibration plan for certain instruments should be implemented to ensure the reliability of measurements obtained with that equipment.

10.2. Use of external equipment and facilities

Instruction manuals for all equipment must be made available to potential users. Access to these manuals shall be controlled by the person responsible for the equipment.

10.3. Information technology and IT equipment

The people in charge of IT and related equipment must ensure the proper functioning and maintenance of the computer equipment provided by the IR to the research groups. This requirement refers to the machines, software, accounts, credentials, and passwords.

[30] Reglamento Europeo de Protección de Datos (RGDP 2016/679)
[31] Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.

The use of IT equipment is restricted to research-related tasks. No personal use is allowed.

Any IT-related event, modification, installation or extension must be reported to the IT department by e-mail at: IR_SISTEMESINFORMACIO@santpau.cat.

It is necessary to guarantee the confidentiality, integrity and availability of the data, information and results of the projects with the means provided by the IR.

11. RECORDING, DOCUMENTATION, STORAGE, SAFEKEEPING, USE OF DATA, AND USE OF BIOLOGICAL OR CHEMICAL MATERIAL OBTAINED FROM RESEARCH

11.1. Specific data collection and preservation material plan

All research protocol must include a data management plan that how the data will be collected and recorded, as well as how the biological or chemical material obtained will be managed, including the storage, conservation, and use of these materials. Sample collection and preservation must comply with the laws, *Ley 14/2007 de 3 de julio de Investigación Biomédica*[32] and *RD 1716/2011*[33]. Particular attention should be paid to article 22 of RD 1716/2011, which refers to the storage and conservation of biological samples of human origin and the European Data Protection Regulation and the Organic Law on Data Protection and guarantees of digital rights.

According to current legislation, samples intended for biomedical research can be obtained for the following purposes:

- Storage in a biobank as part of a collection of samples under a biobanking regime.

[32] Ley 14/2007 de 3 de julio de Investigación Biomèdica

[33] Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica

- Storage as a collection for biomedical research purposes outside the organisational scope of a biobank.
- Conservation for use in a research project; in this case, the samples can only be used specifically for the research project unless the subject has expressly given consent to allow the sample to be used in other research projects or lines of research; in this case, the samples must be stored in a biobank, or become part of a collection that is reported to the National Register of Biobanks for Biomedical Research.

Samples collected for specific purposes through a given line of research must be registered with the National Registry of Collections of the Carlos III Institute of Health. The principal investigator is legally responsible for ensuring the correct application of all pertinent regulations and for the proper management of the collection.

Samples stored in the biobank for generic use will be managed by the biobank, a scientific platform offered as a public service, according to quality criteria and purpose. The biobank will ensure that resources managed by the scientific community are accessible.

11.2. Data registration and correction

All data resulting from experimental and/or research work must be duly recorded in laboratory books, clinical histories, databases, eCRF, CRF or other formats that may be established.

These records must include the names of the people involved in obtaining the data. Any errors in these records, or negative, unexpected or discordant results should not be ignored. Any corrections made must be clear and identificaty the author.

11.3. Data and sample preservation

The principal investigator must be aware of how to properly custody and conserve biological or chemical material obtained from experiments and observations, as well as related documentation.

11.4. Safekeeping and access to data and samples

All records related to study data or biological or chemical material obtained in the course of a research project must be accessible to all members of the research team. All members must provide information about the results obtained, how these were obtained, and the interpretation thereof.

All documentation and biological or chemical material obtained in the course of a research project will be kept in the strictest custody in accordance with the criteria established by the principal investigator and the institution.

The documentation resulting from a clinical trial (experimental and/or observational) is available in the clinical trial documentation management area (AGDAC), which contains all of the archives, thus facilitating compliance with the regulations[34] on document archiving.

11.5. Property of data and samples

All documents related to biological or chemical samples obtained from the research project is subject to the governance and custody of the principal investigator's institution.

If a collaborating researcher moves to a new institution and needs access to the data obtained during their research activity, the principal investigator is authorised to provide a copy of all or part of the record books or electronic data. If the PI is the person switching institutions, the delivery of this documentation will be supervised by the management team.

In both cases, the transfer of aliquots and biological or chemical material to another institution shall be carried out in accordance with current legislation[35].

[34] Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos

[35] Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento

11.6. Sharing data and samples with third parties

Data and material obtained from research must be public. If certain conditions are met, it can be shared with third parties, except when restrictions have been established for possible future commercialisation.

The transfer of material or data may be limited for reasons of availability, competitiveness, or confidentiality. Both material and data must be anonymized. A new informed consent form will be required for the transfer.

The transfer requires the following: i) the qualification to make good use by the person who requests it, ii) the due knowledge of who generates the material, iii) a transfer protocol with the agreement of the main researcher responsible for the material, and iv) the willingness of the applicant to assume the possible costs of production and transmission.

11.7. Data and sample storage period

All data obtained from research projects must be stored for at least 10 years from the time that the results are first released, unless the law requires a longer storage period (e.g., 25 years for clinical trials of drugs, according to the *RD 1090/2015*[36]). In some cases, the law may allow for shorter periods.

Regardless of the storage requirements indicated above, biological and chemical material used or obtained in the course of research cannot be destroyed within 10 years from the first release of the results. In some cases, the material must be kept for longer periods of time when required by law. In all cases, the signed consent of the donor is required.

de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica.

[36] Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos.

The use of biological material must adhere to the regulation regarding the custody, treatment, and management of biological samples established by Spanish law *(RD 1716/2011)*[37].

11.8. IR Sant Pau Biobank

The IR Sant Pau Biobank (biobanc@santpau.cat), registration number B.0000722, is authorised as a Networked Biobank by the government of Catalonia. This biobank is the platform that stores (and makes available to the scientific community) all biological samples of human origin obtained at any of the various institutions that comprise the IR Sant Pau. The IR Sant Pau Biobank is a network biobank with two nodes, the IR-HSCSP node (the coordinating node), and the Puigvert Foundation node.

The IR Sant Pau Biobank is operated in accordance with Spanish and European regulations as well as with national and international bioethics codes to which Spain adheres to.

The main aims of the IR Sant Pau Biobank are to:

1. Identify, record, process, store, and manage **human biological samples, and to provide access to these materials** for biomedical research by research groups at IR Sant Pau.
2. **Advise** research staff in matters related to the creation, management and design of collections of human samples and data, and related documentation.
3. Ensure the **quality and traceability of samples** and their related data, with the aim of promoting quality biomedical research.
4. Coordinate resources and promote **quality practices** with regards to biological samples of human origin and associated data.
5. Foster **scientific collaboration** between different research groups.
6.- Guarantee **respect** for fundamental **rights and freedoms**, **protect** the **dignity and identity** of donors, and ensure the accurate treatment of personal data.

[37] Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para la investigación biomédica

7.- Offer the scientific community a wide **catalogue of standardised, high quality collections** of biological samples (collections within the scope of biobanks, according to RD1716/2011), with a wide diversity of pathologies in order to facilitate high quality **biomedical research**.
8.- Offer **ethical-legal advice** on the creation of new collections.
9.- Offer **scientific and technical advice** on the treatment of human biological samples.
10.- **Promote research that provides value to** donors, the scientific community, and **society**.

12. INTEGRITY IN RESEARCH

In the process of performing research, researchers may make honest errors in the collection or interpretation of data. Of course, intentional misconduct may also occur. In this case, the misconduct may be penalized if the behavior in question is considered to deviate from rigorous, responsible practices. Such behaviour would include violations of scientific integrity (e.g., plagiarism, misuse of funds, fabrication or falsification of data or results, incorrect authorship, misconduct, discrimination, abuse of power, etc…), which would be a breach of the rules established by the scientific community. Importantly, misconduct of this nature would severely damage the perceived reliability of the research process and research itself. The *ALLEA code*[38] is the European framework for scientific integrity, and adherence to this code is considered mandatory by the European Union.

When specific issues arise in relation to the Code of Good Research Practice, the research team should first address these issues before bringing them to the attention of the **Research Integrity Committee** (CIR).

For further guidance, please see the internal procedures that should be followed in case of suspected research misconduct.

[38] The European Code of Conduct for Research Integrity, edition 2023

12.1. Ombudsperson

IR Sant Pau has agreed to notify the CERCA Institute in the event of a significant conflict in scientific integrity. The IR Sant Pau Ombudsperson is an independent, highly qualified person with a high level of personal integrity. The Ombudsperson has been appointed by the management team at IR Sant Pau to mediate in all relevant breaches of scientific integrity. All research and technical staff can contact the Ombudsperson if necessary.

The Ombudsperson is required to act in strict confidentiality, discretion, and respect for the people alleged to be involved in misconduct. In situations of conflict, if the Ombudsperson finds the suspected misconduct reported to be justified, he will ask the CIR to start the corresponding circuit described in the Procedure in cases of suspected scientific misconduct based on the available information.

Arbitration by the Ombudsperson and/or the CIR and/or the ad hoc committee may lead the IR Sant Pau Management to coordinate with the CERCA Institute to determine the appropriate resolution of the case.

In international collaborations, the principles of the *Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations* will be applicable[39].

12.2. Research Integrity Committee

The **Research Integrity Committee** is an independent body at the service of the scientific community, intended to promote knowledge and internal adoption of the **CPBR-IR** as well as attend to inquiries and arbitrate in possible conflicts.

The CIR was established at the request of the IR Sant Pau Board of Director and it is comprised of members of the IR Sant Pau. The Ombudsperson of the IR Sant Pau (president) and the Ombuds officer (secretary) are permanent members of the CIR, by right linked to their position. This committee is governed by a Regulation available on the intranet.

The CIR is an independent committee overseeing research integrity among the research personnel affiliated with the CGPR-IR. The main aim of the CIR is to support research

[39] Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations

quality and to help preserve its integrity. Both the Ombudsperson and the members of the CIR are required to respect the confidentiality and anonymity of all personal data and any other information received in the course of their work.

All communication with the Ombudsperson and the CIR should be done through the following e-mail address: *ombudsperson@santpau.cat*, which is managed by the Ombuds Officer. In the event of questions or potential conflicts, an informal meeting can be arranged with the Ombudsperson or the Ombuds Officer before proceeding with any kind of formal communication to the CIR.

The functions of the CIR are as follows: i) to promote the observance and fulfilment of the precepts included in the CGPR-IR, ii) to act as an advisory and arbitration body for matters related to research integrity, iii) to start the protocol to investigate possible cases of scientific misconduct, iv) to inform and raise awareness among the scientific community at IR Sant Pau about the events, needs, and guidelines related to the ethical and deontological aspects of biomedical research, v) to be aware of and receptive to emerging issues related to research integrity, and vi) to recommend updates to the content of the CGPR-IR to the Internal Scientific Committee at IR Sant Pau.

13. HEALTH AND SAFETY, ENVIRONMENT, AND WASTE MANAGEMENT

13.1. Health and safety

Research personnel must incorporate measures designed to prevent work-related risks in all areas of their activity. In addition, they must follow safe work practices at all times complying with and enforcing the legislation on the prevention of occupational risks and all the complementary regulations that are applicable to the tasks performed and the facilities, materials, products and equipment used. Similarly, they must comply, and ensure compliance with, all pertinent legislation on the prevention of work-related risks[40].

[40] Ley 31/1995, de 8 de noviembre, de prevención de Riesgos Laborales

People responsible for the research groups and the infrastructures must be governed by the basic preventive rules, requesting preventive advice when they consider it necessary.

The preventive modality adopted by the Research Institute is the Joint Prevention Service (SPM), together with the Santa Creu i Sant Pau Hospital and the Sant Pau Private Foundation. In addition, it has the person in charge of prevention management within its organizational chart. The SPM acts as a reference in the specialties of occupational safety, occupational medicine, industrial hygiene, ergonomics and applied psychosociology.

The research staff and their team undertake to provide the complete and truthful information required by the SPM when carrying out risk assessments of workplaces and activities related to research projects.

13.2. Environment

It is important to ensure that sustainability criteria are applied to resource supplies and services in order to minimise emissions and waste associated with our research activity. This is essential in order to meet the sustainable development objectives by the year 2023[41].

In this regard, the new building of the Research Institute, inaugurated in October 2018, includes several features designed to protect the environment, most notably:

- Self-adjusting lights (LED) in offices, which automatically adapt to the intensity of the sunlight.
- Photovoltaic panels on the roof of the building.
- The use of rainwater for toilets.
- Green cover to increase the biodiversity of birds and insects around the building.

[41] ODS 2030

13.3. Waste management

The *Fundació Gestió Sanitària de l'Hospital de la Santa Creu i Sant Pau* and the *Fundació Institut de Recerca* have implemented an intracentre Waste Management Plan designed to minimise waste. This plan regulates all aspects of waste management, including segregation, collection, packaging, transport, treatment and disposal of healthcare waste. The aim of the plan is to ensure that the most suitable measures are applied within a framework of sustainability, health, and safety, in compliance with current legislation in Catalonia[42] and Spain[43].

14. AUTHORSHIP, INTELLECTUAL PROPERTY AND INDUSTRIAL PROPERTY

14.1. Authorship

The status of author does not depend on the profession or rank of the researcher, nor on the nature of the employment relationship, but rather on the contribution to the research work according to the four criteria recommended by the ICMJE as follows[44]: i) have contributed significantly to the creation or design of the paper, or to the acquisition, analysis or interpretation of the data, ii) have participated in the drafting of the paper or the critical review of its intellectual content in a significant way, iii) have given their final approval of the version to be published, iv) have agreed to be responsible for all aspects of the article to ensure that questions relating to the accuracy or integrity of any part of the work are properly substantiated and resolved, and the paper is ready for submission, and v) have contributed to the preparation of the any related communications and publications.

[42] Decret 27/1999, de 9 de febrer, de la gestió dels residus sanitaris
[43] Ley 7/2022, de 8 de abril de residuos y suelos contaminados para una economia circular
[44] The International Committee of Medical Journal Editors

All authors of a publication must approve the text and assume responsibility for the content. For these reasons, the specific contributions of each author should be declared whenever possible.

14.2. Shared lead authorship

When two or more authors have equally contributed to the research and/or the drafting of the manuscript, they will be considered co-first authors and should be identified as such in the article.

14.3. Order of authorship and author's contribution

The order of authorship should generally be determined according to the following criteria: i) the first author is the person who has made the greatest contribution to the research project, ii) the last author is the senior researcher who leads the research project and has overall responsibility for the study, iii) the remaining authors are those that have contributed and participated in the study, and are usually listed in order of their contributions and/or in alphabetical order, iv) the corresponding author is the person mainly responsible for the writing and editing process and for future interactions related to the publication.

The use of CRediT taxonomy is recommended to define the responsibilities of the different authors in the article, as well as the inclusion of the full name of the authors in the bibliographic references to make women visible in research.

Research trainees should have the opportunity to be first authors during their training period, if their advisor considers it appropriate.

Whenever possible, and when the publication guidelines require this, the individual contributions of each author should be defined to indicate the researcher's involvement in the project.

The inclusion of an individual as an author ex officio (i.e., due to o his or her position or employment relationship and association with the research group) is considered a breach of academic freedom and the principle of fairness. By contrast, the omission of someone who has contributed to a publication resulting from a research project implies an undue appropriation of intellectual authorship.

14.4. Acknowledgments

Funding organisations must be mentioned in the acknowledgements (or equivalent) in any scientific publication arising from a research project. This inclusion is important to recognize and validate the funding source. In any case, all publications should explicitly mention the support received from the CERCA/*Generalitat de Catalunya* programme and its structural support for research centres in Catalonia.

Any other organisation, person, or scientific-technical service that has contributed to the publication and is not listed as a co-author can be included in the acknowledgements.

14.5. Affiliation

The affiliations of all authors must be stated, including the institutions and centres where the research was carried out.

IR Sant Pau researchers must clearly state in all publications that they are affiliated with IR Sant Pau, in accordance with IR Sant Pau policies regarding affiliation. The researchers may also indicate other relevant affiliations (i.e., department, centre, research institute, collaborative centres, or universities).

14.6. Curriculum vitae

The *curriculum vitae* (CV) should detail the author's personal data, education & training, and professional experience. The author is responsible for the accuracy of the content. In this regard, all pages of the CV should be signed or initialled.

The research staff are required to keep their centre informed of their professional activity by updating their personal CV using the tools provided by their centre.

14.7. Intellectual and Industrial Property

The IR Sant Pau published a regulation on intellectual and industrial property, (*Normativa sobre la Propietat Intel·lectual i Industrial)*, which has been approved by the Board of Trustees. This order regulates the results of research carried out at the

Institute, establishing rules for the exploitation and distribution of any profits arising from the research. The Institute has also developed rules to regulate the creation of spin-offs (*Reglament de creació d'empreses Spin-off*), which has also been approved by the Board of Trustees.

Also, and in any case, the research staff must follow the mandates and guidelines established in the applicable laws, especially those included at the Llei de la Ciència, la Tecnologia i la Innovació 14/11 de 1 de juny, *Ley 24/2015 de Patentes*, and RD 1/1996 which approves the revised text of intellectual property.

14.8. Communication, dissemination, and publication of results

The dissemination of research results (whether positive or negative, or unexpected) can be considered the culmination of the research process. In fact, dissemination of research findings is an essential part of the research process to make the knowledge obtained widely available. Researchers and/or principal investigators must make all reasonable efforts to disseminate their research findings, both in writing and orally, in forums (congresses, seminars, conferences, and/or scientific meetings) targeted at the scientific community as well as for society. Reporting of results should be done in a manner that is easily understandable for non-experts in order to foster a better understanding of science. In particular, senior researchers should strive to ensure that their research efforts are productive and that the results are widely disseminated and commercially exploited to the extent possible.

The IR Sant Pau has developed and approved the *Responsible Research and Innovation Plan*, which describes the guidelines established by the institution with regard to open access data and publications. The aim of this plan is to follow the FAIR (Findable, Accessible, Interoperable and Reusable) principles for the management of scientific data.

As indicated in the document *Estratègia catalana de ciència oberta: compartir el coneixement*[45], all publications from the Catalan research system that are the product of activities financed with public funds must be found in immediate open access on a publication platform, a repository, a magazine or a book. As well as presenting the data

[45] Estratègia catalana de ciència oberta (17 de gener de 2024 el Ple de la Comissió Interdepartamental de Recerca i Innovació (CIRI).

and metadata necessary to validate the results presented in scientific publications (those cases in which there is industrial exploitation, or for reasons of confidentiality or security will be excluded) and other data specified in the data management plans of the research projects. investigation. To meet the requirement of the data management plan, research staff have the CSUC eina.DMP that allows you to write DMPs for the different funding organizations, share the plans with other researchers, request review and export the plans with different formats for present them.

In this regard, the publication of clinical trial results is regulated by European regulations established on January 31, 2022[46].

Prior to dissemination of research results that may be subject to intellectual and/or industrial property rights, researchers must notify the Innovation and Transfer Unit to ensure that all pertinent rights are protected. The dissemination or publication of results without prior approval is only permitted under highly exceptional situations, such as for public health reasons.

The publication of research findings must include an explicit statement of the following: i) the institutions or centres to which the authors is affiliated and where the research was carried out, ii) the independent ethics committee(s) that supervised the research protocol, as well as pertinent authorisations issued by the authorities, iii) any conflict of interest, financial support, or any other sort of sponsorship received, regardless of whether the support only partially or completely covered the research costs, as well as financial support for individual authors, iv) any other type of conflict of interest.

14.9. Practise of expert review (*peer review)*

This refers to any review process in which a researcher is recruited as an expert to evaluate any type of scientific documents, including manuscripts, reports, projects, or protocols.

These reviews should be objective, based on scientific criteria and not on personal opinions or ideas. The researcher should refuse the offer to review if there is any conflict

[46] COMMISSION DECISION (EU) 2021/1240

of interest. The review should be performed rigorously and diligently, while maintaining confidentiality, impartiality, objectivity, and independence.

Given that many documents reviewed are confidential and may contain sensitive information, it would be advisable for reviewers to sign a confidentiality agreement.

Accordingly, this documentation:

a) cannot be used for the benefit of the reviewer, at least until the information has been published.
b) cannot be shared without the explicit permission of its owner.

ANNEX 1. LEGISLATION AND REGULATIONS

- **Research performed with genetically modified organisms**

  - Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente (BOE núm. 100, de 26 de abril, https://www.boe.es/eli/es/l/2003/04/25/9)

  - Real Decreto 178/2004, de 30 de enero por el que se aprueba el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente (BOE núm. 27, de 31 de enero, https://www.boe.es/eli/es/rd/2004/01/30/178)

- **Research with human embryonic material**

  - Ley 14/2007, de 3 de julio, de Investigación biomédica (BOE núm. 159, de 4 de julio, https://www.boe.es/eli/es/l/2007/07/03/14)

  - Real Decreto 1527/2010, de 15 de noviembre, por el que se regulan la Comisión de Garantías para la Donación y Utilización de Células y Tejidos Humanos y el Registro de Proyectos de Investigación (BOE núm. 294, de 4 de diciembre, https://www.boe.es/eli/es/rd/2010/11/15/1527)

- **Research with animals**

  - Decret 164/98, de 8 de juliol, de modificació del Decret 214/1997, de 30 de juliol, pel qual es regula la utilització d'animals per a experimentació i altres finalitats científiques. (DOGC nº 2680 de 14 de juliol, https://portaljuridic.gencat.cat/eli/es-ct/d/1998/07/08/164)

  - Decret 214/1997, de 30 de juliol, pel qual es regula la utilització d'animals per a experimentació i per a altres finalitats científiques (DOGC 2.450, de 7 d'agost de 1997, https://portaljuridic.gencat.cat/eli/es-ct/d/1997/07/30/214)

  - Decret 286/1997, de 31 de octubre, de modificació del Decret 214/1997, de 30 de juliol, pel qual es regula la utilització d'animals per a experimentació i per a altres

finalitats científiques. (DOGC nº 2518 de 14 de novembre, https://dogc.gencat.cat/ca/document-del-dogc/?documentId=160573)

- Decreto Legislativo 2/2008, de 15 de abril, por el que se aprueba el Texto refundido de la Ley de protección de los animales. (DOGC núm. 5113, de 17 de abril, https://www.boe.es/buscar/doc.php?id=DOGC-f-2008-90016)

- Directiva 2010/63/UE del Parlamento Europeo y del Consejo de 22 de septiembre de 2010, relativa a la protección de los animales utilizados con fines científicos se transpuso en parte en febrero de 2013 con el Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia, y se completó con la modificación de la Ley 32/2007, de 7 de noviembre, para el cuidado de los animales, en su explotación, transporte, experimentación y sacrificio, mediante la Ley 6/2013 de 11 junio (BOE núm. 140, de 12 de junio, https://www.boe.es/eli/es/l/2013/06/11/6)

- Ley 5/1995, de 21 de junio, *de protección de los animales utilizados para la experimentación y otras finalidades científicas*. (.%20(BOE%20nº%20190%20de%2010%20de%20agosto,%20https:/www.boe.es/buscar/pdf/1995/BOE-A-1995-19103-consolidado.pdf)

- Orden ECC/566/2015, de 20 de marzo, por la que se establecen los requisitos de capacitación que debe cumplir el personal que maneje animales utilizados, criados o suministrados con fines de experimentación y otros fines científicos, incluyendo la docencia (BOE núm. 78, de 1 de abril, https://www.boe.es/eli/es/o/2015/03/20/ecc566)

- Real Decreto 1386/2018, de 19 de noviembre, por el que se modifica Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia (BOE núm. 280, de 20 de noviembre, https://www.boe.es/eli/es/rd/2018/11/19/1386)

➢ **Human research**

- Belmont Report. Office of the Secretary. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979. Available in: https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

- Conveni per a la protecció dels drets humans i la dignitat de l'ésser humà en relació a les aplicacions de la biologia i la medicina"- CONVENI EUROPEU SOBRE DRETS HUMANS I BIOMEDICINA - (Aprovat pel Comitè de Ministres del Consell d'Europa el 19 de novembre de 1996. Obert a la signatura dels Estats a Oviedo, el 4 d'abril de 1997 i ratificat per les Corts Generals espanyoles el 5 d'octubre de 1999 (BOE 20 octubre 1999 - núm. 251). Available in: https://canalsalut.gencat.cat/web/.content/_Sistema_de_salut/CBC/xarxa_comites/legislacio/conveni_europeu_drets_humans_i_biomedicina.pdf

- Declaració de Nuremberg, 1967, Comitè Permanent de Metges Europeus (Comité Permanent des Médecins Européens, Standing Committee of European Doctors, CPME). Nuremberg, 1967.

- Declaració Universal sobre el Genoma humà i els Drets Humans: dels principis a la pràctica. UNESCO, 3 de febrer de 2000. Available in: https://unesdoc.unesco.org/ark:/48223/pf0000122990_spa

- DECLARATION OF HELSINKI. Medical Research Involving Human Subjects. Hèlsinki, Finlàndia, juny 1964. Revisada a la 64a Assemblea General, Fortaleza, Brasil, octubre 2013. Available in: https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf

- DECLARATION OF TAIPEI. Research on Health Databases, Big Data and Biobanks. Available in: https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/).

- Decret 406/2006, de 24 d'octubre, pel qual es regulen els requisits i el procediment d'acreditació dels comitès d'ètica d'investigació clínica. DOGC núm. 4748, p. 44904. Departament de Salut de la Generalitat de Catalunya. Available in: https://medicaments.gencat.cat/ca/detalls/Article/10decret_dacreditacio_dels_comites_detica_dinvestigacio_clinica_a_Catalunya

- ISO 14155:2011. Clinical investigation of medical devices for human subjects – Good clinical practice. Available in: https://www.iso.org/standard/71690.html

- Ley 14/2007 de 3 de julio de Investigación Biomédica (BOE núm. 159, de 04 de julio, https://www.boe.es/buscar/pdf/2007/BOE-A-2007-12945-consolidado.pdf)

- Ley 14/2011, de 1 de junio, de la Ciencia, la Tecnología y la Innovación. (BOE núm. 131, de 02 de junio, https://www.boe.es/eli/es/l/2011/06/01/14/con).

- Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Darrera actualització publicada el 05/06/2021 (BOE núm. 274, de 15 noviembre https://www.boe.es/eli/es/l/2002/11/14/41/con).

- Lei 29/2006, de 26 de julio, de garantias y uso racional de los medicamentos y productos sanitarios. (BOE núm. 17827 de julio, https://www.boe.es/eli/es/l/2006/07/26/29/con)

- Norms ICH (International Conference of Harmonization Guideline) for Good Clinical Practice. Available in: https://ichgcp.net/es/

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sanitarios. (BOE núm. 177, de 25 de julio, https://www.boe.es/eli/es/rdlg/2015/07/24/1/con).

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- COMMISSION DECISION (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council. Available in: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021D1240&from=ES

➢ **Biobank/ Human biological samples**

- Decret 234/2013, de 15 d'octubre, pel qual es regulen l'autorització per a la constitució i el funcionament dels biobancs amb fins de recerca biomèdica a Catalunya i de la Xarxa Catalana de Biobancs. (DOGC núm. 6482, de 17 d'octubre, https://portaljuridic.gencat.cat/eli/es-ct/d/2013/10/15/234)

- Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y de tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica. (BOE núm. 290, de 02 de diciembre, https://www.boe.es/eli/es/rd/2011/11/18/1716).

➢ **Workers protection**

- Ley 31/1995, de 8 de noviembre, de prevención de riesgos laborales. (BOE núm. 269, de 10 de noviembre https://www.boe.es/eli/es/l/1995/11/08/31/con).

- Ley 54/2003, de 12 de diciembre, de reforma del marco normativo de la prevención de riesgos laborales (BOE núm. 298, de 13 de diciembre, https://www.boe.es/eli/es/l/2003/12/12/54).

- Real Decreto 664/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes biológicos durante el trabajo o Guía técnica para la evaluación y prevención de los riesgos relacionados con la exposición a agentes biológicos. (BOE núm. 124, de 24 de mayo https://www.boe.es/eli/es/rd/1997/05/12/664/con).

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➢ **Environment protection**

- Decret 27/1999, de 9 de febrer, de la gestió dels residus sanitaris. (DOGC núm. 2828, de 16 de febrer, https://portaljuridic.gencat.cat/eli/es-ct/d/1999/02/09/27)

- Ley 7/2022, de 8 de abril de residuos y suelos contaminados para una economía circular (BOE núm. 85, de 09 de abril, https://www.boe.es/eli/es/l/2022/04/08/7/con).

- Ley 9/2003, de 25 de abril, sobre la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente (BOE núm. 100, de 26 de abril, https://www.boe.es/eli/es/l/2003/04/25/9).

➢ **Data protection**

- Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. Available in: https://www.boe.es/eli/es/lo/2018/12/05/3

- Reglamento Europeo de Protección de Datos (RGDP 2016/679). Available in: https://www.boe.es/doue/2016/119/L00001-00088.pdf

➢ **Us of Artificial Intelligence**

- Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU)

2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). Available in: http://data.europa.eu/eli/reg/2024/1689/oj

- **Other legal regulations**

  - Directiva 2004/10/CE del Parlamento Europeo y del Consejo, de 11 de febrero de 2004, sobre la aproximación de las disposiciones legales, reglamentarias y administrativas relativas a la aplicación de los principios de buenas prácticas de laboratorio y al control de su aplicación para las pruebas sobre las sustancias químicas. Available in: https://www.boe.es/doue/2004/050/L00044-00059.pdf

  - Ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno. Available in: https://www.boe.es/eli/es/l/2013/12/09/19

  - Llei 19/2014 de transparència, accés a la informació pública i bon govern, desembre 2014. (DOGC núm. 6780, de 31 de desembre, https://portaljuridic.gencat.cat/eli/es-ct/l/2014/12/29/19

  - Proyecto de Real Decreto por el que se aprueba el reglamento de desarrollo de la ley 19/2013, de 9 de diciembre, de transparencia, acceso a la información pública y buen gobierno. Available in: https://www.boe.es/eli/es/l/2013/12/09/19/con

  - Real Decreto 919/2014, de 31 de octubre, por el que se aprueba el Estatuto del Consejo de Transparencia y Buen Gobierno. Available in: https://www.boe.es/eli/es/rd/2014/10/31/919

ANNEX 2. INTERNAL DOCUMENTATION

Guidelines to ensure use of non-sexist language
Guidelines for the prevention of sexual harassment
Employee Handbook
Affiliation Regulations
Intellectual and Industrial Property Regulations
Equality Plan
Waste Management Plan
Responsible Research and Innovation Plan
Strategic Plan for Research and Innovation
Procedure in case of suspected misconduct
Shared Scientific Project
Regulations for the creation of SPIN-OFF
Regulations for the functioning of the Equality Committee
Internal Regulations
CEEA Regulations
CEIm Regulations
Regulations of the Integrity Committee for Research
Rules of the Biosafety Committee
Biobank Internal Regulations

ANNEX 3. OTHER REFERENCE DOCUMENTATION

- Camí i Morell, Jordi; López-Botet, Miguel; Beato, Miguel. Codi de bones pràctiques científiques. *Annals de medicina*, 2003, Vol. 86, Núm. 1, p. 44-49, https://raco.cat/index.php/AnnalsMedicina/article/view/143562.
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- Codi de conducta CERCA. Institució CERCA, novembre 2018. Available at: https://www.recercasantpau.cat/wp-content/uploads/2016/04/Adscripcio-Codi-Conducta-CERCA.pdf
- Estatut de l'estudiant Universitari, desembre 2010. Available at: https://www.boe.es/boe_catalan/dias/2010/12/31/pdfs/BOE-A-2010-20147-C.pdf
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013). Disponible a: https://wcrif.org/montreal-statement/file.