Institute of Biomedical Research of Salamanca IBSAL



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In this document, the grammatical **masculine is used** as **generic,** according to linguistic usage, to refer to persons of both sexes.

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ACRONYMS

RC: Governing Board; ECC: External Scientific Committee; SC: External Scientific Committee; DC: Internal Scientific Committee; SC: Scientific Directorate; GC: Management Committee; QC: Quality Committee; TC: Quality Committee; TC: Training Committee; CINN: Innovation Committee; IGC: Equality Committee; TMB: Technical Management Unit; JRC: Joint Committee; JRC: Joint Committee; ISC: Internal Scientific Committee; IGC: Equality Committee; UTG: Technical Management Unit.

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1. INTRODUCTION AND OBJECTIVES

To ensure the quality and ethical integrity of research, it is essential to achieve consensus among scientists regarding the ethical principles that should govern the proper conduct of research. The *Guide to Ethics and Good Practice in Research* represents the commitment of the scientific staff at the Institute of Biomedical Research of Salamanca (IBSAL) to uphold research quality and integrity. This guide serves as a reference to promote good research practices and establish ethical guidelines for the Institute's activities.

IBSAL formally adheres to the principles outlined in the *Commission Recommendation of 11 March 2005 on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers*, having signed a letter of adherence on 16 October 2017. The principles set forth in these documents are applied within this guide to ensure compliance with ethical research standards.

It is important to note that this document does not constitute a standard operating procedure or protocol, nor does it replace existing legal regulations or the responsibilities of other governing bodies, such as the Ethics Committee for Research on Medicinal Products (IRB/IEC).

The development of this *Guide to Ethics and Good Practice in Research* aims to achieve the following objectives:

- Assure funding agencies that research funds will be managed within an ethical framework of good research practice.
- Ensure the veracity of scientific advances and promote their responsible communication and dissemination to both the scientific community and society at large.

- Safeguard honesty and integrity in scientific activities conducted by all Institute staff.
- Protect the rights of human participants in research projects and ensure the humane treatment of animals used for scientific purposes, in alignment with the Institute's commitment to society.

Framework and Responsibilities

This guide serves as a declaration of principles and commitments that form the foundation for ethical research practices at IBSAL. All IBSAL research staff are expected to adhere to the guidelines set forth in this document when conducting research activities.

The IBSAL Internal Scientific Committee is responsible for ensuring compliance with the criteria established in this guide. Additionally, it functions as a body for evaluating and addressing ethical concerns, conflicts, or emerging needs in biomedical research. Specifically, its responsibilities include:

- Reviewing and updating the guide in response to new ethical challenges and developments in research practices.
- Assessing conflicts or ethical issues raised by IBSAL research staff and acting as an arbitration body when applicable, in accordance with current legislation.
- Investigating any breaches of the principles outlined in this guide, preparing reports for the relevant parties, and, if necessary, referring cases to the appropriate authorities.
- Establishing effective communication mechanisms to ensure widespread awareness and understanding of this guide among all professionals involved in research activities.

By adhering to this guide, IBSAL reaffirms its dedication to maintaining the highest standards of research ethics and integrity.

2. GENERAL PRINCIPLES OF ETHICS AND GOOD PRACTICE IN RESEARCH

The Guide to Ethics and Good Practice in Research is based on a series of general principles within the framework of the research activity carried out at the IBSAL, expressing the **institution's responsibility in the practice of scientific research** in accordance with the principles set out below:

2.1. Values of research staff

2.2. Supervision of junior research staff

2.3. Ethical practices in human and animal research

2.4. Planning the research

2.5. Development of the research

2.6. Publication practices

2.7. Audit of scientific results

2.8. Activity report

2.9. Peer review

2.10. Intellectual property rights and commercial exploitation of research results.

2.11. Conflict of interest.

2.1. Values of research staff

In IBSAL research, the primary objective is to generate scientific knowledge that benefits both society as a whole and individuals—whether they are patients (by promoting new diagnostic and therapeutic strategies) or healthy individuals (through

preventive health measures). In alignment with the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, all IBSAL-affiliated researchers must adhere to the following ethical and professional principles:

1. Freedom of Research

Researchers have the right to direct their work toward the betterment of humanity and the advancement of scientific knowledge. They should enjoy freedom of thought, expression, and methodological choice, provided they comply with recognized ethical principles and practices. However, this freedom may be subject to limitations arising from research circumstances (such as supervision, guidance, or operational constraints), financial or structural constraints, or intellectual property concerns—particularly in the industrial sector. These limitations must never violate fundamental ethical standards.

2. Ethical Principles

Researchers must uphold the core ethical standards of their disciplines and adhere to national, sectoral, and institutional codes of ethics.

3. Professional Responsibility

Research should contribute meaningfully to society and avoid redundancy with existing studies. Researchers must stay informed about the latest developments in their field, prevent plagiarism, and respect intellectual property rights, including shared ownership in collaborative projects. The requirement to validate new observations through reproducible experiments does not constitute plagiarism, provided proper citations are included. Furthermore, researchers delegating tasks must ensure that the designated individuals are qualified to perform them.

4. Professional Attitude

Researchers should understand the strategic objectives of their field and potential funding mechanisms. They must secure necessary approvals before commencing research or utilizing resources. Additionally, they must keep employers, funders, or

supervisors informed of any changes to their research timeline, including delays, redefinitions, early completions, or terminations.

5. Contractual and Legal Obligations

Researchers at all levels must be aware of and comply with national, sectoral, and institutional regulations governing training and working conditions. This includes intellectual property laws, sponsor requirements, and contractual obligations. Researchers must fulfill agreed deliverables—such as theses, publications, patents, reports, and project developments—within the stipulated terms.

6. Accountability and Responsibility

Researchers are accountable to their employers, funders, and relevant public or private institutions. In publicly funded projects, they must ensure the efficient use of taxpayer funds, adhering to principles of competence, transparency, and financial efficiency. Compliance with authorized audits and ethical reviews is mandatory. Data collection methods, analyses, and results should be available for external scrutiny when required by relevant authorities.

7. Good Research Practices

Researchers must adhere to safe working practices in line with national legislation. This includes safeguarding health and safety, implementing effective data backup strategies, and complying with data protection and confidentiality laws.

8. Dissemination and Exploitation of Results

Researchers should ensure that their findings are effectively communicated and utilized. This may involve knowledge transfer within the research community, commercialization of findings, or public dissemination. Senior researchers, in particular, are encouraged to maximize the impact of their research by pursuing commercialization or public engagement whenever possible.

9. Public Engagement

Researchers should communicate their work to the broader public in an accessible manner, fostering scientific literacy and awareness. Engaging with society allows researchers to better understand public concerns and priorities regarding science and technology.

10. Continuous Professional Development

Researchers, regardless of their career stage, should continuously update and refine their skills and competencies. This can be achieved through formal training, seminars, conferences, and e-learning opportunities.

By adhering to these principles, IBSAL researchers contribute to a responsible, ethical, and impactful scientific community.

IBSAL researchers must integrate the following values into their research activities:

- **Integrity:** Research must be conducted rigorously in accordance with scientific methodology and logic. Integrity applies to all aspects of research, including experimental design, data generation and analysis, funding applications, publication, reporting to funding agencies, and proper acknowledgment of contributions. Research misconduct—such as fabrication (creating false data), plagiarism (using another's ideas without permission), and falsification (altering research data or results)—is strictly prohibited and may result in sanctions.
- **Transparency:** IBSAL promotes open and transparent communication of research findings among Institute members and the public. However, for scientific competitiveness and confidentiality reasons, temporary restrictions on data dissemination may be necessary. Once research results are published, researchers are encouraged to make relevant data available upon request, provided no ethical or intellectual property conflicts arise. Transparency enhances scientific rigor and helps manage conflicts of interest in line with this code of ethics and good practices.

- **Leadership:** IBSAL area coordinators and principal investigators must foster a research environment that aligns with ethical principles. They should inspire, motivate, and guide their teams toward achieving both research goals and professional development.
- **Cooperation:** IBSAL prioritizes collaboration and knowledge-sharing among researchers. Synergies between research staff contribute to professional growth, scientific progress, and the development of a strong, ethical research community. Particularly in research involving human subjects, maintaining a balance between scientific rigor and ethical safeguards is paramount.

2.2. Supervision of junior research staff

All trainee researchers associated with IBSAL must have an assigned mentor or supervisor. In accordance with the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, trainee researchers are expected to maintain a structured relationship with their supervisors to maximize the benefits of their guidance. This includes keeping records of all research findings, sharing knowledge through reports and seminars, incorporating feedback, and progressing in their work according to agreed timelines, objectives, and the presentation of research results or outputs.

Supervisors or tutors are responsible for ensuring that every individual affiliated with the Institute for scientific training—whether as an undergraduate, pre-doctoral student, or research support technician—receives comprehensive training aligned with their initial objectives and within the expected timeframe. To achieve this, tutors must maintain regular meetings and communication with their assigned research staff, ensuring both the proper execution of scientific work and the progressive acquisition of relevant competencies, as well as overseeing their employment situation.

Senior research staff should approach their supervisory and management responsibilities with the highest professional standards, acknowledging their multifaceted role as supervisors, mentors, career coaches, and science

communicators. In their capacity as mentors, experienced researchers should foster a constructive and positive relationship with junior researchers, creating the conditions necessary for effective knowledge transfer and the successful progression of their careers.

Trainee researchers must receive training on ethical research practices and integrity from the outset of their training and throughout their careers. Mentors and supervisors are responsible for educating their trainees on all aspects of good research practice, including ethical standards for human and animal experimentation, as well as the specific guidelines outlined in this document. A key objective in this regard is for these researchers to obtain a doctoral degree, accompanied by the publication of original research.

In the event of conflicts between trainee researchers and their mentors or other IBSAL research staff, the matter may be referred to the IBSAL Research Committee. The committee will review the issue, ensuring impartiality, fairness, and confidentiality in its decision-making. If both parties involved in the conflict agree, the committee's decision will be binding.

2.3. Ethical practices in human and animal research

2.3.1. Research involving human subjects

Clinical research involves direct interaction with patients and aims to improve both the quality and length of their lives. This research is based on therapeutic actions, clinical data obtained from patients, biological samples, or imaging studies. It relies on three key pillars: the clinical trial, epidemiology, and the clinical laboratory, all supported by biostatistics. Clinical trials are the most effective tool for advancing therapeutic treatments. The progress made in medical therapies is only possible thanks to the generosity of patients who participate in these trials and the dedication of the medical professionals conducting them. Many essential drugs used today to treat or manage diseases have resulted from these efforts.

The primary goal of the clinical research is to identify alterations that enhance the understanding of diseases. This allows for the development of new diagnostic and prognostic criteria, as well as improved parameters for monitoring disease progression and treatment response. The Declaration of Helsinki, issued by the World Medical Association, establishes that the well-being of human subjects must always take precedence over the interests of science and society. Before initiating a clinical trial, the expected risks and inconveniences must be weighed against the anticipated benefits for both the individual and society. A study should proceed only if the expected benefits justify the risks. Furthermore, any investigational product must have adequate legal and ethical support before being tested in clinical research.

In clinical research, informed consent is a fundamental ethical requirement, ensuring that participants voluntarily agree to take part in a study after fully understanding its objectives, potential benefits, risks, discomforts, alternatives, and their rights and responsibilities. It serves as the formal mechanism for upholding autonomy and must include three key elements: voluntariness, information, and comprehension.

Participant confidentiality must be strictly protected in accordance with privacy regulations, particularly Law 41/2002 of 14 November, which governs rights and obligations regarding clinical information and documentation. Compliance with relevant regulatory requirements is essential.

Additionally, all study procedures must adhere to Good Clinical Practice (GCP) standards, ensuring the study follows a scientifically rigorous protocol, safeguards patient rights, and guarantees the validity of collected data. Importantly, any medical care and decisions concerning participants within a research protocol must always remain the responsibility of a qualified physician.

A section on the handling of biological samples and genetic studies is particularly noteworthy within the broader discussion of Good Clinical Practice in Human Research:

a. Biological samples

- The cornerstone of using and studying **biological samples** is informed consent, which patients must sign. This document should clearly outline the study's objectives, potential applications, and confidentiality principles. The appendix includes sample informed consent forms used in various IBSAL structures, such as the Tumor Bank, National DNA Centre, and Biobank. The collection, handling, and disposal of biological samples for research must comply with Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004, which establishes quality and safety standards for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells. Additionally, research must adhere to the relevant legislation applicable to each specific study.
- **Nominal biological samples** (including coded and identified samples) are ethically inseparable from the individuals they originate from and must therefore be handled according to the same ethical standards and practices applied in human research.
- Research on non-nominal biological samples, that is, those in which their origin cannot be linked to any person (unidentified or anonymized samples), may be authorized without the specific intervention of the IRB/IEC.
- Researchers who intend to transform identifiable samples into anonymous samples must provide the IRB/IEC with sufficient written guarantees regarding the procedure, including a description of the procedure to guarantee the protection of the subjects in the event of a potential confidentiality breach.
- **The subject is responsible for explicitly authorising and specifying the intended use and destination their biological samples** for prospective research purposes (regardless of whether they were originally collected for clinical care or research purposes).
  - Any new use of identified biological samples, including their transfer to other researchers, requires the authorization of the person who

provided them, of the person who obtained and stores them, and, in any case, of the IRB/IEC.

- The subject is responsible for authorising research staff to access clinical and analytical data relating to them.
- The subject shall be properly informed about the potential benefits and risks for them, and where appropriate, their family, social or age group to which they belong, or to third parties.
- The patient must also authorize the use for research of normally discarded residues from the samples obtained for their clinical care.
- In cases where a protocol is likely to pose a risk to a particular group, this risk should be described in the informed consent process.
- In retrospective studies involving nominal samples, researchers must respect the expressed wishes of the subjects who provided these materials. If no prior consent has been given, the IRB/IEC will determine whether it is appropriate to waive consent and approve the study. In making this decision, the Committee will consider the objectives of the protocol and require strict confidentiality measures, ensuring that personal data is not disclosed to third parties.

In research projects, previously obtained samples may be used with prior authorization, even if the original collection did not specify the current study's objectives. The IRB/IEC must assess whether the initial consent and documentation remain valid for each specific project. It is advisable to obtain renewed consent, ensuring the donor is explicitly informed about potential uses, particularly sensitive applications such as genetic research, reproductive biology, and neuropsychiatric studies. Donors also have the right to determine whether their samples should remain nominal or be anonymized.

- The primary priority after obtaining biological samples is their pathological or analytical examination to establish the patient's diagnosis and prognosis. This diagnostic assessment must take precedence over

any other potential use. The attending physician and/or research staff must balance the patient's health needs with their willingness to participate in research, ensuring that medical care remains the foremost concern.

- The person donating biological samples may **revoke the donation** at any stage of the research, the research staff and sponsors must guarantee their destruction, together with the data obtained from them. Likewise, the patient must be informed that refusal to authorise the use of biological samples in research projects or revocation of consent will in no way affect his or her clinical care.
- **Both the sponsor and the investigator must give a written undertaking to the IRB/IEC to destroy the biological samples** once the studies authorised by the subjects have been completed.

b. Genetic studies

- **The same criteria** shall apply for these studies **as for other biological samples with regard to informed consent**.
- Any **donation of genetic material shall require a** specific **research protocol and informed consent document** separate from that obtained for the rest of the research or clinical trial. This document should include a sufficient number of options for subjects to clearly understand the nature of their decision.
- Under the following conditions, **research staff should disclose genetic findings to the subjects under investigation**:
  - When the findings are scientifically valid and confirmed.
  - When the findings have significant implications for the health of the subject.
  - When there is a plan to improve or treat the subject's clinical condition.
  -

2.3.2. Animal research

IBSAL conducts animal research using the animal facilities of the University of Salamanca, which include the Departmental Animal Facility, the GMO Animal Facility, and the INCYL Animal House. These facilities are part of the USAL Animal Experimentation Service and are registered with the Department of Agriculture and Fisheries of the Regional Government of Castile and León (PAE SA-001). They are staffed with accredited personnel responsible for the care and maintenance of animals, as well as for providing veterinary technical support and animal welfare guidance.

Each centre or unit under the SEA operates according to specific regulations, which are available for consultation by users. Additionally, all experimental projects involving animals must receive approval from the USAL Bioethics Committee before research can commence in SEA-affiliated centres. The use of animals in research is governed by applicable legislation, including Royal Decree 53/2013 of February 1 and European Directive 2010/63/EU. These regulations outline operational requirements, standards for animal care and housing, record-keeping obligations, and quarterly reporting of animal use. Furthermore, IBSAL adheres to the **3Rs Principle: Replacement** (implementing methods that avoid or replace the use of animals), **Reduction** (using strategies to minimize the number of animals required) and **Refinement** (enhancing methods to reduce pain, distress, and improve animal welfare) which guide both the care and use of live animals in scientific research and the selection of experimental methodologies.

- **Scientific research**, including aspects such as the prevention of diseases, disorders of health and other abnormalities or their effects, as well as their diagnosis and treatment in humans, animals or plants; the development and manufacture of pharmaceuticals, foodstuffs and other substances or products, and the performance of tests to verify their quality, efficacy and safety.

- The **assessment, detection, regulation or modification of physiological conditions in humans, animals or plants**.
- The **protection of the natural environment,** in the interest of the health or welfare of humans, animals and the maintenance of biodiversity.
- **Education and training**.
- **Medico-legal research**.

Experiments may only be conducted in authorized laboratories and facilities by, or under the supervision of, qualified personnel. An experiment should not proceed if a scientifically valid and proven alternative exists that allows the same conclusions to be drawn without using animals. Studies must be designed to achieve the most reliable results while minimizing the number of animals used. Whenever possible, researchers should select species with the lowest neurophysiological sensitivity and ensure that procedures cause minimal and short-lived pain, suffering, stress, or injury. Unnecessary duplication of procedures must be avoided, and alternative methods should be prioritized whenever feasible. Throughout the research process, animals must receive proper care and attention at all times.

Experiments must be conducted under general or local anesthesia unless the anesthesia would cause greater trauma to the animal than the experiment itself or if it is incompatible with the study's objectives.

In any case, all research involving animal experimentation must be submitted as a protocol for approval by the USAL Bioethics Committee, which serves as the Bioethics Committee of IBSAL, as established in the meeting of the Delegated Commission on October 30, 2012 (Annex A.13).

In this regard, the USAL Animal Experimentation Service provides a procedures manual, which is included as an annex.

2.4. Planning the research

Definition of the research protocol

Before initiating any research, a written protocol must be prepared, clearly and precisely outlining the study's objectives and research plan. The protocol should be detailed and comprehensive enough to allow any researcher to replicate the study with similar results or to assess the validity and reproducibility of its methodology.

A written protocol is required for both internal projects within the center and those submitted to external agencies for funding. Its structure should comply with the requirements set by the institution or funding agency. All research steps must be clearly explained to allow evaluation by independent experts. Ideally, every research protocol should undergo an independent review, except in cases where such a review is already mandatory and institutionalized, such as research grant applications and studies involving animals or human participants.

The basic components that a research protocol must include are as follows: title, date, details of the researchers and participating institutions, summary, problem statement, justification and theoretical framework, study objectives, methodology, bibliographic references, timeline, and available resources. For studies involving animals or human participants, the protocol must also address ethical considerations and safety measures.

Under no circumstances can the absence of a written protocol or a poorly drafted document that fails to meet basic research standards be justified, even for projects requiring immediate initiation or simplified protocols involving human participants or experimental animals. Any simplified or expedited protocols must still undergo external review in parallel and comply with the same procedural requirements as standard protocols.

Approval of the protocol

If a study requires the involvement of a healthcare service, prior written approval must be obtained from the service's responsible authority. This approval should include any financial agreements reached if the collaboration incurs costs for the service. For agreements with central services, such as clinical analysis or radiology, individual approval with the service head's signature will not be necessary for each specific study if a prior agreement has been established for ongoing collaboration. In such cases, financial compensation should be outlined for any study procedures considered extraordinary (i.e., not part of routine clinical practice).

Once this approval is granted, institutional authorization must follow. In the case of the IRB/IEC, it is important to recognize that this is an independent body, separate from the researcher, sponsor, and research institution. The IRB/IEC is composed of both healthcare professionals and non-medical members, with the primary mission of safeguarding the rights, safety, and well-being of research participants while providing public assurance in this regard.

The IRB/IEC's responsibilities include evaluating methodological, ethical, and legal aspects of research, assessing the risk-benefit balance, reviewing the suitability of the protocol, research team, and patient information, verifying liability insurance coverage, overseeing financial compensation for researchers, and monitoring the study from start to finish.

None of its members may have conflicts of interest with the study sponsor. Both the composition and functions of the IRB/IEC comply with current legal regulations.

The institution's management must be informed of and approve all research projects, assuming shared responsibility for ensuring the necessary conditions for their proper execution.

In accordance with **Royal Decree 1090/2015 of December 4,** clinical trials involving medicinal products and medical devices require approval from the **Spanish Agency of Medicines and Medical Devices (AEMPS)**. For **post-authorization studies with**

medicines (prospective follow-up EPAs, EPA-SP), authorization must be obtained from the **Regional Ministry of Health of Castile and León**.

The **research protocol** must be signed by the principal investigator and all members of the research team, affirming their commitment to carrying out the project and confirming the accuracy of the data provided in the study records. If the project involves **financial compensation**, a written financial agreement must be signed by the **sponsor and the institution's responsible authority**.

To prevent unnecessary delays in publishing the results of completed projects, requests for funding for new research should be carefully considered. Given the complexity of data collection in clinical research and the potential challenges in replicating studies, the **principal investigator and research team** must ensure **high-quality data collection and secure data management** throughout the study.

Applicable regulations

Research projects must adhere to the fundamental principles set forth in the Declaration of Helsinki, the Council of Europe Convention on Human Rights and Biomedicine, and the UNESCO Universal Declaration on the Human Genome and Human Rights. Additionally, they must comply with the requirements established in Spanish legislation concerning biomedical research, personal data protection, and bioethics.

a. *Human research*

Clinical trial projects must comply with the provisions of **Royal Decree 1090/2015 of December 4**, which regulates **clinical trials with medicinal products, Research Ethics Committees for medicinal products (IRB/IEC), and the Spanish Clinical Studies Registry**.

Research projects involving the use of **human cells and tissues in the field of regenerative medicine** must adhere to the provisions of **Law 14/2006 of May 26** on **Assisted Reproduction Techniques**, **Royal Decree 1825/2009 of**

November 27, which approves the **Statute of the National Transplant Organization,** and **Royal Decree 2132/2004 of October 30,** which establishes the **requirements and procedures for requesting the development of research projects using stem cells obtained from surplus pre-embryos**.

Any **research protocol involving the use of institutional digital records or the creation of databases containing personal information** must ensure the **anonymity of participants** and comply with the **current regulations on database registration,** as established by **Organic Law 3/2018 of December 5** on **Personal Data Protection and Digital Rights (LOPDGDD)**.

Any **research protocol involving studies with human subjects** shall never be implemented without prior approval from the **Research Ethics Committee (CEI)** or the **IRB/IEC** when the research involves medicinal products.

Research protocols that involve the **collection and/or storage of biological samples** must guarantee the **confidentiality of donors,** regardless of the level of identification at which the samples are stored. If **non-anonymous samples are preserved for genetic testing, renewed consent** must be obtained each time new analyses are intended, provided they differ from those initially planned in the original protocol.

The **principal investigator and collaborators** of a **research project involving human subjects** must strictly follow the **approved research protocol,** especially concerning:

- **Obtaining informed consent** from participants.
- **Ensuring the confidentiality** of **data, samples, and results**.

b. Animal research

Projects involving animal experimentation must comply with the applicable legal regulations as established by Royal Decree 53/2013 of February 1, which sets forth the basic standards for the protection of animals used in

experimentation and other scientific purposes, including education, as well as Order ECC/566/2015 from the Ministry of Economy and Competitiveness.

Projects involving the use of genetically modified organisms (GMOs) must adhere to the provisions of Law 9/2003 of April 25 on the Contained Use, Voluntary Release, and Commercialization of Genetically Modified Organisms, as well as its implementing regulations.

Additionally, protocols involving animal experimentation require prior approval from the Bioethics Committee. Animal research must also comply with the provisions of Law 32/2007 of November 7, which regulates the care of animals in farming, transport, experimentation, and slaughter.

c. Research with biological agents

Projects involving the use of biological agents must comply with the provisions of Law 31/1995 of November 8 on the Prevention of Occupational Risks and with current legislation on risks related to exposure to biological agents, specifically Royal Decree 664/1997 of May 12, which regulates the protection of workers against risks associated with exposure to biological agents in the workplace.

Responsibility of research staff

In any research funding application, the principal investigator responsible for the proposal is also accountable for the accuracy of the committed resources. Any research protocol that involves the use of healthcare facilities or equipment, whether owned or external, or any research infrastructure shared by the institution, must also obtain approval from the responsible authority of the institution, facility, or equipment.

It is advisable for the principal investigator, in collaboration with the rest of the research team, to develop a **communication and publication plan** for the potential research findings. When preparing a personal curriculum vitae, the author is responsible for the accuracy of its content. As proof of this, signing the CV document is recommended. In the case of a collective CV, it must be signed by the individual responsible for the application.

In all cases, the **principal investigator and collaborating research staff, as they are not responsible for the clinical treatment of any involved subjects, must refrain from interfering in any decisions made by the medical personnel responsible for those individuals.**

Collaborative projects

When a research project anticipates the participation of multiple groups within the same institution or from different institutions, it is advisable to formalize a protocol that defines the terms of joint collaboration. This collaboration agreement should include, in addition to the standard requirements of a research protocol, the following points:

a. A clear and precise description of all aspects of the research plan established within the framework of the collaboration.

b. The criteria for updating the progress of the studies among the participating groups or centers.

c. The explicit distribution of responsibilities, rights, and obligations of the involved groups or centers, both regarding the tasks to be performed and the expected results, including the custody and storage of data or samples obtained.

d. A preliminary plan for presenting and communicating results in any setting.

e. The procedures for storing and distributing data and samples, ensuring the protection of anonymity.

f. Any other relevant considerations, including potential commercial implications, funding arrangements, and conflict resolution mechanisms.

2.5. Research development

Documentation, storage, safekeeping and sharing of data, records, and biological or chemical material resulting from investigations

Every research protocol must include a specific plan for the collection of data, records, and biological or chemical material resulting from the execution of the research, as well as guidelines for their custody and preservation.

The principal investigator and their research staff are responsible for documenting every detail observed in experiments and research observations.

All information must be permanently recorded and incorporated into logbooks or ad hoc data collection notebooks. Any intermediate or final data must correspond accurately to the original documents, such as the medical records of patients in clinical trials. Experiments and observations must include the number of participants, along with the time and circumstances of their execution. Errors, negative, unexpected, or conflicting results should never be omitted. Any corrections must be clearly traceable, with a systematic identification of the person responsible for making them.

The principal investigator must anticipate the necessary resources to ensure the proper custody and preservation of all documentation, and biological or chemical material obtained from experiments and observations, including unpublished data.

Additionally, a **tracking system** must be maintained for **data logbooks** and **biological or chemical material repositories**. Any **primary data records stored electronically** must have a **protocol** outlining a **specific storage plan** and **backup procedures**, ensuring protection against **accidental loss of digital or physical records**, as well as **controlling access and data security**.

Any **documentary record of data** or **sample forming part of a bank of biological or chemical material** collected during research should be **accessible** to all members of the research team. There is a **mutual obligation** among them regarding the **reporting, processing, and interpretation** of the data obtained.

All **documentation and biological or chemical material** obtained during research is the **final property of the institution** and must remain under its **custody** in accordance with the criteria set by the **principal investigator** of the project. If a **collaborator** from the research group **moves to a different institution** and requires access to information obtained during their work, the **principal investigator** may provide **photocopies of data collection notebooks** or **aliquots of available biological or chemical material**. In cases where the **principal investigator** of the project changes institution, the provision of **copies of documentation or biological or chemical material** must be carried out under the **supervision of the institute's management**.

All **primary and original data** must be stored for **at least 25 years** after the completion of the study, or for a longer period if required under applicable regulations, in accordance with **Royal Decree 1090/2025, of 4 December**, which governs **clinical trials involving medicinal products**. In any case, there is **no restriction** on longer storage periods, though the final **disposition of the data requires the approval of the principal investigator**.

The **biological or chemical material and digital data** resulting from research must be **publicly accessible and shareable** with **third-party researchers**, except in cases where **restrictions apply** due to potential future **commercialization**. Transfers require:

- **Verification of the requester's qualifications** for proper use of the material.
- **Adequate knowledge** of the material by the research personnel responsible for its generation.
- A **transfer protocol** approved by the **principal investigator responsible for the material**.
- A **commitment from the requester** to cover any **production and shipping costs**.

The transfer may be **limited** due to considerations of **availability, competitiveness, or confidentiality**. Any transferred material or data must be **anonymized**; otherwise, **new informed consent** for the transfer must be obtained. These criteria apply **regardless of the form of publication** of the research.

Research projects sponsored by the healthcare industry or other for-profit entities

When research projects are sponsored by private entities and conducted within the public sector, the following considerations must be observed:

- Industry often requires collaboration with public institutions, particularly in experimental and technological development.
- Industry-sponsored research is both valuable and necessary, as it fosters technology transfer and provides significant financial resources.
- Clear boundaries must be established in scientific collaborations with industry to safeguard intellectual freedom and ensure research integrity.
- Researchers who benefit from public funding and credibility have a duty to conduct their work in alignment with the public interest.

While researchers may require access to confidential information from the sponsoring entity, this should never restrict their ability to publish new findings, except in the following circumstances:

- Researchers involved in an industry-sponsored project remain responsible for the study's design and methodology.
- The publication of research findings, even in industry-sponsored projects, is an ethical obligation.
- Agreements may be established to grant the sponsoring entity a limited review period for manuscripts or discoveries due to commercial considerations. Intellectual property rights must also be clearly defined, and the sponsor may retain exclusive access to research findings for up to 90 days.

For researchers participating solely in the data collection phase of a study developed by another group or institution, the conditions for communication and publication of results must be established by mutual agreement with the sponsoring entity.

All financial agreements between the sponsor and the researcher or research group, as well as any other form of compensation related to the project, must be documented in a single formal agreement between the sponsor and the researcher's affiliated institution. These financial agreements must be accessible to relevant oversight bodies, committees, and officials responsible for research governance.

2.6. Publishing practices

The publication of research results is an integral and unavoidable part of any investigation, as it is the only standardized means by which findings become available for universal scientific scrutiny. Failure to publish research results or excessive delays in their dissemination is considered a misappropriation of the resources invested. Specifically, publishing negative results or outcomes that differ from initial expectations is also an ethical obligation in research. Additionally, any post-publication corrections or retractions must be made publicly available when necessary, clearly specifying the procedures and reasons for such actions.

The final publication of results must explicitly declare:

- The institutions or research centers to which the authors belong and those in which the research was conducted.
- The independent ethics committees that supervised the research protocol, as well as any approvals granted by relevant authorities.
- Any financial or other types of sponsorship received, whether for the entire research project or for specific authors.

These details should also be disclosed in conference presentations or any preliminary communications before the final publication, particularly when the research involves human subjects, animal experimentation, or financial support from companies with commercial interests. Citations of third-party work in publications must properly acknowledge their contributions. References should be directly relevant to the research and unnecessary citations should be avoided.

Communicating or disseminating research findings to the media before their appearance in a scientific publication is unacceptable. However, early or preliminary disclosure of results may be justified in exceptional cases for public health reasons. In such cases, authors should consider submitting the results for expedited peer review in a scientific journal or coordinate the scope of the early communication with the editors of the intended publication.

Fragmented publication of a unified study should also be avoided unless justified by length considerations. Duplicate or redundant publication is deemed an unacceptable practice. Accordingly, in individual or collective assessments where scientific publications are considered for promotions or other forms of recognition, evaluators should base their judgments on the quality and content of the research output rather than merely its quantity.

2.7. Authorship of scientific work

To qualify as an author, the following criteria must be met:

- A substantial contribution to the conception and design of the research or to the analysis and interpretation of the data.
- Participation in the preparation of resulting communications and publications.
- The ability to present a detailed account of one's personal contribution to the research and discuss the key aspects of other contributions.

All co-authors share an indivisible responsibility to uphold ethical authorship standards, ensuring that no one is granted authorship without merit and that no deserving contributor is excluded. The rigorous enforcement of these criteria should be accompanied by a generous attitude from senior researchers, demonstrating a commitment to fostering the careers of younger investigators. Highlighting the valuable contributions of these collaborators should be a constant priority within the Institute.

Additionally, authorship cannot be granted based solely on employment status or hierarchical position. The common practice of listing an Area Coordinator as a co-author on all publications from their department is also considered inappropriate unless they have met the authorship criteria for each specific work. To prevent fictitious or unwarranted authorship, it is recommended that the contributions and authorship order of all prospective authors be detailed at the time of submitting the study protocol, as required by many journals for manuscript publication.

All contributions stemming from formal collaborations or other direct or indirect support for the research that do not meet the criteria for scientific authorship must be properly acknowledged. Failure to do so would constitute an improper appropriation of intellectual credit.

The order of authorship should generally follow these established guidelines, ideally determined as early as possible in the research project based on each team member's assigned role:

- **First author**: The individual recognized by the group as having made the most significant contribution to the experimental phase, including data collection, analysis, and interpretation, as well as drafting the initial manuscript.
- **Senior or last author**: The individual with ultimate responsibility for the research protocol and project supervision.
- **Other authors**: Contributors who have participated in the study, typically listed according to the quantitative or qualitative significance of their work, though sometimes arranged alphabetically.
- **Corresponding author**: The individual responsible for managing the editorial process and any future communications related to the publication.
- **Justification of authorship order**: In cases where two or more authors have contributed equally to the research and manuscript preparation, they may be designated as co-first authors, provided this is acknowledged by the group and explicitly stated in the final publication.
- **Defined author contributions**: If any author is unable to assume responsibility for the entire content of a publication, their specific contribution should be identified separately, except where editorial guidelines already regulate this aspect.

For internal drafts, reports, technical documents, or any written work intended for third parties, the names of contributing researchers should be included in the same manner as they would be in a scientific publication.

In multicenter studies involving a large number of contributors, collective authorship and the appointment of a writing committee should be accepted. If a nominal list of authors is provided, the order should be based on objective criteria, such as the number of patients contributed to the study. Individual centers may negotiate separately with the writing committee for the independent publication of their specific contributions. The **Area Coordinator** may review the manuscript before

submission, offering feedback and recommendations as needed. They also retain the right to require a disclaimer to clarify their own or the area's lack of responsibility for the publication.

Finally, the **acknowledgments section** should include significant contributions that do not meet the authorship criteria, limited to roles such as resource acquisition or similar functions, while avoiding marginal or gratuitous mentions. Every acknowledgment must explicitly state the nature of the support provided. Authors are responsible for obtaining written consent from individuals whose names are mentioned in the acknowledgments.

2.8. Activity report

The Institute will draft an **Annual Activity Report** that documents and reflects the research activities of IBSAL. This report will include the institute's **strategic research plan** as well as proposed actions for the coming years.

Systematic and periodic **evaluation mechanisms** must be implemented to assess the quality of research activities, with the aim of fostering improvements in **innovation and development**.

2.9. Peer review

The evaluations conducted by the Institute are primarily based on **expert review**, which may involve assessing and critiquing a manuscript submitted for publication, a report requesting individual or collective funding, a clinical or experimental protocol under ethical committee review, or a report compiled during an **on-site visit**.

All reports and documents subject to review are considered **confidential and privileged information**. As such, this documentation:

- **Cannot be used** for the personal benefit of the reviewer until the information has been officially published.
- **Cannot be shared** with colleagues unless for specific, justified reasons or with **explicit permission** from the editor or research agency.

- **Cannot be retained or copied,** unless authorized by those overseeing the editorial process or the research agency. Typically, the material must be either **destroyed or returned** once the review process is completed.

2.10. Intellectual property rights and commercial exploitation of research results

Protection of results of potential commercial interest

If the results of a research project have the potential to lead **to inventions or applications that** could be commercially protected**, the principal investigator** is required to notify the **Institute's Innovation Unit.** This allows for an assessment of whether to initiate the **process for protecting the results.**

Intellectual property rights

When researchers participating in an **industry-sponsored project** contribute significantly to its **design and execution,** the necessary agreements will be established with the sponsoring entity to ensure the **shared ownership of intellectual and industrial property**. In this case, the sponsoring entity may retain **exclusive access to all obtained results for up to 90 days** to assess their **commercial potential,** as outlined in **Section 2.6: Research Development** of this Guide.

If the **research group provides a technical service** or if researchers are involved **exclusively in data collection** for a protocol developed by a third party, the conditions for **communication and publication of results** will be mutually agreed upon with the sponsoring entity. These agreements must always comply with the provisions set forth in the **"Authorship of Scientific Works"** section of this document.

2.11. Conflict of interest

A **conflict of interest** is defined as any situation in which a person's judgment, concerning the **primary objective of scientific knowledge,** may be influenced by a **secondary interest,** such as financial, academic, political, or personal gain.

Being in a conflict of interest situation is not inherently unethical, **provided it does not compromise the objectivity and integrity** of the research's **design, development, interpretation, or publication**. To prevent such compromises, attention must be given to **actual, perceived, and potential conflicts of interest**.

All **Institute members** are expected to recognize when they are in a conflict-of-interest situation, **disclose it to their superiors**, and **manage it in an ethically responsible manner**. The way one is perceived to act can influence the attitudes of others and may **undermine the credibility** of the Institute as a whole.

2.12. Non-compliance with research integrity

The Guide to Ethics and Good Research Practices represents the commitment undertaken by the scientific personnel of the Institute of Biomedical Research of Salamanca (IBSAL) regarding research quality and integrity. Its purpose is to serve as a reference for promoting good practices and guiding ethical conduct in the Institute's research activities.

IBSAL's objectives in terms of integrity, respect, and honesty are to ensure the truthfulness of scientific advancements, safeguard honesty and integrity in all scientific activities, and uphold the credibility of research. Failure to meet these objectives is incompatible with professional responsibilities and harms research development, relationships among researchers, and public trust. It also leads to a waste of resources and unnecessary risks for researchers, society, and the environment.

Research misconduct is recognized as any breach of research integrity, including fabrication, falsification, or plagiarism in the proposal, execution, review, or presentation of research and its results. Additionally, the following actions are considered unacceptable research practices:

- Manipulation of authorship concerning one's own or others' contributions.
- Duplicate publication of substantial parts of prior work, including translations or unreferenced publications (self-plagiarism).
- Misuse of citations, including unnecessary expansion of references or selective citation for external benefit.

- Introduction of bias, distortion, or withholding of research results for personal or sponsor-related gains.

Research misconduct will be subject to sanctions of varying severity, ranging from minor to serious offenses. The Institution is committed to protecting the rights of whistleblowers during investigations and ensuring transparency in handling research integrity violations. Individuals reporting misconduct will not face any professional repercussions because of their allegations. At the same time, accused individuals will have full access to the details of the allegations and will be ensured a fair process regarding the presentation of evidence and responses to the accusations. The Institution places particular emphasis on preventing malicious accusations and inappropriate obstruction during the reporting and response process. If an individual is exonerated, appropriate remedial actions will be implemented to restore their reputation.

The Institution is also committed to preventing research misconduct through education and dissemination of this Guide to Ethics and Good Research Practices. It will actively evaluate conflicts or concerns raised by IBSAL researchers, acting as a mediating body when requested by the involved parties and when legally feasible. Furthermore, all researchers are encouraged to uphold the principles of Integrity and Impartiality in all research processes, fostering a positive and collaborative research environment through responsible supervision and ethical leadership.

3. REGULATORY ENVIRONMENT

- Commission Recommendation of 11 March 2005 on **the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers.**
- World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th World Medical Assembly Helsinki, Finland, June 1964; last amended by the 64th General Assembly, Fortaleza, Brazil, October 2013 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Convention on Human Rights and Biomedicine Oviedo Convention, 4 April 1997.
- The Belmont Report. 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.
- European Code of Conduct for Research Integrity. European Federation of Academies of Sciences and Humanities, ALLEA.

Data Protection

- Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights.
- 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).
- Law 41/2002, of 14 November, basic law regulating patient autonomy and the rights and obligations regarding clinical information and documentation.

Experimental research

- *Law 31/1995 of 8 November 1995 on the prevention of occupational hazards.*
- *Royal Decree 664/1997 of 12 May 1997 on the protection of workers against risks related to exposure to biological agents at work.*

- Royal Decree 1090/2015 of 4 December 2015, which regulates clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Clinical Trials Register.
- Law 14/2007 of 3 July 2007 on biomedical researchRoyal Decree 192/2023 of 21 March 2007 regulating medical devices.
- Royal Decree 577/2013 of 26 July 2013 regulating the pharmacovigilance of medicinal products for human use.
- Royal Decree 957/2020 of 3 November on the regulation of observational studies with medicinal products for human use.
- 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.
- Royal Legislative Decree 1/2015 of 24 July 2015 approving the Consolidated Text of the Law on Guarantees and Rational Use of Medicines and Medical Devices.
- Regulation (EU) 2017/745 of 5 April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Royal Decree 1662/2000 of 29 September 2000 on medical devices for in vitro diagnostics.

Biological samples and genetics

- *Royal Decree 1716/2011 of 18 November establishing the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulating the operation and organisation of the National Register of Biobanks for biomedical research.*Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Law 14/2006 of 26 May 2006 on assisted human reproduction techniques

- Royal Decree 1825/2009, of 27 November, approving the Statute of the National Transplant Organisation
- Royal Decree 2132/2004 of 29 October establishing the requirements and procedures to apply for the development of research projects with stem cells obtained from surplus pre-embryonic stem cells.

Animal experimentation

- Royal Decree 53/2013 of 1 February establishing the basic rules applicable to the protection of animals used for experimental and other scientific purposes, including teaching
- Royal Decree 1143/2007, of 31 August, amending Royal Decrees 634/1993, of 3 May, on active implantable medical devices; 414/1996, of 1 March, regulating medical devices; and 1662/2000, of 29 September, on medical devices for in vitro diagnosis (BOE no. 210, of 1 September).
- 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.
- Order ECC/566/2015 of 20 March 2015 establishing the training requirements to be met by personnel handling animals used, bred or supplied for experimental and other scientific purposes, including teaching.+
- Law 32/2007, of 7 November, for the care of animals, in their exploitation, transport, experimentation and slaughter.+
- Law 9/2003 of 25 April 2003 establishing the legal regime for the contained use, voluntary release and placing on the market of genetically modified organisms.

Bibliography

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- Laporte JR. Basic principles of clinical research. Madrid: Zeneca Farma, 1993.
- BIO-Ethics and Research at CIMA.
- Guide to Good Practice in Health Sciences Research. Catalan Health Institute. Generalitat de Catalunya. Departament de Sanitat i Seguretat Social.
- Code of Good Scientific Practice, IMIM (Municipal Institute of Medical Research, attached to the Pompeu Fabra University).
- UK Medical Research Council "Good Research Practice".
- Office of Research Integrity, U.S. Department of Health & Human Services.
- Guidelines for Investigators in Scientific Research; University of Medicine & Dentistry of New Jersey.
- Guideline for agreements at the initiation of research projects", in The Danish Committee on Scientific Dishonesty Guidelines for Good Scientific Practice.
- Good Scientific Practice; Biotechnology and Biological Sciences Research Council.
- Code of Good Scientific Practice. Illinois Institute of Technology.

4. ANNEXES

- Informed consent form for CIC in the Castilla y León Regional LV Network. (Code 9.01)
- Informed consent model for the Castilla y León Regional LV Network. (Code 9.02)
- Informed consent form DNA Bank (Code 9.03)
- Manual of procedures of the Animal Experimentation Service of the USAL. (Code 9.04)
- Composition, functions and procedure IRB/IEC IBSAL. (Code 2.08)
- Resolution of the Directorate General for Public Health on the accreditation of IRB/IEC (29.1.2018). (Code 2.12)
- Composition of the Bioethics Committee (Code 2.05)
- Rules of Procedure of the Bioethics Committee (Code 2.06)