

UNIT FOR RESPONSIBLE CONDUCT IN RESEARCH (URCR)

I3S Ethics/Integrity Statement on Research Integrity

Statement approved by governing body (10/09/25)

Web address of i3S research integrity page: https://www.i3s.up.pt/responsible-

research.php

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Preamble

Research integrity goes beyond meeting regulatory and contractual requirements. While these obligations should be accomplished, the aim should be the broader implementation of the European Code of Conduct for Research Integrity. i3S is therefore committed to upholding responsible conduct of research and of service provision, in line with the definition of Research Integrity adopted by the UK in the 2025 edition of the Concordat¹: research has integrity when it is carried out according to the following principles: honesty, rigour, transparency and open communication, care and respect, accountability.

Research should always be conducted in a trustworthy, ethical, and responsible way. In order to ensure that i3S research culture is ethics and integrity-based, all the

¹ https://ukrio.org/research-integrity/the-concordat-to-support-research-integrity/



stakeholders in the research ecosystem have to play a role by respecting the following principles²:

"Honesty, demonstrated from the presentation of research ideas and goals, through to authorship and financial contributions, and on to findings.

Examples: honesty in reporting research methods and procedures; gathering data and information; referencing work; representing and acknowledging the work of others; conveying interpretations; and making justifiable claims based on research findings;

Rigor, demonstrated by behavior that is in line with prevailing disciplinary norms and standards, including the use of appropriate methods.

Examples: adherence to procedures, standards of practice and agreed protocols, as appropriate; accurate interpretations and conclusions from research, including the communication of findings.

Accountability requires researchers to be responsible for the entire research lifecycle, being expected of everyone individually and collectively.

Examples: be accountable to participants involved in research; be accountable when behavior falls short of the standards set by national and international guidelines.

Transparency and open communication provide the foundation for the actions taken when conducting or communicating about research.

Examples: declare potential competing interests; report research data collection methods; acknowledge the use of tools such as Artificial Intelligence; analyze and interpret data honestly and transparently; publish or otherwise share findings, including open research practices; demonstrate humility in the process, acknowledging errors committed in good faith and ensuring honest mistakes are seen as productive elements of research.

Care and respect are pillars of a healthy research culture in every research performing organization. They are not abstract concepts; they are values that demand being enacted and should be extended to all the stakeholders involved in the research process, including humans, animals, the environment and cultural objects."

 $^{^2}$ Adapted from "Self-assessment tool for the Concordat to Support Research Integrity", Version 3.0 $\mbox{\ensuremath{\mathbb C}}$ UK Research Integrity Office 2025



Regulatory Framework

With these standards in mind, i3S has already implemented a series of codes and abides by regulations and decrees, such as:

- Law no. 21/2014 of 16 April/amendment Law no. 73/2015 of 27 July that implements <u>Directive 2001/20/EC</u> of the European Parliament and of the Council of 4 April in Portuguese legislation, regarding clinical research;
- Decree-Law No. 80/2018 of October 15, which governs the Healthcare Ethics Committees;
- Ordinance No. 135-A/2014 that sets rules for CEIC and Health Ethics Committees (CES).
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014, which repeals Directive 2001/20/EC and concerns clinical trials on medicinal products for human use
- Law No. 58/2019 of August 8, which implements Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data:
- Law No. 12/2005 of January 26, which establishes the legal concepts of health and genetic information and outlines the conditions for handling them within the health system;
- 7. <u>Decree-Law No. 131/2014 of August 29</u>, which provides a framework for safeguarding genetic information, including the respect for confidentiality, particularly in healthcare and research contexts;
- The General Rules for Preventing Corruption (GRPC) and Data Protection Policy (DPP), as well as the protection of the Whistleblower (<u>Law no. 93/2021</u> of 20 <u>December</u>, or <u>Whistleblower Law</u>);
- i3S Authorship Guidelines, in line with the Authorship Guidelines by ICMJE;
 compliance with <u>The European Code of Conduct for Research Integrity</u>
 (ALLEA), the <u>Declaration on Research Integrity in Responsible Research and</u>



Innovation (UNESCO) and the Agreement on Reforming Research Assessment (i3S is one of the signatories of the Coalition for Advancing Research Assessment)

- 10. Compliance with Open Science Principles
- 11. Compliance with Código Ético de Conduta Académica da UPorto.

I3S has an <u>Ethics Committee</u>, <u>An Animal Welfare and Ethics Body (ORBEA)</u>, an <u>Integrity Officer</u>, and a <u>Data Protection Officer</u> that support researchers in complying with all the ethical requirements in their research projects and provide support throughout the implementation of the projects. No regulated procedures will be started without the approval of the appropriate ethical committees, as required by law.

All I3S researchers have the opportunity to get regular training in ethics and integrity of research provided by the Integrity Office. Good research practices are encouraged in order to define the criteria for proper research behavior, to maximize the quality and robustness of research, and to respond adequately to threats or violations of research integrity.

I3S guiding principles for responsible research are laid down in policy documents available on the webpage of the Institute.

The Institute is also responsible for ensuring that, when dealing with biological material, strict safety procedures are in place in compliance with national and EU regulations on biosafety. Entry to the dedicated facilities is regulated and restricted, ensuring that employees can only enter after they are appropriately trained.

According to <u>EU Directive 2004/23/EC</u> | <u>Consolidated version: Regulation (EC) No 596/2009 No 596/2009</u>, the handling of cells and tissues is subject to specific rules, in particular, concerning:

 Donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling,



packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries.

In Portugal, <u>Law No. 12/2009</u> transposes the directive and its amendments into Portuguese legislation.

Regarding animal experimentation, the animal care and use program at i3S is the first and presently only in Portugal to be accredited by AAALAC International. In addition to the ORBEA and the animal facility, the program also includes training for researchers in the 3Rs and other aspects of responsible research with animals, with a FELASA accredited course. In addition, i3S is one of the signatories of the <u>Transparency</u> Agreement on Animal Research in Portugal.

DATA SECURITY

All i3S users have access to a personal and/or group network drive, which can be used to save information. All information stored in i3S file servers is backed up on a daily basis by the IT Unit.

Personal human data is processed in accordance with national and European legislation on the protection of individuals, as well as other legal, regulatory and good practices. Methods used for processing sensitive/personal data entail: pseudonymization or anonymization of data where necessary; privacy constraints and applicable ethical norms; data accompanied by informed consent statements; privacy policies, national laws. Researchers should ask for support from the Data Protection Officer whenever there are queries regarding personal data protection in their studies.

ENVIRONMENT, HEALTH AND SAFETY ISSUES

I3S has adhered to <u>The European Charter for Researchers</u> and <u>The Code of Conduct</u> <u>for the Recruitment of Researchers</u> -- by adhering to this Charter and Code of Conduct, it commits itself to following the principles laid out in the documents, with the aim to



keep and improve an adequate framework for all its researchers (see https://www.i3s.up.pt/hr-excellence). Moreover, The Unit for Career Development aims to ensure that i3S staff set their long-term career objectives, understand the curricular needs befitting the set career path, and are given opportunities to develop the required skills and knowledge.

At i3S there is also a <u>Health, Safety and Quality Unit</u> that promotes workplace health and safety programs, providing information, training and education in the management of biological, chemical, physical, radiological and environmental hazards, in such a way that all research and technical activities have the least possible impact to the people's health. This Unit is responsible for the following issues: Emergency Planning and Response; Environmental Compliance; Environmental Public Health; Environmental Project Support and Building Renovation.

There is also a <u>Lab Support Unit</u> that assures a diverse number of key tasks such as: collecting biological and chemical wastes, material to wash/sterilize and also distribute clean/sterilized material; lab coat laundry, clean specific equipment such as biological safety cabinets, baths, incubators, etc., as well as assuring differentiated support in several specific rooms such as cell culture rooms.

Considering the environmental and ethical/security issues underlining lab work, i3S conducts regular safety and health training sessions for all researchers and safeguard the health and safety of all human participants in research - as subjects, investigators or uninvolved third parties.



DEALING WITH RESEARCH MISCONDUCT

In spite of our focus on responsible research, misconduct can still happen in many different forms³:

"Fabrication: making up results, other outputs (for example, artefacts) or aspects of research, including documentation and participant consent, and presenting and/or recording them as if they were real;

Plagiarism: using other people's ideas, intellectual property or work (written or otherwise) without acknowledgement or permission;

Failure to meet legal, ethical, and professional obligations, for example:

- not observing legal, ethical, and other requirements for animal subjects, human research participants or human organs or tissue used in research, or for the protection of the environment;
- breach of duty of care for humans involved in research whether deliberately, recklessly, or by gross negligence, including failure to obtain appropriate informed consent;
- misuse of personal data, including inappropriate disclosures of the identity of research participants and other breaches of confidentiality;
- improper conduct in peer review of research proposals, results, or manuscripts submitted for publication, including: failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for the purposes of peer review."
- failure in reporting the use of AI in research tasks and/or paper drafting.

³ We have quoted the definitions and examples of research misconduct from the following source https://ukrio.org/research-integrity/the-concordat-to-support-research-integrity/, because we believe these are good definitions and the examples provided are relevant for their scope and up-to-dateness.



"Misrepresentation of:

- data, including suppression of relevant results/data or knowingly, recklessly, or by gross negligence presenting a flawed interpretation of data;
- involvement, including inappropriate claims to authorship or attribution of work and denial of authorship/attribution to persons who have made an appropriate contribution;
- interests, including failure to declare competing interests of researchers or funders of a study;
- qualifications, experience, and/or credentials;
- publication history, through undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication.

Improper dealing with allegations of misconduct: failing to address possible infringements, such as attempts to cover up misconduct and reprisals against whistleblowers, or failing to adhere appropriately to agreed procedures in the investigation of alleged research misconduct accepted as a condition of funding; inappropriate censoring of parties through the use of legal instruments, such as non-disclosure agreements.

Be aware that honest errors and differences in, for example, research methodology or interpretations, do not constitute research misconduct."

In order to give everyone the opportunity to report research misconduct in confidence, without being afraid of retaliation, we have included Research Misconduct as a topic for report in the *Whistleblower Channel for Corruption and Other Infractions*. It is highly important to be aware that the Whistleblower Channel is not the only Speak Up Channel. The Unit for Responsible Conduct in Research | a supervisor | a senior colleague and the Committee for Ethical and Responsible Conduct of Research (CECRI) can also be good interlocutors for this kind of report, providing support and clarifying doubts about the nature of the allegation. In case there is evidence that the



report is made in good faith, an inquiry committee proceeds to investigate the allegation and a conclusion must be reached and communicated to the author of the report within reasonable time (depending on the nature of the investigation, it can take up to 90 days).

I3S COMMITMENT TO CONTINUOUS IMPROVEMENT IN RESEARCH INTEGRITY

At i3S we aim to uphold, reward, and continuously improve responsible research practice. Every stakeholder in research can play their part by acting as ethical leaders, showing care and respect for all those involved in the research ecosystem, being accountable and conducting their professional activities in an open and transparent way.