IR Sant Pau Procedure in cases of suspected misconduct

Version: 1

Versions

Version	Date	Amendment
1	07/05/2024	Drafting of the IR Sant Pau Procedure in cases of suspected misconduct

Approvals

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Contents index

1. BACKGROUND 5
2. OBJECTIVE AND SCOPE 6
3. DEFINITIONS 6
4. RESPONSIBILITIES 9
5. PROCEDURE 11
5.1 Phase 1: Complaint 13
5.2 Phase 2: Preliminary Investigation 15
5.2.1 Objective 15
5.2.2 Composition of the Preliminary Investigation Commission 15
5.2.3 Notification to the Respondent 15
5.2.4 Custody of records 15
5.2.5 Preliminary Investigation Procedure 16
5.3 Phase 3: Formal Investigation 18
5.3.1 Objective and beginning of the investigation 18
5.3.2 Establishment of the Formal Investigation Commission 19
5.3.3 Notification to the Respondent and custody of records 19
5.3.4 Investigation Procedure 20
5.3.5 Investigation Report 21
5.3.6 Decision and notification 22
5.3.7 Right of Appeal 23
5.3.8 Communication to the Complainant 24
5.3.9 Custody of records 24
5.4 Restoration of reputation and protection of participants against retaliation 25
5.5 Right to compensation. 25
5.6 Malicious complaints 26
6. REFERENCES 27

7. ANNEXES 28

1. BACKGROUND

IR Sant Pau has a Responsable Research and Innovation Plan[1] and a Code of Good Practice in Research[2] (CBPR-IIB) updated and approved on December 12, 2024.

The IIB Sant Pau Code of Good Practice in Research (CBPR-IIB) is a tool to self-regulate scientific practices, and it provides rules, recommendations and commitments that the scientific staff linked to the Institution must bear in mind. It represents a general framework, which must be translated into a detailed procedure establishing clear and transparent mechanisms to manage cases of scientific misconduct that may arise. The ALLEA code[3] is the framework of European scientific integrity, therefore, the European Union establishes it as a mandatory compliance document.

In addition, IR Sant Pau adheres to the CERCA Code of Conduct[4] signed in November 2018.

The Committee for Research Integrity IR Sant Pau (CIR-IR)[5], appointed by the Governing Council on June 15, 2023, is responsible for answering queries, mediating in any conflicts that may arise to promote research integrity, and managing possible cases of scientific misconduct according to the Procedure described in this document.

This Procedure (SOP) is included in the Institute's Compliance Plan. It is based on the procedure in cases of Suspected Scientific Misconduct of the Institut Hospital del Mar d'Investigacions Biomèdiques (IMIM)[6] and the Institut de Salut Global de Barcelona (ISGlobal)[7]. It is also based on the NIH paper "*National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings*"[8].

[1] IIB Sant Pau Responsible Research and Innovation Plan
[2] Code of Good Practice in Research IIB Sant Pau
[3] The European Code of Conduct for Research Integrity
[4] CERCA Code of Conduct
[5] Committee for Research Integrity (*Comitè per a la Integritat de la Recerca*) IR Sant Pau
[6] IMIM Procedure in Cases of Suspected Scientific Misconduct – v2 (April 25, 2018)
[7] Management of Suspected Scientific Misconduct ISGlobal v1.0 (17/09/2020)
[8] National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings (November 19, 2018)

This code has been written in an inclusive, non-sexist language. Any gender-marked noun that might remain will be understood as an unmarked and inclusive grammatical gender.

2. OBJECTIVE AND SCOPE

The purpose of this document is to establish the process to be followed in the event of a report of suspected scientific misconduct, in order to have a transparent and fair procedure for all staff involved.

This SOP applies to all IR Sant Pau staff, both contracted and seconded, and other related staff.

3. DEFINITIONS

Complaint: A disclosure, by means of a written or oral statement, of potential scientific misconduct. The written statement may be signed or anonymous but must refer to specific evidence. There are two types of complaints:

- Complaint in good faith: The disclosure of potential scientific misconduct of an individual by someone who believes in the truth of the complaint that they make, as a reasonable person, and taking into account the information known at that time and the position of the individual suspected of misconduct.
- Bad faith or malicious complaint: The disclosure of potential scientific misconduct of an individual that is not based on real facts, with the purpose of damaging or harming the reputation of an individual or a group of people.

Assessment: The review of the information gathered about a scientific misconduct complaint to determine whether or not a formal investigation is warranted.

Malicious conduct: The intentional act of using falsified, fabricated or plagiarized material to propose, perform, review or report the results of research knowing that the material has been falsified, fabricated or plagiarized.

Conflict of interest: Risk situation in which the particular interest of an individual may interfere, or indeed interferes, with the proper exercise of their professional

discernment to the detriment of another individual who, legitimately, trusts that judgment.

Right of Appeal: The right of the parties to appeal the resolution of the Formal Investigation Commission against the President of the Compliance Commission for a complete review of the matter.

Complainant: A person who makes an allegation or reports scientific misconduct. This person will receive special protection to avoid possible retaliations for having filed a complaint.

Respondent: The person against whom an allegation of research misconduct is directed.

Research file: The record of data or results, both physical and electronic, that incorporate the facts resulting from an investigation of suspected scientific misconduct. This record will include, but is not limited to, e-mails, research projects, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, videos, photographs, biological materials, animal facility records, consent forms, medical records, and any additional documents and materials obtained during the research procedure subject to misconduct review.

Evidence: Any document, tangible item or testimony offered or obtained during a scientific misconduct activity or procedure to prove or disprove the existence of an alleged fact.

Recklessness or negligence: The use of falsified, fabricated or plagiarized material to propose, conduct, or review research, or to report the results of said research without exercising due care or caution, while ignoring or showing indifference to what the use of falsified, fabricated or plagiarized material entails.

Formal Investigation: The formal development of an investigation file where all the evidence of the case is collected and that, once examined, it is decided whether or not scientific misconduct has been found. An investigation may conclude with a recommendation to carry out the appropriate actions, including administrative actions, or to improve the protocols of research procedures.

Preliminary Investigation: The collection of information and determination of the previous facts to decide whether a complaint of scientific misconduct justifies a formal investigation.

Scientific misconduct: includes fabrication, falsification, or plagiarism when proposing, conducting or reviewing research, or when reporting research results[9].

- **Fabrication** is making up results and recording them as if they were real.
- **Falsification** is manipulating materials, equipment or research processes, or changing, omitting or deleting data or results without justification.
- **Plagiarism** is using the work or ideas of others without giving proper credit to the source. The concept includes all sources obtained through a confidential review of other people's research proposals and manuscripts.

It also includes questionable research practices that are contrary to or seriously deviate from those included in the IR Sant Pau Code of Good Practice in Research or current regulations. Honest mistakes or honest differences of opinion are not considered scientific misconduct. (See Annex 1)

Retaliation: An adverse action taken against a Complainant, witness, or Committee member as a result of their participation in a complaint of scientific misconduct made in good faith or their cooperation in good faith in a scientific misconduct procedure.

Violations of intellectual property (IP): Cases in which a third party, explicitly or implicitly, commits an action or omission contrary to IP rights including, but not limited to, misappropriation, reproduction, plagiarism, or public communication, in whole or in part, of a literary (book), artistic (photography or similar) or scientific (specific theory, discovery, applications, methodologies or computer programs) work, or its transformation, interpretation or artistic execution on any type of support or communicated through any means, without the authorization of their lawful owners.

Violations of industrial property: Cases in which a third party, explicitly or implicitly, commits an action or omission contrary to industrial property rights, including, but not limited to, reproducing or imitating a distinctive sign without its lawful owner's consent,

[9] The European Code of Conduct for Research Integrity

so that another identical or confusable sign is obtained to distinguish the same or similar products, services, activities or establishments.

4. RESPONSIBILITIES

The **Complainant** must always act in good faith, providing evidence-based facts that objectively serve as a basis for starting the investigation of the reported facts.

The **Respondent** as alleged to have committed the facts has the right and the obligation to cooperate during the investigation process.

The **IR Sant Pau Integrity Committee (CIR-IR)** is the body with the power to carry out the investigation and deliver a resolution of the facts reported, and it can also act ex officio. Its composition and functions are detailed in the CIR Charter. The CIR-IR is responsible for appointing the members of the Preliminary Investigation Commission and the Formal Investigation Commission. The CIR-IR will notify the Respondent of the names of the proposed members of the Investigation Commission (preliminary or formal) and, if the latter opposes them in a justified manner, the CIR-IR may replace the members or provide the reasons for keeping their initial choice in writing.

When scientific misconduct has been demonstrated, the CIR-IR is responsible for informing those involved in the alleged case of misconduct.

The **person who holds the position of President of the CIR-IR** together with the **Secretariat of the CIR-IR** are the people responsible for evaluating the complaints received and making a decision on whether or not a Preliminary Investigation is necessary. The Secretariat is responsible for informing the CERCA Entity of the existence of the scientific integrity conflict once the Formal Investigation Commission has issued its positive opinion on the misconduct. In addition, they will also inform CERCA's Ombudsperson keeping the most strict confidentiality and respect for the people involved. In addition, the IR Sant Pau has the power to apply the appropriate sanctions.

Likewise, if the person who holds the position of President of the CIR-IR is aware of the filing of a complaint, they must notify the Institute's Compliance Committee, through the internal Complaints Channel (IR_canaldenuncies@santpau.cat), or the enabled space on the website: www.recercasantpau.cat, if the allegation contains reasonable indications of an alleged crime.

The **Preliminary Investigation Commission** is responsible for carrying out a preliminary evaluation of the evidence provided by the Complainant, the evidence obtained from the Respondent and the possible witnesses that justify the start of the investigation. The Secretariat will write a report including this decision.

The **Formal Investigation Commission** is responsible for exploring the complaint in detail, scrutinizing the evidence and determining specifically if misconduct has occurred, who has committed it and its level of seriousness. The Research Commission is in charge of requesting the advice of the CIR-CAT (*Comitè d'Integritat de la Recerca de Catalunya*) through the Secretariat/Presidency of the CIR: (https://recercaiuniversitats.gencat.cat/ca/01_departament_recerca_i_universitats/el_departament/organismes/comite-per-a-la-integritat-de-la-recerca-a-catalunya-circat/index.html) if deemed necessary.

The **Decision Committee** will include the director of Legal Advice and RRLL and two lawyers from IR Sant Pau. The mentioned Committee will be responsible for drafting the corresponding resolution that puts an end to the investigation, raising it to the Compliance Commission, (whose functions are regulated in the Compliance Commission's Charter), and, with the Compliance Commission's approval, executing the corresponding actions and precautionary measures. The Decision Committee will also prepare and submit the relevant written reports and complaints to the competent authorities.

The person who holds the position of director of the Compliance Commission is in charge of receiving and initiating the complaint process, submitting the complaint to the IR Sant Pau Integrity Committee (ombudsperson@santpau.cat), which will ensure the identity of the Complainant is kept confidential.

In regulated research, i.e. clinical trials, the scientific director (or their delegate) is responsible for reporting to the regulatory authorities and ethics committees (if applicable) following the process and deadlines set up in the applicable regulations.

All persons involved are bound by the duty of secrecy. For this reason, they will sign a confidentiality document.

5. PROCEDURE

Any person linked (internally or externally) to IR Sant Pau, who knows of any significant evidence of scientific misconduct as per the definitions in Annex 1, must notify it in writing or orally through the mechanisms detailed below. The CIR must notify this person that it has received the report within a maximum period of 7 days.

Complaints can be notified by the following means:

A.- In writing:

- Via e-mail to the address ir_canaldedenuncies@santpau.cat, this being the preferred means and the means by which the resolution will be communicated to the Complainant.
  To ensure the confidentiality of the aforementioned email address, only the Director of Compliance will have access to it. Access to the email address will be restricted using passwords, which will be subject to an expiration date, so they must be updated periodically, within a period of no more than 3 months, and can only be known and guarded by the Compliance Commission.

- Via a specific form enabled on the website, "Complaints Channel": IR Sant Pau will enable a specific section on its website, called "Complaints Channel", which will include a form to submit communications in writing.

- Via postal mail by means of a letter addressed to the IR Sant Pau Compliance Committee, to: Carrer Sant Quintí, número 77-79, 08041, Barcelona.

B.- Orally:

The IR Sant Pau accommodates the possibility of filing verbal complaints or communications, by telephone or other voice messaging systems, and also in person through a hearing procedure, if requested by the Complainant.

Verbal communications will be submitted by the Complainant to the member designated by the Compliance Commission, who will request the consent of the Complainant to draw up the written or recorded minutes, in which the entire content of this will be collected and recorded verbatim.

As a general rule, and always ensuring the confidentiality of the Complainant's data, the Complainant will be encouraged to formulate the communication or complaint

nominally. However, the fact that nominal communications are encouraged does not mean that those received anonymously are not accepted and taken into consideration. In any case, under this Procedure, the individuals who report anonymously will enjoy the same level of protection as nominal Complainants, if they are subsequently identified.

Once a complaint of suspected scientific misconduct is received, the Procedure includes three phases:

Phase 1: Complaint

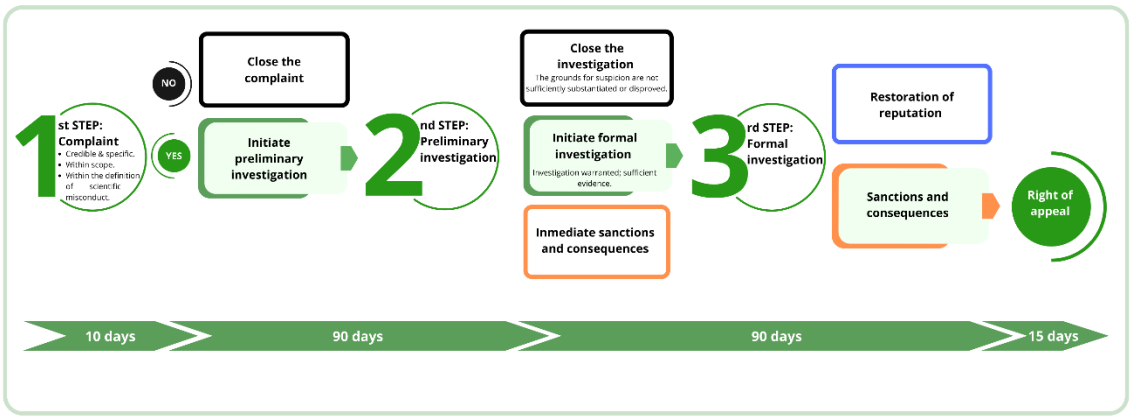
Phase 2: Preliminary Investigation

Phase 3: Formal Investigation

At all stages of the Procedure, all parties involved in the investigation will sign a non-disclosure agreement regarding any information related to the case.

The CIR-IR will remove any of its members who may be considered to have a conflict of interest with any party involved in the complaint. The documentation received related to the case will be stored in compliance with the relevant security measures that are already included in the complaint management program. Access to this folder will be secure and traceable, and the information will be kept for the maximum period contemplated in current regulations, which at the date of approval of this document is 3 months extendable to 10 years if deemed necessary, as long as and when personal data have been anonymised.

For clinical trials, the information will be kept for the period of time indicated in the applicable regulations. Misconduct and fraud in a clinical trial must be reported as serious violations to regulatory authorities under current regulations (Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol).



5.1 Phase 1: Complaint

The purpose of this phase is to determine whether an investigation is warranted.

The complaint, which can be submitted in either of the two ways mentioned above, must be accompanied by a document including details, such as parties involved, witnesses, dates, locations, publications and any type of evidence in relation to the complaint in question that allows the assessment by the members of the CIR-IR.

It must be remembered that, in any case, the CIR-IR will ensure that all the information received remains confidential.

If the Complainant has doubts about whether an incident falls within the definition of scientific misconduct, he can contact a member of the CIR-IR to solve their doubt.

Once the CIR-IR receives a complaint, the people who hold the positions of President and Secretary will assess whether the complaint:

i) Falls within the definition of scientific misconduct (action).
ii) Is credible and specific, so that possible evidence of scientific misconduct can be identified.
iii) Is within the scope and applicability of this Procedure (person and location).

If at this stage it is considered that there is no solid basis for continuing with the Procedure, the Procedure will be terminated. Depending on whether the Complainant lodged the complaint:

i) In good faith: they will be notified about the filing of the actions.
ii) Bad faith: The CIR-IR will proceed as described in clause 5.6 "Malicious complaints".

The CIR-IR will draw up the final report indicating the decision and the reasoning behind it, and will send it to the Compliance Commission and the Complainant. Although the decision of the CIR-IR is unappealable, the Complainant may take the actions they deem appropriate before other establishments or competent authorities in defence of the legitimate interests they deem appropriate.

Although the deadline for evaluating complaints will preferably conclude within 10 working days following the receipt of the complaint, it may be extended if the phase or circumstances require it.

As indicated above, if the people who hold the Presidency and the Secretariat of the CIR-IR consider the complaint credible and specific, within the scope and applicability of this Procedure and within the definition of scientific misconduct, a preliminary investigation will be conducted. In addition, in cases related to the revision or retraction of articles and that may lead to disciplinary proceedings or that involve the direction or management of the centre, the person who holds the Presidency will inform the CERCA Entity through the CERCA's Ombudsperson, keeping the most strict confidentiality and respect for the people allegedly involved.

In the field of clinical trials, it is essential to carry out a comprehensive assessment of the impact of the complaint on the safety and rights of the participants or the reliability and robustness of the data generated. Complaints that require immediate action to prevent harm will be treated as a priority, and, where appropriate, an expedited complaint review will be considered.

In the event that the complaint contains reasonable evidence of scientific misconduct, the CIR-IR will initiate the second phase, the preliminary investigation, and notify the Compliance Commission.

The investigation process and the guarantees of Complainants and Respondents are regulated in the IR "Regulatory Compliance Commission Charter", approved by the Board of Trustees of the IR Sant Pau on December 18, 2023.

All the rights, duties and procedures of the parties involved are included in the CIR-IR Charter.

5.2 Phase 2: Preliminary Investigation

5.2.1 Objective

The purpose of this phase is to carry out a preliminary assessment of the evidence gathered and available testimonies of any Respondent, the Complainant and key witnesses to determine whether there is sufficient evidence of potential scientific misconduct to warrant an investigation. The goal of this preliminary phase is not to issue a final conclusion on the case or liability.

5.2.2 Composition of the Preliminary Investigation Commission

The CIR-IR will assign two of its members and a researcher from IR Sant Pau with experience in the subject of the complaint (a senior researcher, preferably within the research area or the field of knowledge of the Respondent), to form the Preliminary Investigation Commission. The members of this Commission will sign the document of confidentiality and absence of conflict of interest with the ongoing investigation, to ensure that there is no conflict of interest and to ensure fairness and prompt action to protect all parties in the Procedure.

5.2.3 Notification to the Respondent

The CIR-IR must communicate in writing the complaint lodged and the steps to be followed to the Respondent. The CIR-IR will also verbally explain the complaint process to the Respondent and inform them that they can request their own legal advice. The CIR-IR will also provide the Respondent with a copy of this Procedure. If there is more than one Respondent, each person will be notified separately. The CIR-IR will also give written notice of any new complaint of scientific misconduct other than the one that motivated the initial complaint.

5.2.4 Custody of records

Once the Respondent has been notified, the CIR-IR and the members of the Investigation Commission shall take all reasonable and practical steps to secure the safe custody of all records and evidence necessary to conduct the investigation. When the records or evidence include scientific records of instruments shared by several users, custody may

be limited to copies of the data or evidence of these instruments, provided that these copies are authentic reproductions of the original, for evidentiary purposes.

5.2.5 Preliminary Investigation Procedure

a. Beginning of the investigation

The CIR-IR will determine:

(i) The specific mandate of the Preliminary Investigation Commission.
(ii) The description of the complaint.
(iii) The identification of the Respondent or Respondents, and of the Complainant (if any).
(iv) The alleged scientific misconduct.
(v) The preliminary investigation process and its objective.

The Preliminary Investigation Commission will hold a meeting with the Respondent to inform them of the potentially incriminating facts, and to provide them with a written document that will include the potentially incriminating facts and evidence. In addition, once the Respondent has been notified, the Commission will take all reasonable and practicable steps to obtain safe custody of all records and evidence necessary to conduct the preliminary investigation.

The Preliminary Investigation Commission will interview the Respondent, the Complainant (if known), and the key witnesses, as well as examine relevant records and materials. The CIR-IR Secretariat will write a summary of the interview that will be made available to the interviewees for their approval, giving them the possibility of suggesting corrections. In order to ensure the traceability of the information collected, the Preliminary Investigation Commission may request the recording of the interviews. All the people interviewed must sign a document of confidentiality and absence of conflict of interest with the ongoing investigation (Annex 2). The identity of the Complainant is not revealed at this stage unless they have given their express consent.

b. Preliminary Investigation Report

The Preliminary Investigation Commission will evaluate the evidence and testimonies obtained within 60 working days of its first meeting and prepare a draft written report using a predefined template (Annex 3) containing:

- Name, academic education and affiliations of the members of the Preliminary Investigation Commission.
- Name of the Respondent.
- Reviewed complaints.
- Summary of the research process used
- List of research records reviewed.
- Summary of the interviews conducted.
- Description of evidence to demonstrate whether further investigation is warranted.
- Conclusion.
- Recommendations.

This draft will be shared with the Respondent, who will have 15 working days from its receipt to make any allegations/comments/questions they deem appropriate. The Preliminary Investigation Commission will also share the draft report and the opinions of the Respondent in the investigation with the Complainant. The Complainant will also have 15 working days to send the claims they consider appropriate to the Commission.

All information related to the case will be stored in digital format in a folder on the intranet provided by the CIR-IR with secure and traceable access.

c. Decision and notification

The Preliminary Investigation Commission will draw up the final report taking into account the observations received by both parties (reporting and Respondents), and will send it to the CIR-IR, the compliance committee, the Respondent and the Complainant.

The purpose of this report is to help make a decision on the need to warrant further investigation in accordance with the criteria of this Procedure.

The consultation will be completed (to the extent possible) within 60 days from its start, defined as the date of assignment to the Investigation Commission.

The recommendations of the Preliminary Investigation Commission may be:

a. **Ending the investigation** if the reasons for the suspicion are not sufficiently substantiated or are disproved. In this case, the Preliminary Investigation Commission will determine if the Complainant did so in good faith or if the

complaint was not lodged in good faith. In this second case, IR Sant Pau will proceed as described in clause 5.6 "Malicious complaints".

b. **Initiating a Formal Investigation** if warranted by sufficient evidence of a possible misconduct in research. See clause 5.3.

c. **Applying sanctions or consequences** if the preliminary investigation unequivocally shows evidence of misconduct, such as the acknowledgement of misconduct by the Respondent.

In the event that the Preliminary Investigation Commission does not reach an agreement on the recommendations to be made, a formal investigation will be warranted.

If a formal investigation is not recommended, all materials in custody must be returned to the parties involved as soon as possible.

If precautionary measures (point c) need to be taken, the Decision or Resolution Committee will decide on the sanctions to be applied as described in Annex 4 (Sanctions and consequences in cases of scientific misconduct). In addition, the CIR-IR will inform the persons responsible in the associated institutions that a case of misconduct has been committed by the Respondent (see Annex 1).

The final report of the preliminary investigation must preferably be completed within 60 calendar days following the formal establishment of the Commission.

5.3 Phase 3: Formal Investigation

5.3.1 Objective and beginning of the investigation

The purpose of this phase is to investigate the complaint in detail, examining in depth the evidence gathered during the preliminary investigation, to decide whether scientific misconduct has been committed and by whom.

An investigation could also be initiated when the Complainant is the publisher of a magazine. This process must begin within 30 calendar days of the conclusion that a formal investigation is warranted.

The investigation will also determine whether there are additional cases of potential scientific misconduct that warrant expanding the scope beyond the initial complaint.

The findings of the investigation must be set out in an Investigation Report.

5.3.2 Establishment of the Formal Investigation Commission

The investigation will be carried out by an Investigation Commission appointed ad hoc by the CIR-IR, which will be made up of at least three people, two of whom are employed/assigned by the IR Sant Pau (one of them from the CIR- IR, and one external to the IR.) These people must not have conflicts of interest with the Respondent or the case under investigation, and must have the necessary expertise in the research subject to be investigated to evaluate the evidence and key witnesses, and conduct the investigation. These can be research staff, experts in the field, lawyers or other qualified people, and they can be from inside or outside the institution.

The Secretariat, on behalf of the CIR, will notify the Respondent of the names of the individuals proposed as members of the Commission of Investigation, and will allow the Respondent to challenge one of these individuals on the basis of a conflict of personal, professional or financial interest. The Respondent must inform the CIR-IR of any objection within 7 calendar days from notification. The CIR-IR will then rule if there is a personal, professional or financial conflict of interest that cannot be resolved and, consequently, requires the replacement of the person challenged as a member of the commission.

The designated members of the Investigative Commission will sign the "Document of confidentiality and absence of conflict of interest" (Annex 2) in which they will agree to maintain confidentiality, ensure that they have no conflict of interest and guarantee fairness, ensure fairness and prompt action to protect all parties in the Procedure.

5.3.3 Notification to the Respondent and custody of records

The CIR-IR must communicate in writing the complaint under investigation and the steps to be followed to the Respondent. The CIR-IR will also notify the Respondent in writing of any new report of scientific misconduct other than the one that motivated the initial complaint. The CIR-IR will also verbally explain the investigation process to the Respondent and inform them that they can request external legal advice. The CIR-IR will also provide the Respondent with a copy of this Procedure. If there is more than one Respondent, each person will be notified separately.

The CIR-IR and the members of the Investigation Commission shall take all reasonable and practicable steps to obtain safe custody of all records and evidence necessary not previously held for the purpose of conducting the investigation of the Procedure of scientific misconduct.

5.3.4 Investigation Procedure

The CIR-IR will deliver a document (Annex 6) to each member of the Investigation Commission that includes: (i) the specific mandate of the Commission, (ii) the description of the complaint and the Preliminary Investigation (if carried out), (iii) the identification of the Respondent(s) and the Complainant (if any), (iv) the definition of the potential scientific misconduct, and (v) the description of the investigation process and its objective. The President of the CIR-IR (Ombudsperson) can also assist the Investigation Commission and answer any questions addressed to them, and will be the one who will notify the Respondent in writing of the charges to be investigated, as well as the location, time and date of any meeting which they must attend.

The Investigation Commission must:

- Make diligent efforts to ensure that the investigation is thorough, sufficiently documented, and includes examination of all relevant research records and evidence, (such as computer files, financial documentation, publications, correspondence, memoranda, notes of telephone calls, or e- emails) to make a decision on the basis of the complaint.
- Take reasonable steps to ensure an impartial and unbiased investigation as far as possible.
- Interview, whenever possible, the Respondent and the Complainant, (if known), and any other person available who can provide information on relevant aspects of the Investigation, including witnesses identified by the Respondent. Each interview will be audio recorded and, when feasible, transcribed. The person interviewed will have the opportunity to listen to the transcription or in the audio and to correct any errors. Changes to a transcript or recording will be included as an addendum to the original transcript or recording. The transcript (or, if no transcript is prepared, the audio recording) will be incorporated into the minutes of the Procedure The interviewees will have to sign the confidentiality and absence of conflict of interest with the ongoing investigation document (Annex 2)

- Diligently pursue all significant evidence and leads deemed relevant to the investigation, including any evidence of additional instances of potential research misconduct, and continue the investigation to completion.

Both the Investigation Commission and the Respondent have the right to request the advice of experts on the case. In addition, the Formal Investigation Commission will request, if it deems it necessary, advice from the CIR-CAT through the Secretariat/Presidency of the CIR-IR.

The Investigation Commission will make every effort to reach a unanimous decision on the existence of scientific misconduct. When a unanimous decision cannot be reached, the Investigation Commission will decide by a two-thirds majority whether the scientific flaw that has caused the demand has been sufficiently established.

5.3.5 Investigation Report

The Investigation Commission will prepare a draft written report using a predefined template (Annex 3) that will contain:

- Name, academic education and affiliations of the members of the Investigation Commission.
- Name of the Respondent.
- Reviewed complaints.
- Summary of the research process followed.
- List of the reviewed documents.
- Summary of the interviews conducted.
- Description of the evidence reviewed.
- Conclusions.
- Recommendations.
- Attachments.

This draft report will be shared with the Respondent, who will be able to comment on it within 15 days of delivery of the draft Investigation report. The final Investigation report will take into account these comments, if any. In addition, the Investigation Commission will share with the Complainant the parts of the draft report that contain their views in the process of the investigation. The Complainant will also have 15 calendar days to send comments to the Commission. The report must be modified, if necessary, based on the

comments of the Complainant. This draft with comments from both parties will be reviewed by the CIR-IR.

When submitting the draft report, or parts of it, to the Respondent and the Complainant, the Investigation Commission will inform of the confidentiality under which the draft report is made available to the recipient and may establish reasonable conditions to ensure such confidentiality (for example, requiring the recipient to sign a confidentiality statement or to review the report in the Presidency headquarters).

The Investigation Commission will present the final report to the CIR-IR within 60 calendar days following its first meeting. In the event of unavoidable delays in the collection of witnesses and/or other evidence, or if the advice of the CIR-CAT has been requested, the duration of the Commission's work may be extended upon request to the CIR-IR.

5.3.6 Decision and notification

Once the final report has been received by the Investigation Commission, the CIR-IR will send it to the Compliance Commission, the Respondent and the Complainant.

The recommendations of the Investigation Commission may be:

a. **Restoration of reputation** if no evidence of scientific misconduct is found. In this case, the Investigation Commission will have to determine whether the Complainant raised the complaint in good faith or whether it was a malicious complaint. In case of malicious complaints, the Investigation Commission will recommend to IR Sant Pau to proceed as described in clause 5.6 "Malicious complaints". In addition, measures must be taken, if necessary, to restore the reputation of the Respondent (clause 5.4).

b. Sanctions or consequences if the evidence of misconduct is unequivocally proved.

It should be noted that the Investigation Commission and the CIR-IR act as expert advisory bodies and have no authority to establish administrative or disciplinary measures.

For this reason, the **Decision Committee** (made up of the director of Legal Advice and RRLL and two lawyers from IR Sant Pau) will be responsible for drafting the corresponding resolution that puts an end to the research, raising it with the Compliance Commission and, with its approval, executing the corresponding actions and

precautionary measures. The Decision Committee will also prepare and submit the relevant written reports and complaints to the competent authorities.

Disciplinary measures related to work must be respectful of the applicable regulations.

If the facts have legal and criminal significance, the necessary measures will be adopted so that the facts that occurred and all the evidence collected are brought to the attention of the competent judicial authorities in the shortest possible time.

The Investigation Commission may recommend to the Ombudsperson to agree on the adoption of the precautionary measures deemed appropriate or necessary, with the aim of ensuring the successful completion of the internal investigation and avoiding any harm to the IR Sant Pau and its members or affected third parties.

Motivation for the adoption of precautionary measures.

A. The adoption of these measures must be agreed in writing and must detail:

- The reasons and needs that lead to the adoption of precautionary measures.
- The duration of the precautionary measures.
- The identification of the specific measures that are taken.
- A judgment of proportionality between the measures taken and the aims pursued.

B. The adoption of precautionary measures will be exceptional, and the least expensive measure will always be chosen among the most effective, necessary and useful to achieve the goals pursued.

C. Communication of the adoption of precautionary measures.

The adoption of such measures must be brought to the attention of the IR Sant Pau Compliance Commission, immediately and in writing, and communicated to the person or persons directly or indirectly affected by them, as long as this does not endanger the investigation or aggravate the facts subject of the complaint.

5.3.7 Right of Appeal

The Respondent has the right to appeal on grounds of, including but not limited to:

- Failure to follow proper procedures in the investigation.
- New evidence.

- Making arbitrary, capricious or erroneous decisions.
- Inadequate disciplinary measures.

An appeal must be submitted within 15 calendar days of receiving the final determination.

The Compliance Commission is responsible for the institution receiving and initiating the appeal process. To lodge an appeal, the Respondent must prepare a written appeal addressed to the President of the Compliance Commission, clearly indicating the basis and nature of the appeal, and including all the relevant evidence. During the appeal process, the Compliance Commission may interview any party involved in the initial investigation, and will take appropriate steps to consider any new evidence.

The Compliance Commission will issue a resolution to the Respondent and the Complainant within 60 calendar days. If the appeal is upheld, the IR Sant Pau will make all reasonable efforts to ensure that the reputation of the accused is restored.

5.3.8 Communication to the Complainant

Using the same channel through which the complaint was received, the CIR-IR will notify the Complainant of the result of the investigation and the measures taken in this regard, if any.

Finally, if after the investigation the existence of a violation of the law or the Code of Ethics is proven, the IR Sant Pau will carry out a review and an update of the existing protocols, measures and controls, in order to implement the improvements to the model that are necessary and to prevent new breaches from re-occurring.

5.3.9 Custody of records

Regardless of the decision made by the Investigation Commission in relation to the completion of the investigation, this resolution will be documented in the relevant file.

Complaints will only be kept during the period that is necessary for the purposes of fulfilling the requirements imposed by this Procedure, and in accordance with the provisions of the current applicable legislation, which at the date of approval of this document is 3 months in accordance with the current Data Protection Act.

For clinical trials, the applicable regulation on the custody of records will be followed.

5.4 Restoration of reputation and protection of participants against retaliation

When appropriate, the CIR-IR will take all reasonable steps to restore the reputation of the Respondent if they are not found guilty of scientific misconduct. The Respondent will be consulted about any appropriate publicity to be given to the outcome of the investigation or other actions that can be taken on their behalf to restore their reputation.

The Human Resources Department will ensure that all references to the matter are removed from the personal file of the Respondent. All persons who have been interviewed or otherwise informed of the allegation will be notified in writing that the charges have been found to be unfounded.

5.5 Right to compensation.

In any case, the adoption by IR Sant Pau of any type of retaliation or attempted retaliation against the Complainant as a result of the communication lodged is prohibited (as long as it was lodged in good faith), as well as prejudice, damage or harm, and in particular, in the form of:

(a) suspension, dismissal, discharge or equivalent measures;
(b) degradation or denial of professional promotion;
(c) change of workplace, workplace location, salary reduction or change of schedule;
(d) prohibition to receive training;
(e) evaluation or negative references regarding work results;
(f) imposition of any disciplinary measure, reprimand or other penalty, including monetary penalties;
(g) coercion, intimidation, harassment or ostracism;
(h) discrimination, or unfavourable or unfair treatment;
(i) non-conversion of a temporary employment contract into an indefinite one, in case the worker had legitimate expectations that he would be offered indefinite employment;
(j) non-renewal or early termination of a temporary employment contract;
(k) damage, including to your reputation, especially on social media, or financial losses, including loss of business and income;
(l) inclusion in blacklists on the basis of a sectoral agreement, informal or formal, which may imply that in the future the person will not be able to find work in this sector;

(m) early termination or cancellation of contracts for goods or services;
(n) cancellation of a license or permit;
(o) medical or psychiatric references.

For the purposes of the provisions of the previous paragraph, in the event that there is retaliation or attempted retaliation from the person under investigation, the victims, those affected or third parties directly or indirectly involved in the events (due to having knowledge of the case), IR Sant Pau will adopt the necessary and corresponding measures in each case for the protection of the Complainant.

This prohibition on the adoption of reprisals extends to those who have cooperated with the Complainant to promote communication (facilitators) and/or third parties who are related to the Complainant and may suffer reprisals.

5.6 Malicious complaints

1. A complaint will be considered a complaint in good faith if: (a) it informs of a series of facts or indications of irregular, illegal or criminal behaviour, acting as the Complainant in the rational belief that the related facts or indications are true; and (b) it is carried out without revenge, without moral harassing, and without causing occupational or professional harm or dishonour to the Respondent or a third party.

2. On the other hand, it will be understood that the Complainant does not act in good faith when they are aware of the falseness of the facts, or they act with manifest contempt for the truth, or with the intention of revenge, to morally harass the Respondent, or to cause them working or professional harm or dishonour.

In this sense, the Complainant has the obligation to tell the truth about the facts reported. In the event that a complaint is proven to be false or was made maliciously, IR Sant Pau will consider it as a serious infraction, which may be sanctioned in accordance with what is established in the internal system of infractions and sanctions, and in accordance with the labour and/or criminal regulations, as a crime of false accusation or complaint typified in the Criminal Code.

6. REFERENCES

IR Sant Pau Code of Good Practice in Research v4 (June 6, 2022)

CERCA Code of Conduct

Charter of the Committee for Research Integrity IR Sant Pau

IMIM Procedure in Cases of Suspected Scientific Misconduct – v2 (April 25, 2018)

Management of Suspected Scientific Misconduct ISGlobal v1.0 (17/09/2020)

National Institutes of Health Intramural Research Program Policies & Procedures for Research Misconduct Proceedings (November 19, 2018)

Pla de recerca i Innovació Responsable IIB Sant Pau v1 (June 6, 2022)

The European Code of Conduct for Research Integrity (2023). https://allea.org/portfolio-item/european-code-of-conduct-2023/

Best Practices for Ensuring Scientific Integrity and Preventing Misconduct, OECD Global Science Forum: https://oeawi.at/wp-content/uploads/2018/09/OECD_bestPractices40188303.pdf

7. ANNEXES

Annex 1: Catalogue of behaviours that should be considered scientific misconduct

Scientific misconduct

Scientific misconduct occurs when, in a scientific process or research, false claims are made knowingly or as a result of gross negligence, when other people's intellectual property is infringed, or if their research work is significantly impaired in some other way. Scientific misconduct does not include honest mistakes or honest differences of opinion.

A complete list of acts that can be considered scientific misconduct does not exist. Deviations from the rules of good practice described in the IR Sant Pau Code of Good Practice in Research can serve as a reference and must be considered scientific misconduct.

The following list, which is not exhaustive, includes examples of practices that may constitute misconduct[10,11]:

- **Core of "Research Misconduct"**

  Data fabrication

  Data falsification

  Plagiarism

Fabrication, Falsification and Plagiarism typically include practices such as:

- the selective exclusion of data in the analysis phase;
- the misinterpretation of data to obtain the desired results (including the inappropriate use of statistical methods);

Based on document definitions:
[10] Best Practices for Ensuring Scientific Integrity and Preventing Misconduct, OECD Global Science Forum
[11] The European Code of Conduct for Research Integrity (2023)

- the manipulation or distortion of electronic or physical data records, including images;
- the production of false data or results, either voluntarily or under pressure from a sponsor.

- **Research misconduct**
  - Use of inappropriate (harmful or dangerous) research methods.
  - Poor research design.
  - Experimental, analytical or computational negligence.
  - Breach of research protocols in humans (any unapproved change or deviation in the design or procedures of a research project that is under the control of the researcher and that has not been reviewed and approved by the CEIm —Ethics Committee).
  - Use of laboratory animals not approved by the CEEA (Ethical Committee for Animal Experimentation).
  - Not looking after animal welfare.
  - Making irresponsible use of AI tools.[12]

- **Misconduct related to data**
  - Not retaining primary data or research materials within legally required terms.
  - Bad management of data or research material or storage.
  - Concealment of data from the scientific community.

- **Misconduct related to publications**
  - Promoting biases in the dissemination of research results.
  - Encouraging or admitting undeserved authorship.
  - Denial of authorship to contributors who deserve it.
  - Proliferation of publications through unnecessary chopping of publications.
  - Breach of duties of confidentiality (professional secrecy) or privacy.

[12] With regard to the use of artificial intelligence (AI) tools, it must be done with responsibility and being aware of its limitations. All AI-generated content must be carefully reviewed and traced back to its original source to avoid potential plagiarism, and ensure that its contents are appropriate and comply with intellectual property principles. It is necessary to be transparent in its use and to cite appropriately which AI tools have been used and in what way.

- Deliberately incorrect evaluation of projects, programs or original texts.
- Intentional misquotation or omission of previous publications from other groups.
- Purchase of articles (research paper mills).
- Purchase of quotations.
- Attribution of authorship of texts generated by AI.

- **Personal misconduct**
  - Inappropriate personal behaviour and/or harassment.
  - Inadequate leadership, mentoring or counselling of trainees.
  - Insensitivity to social or cultural norms.

- **Financial misconduct and others**
  - Abuse of peer review.
  - Prevarication of credentials or publications.
  - Misuse of research funds for unauthorized purchases or for personal gain
  - Lodging unfounded or malicious misconduct complaints.

Annex 2: Document of Confidentiality and Non-existence of Conflict of interest

IR Sant Pau (Fundació Institut de Recerca de l´Hospital de la Santa Creu i Sant Pau) is carrying out an Investigation Procedure on scientific misconduct in relation to which you have, or may have, some knowledge.

IR Sant Pau must guarantee the confidentiality of the Investigation Procedures for scientific misconduct, with the aim of not altering or disrupting the investigation of these scientific misconducts and safeguarding the scientific reputation of all people involved.

In light of the foregoing,

Mr./Ms. _____, with tax ID _____, acting in his/her own name and behalf,

By signing this document, **I DECLARE**, under my responsibility and in order to ensure the principles of legality, satisfaction of the public interest, impartiality, independence, equity and ethics, that there is NO apparent, potential or real conflict of interest, now or in the near future, in my intervention and participation in the Investigation Procedure of scientific misconduct. Likewise, if during the course of my intervention, a possible conflict of interest situation arises in which I am involved, I will immediately notify the Committee for Research Integrity of IR Sant Pau.

AND I COMMIT TO:

Maintain the most strict and absolute confidentiality of all the information and/or documentation of this Scientific Misconduct Investigation Procedure, especially I commit to not reveal or divulge, unnecessarily and/or intentionally, the identity of the Defendants, Complainants, and/or Witnesses except for those who need to know it, as long as the applicable legislation allows it, for this Scientific Misconduct Investigation Procedure, in order for it to be carried out in an exhaustive, competent, fair and objective manner, and/or a Court authorizes it.

At the same time, I agree not to disclose any records or evidence and/or information from which individuals in the investigation can be identified, except to those who need

to know it in order to carry out this Scientific Misconduct Investigation Procedure, as long as the applicable legislation allows it, and/or if the law requires it.

Additionally, I acknowledge that I do not have the right to make copies of any information or documentation that has been provided to me or may be provided to me, unless it is the Respondent. Equally, I undertake to return all the materials I may receive to the President of the Committee for Research Integrity of IR Sant Pau upon concluding my participation in this Procedure.

Likewise, I expressly acknowledge that failure to comply with these obligations and commitments may cause detriment and/or harm to the Procedure and/or to the participants.

As a witness to the assumed responsibility, I sign this document.

Signature

First and last name(s)

As of [date] _____

Annex 3: Template for Preliminary Commission and Investigation Commission Reports

The investigation report must include the following information:

I. Name, academic education and affiliations of the members of the Investigation Commission.
II. Name of the Respondent.
III. Reviewed complaints.
IV. Summary of the research process followed.
V. List of the reviewed documents.
VI. Summary of the interviews conducted.
VII. Description of the evidence reviewed.
VIII. Final conclusions:

For each of the research misconducts identified during the investigation process, it is necessary to include a conclusion on whether or not a research misconduct occurred and, if so:

a) report whether the identified lack of ethics consisted of falsification, fabrication, or plagiarism, and whether it was intentional or due to reckless endangerment;
b) summarize the facts and analysis that support the conclusion, and take into account any reasonable explanation of the Respondent, including any effort by them to demonstrate, through evidence, that they did not commit an ethical breach in the research;
c) identify the person or persons responsible for the lack of ethics in research;
d) identify if any publication needs correction or retraction;
e) identify if there are grant applications or granted projects potentially affected by the lack of ethics in research.

IX. Recommendations
X. Attachments (documents, emails, and evidence to support the conclusion.)

Annex 4: Sanctions and consequences in cases of scientific misconduct

The possible sanctions or consequences in the event that scientific misconduct has been demonstrated are detailed below as a guideline. Because no two cases are likely to be the same, and because the seriousness of any established scientific misconduct must be considered, there is no uniform guide to the penalties to be applied, but rather the penalties must be tailored to the individual circumstances of each case. The potential sanctions or consequences are listed below:

– **Academic consequences** (for example, notification of scientific misconduct to the University or the body that awarded a degree for consideration of withdrawal of the academic degree).

– **Labour consequences** according to current Spanish labour regulations, including disciplinary dismissal from work.

– **Civil consequences**, such as the order not to enter the premises, claims for the restitution of stolen scientific material, claims related to subsidies, and any other claims for damages.

– **Criminal consequences**, when scientific misconduct constitutes a crime according to the current Spanish Criminal Code

– **Revocation of scientific publications**, meaning that the scientific articles affected by the scientific misconduct must be withdrawn if they have not yet been published, and must be corrected or withdrawn if they have already been published.

In the case of scientific collaborators, assignments or jointly appointed positions, the possible consequences could be the termination of the collaboration relationship with IR Sant Pau, without prejudice to the right of IR Sant Pau to claim an indemnity for the damages caused, as well as the additional consequences as the case may be.