IMIM PROCEDURE IN CASES OF SUSPECTED SCIENTIFIC MISCONDUCT

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1 Introduction

1.1 Background

The IMIM (Hospital del Mar Medical Research Institute) holds that scientific integrity following the observance of the principles of good scientific practice is essential in scientific research. This is necessary also to ensure public trust as well as trust among scientists themselves. The IMIM commits to follow and actively disseminate among its employees and collaborators the Code of Good Scientific Practice from the PRBB (Barcelona Biomedical Research Park), a set of recommendations and commitments governing scientific activities that constitute a framework for self-regulation[1]. To this end, the IMIM has established its own Code of Good Scientific Practices and its Integrity and Good Scientific Practice Committee (IGSPC). One of the main functions of this Committee is to investigate cases of suspected scientific misconduct, elaborate a report on those cases and submit the report to the IMIM director. The IMIM director has the final decision on the resolution of a case investigated by the IGSPC.

This Code also considers the possibility that the IMIM Director could be considered to have a conflict of interest in relation with a case investigated. In such cases, the IMIM Director must refrain from participating in the process, and the IMIM Board will be responsible to pursue the due process according to the content of this Code.

This document has been adopted by the Executive Board of the IMIM on January 2017. This document is based on the "**CRG Procedure in Cases of Suspected Scientific Misconduct**" and the "**NIH Intramural Research Policies. Procedures for Research Misconduct Proceedings**" (https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/policy-nih_irp_research_misconduct_proceedings.pdf).

1.2 Purpose

The IMIM procedure in cases of suspected scientific misconduct aims at ensuring confidentiality, fairness, and prompt action to protect all parties in the proceedings:

i) **confidentiality** to protect innocent people who are incorrectly or unjustly accused by a Complainant who bring allegations;

ii) **fairness** to guarantee that all those who become involved in an alleged scientific misconduct case will have the proper opportunity to participate in addressing the relevant issues raised while protecting innocent participants from adverse consequences;

iii) **prompt response** to an allegation in order to minimize any harm to the public that could result from a proven scientific misconduct or clear the names of those incorrectly accused without going through a lengthy process.

The process of assessing allegations must be balanced by equal concern for protecting the integrity of the proceedings, the Complainant, as well as the careers and reputations of researchers..

[1] https://prbbgoodpractice.wordpress.com/

1.3 Scope and applicability

This Policy applies to all IMIM, Mar Institute of Medical Research Foundation and Mar Health Park employee, trainee or scientific collaborator as part of his/her official duties or training activities regardless of location. This Policy enters into force as of May, 2nd 2018.

1.4 Definitions

Allegation means a disclosure of possible scientific misconduct of any individual bound by this regulation. The disclosure shall be a written and signed statement referring to specific evidence. Anonymous allegations or those without mention to specific evidence will not be considered.

- **Good Faith Allegation** means a disclosure of possible scientific misconduct of a person bound by this regulation by an individual having a belief in the truth of the allegation that a reasonable person in the individual's position could have, based on the information known to the individual at the time.
- **Malicious Allegation or Bad Faith Allegation** means a disclosure of possible scientific misconduct to an institutional employee or collaborator that is not based on real facts with the purpose of damaging the reputation of an individual or group.

Assessment is the review of an allegation of scientific misconduct to determine whether an Inquiry (see below) is warranted.

Complainant is a person who makes an allegation of scientific misconduct. In some proceedings this person is also called **whistle-blower**. A complainant will be awarded special protection as described herein.

Respondent is the person against whom an allegation of scientific misconduct is directed or who is the subject of scientific misconduct proceeding.

Scientific misconduct includes fabrication, falsification or plagiarism in proposing, performing or reviewing research or research results[2]. It also includes the Respondent's failure to provide research records accurately documenting the questioned research as a result of destruction, lack of proper retention procedures, etc.. Scientific misconduct does not apply to honest error or honest differences of opinion (Annex 1).

- **Fabrication** is intentional misrepresentation of research results by biased data analysis, invention of data or reporting of findings or procedures that were not conducted.
- **Falsification** is the modification or incomplete or inaccurate reporting of findings in order to deceive.
- **Plagiarism** is the appropriation and use of another person's ideas, methods, processes, results, or text, without giving appropriate credit to the source. The concept includes all those obtained through confidential review of others' research proposals and manuscripts.

Intellectual Property (IP) Violations, are instances where a third party, explicitly or implicitly, commits an action or omission contrary to the IP Rights. IP Rights shall include, but not be limited to, discoveries, know-

[2]Definitions as established in the PRBB Code of Good Scientific Practice (https://prbbgoodpractice.wordpress.com/).

how, inventions, copyrights, trademark, trademark applications, patent applications, patents, together with any divisions, continuations, continuations-in-part, reissues or extensions thereof and any future national or foreign patents or patent applications which may issue therefrom.

Scientific Misconduct Inquiry is the process of gathering information and initial fact-finding to determine whether an allegation of scientific misconduct warrants an Investigation.

Scientific Misconduct Investigation means the formal development of an investigation file where all the evidence collected on the case is gathered and the examination of such file leading to a decision on whether or not scientific misconduct took place. An Investigation may include a recommendation for other appropriate actions, including administrative actions.

Evidence means any record, document, tangible item or object, or witness testimony obtained during a scientific misconduct proceeding to prove or disprove the existence of an alleged fact.

Investigation file is the record of data or results, both physical and electronic, that embody the facts resulting from a scientific misconduct Inquiry or Investigation, including but not limited to, e-mails, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles and any additional documents and materials obtained during the research misconduct proceeding.

Retaliation means an adverse action taken against a Complainant, Witness, or committee member as a consequence of their participation in relation with a case of allegation of scientific misconduct made in good faith.

2 Procedure in case of suspected scientific misconduct

Any person bound by this procedure (Point 1.3) who becomes aware of any significant indication that scientific misconduct, within the meaning of the catalogue of misconduct (Annex 1), has occurred at IMIM has the obligation to notify such indications by presenting an Allegation to the IGSPC or delegate such presentation by notifying his/her immediate superior who will present the Allegation.

Allegations of suspected misconduct can also arise from persons outside the IMIM (e.g. scientific collaborators, journal editors, etc.).

Anonymous allegations will not be considered unless they are supported by specific and consistent evidences.

The procedure once an Allegation of suspected scientific misconduct has been received includes a three-stage process, as described below (Figure 1):

• Step 1: Allegation assessment and initial inquiry

• Step 2: Investigation

At this, and all subsequent stages of the proceedings, all parties involved will agree in writing to observe absolute confidentiality on any aspect related with the case (Annex 2). Persons who may be considered to be potentially biased or have a conflict of interest because of but not limited to close relationship, friendship or

enmity, competitive situation, financial or organizational dependency, etc. will not participate in any stage of the proceedings.

2.1 Step 1: Allegation assessment

The aim of this assessment is to determine whether an Inquiry is warranted.

The Allegation should be presented in a document with sufficient detail to enable the IGSPC members to assess it properly. This may include details such as relevant parties, witnesses, dates, locations, publications and the specific matter of the Allegation in question. The IGSPC will guarantee the confidentiality to protect the Complainant.

In case the Complainant has doubts about whether an incident falls within the definition of scientific misconduct, he/she may contact a member of the IMIM's IGSPC to discuss the particular case.

Once the IGSPC receives an Allegation of scientific misconduct the IGSPC will assess it to determine whether the allegation is:

i) credible and specific so that potential evidence of scientific misconduct may be identified;

ii) within the scope and applicability of this policy (person, place);

iii) within the definition of scientific misconduct (action).

If all these criteria are met an Inquiry will be warranted.

If the IGSPC considers that no Inquiry should be initiated, the IGSPC will notify to the Complainant in writing of this decision and the reasoning supporting it. The decision of the IGSPC is final. However, the IGSPC could refer the Complainant to other IMIM's offices or officials where the problem may be solved. The IGSPC could also decide to notify this Allegation to other institutions when the persons and actions so require.

The Allegation assessment period should be brief, preferably concluded within two weeks of the reception of the Allegation.

In all cases (proceeding to Step 2 or not requiring an Inquiry), all records related to the allegation will be stored for at least 5 years.

2.2 Step 2: Inquiry in case of suspected scientific misconduct

2.2.1 Purpose and Initiation of the Inquiry

The purpose of the Inquiry is to gather all the evidence on the alleged case and conduct an initial review to determine whether an Investigation shall be conducted or not. It is not for the purpose of reaching a final conclusion as to whether scientific misconduct has, or has not, occurred.

2.2.2 Composition of the Inquiry Panel

The IGSPC will assign two of its members, or one of its members and an investigator of the IMIM with

expertise in the topic of research of the Respondent, to constitute the "Inquiry Panel" and carry out the Inquiry. This process must begin within 15 calendar days after the determination that an Inquiry is warranted.

The IGSPC will notify the Respondent the names of the proposed Inquiry Panel. Within a period of 7 calendar days, the Respondent may object to any member(s) providing an appropriate reasoning that will be considered by the IGSPC. The IGSPC will then determine whether a personal, professional, or financial conflict of interest exists that cannot be resolved and, as a result, necessitates replacement of the challenged Inquiry Panel member.

The Inquiry Panel members will sign the **Scientific misconduct proceeding participant statement** and the **Confidentiality statement** documents (Annex 5 and 2, respectively) in which they will agree to maintain the confidentiality, guarantee that they do not have a conflict of interest and ensure fairness, and prompt action to protect all parties in the proceeding

2.2.3 Notice to the Respondent

The IGSPC must notify the Respondent in writing of the Allegation made and the steps that will be followed. The IGSPC will also seek to explain verbally the Inquiry process to the Respondent and to inform the Respondent that he/she may acquire his/her own counsel. The IGSPC will also provide the Respondent a copy of this policy. If there is more than one Respondent, each should be notified separately. The IGSPC must also give the Respondent written notice of any new allegations of scientific misconduct not in the initial notice of the Allegation.

2.2.4 Sequestration of records

The IGSPC and the members of the Inquiry panel, will take all reasonable and practical steps to obtain custody of and sequester in a secure manner all records and evidence needed to conduct the Inquiry, at the earliest convenience once the Respondent is notified.

When the records or evidence encompass scientific records from instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. When appropriate, the Respondent may be provided copies or supervised access to the materials to facilitate continuation of his/her regular work.

2.2.5 Inquiry procedure

The IGSPC will determine: the specific mandate to the Inquiry panel; description of the allegation; identification of the Respondent(s) and the Complainant (if exists); the potential scientific misconduct; the Inquiry process and its aim.

The Inquiry Panel usually interviews the Respondent, the Complainant, if known, and key witnesses as well as examine relevant records and materials. When feasible, a written summary of the interview will be recorded. In such instances, each interviewee will be provided with the summary of his/her transcript and given the opportunity to request corrections. All the interviewees should sign a confidentiality statement (Annex 2)

The Inquiry Panel will evaluate the evidence, including testimony obtained during the Inquiry. The objective of the Inquiry is not deciding whether scientific misconduct definitely occurred or not, or conducting exhaustive interviews and analyses. The Inquiry Panel will produce a report that will help taking the decision on the need for a further Investigation is warranted based on the criteria in this Policy.

The Inquiry Panel will prepare a written draft report using a predefined template (Annex 3) and will include the following information:

- Names, academic titles and institutional affiliations of Inquiry Panel members
- Name of Respondent
- Specific allegations reviewed
- The specific mandate to the Inquiry Panel
- Description of procedures and evidence examined during the Inquiry
- Summaries of the concerns and the evidence
- Final determinations
- Recommendations
- Attachments

This draft report will be shared with the Respondent. The Respondent will be able to make comments to this report within 15 days of the delivery of the Inquiry draft report. The final report will consider these comments, if any, and will be reviewed by the IGSPC.

The final report will be sent to the IGSPC and through the IGSPC to the Director of IMIM and to the Respondent within 15 days of the delivery of the Inquiry final report.

The disclosure of the name of a Complainant may become necessary if the Respondent cannot otherwise defend herself or himself effectively, in particular when the credibility of the Complainant has an important bearing upon a finding of misconduct. The decision of such disclosure resides with the IGSPC who will inform the Complainant prior to such disclosure.

All the information related to the case will be stored in a folder provided by IMIM. The access to this folder will be secure and traceable. The communications that include confidential information (e.g. draft or final report, transcriptions) will use secure proceedings provided by IMIM (e.g. encrypted https links) (Annex 4).

The Inquiry should normally be completed within the period of 60 days from its initiation (defined as the date of the assignment to the Inquiry Panel).

2.2.6 Inquiry resolution

The procedure could be terminated if the Inquiry Panel concludes that there is no solid ground to continue the Inquiry. This decision is final. In this case, the IGSPC could initiate measures to restore the reputation of the Respondent (Section 2.3.6). Moreover, the Inquiry Panel will determine if the Complainant informed in good faith, in which case the Complainant will be informed writing of the outcome of the Inquiry. In case the Inquiry indicates that the Allegation has not been made in good faith, the IGSPC will proceed as explained in Section 2.3.7 on "Malicious allegations".

Should the Inquiry confirm adequate grounds for suspicion in the matter, the IGSPC could decide, in agreement with the Director, to initiate an Investigation procedure. This initiation should take place within 15 days of the delivery of the Inquiry Panel final report.

If sufficient admission of scientific misconduct is made by the Respondent, the decision of the occurrence of scientific misconduct can be made by the Inquiry Panel in its final report, provided all relevant issues are resolved. In such case, IGSPC will inform the Director to define appropriate disciplinary and/or administrative

actions (Section 2.3.5). The IGSPC will also inform the responsible persons of those institutions associated to the Respondent or associated to the case of misconduct (e.g. co-authors in publications) provided the matter is not assigned to a formal Investigation. If such is the case, this informative actions will be postponed until the final conclusions of the Investigation.

If the Inquiry Panel cannot reach agreement on a decision within the framework of the Inquiry, the IGSPC will assign the matter to a formal Investigation.

If the Respondent or the Complainant does not agree with the decision of the Inquiry Panel, the IGSPC will assign the matter to a formal Investigation.

2.2.7 Return of sequestered records and materials

If the IGSPC decides that an Investigation is not warranted, all sequestered materials should be returned to the Respondent or other parties, as appropriate, as soon as practicable following closure of the case.

2.3 Step 3: Investigation in case of suspected scientific misconduct

2.3.1 Purpose and initiation of the Investigation

The purpose of the Investigation is to develop a factual record by exploring the Allegation in detail and examining in depth the evidence gathered during the Inquiry, leading to a decision of whether scientific misconduct was committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible scientific misconduct that would justify broadening the scope beyond the initial Allegation. This is particularly important where the alleged scientific misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the Investigation must be set forth in an Investigation Report.

The investigation could also be initiated when the allegation comes from a Journal Editor. This process must begin within thirty calendar days after the determination that an Investigation is warranted.

2.3.2 Composition of the Investigation Panel

The Investigation will be conducted by a scientific misconduct Investigation Panel appointed ad hoc by the IGSPC, and will consist of three persons, two from IMIM and one external to IMIM. One of the IMIM members should be from the same Program of the Respondent, the other should ideally be from a different Program. The members should have expertise in the topic of research of the Respondent or be expert in dealing with this type of cases and none of them having a conflict of interest with the Respondent or the case investigated. The external member should have expertise in the topic of research of the Respondent and not having a conflict of interest with the Respondent or the case investigated.

The IGSPC will notify the Respondent of the names of the proposed Investigation Panel members and provide

an opportunity for the Respondent to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Respondent must inform the IGSPC of any objections within 7 calendar days. The IGSPC will then determine whether a personal, professional, or financial conflict of interest exists that cannot be resolved and, as a result, necessitates replacement of the challenged committee member.

The members of the appointed Investigation Panel will sign the **Scientific misconduct proceeding participant statement** and the **Confidentiality statement** documents (Annex 5 and 2, respectively) in which they will agree to maintain the confidentiality, guarantee that they do not have a conflict of interest and ensure fairness, and prompt action to protect all parties in the proceeding.

2.3.3 Notice to the Respondent and sequestration of records

The IGSPC must notify the Respondent in writing of the Allegation to be investigated and the steps that will be followed. The IGSPC must also give the Respondent written notice of any new Allegations of scientific misconduct not addressed during the Inquiry or in the initial notice of the Investigation. The IGSPC will also seek to explain verbally the Inquiry process to the Respondent and to inform the Respondent that he/she may acquire his/her own counsel. The IGSPC will also provide the Respondent a copy of this policy. If there is more than one Respondent, each should be notified separately.

The IGSPC and the members of the Investigation panel will take all reasonable and practical steps to obtain custody of and sequester in a secure manner all records and evidence needed to conduct the scientific misconduct proceeding that were not previously sequestered during the Inquiry.

2.3.4 Investigation procedure

The IGSPC will provide a written document to the Investigation Panel including (Annex 6): the specific mandate to the Panel; description of the allegation and the Inquiry (if performed); identification of the Respondent(s) and the Complainant (if exists); definition of the potential scientific misconduct; description of the investigation process and its aim. The Chair could also assist the Panel and answer any question raised by the Panel.

The Investigating Panel will examine all available documentation and will conduct closed oral proceedings that are confidential. The Panel must:

- use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the Allegations;
- take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
- interview each Respondent, each Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including Witnesses identified by the Respondent or the Complainant. The interviews could be recorded, the transcription will be provided to the interviewee for correction of errors. All the interviewees should sign a confidentiality statement (Annex 2);
- review all significant pieces of information, such as raw data, laboratory books, raw images, scripts, that could contribute to clarify the issues under investigation. The Respondent should provide all the requested information required to investigate the case. The Respondent will be given a period of thirty days to respond;
- pursue diligently all significant issues and leads discovered that are determined relevant to the

Investigation, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion;
- prepare a written draft report using a predefined template (Annex 3);
- this draft report will be shared with the Respondent. The Respondent could make comments to this report within 15 days of the delivery of the Investigation draft report.
- the final Investigation report will consider these comments, if any, and will be reviewed by the IGSPC.

The final report will be sent to the IGSPC and through the IGSPC to the Director of IMIM and to the Respondent within 15 days of the delivery of the Investigation final report.

All the information related to the case will be stored in a folder provided by the IMIM, the access to this folder will be secure and traceable. The communications that include confidential information (e.g. draft or final report, transcriptions) will use secure proceedings provided by the IMIM (e.g. encrypted https links) (Annex 4).

During this process the Investigation Panel, the Complainant and the Respondent are entitled to ask for expert advice on the case.

The members of the Investigation Panel will give the Respondent written notification of the place, time, and date of any meeting at which her/his appearance is requested. The Respondent must be granted an oral hearing if she or he so desires and may call on the assistance of a person whom she or he trusts.

The disclosure of the name of a Complainant may become necessary if the Respondent cannot otherwise defend herself or himself effectively, in particular because the credibility of the Complainant has an important bearing upon a finding of misconduct. The decision of such disclosure resides with the IGSPC who will inform the Complainant prior to such disclosure.

The Investigation Panel will make its best efforts to reach a unanimous decision for the existence of scientific misconduct. When a unanimous decision cannot be taken, the Investigation Panel will decide by two-thirds majority whether scientific misconduct has been sufficiently established.

If, with due regard to Complainant protection, the Investigation Panel finds: 1) the allegations of misconduct were based on information that the person bringing the Allegations knew or should have known was without substantial basis and, 2) the person bringing the allegations acted in bad faith, and with intent to damage the Respondent, appropriate disciplinary actions may be instituted.

In case the Investigation Panel finds no evidence of scientific misconduct, actions will be taken to restore the reputation of the Respondent (see Section 2.3.6 below).

In case the Investigation Committee finds evidence of scientific misconduct, actions or consequences will be applied. In no case the Committee will make publicity of the case, contact the press, or disseminate publicly the results of the inquest, unless required legally or by other parties involved (i.e. organizations with whom the Respondent is affiliated, grants organizations, journal editors and publishers, etc.).

The IMIM nevertheless will inform all those institutions associated to the Respondent or associated to the case of misconduct (e.g. co-authors in publications, journal editors in which the results of the research were published, public or private agencies or entities that have funded the research under investigation).

2.3.5 Administrative or Disciplinary Actions and Appeals

The Investigation Panel and the IGSPC act as expert advisory bodies and do not have any authority to define and

establish administrative or disciplinary actions. Any warning or any other disciplinary or administrative measures shall be issued by the Director of the IMIM. A formal letter signed by the Director shall be sent to the Respondent, stating the detailed results of the Investigation and corresponding disciplinary actions and shall inform the Respondent of his/her right to appeal to the disciplinary actions.

The Respondent will have the right to lodge an appeal within 15 calendar days from the date of receipt of this communication. The appeal shall be addressed in writing to the Director, who shall acknowledge receipt informing the appellant of her/his right to be assisted by a person whom he or she trusts and shall state the composition of the Advisory Appeals Committee and her/his right to object to it. The Advisory Appeals Committee is an ad hoc Committee appointed by the Director of the IMIM to judge the appeal submitted by the appellant. It shall be composed by internal and external appropriately qualified persons without a conflict of interest with the appellant. The Committee will also include the chairperson or at least another member of the Investigation Panel in order to properly report about the formal Investigation.

The appeal shall be accompanied by all documentary evidence in support thereof. The Advisory Appeals Committee shall judge the appeal. The appellant may object to one or more members of the Advisory Appeals Committee providing an appropriate argument. Grounds for appeal include, but are not limited to, new unconsidered evidence not previously available, recommended sanctions not in keeping with the findings, conflict of interest not previously known among those involved in the investigation, failure to disclose to the Respondent in a timely manner evidence considered supportive of the allegation, failure to consider relevant information proffered by the person who was the subject of the allegation, prejudicial lapses in providing the Respondent due process as defined by the procedures and failure to follow them. The Advisory Appeals Committee shall give a full hearing to the appellant and/or his representative, to the representative of the research group, to the Witnesses cited and any other Witnesses whose evidence is considered relevant by the Advisory Appeals Committee, and cross-examinations shall be allowed. A record shall be kept of all statements and shall be communicated to the parties and approved by them. The Advisory Appeals Committee shall submit its recommendations to the Director in writing within 15 calendar days after the date of the last hearing. The Director shall notify the appellant of his/her decision in writing, within 30 calendar days after the date of the last hearing. If so decided by the Director, this decision and the recommendations of the Advisory Appeals Committee shall be brought to the notice of the personnel and made available to the general public.

2.3.6 Restoration of reputation

When appropriate, the IMIM will take all reasonable action to restore the reputation of the Respondent if the Respondent is not found guilty of scientific misconduct. The Respondent will be consulted concerning any appropriate publicity to be given to this outcome, or other actions that might be taken on his/her behalf to restore his/her reputation.

The Human Resources Department will ensure that all reference to the matter is expunged from the Respondent's personal file. All persons who have been interviewed or otherwise informed of the charge will be notified in writing that the charges have been found to be without foundation.

2.3.7 Malicious or bad faith allegations

Where the outcome of an Inquiry or Formal Investigation indicates that an Allegation has not been made in good faith, the IMIM will:

• pursue disciplinary action against the Complainants;

• pursue action as appropriate against external Complainants, such as informing the Institutions that employ them;

• take action to safeguard reputations as necessary.

Allegations not made in good faith may include frivolous, vexatious and malicious allegations.

2.3.8. Protection of the Complainant, Witnesses and Committee members

During the research misconduct proceeding and upon its completion, regardless of whether the IGSPC determines that research misconduct occurred, the Chair of the IGSPC and the Director of the IMIM must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any Witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The Chair of the IGSPC and the Director of the IMIM may consult with, or refers matters to, other appropriate IMIM officials (e.g. Director of Human Resources) to determine, after consulting with the Complainant, Witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them.

3. Roles and Responsibilities

3.1 Chair of the Integrity and Good Scientific Practice Committee of the IMIM

The Chair of the IGSPC is designated by the Director of the IMIM. In this specific procedure his/her responsibilities are to:

- assess allegations of research misconduct to determine whether they fall within the scope and applicability of the IGSPC;
- nominate, along with the other members of the IGSPC, the members of the Inquiry and Investigation Panels;
- notify the Respondent in writing of the allegations to be investigated and the steps that will be followed;
- take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the Inquiry or Investigation;
- oversee and support Inquiries and Investigations to guarantee the confidentiality, fairness and prompt action;
- undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of scientific misconduct in good faith and of any Witnesses and Panel members who cooperate in good faith with the scientific misconduct proceeding.

3.2 Complainant

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the research misconduct proceeding, including any Enquiry or Investigation.

During the Inquiry stage, the Complainant usually is interviewed and, when feasible, provided a copy of the transcript and an opportunity to correct errors in transcription. The Inquiry or Investigation Panel may choose to provide the Complainant the portions of the draft Report that address the Complainant's role and statements and give the Complainant an opportunity to submit comments.

The Complainant may consult with his/her own legal counsel or a non-lawyer personal adviser (who may not be a principal or Witness in the case) and, subject to the Committee prior approval, bring the counsel or personal adviser to interviews or meetings on the case. When a counsel or personal advisor is present at an Inquiry or Investigation Panel interview or meeting, his/her activities will be limited to advising the Complainant, as opposed to representing the Complainant before the Panel. The advisor or counsel should not direct questions to the Panel.

3.3 Respondent

The Respondent is responsible for maintaining confidentiality and cooperating with the research misconduct proceeding, including any Enquiry or Investigation. The Respondent should provide all the requested information required to investigate the case in a period of thirty days. The Respondent may:

- expect a good faith effort by the Chair of the IGSPC to notify the Respondent of the Allegation(s) in writing at the time of, or before beginning, an Enquiry or Investigation and receive a copy of, or reference to, this Policy.
- have an opportunity, at both the Enquiry and Investigation stages, to object to a proposed committee member based upon a personal, professional, or financial conflict of interest. The Respondent must inform the Chair of

the IGSPC of any objections within seven (7) calendar days. The Chair will then determine whether a personal, professional, or financial conflict of interest exists that cannot be resolved and, as a result, necessitates replacement of the challenged committee member.

- be interviewed during the Inquiry and Investigation, be provided a transcript of each interview and an opportunity to correct errors in transcription, and have the transcript included in the record of the Inquiry and Investigation.
- request that any Witness who has been reasonably identified by the Respondent as having information on relevant aspects of the Investigation be interviewed during the Enquiry or Investigation, have the transcript provided to the Witness for an opportunity to correct errors in transcription, and have the transcript included in the record of the Investigation.
- consult with his/her own legal counsel or a non-lawyer personal adviser (who may not be a principal or Witness in the case) and bring the counsel or personal adviser to interviews or meetings on the case. When a counsel or personal adviser is present before an Inquiry or Investigation Panel during an interview or meeting, his/her activities will be limited to advising the Respondent, as opposed to representing the Respondent before the Panel. The advisor or counsel should not direct questions to the Panel.
- have an opportunity to comment on the draft Inquiry or Investigation Report and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the Panel and addressed in the final report.
- be notified of the outcome of the Inquiry or Investigation, and receive a copy of the final Report.
- where no finding of research misconduct is made, request the Chair of the IGSPC to undertake, as appropriate, all reasonable and practical efforts to protect or restore the Respondent's reputation.

3.4 Members of the Inquiry or Investigation Panel

The Inquiry/Investigating Panel will examine all necessary and available documentation and will conduct closed oral proceedings that are confidential. The Panel must:

- use diligent efforts to ensure that the Inquiry/Investigation proceeding is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the Allegations;
- take reasonable steps to ensure an impartial and unbiased proceeding to the maximum extent practical;
- interview each Respondent, each Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the proceeding, including Witnesses identified by the Respondent;
- review all significant pieces of information, such as raw data, laboratory books, raw images, scripts, that could contribute to clarify the issues under investigation;
- pursue diligently all significant issues and leads discovered that are determined relevant to the proceeding, including any evidence of additional instances of possible research misconduct, and continue the Inquiry/Investigation to completion;

- prepare a written draft report. This draft report will be shared with the Respondent. The Respondent could make comments to this report within 15 days of the delivery of the Investigation draft report;
- prepare a written final Investigation report that will consider the Respondent's comments, if any.

3.5 IMIM Director

The Director is responsible for the implementation of administrative actions, if any. The Director will also undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any Witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

Annex 1: Catalogue of conduct to be regarded as scientific misconduct

a) Scientific misconduct

Scientific misconduct occurs when in a scientific process or research false statements are made knowingly or as a result of gross negligence, when the intellectual property of others is infringed, or if their research work is significantly impaired in some other way. It does not include honest error or honest differences of opinion. There is no exclusive or exhaustive list of acts that can be regarded as scientific misconduct. The rules of good practice listed in the present document as well as those described in the PRBB Code of Good Scientific Practice may serve as a reference in this regard. Deviations from good scientific practice are to be regarded as scientific misconduct. In particular, the following may amount to misconduct[3]:

Core "Scientific Misconduct"

- Fabrication is making up data or results and recording or reporting them
- Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record;
- Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit;

Fabrication, falsification and plagiarism includes the following cases: Incorrect data analysis such as selective exclusion of data from analysis; Misinterpreting data to obtain desired results (including inappropriate use of statistical methods); Manipulating or misrepresenting electronic data records including images; Producing false data or results even if under pressure from a sponsor; Incorrect statements in a letter of application or in an application for support (including false statements concerning the publication in which work is said to have appeared, and concerning work accepted for publication)

Other "Scientific Misconduct"

- Intellectual Properties Violations
- Research practice misconduct: Using harmful or dangerous research methods; Violation of human subject protocols; Publishing with not-appropriate consent from the sample donor or study participant; Abuse of laboratory animals; The sabotage of research work (including damaging, destroying or manipulating experimental arrangements, equipment, documents, hardware, software, chemicals or other items required by another person for carrying out an experiment)
- Data-related misconduct[4]: Not preserving primary data or research materials within the legally-required

[3] Based on definitions from the Best Practices for Ensuring Scientific Integrity and Preventing Misconduct, OECD Global Science Forum (https://www.oecd.org/sti/sci-tech/40188303.pdf)

[4] Biomedical research data should be kept only for the time necessary for the purpose for which they were collected, except in cases where there is a specific obligation, related to a project or legal requirement, which obliges to maintain this data. Biological samples will be kept only as necessary for the purposes which justified its collection, unless explicit consent of the person from which they were obtained. This limitation only applies if the samples were not anonymized. Personal

terms; Incorrect data or research material management or storage; Withholding data or research materials from the scientific community upon publication

- Publication-related misconduct: Claiming undeserved authorship; Denying authorship to contributors; Failure to correct an incorrect publication record; Violation of duties of discretion (professional secrecy); Negligent or intentional wrong assessment of projects, programs or manuscripts in order to create advantage, either personal or for the benefit of third parties; Intentional incorrect citation or omission of previously published data by other groups
- Financial and other misconduct: Peer review abuse e.g., non-disclosure of conflict of interest, unfairly holding up a rival's publication; Misrepresenting credentials or publication record; Misuse of research funds for unauthorized purchases or for personal gain; Making an unsubstantiated or malicious scientific misconduct allegation; Forging of official documents

b) Joint accountability

Joint accountability may be the result of:

- Active participation in the misconduct of others
- Leaving unreported knowledge or strong evidence of falsification committed by others
- Gross neglect of supervisory duties

Final decisions must depend upon the circumstances of each case.

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genetic data should be kept for a minimum period of five years from its production. If the researcher wants to keep them longer, they must be anonymized and for research purposes. If the data are dissociated, they lose their consideration of personal data and there is no legal obligation of preservation. In research with tissues and cells intended for human application, the data to ensure traceability must be kept for at least thirty years. IMIM has established a period of six years for the conservation of laboratory notebooks.

Annex 2: Confidentiality statement

The IMIM (Institut Hospital del Mar d'Investigacions Mèdiques) is conducting a research misconduct proceeding to examine allegations of research misconduct about which you may have, or may acquire, some knowledge. The IMIM maintains confidentiality of research misconduct proceedings, in order not to disrupt the research misconduct investigation and to protect the scientific reputation of all the individuals involved.

It is your obligation to maintain the confidentiality of this research misconduct proceeding. You agree not to disclose the identity of Respondents, Complainants or Witnesses, except to those who need to know in order for this research misconduct proceeding to be carried out in a thorough, competent, objective and fair manner, or unless otherwise allowed by law. In addition, you agree not to disclose any records or evidence from which research subjects might be identified except to those who need to know in order to carry out this research misconduct proceeding or as otherwise prescribed by applicable law.

Unless you are a Respondent in this proceeding, you should not make copies of any information provided to you and should return all materials you received to the Chair of the Good Scientific Practice Committee of the IMIM at the conclusion of your involvement in this proceeding.

Please sign below to indicate that you have received and read this statement and understand your obligation to maintain confidentiality.

Name (please print):

Signature Date

Annex 3: Elements of the Enquiry/ Investigation Report

The Investigation report should include the following information:

I. Names, academic titles and institutional affiliations of Enquiry Panel members
II. Name of Respondent
III. Specific allegations reviewed
IV. The specific charge to the Investigating Committee
V. Description of procedures, interviews and evidence examined during the Enquiry/Investigation including dates of Committee meetings and interviews
VI. Summaries of the concerns and the evidence
VII. Final determinations and statements of findings. For each separate allegation of research misconduct identified during the Investigation, includes a finding as to whether research misconduct did or did not occur, and if so:
    A. identifies whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
    B. summarizes the facts and the analysis which support the conclusion and considers the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
    C. identifies the person(s) responsible for the research misconduct;
    D. identifies whether any publications need correction or retraction.
    E. Identifies whether there are grant applications or granted projects potentially affected by the research misconduct.
VIII. Recommendations
IX. Attachments (relevant documents, e-mails, etc. to be included as evidence)

Annex 4: Communication proceedings

In order to guarantee the confidentiality of all the information registered during the Assessment, Enquiry and Investigation process:

- the IMIM will provide with a secure and traceable storage place where all the documents related to a particular process will be stored and shared (Document management platform-e.g. Alfresco-);
- the communications among the members of the Enquiry or Investigations Committees, and the communications with the Respondent, Complainant, or Witnesses that include confidential information (e.g. draft or final report, transcriptions of an interview) will use secure proceedings provided by the IMIM (e.g. encrypted https links). The use of standard e-mails that included confidential information (attached or in the body of the mail) must be avoided.
    - IMIM employees could share confidential information by using the application available in the intranet: https://intranet.imim.cat/recursos-humans/els-meus-arxius. In this application they can upload and share files, create a secure link and define a password to access to the file included in the link. They can send the link by mail and communicate the password by phone or in a different mail.
    - External personnel, a member of the Enquiry or Investigation Committee working at IMIM or the Chair of the IGSPC will provide the external personnel with a secure link and password by using the application available in the intranet: https://intranet.imim.cat/accesexterns. Through this link the external personnel can upload and share files.

Annex 5: Research misconduct proceeding participant statement

TO WHOM IT MAY CONCERN:

I, (name)....., offer to assist the Hospital del Mar Medical Research Institute (IMIM) by sharing my scientific expertise and participating in an IMIM research misconduct proceeding. In making this offer, I understand and agree with the following statements:

1. To the best of my knowledge, I do not have unresolved personal, professional, or financial conflicts of interest with those involved with the research misconduct proceeding, and I have appropriate scientific or good scientific practice expertise to participate in it.

2. For purposes of this assignment, I agree to be bound by the provisions of the IMIM Policies & Procedures for Research Misconduct Proceedings.

3. I will maintain the confidentiality of the research misconduct proceeding. I will not disclose the identity of Respondents, Complainants, or Witnesses except to those who need to know in order for the research misconduct proceeding to be carried out in a thorough, competent, objective and fair manner, or unless otherwise allowed by law. In addition, I will not disclose any records or evidence from which research subjects might be identified except to those who need to know in order to carry out the research misconduct proceeding or as otherwise prescribed by law.

4. I will be fair in my actions and determinations to guarantee all of those who become involved in research misconduct cases to have the opportunity to participate appropriately in addressing the relevant issues and seeks to protect innocent participants from adverse consequences.

5. I will not make copies of any information provided to me and will return all materials I received at the conclusion of my involvement in this proceeding.

I understand that my assignment becomes effective upon the date of my signature below and ends upon the completion of my services with regard to the research misconduct proceeding. I also understand that my assignment may be terminated at any time by the Chair of the Good Scientific Practice Committee of IMIM, and that a request by me to terminate my assignment may be considered by the Chair of this Committee in his or her discretion.

Name (please print):

Signature Date

Annex 6: Description of the charge to the Investigation Panel

Research Misconduct

Investigation Panel

Barcelona, xxxxxx 20xx

Dear member of the Investigation Panel,

First, I would like to appreciate your participation in this Panel. This Investigation is the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct, which may include a recommendation for other appropriate actions.

The Investigation Panel must evaluate all the evidence and testimonies to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent and who was responsible.

To determine that the Respondent committed research misconduct the Panel must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in the IMIM Policy, occurred; (2) the research misconduct is a significant departure from accepted PRBB good scientific practices; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly. The Panel's decision need not be unanimous.

The Panel must prepare, or direct the preparation of, a written Investigation Report that meets the requirements of the IMIM proceedings. The complete investigation should be completed within 120 days of its initiation (defined as the date of the first meeting of the Investigation Panel). As a member of the Panel you will use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations; and you will take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical.

The Integrity and Good Scientific Practice Committee (IGSPC) of the IMIM expects that confidentiality will be maintained. Outside of the official proceedings of the Investigation Panel members are directed not to discuss the proceedings with the Respondent, Complainant, Witnesses, or anyone not otherwise authorized to discuss the Investigation.

The Chair of the IGSPC will assist the Committee with organizing plans for the Investigation; and answer any questions raised by the Committee during the process.

In this document you will find a description of the charge of this Panel and of the Investigation process:

• description of the allegations and related issues identified during the Enquiry:

• identity of the Respondent(s):

• identity of the Complainant (if exists):

• definition of the potential research misconduct:

• description of the Investigation process:

Name (please print):
Chair of the Research Integrity and Good Scientific Practice Committee of the IMIM

Signature Date