Title: Procedure for the management of Suspected Scientific Misconduct

Author:	Approved by:	Version:	Approval date:
Scientific Coordinator	Core Scientific Committee	1.0	17/09/2020

1. BACKGROUND

ISGlobal has adopted the PRBB Code of Good Scientific Practice[1] with Addendums approved on the 21st July 2016 (see *Adoption of PRBB Code of Good Scientific Practice and addendums_vF*). The Code represents a set of recommendations and commitments governing scientific activities at ISGlobal, and it is monitored by the PRBB Group on Good Scientific Practices, which provides a multi-institutional environment. The Code, therefore, represents a general framework, that must be translated into a detailed procedure establishing clear and transparent procedures to manage cases of scientific misconduct that may arise. In addition, ISGlobal is bound to the CERCA Code of Conduct signed on the 12th December 2018.

The Core Scientific Committee (CSC) was assigned as the committee in charge of Research Integrity to promote awareness and internal implementation of the Code of Good Scientific Practice within ISGlobal and responsible to respond to enquiries or arbitrate conflicts that may arise. The CSC and the Direction Committee approved on the 17th September and 11th November 2020 respectively, the terms of reference of the ISGlobal Good Scientific Practice Committee (GSPC) as the delegated CSC body to promote research integrity and handle potential cases of scientific misconduct (See *ToR_ISGlobal_Good_Scientific_Practice_Committee*).

This SOP has been mostly inspired by and adapted from the CRG Procedure in Cases of Suspected Scientific Misconduct adopted by the Centre for Genomic Regulation (CRG), the IMIM procedure in cases of suspected scientific misconduct adopted by the Institut Hospital del Mar d'Investigacions Biomèdiques and the DCU Policy for Responding to Allegations of Research Misconduct from the Dublin City University. Both CRG and IMIM are members together with ISGlobal and others of the PRBB Group of Good Scientific Practices.

2. OBJECTIVE

This policy aims to establish the procedure to follow in case of a scientific misconduct allegation in order to have a transparent and fair procedure for all those involved.

3. SCOPE

This SOP applies to all ISGlobal staff and scientific collaborators working at ISGlobal.

4. DEFINITIONS

- ***Allegation*** is a disclosure of possible research misconduct. The disclosure shall be a written statement.
- ***Complainant/Whistle-blower*** is a person who makes an allegation of research misconduct. This person will be awarded special protection as described herein.

[1] PRBB Code of Good Scientific Practice

- **Evidence** means any document, tangible item, or testimony offered or obtained during a scientific misconduct proceeding that tends to prove or disprove the existence of an alleged fact.
- ***Fabrication***[2] is making up results and recording them as if they were real.
- ***Falsification***[2] is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.
- **Formal investigation** means the formal development of a factual record and the examination of that record leading to a decision on whether or not to make a finding of scientific misconduct, which may include a recommendation for other appropriate actions, including administrative actions.
- **Malicious Allegation** means a disclosure of possible scientific misconduct to an institutional representative that is not based on real facts with the purpose of damaging the reputation of an individual or group.
- ***Plagiarism***[2] is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.
- **Preliminary enquiry** means preliminary information gathering and preliminary fact-finding.
- ***Scientific Misconduct***[2] is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It also includes questionable research practices that seriously deviate from those included in the PRBB Code of Good Scientific Practices for proposing, conducting or reporting research. It does not include honest error or honest differences of opinion. (See Annex 1).
- ***Respondent*** is the person against whom an allegation of research misconduct is directed.
- **Retaliation** means an adverse action taken against a complainant, witness, or committee member in response to an allegation of scientific misconduct made in good faith or to cooperation in good faith with a scientific misconduct proceeding.
- **Serious breach in a clinical trial** means a breach likely to affect to a significant degree the safety and rights of a participant or the reliability and robustness of the data generated in the clinical trial (Spanish Royal Decree [R.D.] 1090/2015 on clinical trials on medicinal products for human use).

5. RESPONSIBILITIES

- The **Complainant** is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the research misconduct proceeding.

[2] The European Code of Conduct for Research Integrity

- The **Respondent** is responsible for maintaining confidentiality and cooperating with the research misconduct proceeding.
- The **ISGlobal-GSPC** is the committee in charge of managing and following up all research misconduct allegations. The ISGlobal-GSPC is responsible for the nomination of the Preliminary Enquiry Committee, the Investigation Panel and its Chair. The ISGlobal-GSPC will notify the Respondent of the names of the proposed Investigation Committee members and if the Respondent objects, the ISGlobal-GSPC may either choose a substitute or provide in writing the reasons for maintaining the initial choice.
  When scientific misconduct has been proved, the ISGlobal-GSPC is responsible for informing the responsible persons at any institutions associated to the Respondent or associated to the case of misconduct (eg co-authors in a publication, funders, etc.)
- The **ISGlobal-GSPC chair** together with the **ISGlobal-GSPC secretary** are responsible for the assessment of the allegations received and for making a decision on whether a Preliminary Enquiry is required. They are also responsible of informing the CERCA Institution of the existence of a conflict of scientific integrity that is of sufficient relevance at the initial moment in which it is generated and, in parallel, elevate it to the CERCA Ombudsperson, under parameters of strict confidentiality and respect for the people allegedly involved. These relevant cases may be those related to the review or retraction of articles and which may lead to disciplinary action or involving the direction or management of the center.
  In addition, the ISGlobal-GSPC chair shall communicate the allegation to the Law Firm "Cuatrecases Gonçalves Pereira", through the external Complaints Channel (*canaldenunciasisglobal@cuatrecases.com*), in the event that the allegation contains reasonable evidence of an alleged crime (subsidy fraud, intellectual or industrial property crime).
- The **Preliminary Enquiry Panel** is responsible for performing a preliminary evaluation of the available evidence and testimony of the Respondent, Complainant and key witnesses to determine whether there is sufficient evidence of a possible research misconduct to warrant an investigation.
- The **Investigation Committee** is responsible for exploring in detail the allegations, examining the evidence in depth, and determining specifically whether misconduct has been committed, by whom, and to what extent. The Investigation Committee is responsible for seeking advice from the CIR-CAT (Committee for the Integrity of Research in Catalonia) (http://universitatsirecerca.gencat.cat/en/01_secretaria_duniversitats_i_recerca/la_secretaria/organismes/comite-per-a-la-integritat-de-la-recerca-a-catalunya-circat/index.html) if deemed necessary. The **chair of the Investigation Committee** is responsible for deciding whether the disclosure of the name of the Complainant is necessary because the Respondent cannot otherwise defend herself/himself effectively, in particular because the credibility of the Complainant has an important bearing upon a finding of misconduct. The chair of the Investigation Committee is responsible for informing the Complainant prior to the disclosure.
- The **General Director** andthe **Scientific Director, with the assessment of** the **head of Human Resources** are responsible for deciding and applying appropriate sanctions if a

scientific misconduct have been proved. Any warning or any other disciplinary measure shall be issued by the Human Resources Department in the form of a letter from the Director.

The **General Director** is the institution's responsible for receiving and initiating the appeal process if requested by respondent. In case of conflict of interest of the General Director or when decided by him, the appeal will be managed by the **Scientific Director**.

The **General Director** is responsible, after hearing from the GSPC, for the decision on whether the recommendations from the Investigation Committee shall be brought to the notice of the personnel and made available to the general public.

The **chair of the ISGlobal-GSPC, the General Director and the Scientific Director** are responsible for undertaking 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. In addition, they will take all reasonable action to restore the reputation of the Respondent if not found guilty of scientific misconduct. They are also responsible for deciding the actions to be taken in case of Malicious Allegations.

In regulated research i.e clinical trials, the **General Director** (or delegate) is responsible for the notification to the regulatory authorities (RA) and ethics committees (EC) (if applicable) following the process and timelines in accordance with the applicable regulations.

6. PROCEDURE

Any ISGlobal employee (affiliated or contracted) or external persons (e.g collaborators, vendors, journal editors) who becomes aware of any significant indication of scientific misconduct within the meaning of definitions in Annex 1, shall notify in writing the ISGlobal Good Scientific Practice Committee (ISGlobal-GSPC, research.integrity@isglobal.org). The ISGlobal-GSPC will guarantee the confidentiality of the complainant if it is necessary to protect the complainant and the identity of the complainant is not necessary to the enquiry.

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

The Allegation document should include details such as relevant parties, witnesses, dates, locations, publications and the specific matter of the Allegation in question.

The procedure once an allegation of suspected scientific misconduct has been received includes three steps:

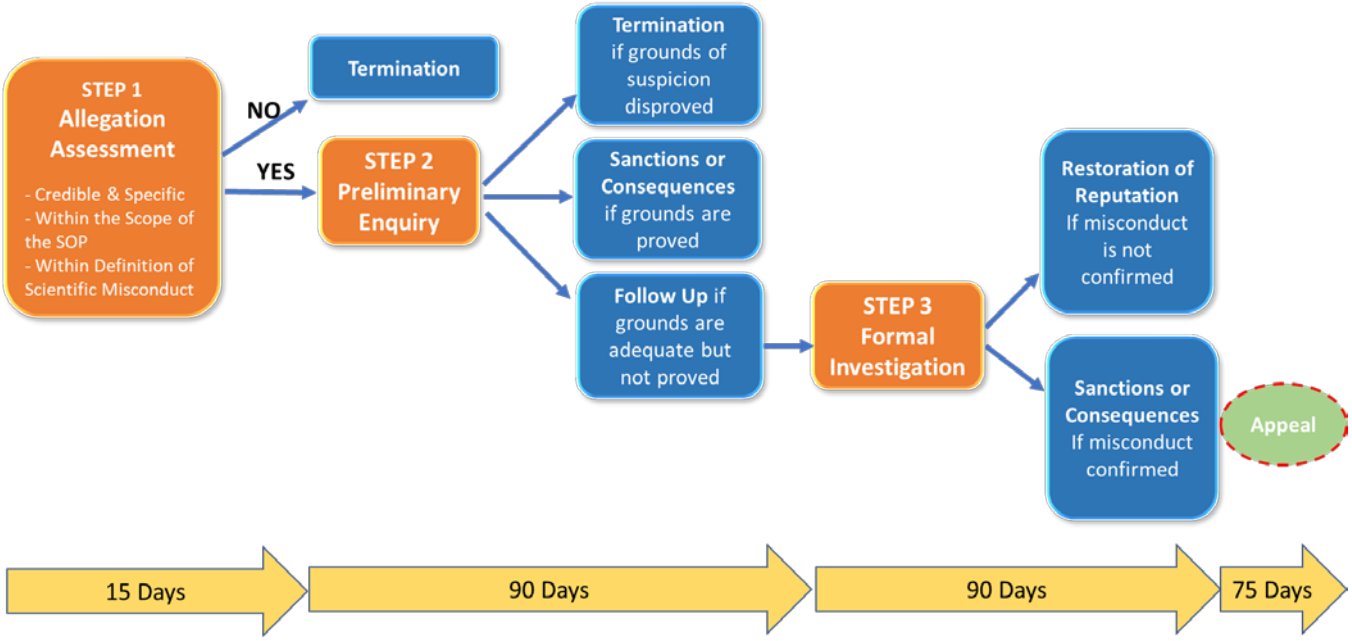
Step 1: Allegation Assessment
Step 2: Preliminary Enquiry
Step 3: Formal Investigation

At all stages of the procedure, all parties involved in the investigation will agree on writing to observe absolute confidentiality on any information related to the case. Persons who might be considered to have conflict of interest because of (but not limited to) friendship, enmity, a

former or present competitive situation, financial or organizational dependency on the respondent, will not participate in any stage of the procedure.
When an allegation is received, ISGlobal IT department will provide a secure folder to store all the information related to the case. The access to this folder will be secure and traceable and the information within kept for at least 5 years.

For clinical trials, the information will be retained for a period of time indicated in the applicable regulation.

Note: Clinical trial misconduct and fraud are to be reported as **serious breaches** to the Regulatory Authorities, EC and any other regulatory/governance body. The Spanish Royal Decree 1090/2015 which transposes into national law the EU Regulation 536/2014, sets a notification period of **7 calendar days** since becoming aware of a serious breach. EU guidelines state that it is expected that the sponsor of a clinical trial reports the breach first within 7 calendar days, investigate and take action simultaneously or after notification (Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol).



6.1 STEP 1: Allegation Assessment

Once the ISGlobal-GSPC receives an allegation, its chair and secretary will assess whether the allegation is:

- Credible and specific so that potential evidence of scientific misconduct may be identified;
- Within the scope and applicability of this policy;

- Within the definition of Scientific Misconduct (Annex 1)

At this stage, if it is considered that there is no solid ground to continue the enquiry, the procedure may be terminated. If it is determined that the Complainant informed in good faith, him/her shall be informed of the outcome of the assessment. If it is considered that an allegation has not been made in good faith, ISGlobal will proceed as explained in Section 6.5 "Malicious Allegations".

The allegation assessment period should preferably conclude within 15 calendar days of the reception of the allegation.

Should the chair and secretary of the ISGlobal-GSPC consider the allegation credible and specific, within the scope and applicability of this policy and within the definition of Scientific Misconduct, then a Preliminary Enquiry will take place. In addition, in cases related to the review or retraction of articles and which may lead to disciplinary action or involving the direction or management of the center, the ISGlobal-GSPC chair will inform the CERCA Institution through the CERCA Ombudsperson, under parameters of strict confidentiality and respect for the persons allegedly involved.

In clinical trials, it is paramount to conduct a thorough assessment of the impact of the allegation on the safety and rights of the participants or the reliability and robustness of the data generated in the clinical trial. Allegations that require **immediate** action to prevent harm, will be dealt with as a priority and, if necessary, an expedited allegation evaluation considered.

In the event that the allegation contains reasonable evidence of an alleged crime (subsidy fraud, intellectual or industrial property crime), the ISGlobal-GSPC shall communicate the allegation to the Law Firm "Cuatrecases Gonçalves Pereira", through the external Complaints Channel (canaldenunciasisglobal@cuatrecases.com) that ISGlobal has enabled in order to receive complaints with criminal significance. The investigation process and the guarantees of complainants and denounced are regulated in the "Protocol of Management, Investigation and External Response of Complaints", approved by ISGlobal's Executive Committee on May 3, 2018.

6.2 STEP 2: Preliminary Enquiry

- **6.2.1. Aim**

The aim of the preliminary enquiry is to make a preliminary evaluation of the available evidence and testimony of the Respondent, Complainant and key witnesses to determine whether there is sufficient evidence of a possible scientific misconduct to warrant an investigation. It is not purpose of the enquiry to reach a final conclusion about the case or the responsibility.

- **6.2.2 Composition of the Preliminary Enquiry Panel**

The ISGlobal-GSPC will assign two of its members and an ISGlobal researcher with expertise in the topic of the allegation (preferably a senior investigator within the Respondent's program), to form the Preliminary Enquiry Panel. The Preliminary Enquiry Panel members will agree in

writing to maintain confidentiality, guarantee no conflict of interest and ensure fairness and prompt action to protect all parties in the proceeding.

- **6.2.3 Enquiry Procedure**

The Preliminary Enquiry Panel will hold a meeting with the Respondent to inform him/her of the potentially incriminating facts. At the meeting, he/she will be provided with a written document including the potentially incriminating facts and evidence. In addition, the 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 preliminary enquiry, at the earliest convenience once the Respondent is notified.

The Preliminary Enquiry Panel in addition to the Respondent usually interviews the complainant (if known) and key witnesses as well as examine relevant records and materials. All interviewees should sign a confidentiality statement. The identity of the complainant is not disclosed at this stage unless he/she has given express consent.

If deemed adequate, the Quality Assurance Coordinator may arrange or conduct an Audit.

- **6.2.4 Preliminary Enquiry Report**

The Preliminary Enquiry Panel will evaluate the evidence, including the testimony obtained and within 40 calendar days of their first meeting will prepare a draft report containing:

- Name, academic titles and affiliations of the Preliminary Enquiry Panel members
- Name of Respondent
- Allegations reviewed
- Summary of the enquiry process used
- List of research records reviewed
- Summary of interviews performed
- Description of the evidence to demonstrate whether an investigation is warranted
- Conclusion
- Recommendations

In the event of unavoidable delays in gathering testimony and/or other evidence, the delivery of the draft report can be delayed.

- **6.2.5 Preliminary Enquiry Decision and Notification**

The draft report will be shared with the Respondent who will have 15 calendar days to provide comments. The Preliminary Enquiry Panel will also share with the Complainant the portions of the draft report that address the Complainant's role and opinions in the investigation. The Complainant will also have 15 calendar days to send comments to the panel.

The Preliminary Enquiry Panel will make the final report considering the comments received and send it to the ISGlobal-GSPC, the General Director, the Scientific Director, the Respondent and the Complainant.

The recommendations from the Preliminary Enquiry Panel can be:

a. Terminate the enquiry should the grounds for suspicion not be sufficiently substantiated or disproved. In this case the Preliminary Enquiry Panel should determine if the Complainant informed in good faith or if the allegation has not been made in good faith, ISGlobal will proceed as explained in Section 6.5 "Malicious Allegations".

b. Initiation of a formal investigation if it is justified by sufficient evidence of possible research misconduct. See section 6.3.

c. Take immediate sanctions or consequences if the preliminary enquiry unequivocally shows proof of misconduct, including acknowledgement of wrong doing by the respondent.

In the event that the Preliminary Enquiry Panel does not reach agreement on the recommendations to make, a formal investigation will be guaranteed.

If a formal investigation is not recommended, all sequestered materials should be returned to the Respondent or parties involved, as soon as possible.

In the last case (c), the General Director, Scientific Director and the head of Human Resources will decide on the sanctions to be applied according to Annex 2. In addition, the ISGlobal-GSPC will inform the responsible persons of any institutions associated to the Respondent or associated to the case of misconduct (e.g. co-authors in a publication, funders…).

The Preliminary Enquiry should preferably be completed within 60 calendar days of the formal composition of the panel.

6.3 STEP 3: Formal Investigation

- **6.3.1 Aim**

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. The findings of the investigation will be set forth in an investigation report.

- **6.3.2 Composition of the Investigation Committee**

The ISGlobal-GSPC will appoint an Investigation Committee and designate a chair. The investigation committee will consist of at least three persons with no real or apparent conflicts of interest and who have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the key witnesses, and conduct the investigation. These individuals may be researchers, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. At least one of the members of the Investigation Committee will be from ISGlobal and one external.

The ISGlobal-GSPC will notify the Respondent of the proposed Investigation Committee members. The Respondent may object to member selection providing an appropriate argument within 5 calendar days. The ISGlobal-GSPC may either choose a substitute or provide in writing the reasons for maintaining the initial choice.

The Investigation Committee will agree in writing to maintain confidentiality, guarantee no conflict of interest and ensure fairness and prompt action to protect all parties in the proceeding.

The Investigation Committee will be appointed and the process initiated within 30 calendar days of the decision of the preliminary enquiry panel.

- **6.3.3 Investigation Procedure**

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, financial records, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Additional research records, not previously considered may be sequestered by the committee.

Whenever possible, the committee will interview the Complainant, the Respondent, and other individuals who might have information regarding aspects of the allegations. Interviews should be taped or transcribed. The chair of the Investigation Committee will give the Respondent written notification of the charges to be investigated, as well as the place, time and date of any meeting at which he/she is requested.

Both the Investigation Committee and the Respondent are entitled to ask for expert advice on the case. In addition, the Investigation Committee will seek advice from the CIR-CAT if deemed necessary.

The disclosure of name of the Complainant may become necessary if the Respondent cannot otherwise defend herself/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 chair of the Investigation Committee who will inform the Complainant prior to the disclosure.

The Investigation Committee 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 Committee will decide by two-thirds majority whether scientific misconduct has sufficiently been established.

- **6.3.4 Investigation Report**

The Investigation Committee will submit the final report to the ISGlobal-GSPC within 60 calendar days of its first meeting. In the event of unavoidable delays in gathering testimony and/or other evidence, or if the advice of the CIR-CAT has been requested, the duration of the Committee's work can be extended upon request to the ISGlobal-GSPC.
The final report must include:

- Name, academic titles and affiliations of the Investigation Committee members
- Name of Respondent
- Description of the policies and procedures under which the investigation was conducted
- Description of how and from whom information relevant to the investigation was obtained and list of research records reviewed
- Actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct
- Description of the findings
- Conclusion
- Recommendation including a warning or sanctions to be considered if scientific misconduct has been proved

The Investigation Committee may decide to produce a separate report for each Respondent, or to differentiate and detail the responsibilities of each Respondent in a single report.

The draft investigation report will be shared with the Respondent who will have 15 calendar days to provide comments. The Respondent's comments will be attached to the final report. The findings of the final report should consider the Respondent's comments in addition to all the other evidence. In addition, the Investigation Committee will also share with the Complainant the portions of the draft report that address the Complainant's role and opinions in the investigation. The Complainant will also have 15 calendar days to send comments to the committee. The report should be modified, as appropriate, based on the Complainant's comments.

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the Investigation Committee will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality (e.g. by requesting the recipient to sign a confidentiality statement or to come to the chair office to review the report).

- **6.3.5 Decision and Notification**

The Investigation Committee will make the final report considering the comments received and send it to the ISGlobal-GSPC, the General Director, the Scientific Director, the Respondent and the Complainant.
The recommendations from the Investigation panel can be:

a. Restoration of Reputation if no evidence of scientific misconduct has been found. In this case the Investigation Committee should determine if the Complainant informed in good faith or if it was a Malicious Allegation. In case of Malicious Allegations, the Investigation Committee will recommend ISGlobal to proceed as explained in Section 6.5 "Malicious Allegations". In addition, actions should be taken if needed to restore the reputation of the Respondent (Section 6.4).

b. Sanctions or consequences if proof of misconduct is unequivocally shown.

In the last case (b), the General Director, Scientific Director and the head of Human Resources will decide on the sanctions to be applied according to Annex 2. Any warning or any other disciplinary measure shall be issued by the Human Resources Department in the form of a letter from the Director. This letter should state the cause for complaint and shall inform the Respondent of his/her right to appeal (see next section). The letter will be sent together with the Investigation Committee's final report.

- **6.3.6 Right to Appeal**

The Respondent has the right to appeal on grounds which include (but are not restricted to): failure to follow appropriate procedures in the investigation; new evidence; arbitrary, capricious or erroneous decision-making, and; inappropriate disciplinary action. An appeal must be filed within 15 calendar days of receipt of the final determination.
The General Director is the institution's responsible for receiving and initiating the appeal process. In order to make an appeal, the Respondent must prepare an appeal submission for issue to the General Director, which clearly states the basis for and nature of the appeal and which includes all relevant evidence. During the appeal process, the General Director may interview any party involved in the original investigation and will take appropriate actions to consider any new evidence.
The General Director will issue a decision to the Respondent and Complainant within 60 calendar days. In the event that an appeal is successful, ISGlobal will make all reasonable efforts to ensure that the reputation of the Respondent is restored.
In case of conflict of interest of the General Director, the appeal will be managed by the Scientific Director.

- **6.3.7 Communication**

The ISGlobal-GSPC will inform the responsible persons of any institution associated to the Respondent or to the case of misconduct.

In no case, the Investigation Committee will make publicity of the case, contact the press or disseminate publicly the results of the investigation, unless required legally or by other parties involved (e.g. organizations with whom the Respondent is affiliated, funders, journal editors and publishers…).

If so decided by the General Director, the recommendations from the Investigation Committee shall be brought to the notice of the personnel and made available to the general public.

For clinical trials, notification of scientific misconduct to the regulatory authorities and ethics committee will be done in accordance with the applicable regulations.

- **6.3.8 Record Retention**

All records relating to the case will be maintained for a period of five years, for the purposes of reporting and case evaluation.

For clinical trials, record retention will follow all applicable regulations.

6.4 Restoration of Reputation and Protection of Participants against Retaliation

When appropriate, the chair of the ISGlobal-GSPC and the ISGlobal Scientific and General Directors 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 the investigation 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.

In addition, during the research misconduct proceeding and upon its completion regardless of the outcome, the Chair of the ISGlobal-GSPC and the ISGlobal Scientific and General Directors will 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 ISGlobal-GSPC in agreement with the ISGlobal Scientific and General Directors may consult with, or refer the matter to, other appropriate ISGlobal departments (e.g. Head 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.

6.5 Malicious Allegations

Allegations not made in good faith may include allegations of misconduct based on information that the complainant knew or should have known and is without substantial basis. Also, when the complainant acted in bad faith, and with intent to damage the respondent.
Where the outcome of a Preliminary Enquiry or a Formal Investigation indicates that an Allegation has not been made in good faith, the Chair of the ISGlobal-GSPC in agreement with the ISGlobal Scientific and General Directors will:

- pursue disciplinary action against the Complainant(s);
- pursue action as appropriate against external Complainant(s), such as informing the Institutions that employ him/her (them);
- take action to safeguard reputations as necessary.

7. ASSOCIATED DOCUMENTS

- PRBB Code of Good Scientific Practice
- Adoption of PRBB Code of Good Scientific Practice and addendums_Vf
- ToR_ISGlobal_Good_Scientific_Practice_Committee

8. VERSION CONTROL

Version	Date of revision	Changes

9. REFERENCES

- CRG Procedure in Cases of Suspected Scientific Misconduct
- IMIM Procedure in Cases of Suspected Scientific Misconduct
- DCU Policy for Responding to Allegations of Research Misconduct
- Codi de Conducta CERCA
- Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol
- The European Code of Conduct for Research Integrity – ALLEA
- OECD Global Science Forum – Best Practices for Ensuring Scientific Integrity and Preventing Misconduct
- Recommendations for the Investigation of Research Misconduct – ENRIO Handbook
- Programme for the Integrity of Research in Catalonia – CIR-CAT Committee for the Integrity of Research in Catalonia

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. Scientific misconduct **does not include honest error or honest differences of opinions**.

There is no exhaustive list of acts that can be regarded as scientific misconduct. Deviations from the rules of good practice described in the PRBB Code of Good Scientific Practice may serve as reference and are to be regarded as Scientific Misconduct. In particular the following may amount to misconduct[3]:

Core Scientific Misconduct

- ***Fabrication*** is making up results and recording them as if they were real.
- ***Falsification*** is manipulating research materials, equipment or processes or changing, omitting or suppressing data or results without justification.
- ***Plagiarism*** is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

It includes:

Selectively excluding 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 under pressure from a sponsor

Research practice misconduct

Using inappropriate (e.g., harmful or dangerous) research methods

Poor research design

Experimental, analytical, computational errors

Violation of human subject protocols

Abuse of laboratory animals

Sabotage of research work

[3] Adapted from the CRG Procedure in Cases of Suspected Scientific Misconduct, The European Code of Conduct for Research Integrity – ALLEA and OECD Global Science Forum – Best Practices for Ensuring Scientific Integrity and Preventing Misconduct

Data-related misconduct

Not preserving primary data

Bad data management, storage

Withholding data from the scientific community

Publication-related misconduct

Claiming undeserved authorship

Denying authorship to contributors

Artificially proliferating publications ("salami-slicing")

Failure to correct the publication record

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 unauthorised purchases or for personal gain

Making an unsubstantiated or malicious misconduct allegation

Misconduct in clinical trials

Possible signs of fraud or data fabrication at a trial site may include but not be limited to the following examples. Also trends should be considered, events that occurs repeatedly (i.e. three or more times) for the same participant, across three or more participants or across three or more trial sites.

- Missing or incomplete source documents and/or slow completion of e/CRFs
- Unavailability of source documents and e/CRFs
- Obliteration of data and/or frequent corrections to the source documentation especially those that change ineligible participants to eligible participants or data that is non-compliant with protocol to compliant.
- Total obliteration of participant's names on medical records or tests in the participant file (i.e. not redacted for external transmission)

- Significantly more or fewer screen failures or early terminations than at other trial sites
- Fewer adverse events, concomitant medications, and physical exam findings than at other sites
- Repeated values or number preference where variability is expected e.g. blood pressure readings across participants
- Exceptional protocol and event schedule adherence
- Greater-than-average occurrence of laboratory sample issues (e.g., shipped beyond stability, lost, not done)
- Participant diary cards that have too many or no changes, appear to be completed all at once, or seem to be in pristine condition (e.g., free from normal wear and tear, same ink colour, etc.)
- Similar handwriting on several consent forms, or varying signatures attributed to the same participant
- Discrepancies in dates and events in source notes versus trial documents such as informed consents or questionnaires
- Too many participant visits on the same day
- Participant visits that occur on holidays, weekends, or dates on which the key study staff were known to be away from the clinic
- Non-chronological data or data entries compressed between lines to make it chronological
- Site staff absence or unavailability during monitoring visits

Important: In collecting evidence, photocopies without certification are not acceptable. Copies of participants' records should be de-identified.

b. Joint accountability as a 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.

Annex 2. Sanctions or Consequences in Case of Scientific Misconduct

The following catalogue of possible sanctions or consequences in case scientific misconduct has been proven, is intended as an orientative 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 appropriate reactions; rather, these must be tailored to fit the circumstances of each case. Possible sanctions or consequences may be the following:

– **Academic consequences** (e.g. notification of the scientific misconduct to the University or body which conferred a degree for consideration of the academic degree withdrawal)

– **Labour consequences** according to current Spanish labour regulations, including disciplinary dismissal of employment

– **Civil consequences**, like an order not to enter the premises, claims for the restitution of stolen scientific material, claims related to grants and any other damages claims

– **Penal consequences**, when scientific misconduct amounts to an offence under the Spanish Criminal Code in force (e.g. unauthorized use of works protected by copyright, falsification of documents)

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

In case of scientific collaborators, adscriptions or joint appointment positions, possible consequences could be the termination of the collaboration relationship or the dual appointment position at ISGlobal, without prejudice to the right of ISGlobal to claim for a compensation for the damages caused, as well as additional consequences depending on the case.