

Scientific Integrity Committee (CIC) Regulations

Approved version 2025-11-05

Preamble:

Identification and Foundations

The Scientific Integrity Committee (hereinafter the CIC) is a body made up of experts in scientific integrity belonging to the Gregorio Marañón Health Research Institute (hereinafter the liSGM), whose legal identity is represented by the Gregorio Marañón Hospital Biomedical Research Foundation (hereinafter FIBHGM) and/or external members. The composition of its members shall be based on the principle of gender parity and the number shall be odd.

The purpose of the CIC is to be an accessible resource for the institute's researchers on issues related to scientific integrity. The CIC will be confidential and will act as a neutral mediator and advisor. It will therefore be an advisory body, whose ultimate goal will be to promote an ethical research environment. It is not a punitive body, but rather a support mechanism for researchers and a means of preventing scientific malpractice. This does not exclude the possibility that, on some occasions, such malpractice may lead to a labour dispute, which will be dealt with separately, including the activation of the protocol for processing a request for intervention due to internal conflict or whatever else may be required.

The CIC's tasks will include resolving conflicts in research, understanding conflicts to be those problems, issues or confrontations that may violate the provisions of the liSGM Code of Good Scientific Practice or that involve a deviation from good scientific practice.

The GENERAL OBJECTIVE of the CIC is to promote and safeguard integrity, transparency and responsibility in scientific research, seeking compliance with national and international regulations.

The Specific Objectives are:

- To establish channels for compliance with ethical and scientific standards in research.
- Detect, prevent and address cases of scientific misconduct.
- To train researchers and staff in scientific integrity and good practices.
- To promote responsibility in the communication of results, including openness and open data.
- Ensure the protection of participants in medical studies.
- Comply with the Code of Good Scientific Practice as required by national and European regulations.

Article 1. Purpose of the Regulations.

The purpose of these regulations is to regulate the functions and operating procedures of the liSGM's CIC in order to mediate, prevent and promote good practices in scientific research.

The members involved in the CIC's processes must act impartially and objectively. They are required to disclose any conflicts of interest and to recuse themselves from proceedings in which they have or may have any kind of conflict of interest.

The CIC is committed to the maximum protection of information and of the persons involved in the processes. It shall guarantee the right to defence and protection of all parties involved, whether complainant or defendant, at the different stages of the procedures to be followed.

Article 2. Composition, appointment, dismissal and renewal

2.1 The CIC is made up of the following positions:

- Chair: a member of the liSGM who is elected by the CIC and ratified by the liSGM management.
- Secretary: a member of the CIC elected by the CIC.
- Deputy Secretary: a member of the CIC elected by the CIC.
- Ex officio members: the chair or secretary of the following commissions/committees are ex officio members: Training Commission, Medicinal Product Research Ethics Committee (CEIm), Animal Experimentation Ethics Committee (CEEa) and Biosafety Committee, to be elected by these bodies.
- A representative of the FIBHGM.
- Internal members: the rest of the committee members, belonging to the liSGM, whose number will be established according to needs and with prior training in scientific integrity.
- External member(s): an advisory member with experience and knowledge in scientific integrity who has no direct relationship with the centre or the procedure in question.

In total, the number of people who will make up the CIC will be between 9 and 11.

2.2 Functions of the positions:

2.2.1 The Chair shall have the following functions:

- To represent the CIC.

- Convene and preside the meetings of the CIC, both ordinary and extraordinary; as well as opening, chairing and closing the sessions.
- Sign the corresponding minutes after they have been approved.
- Sign the decisions of the CIC.
- Authorising with his signature the documents authorising procedures, certificates, reports and communications addressed to third parties.
- Break ties with his vote for the purpose of adopting agreements.
- Ensuring compliance with the law.
- Endorse the minutes, agreements and reports of the CIC.
- Respond, on behalf of the CIC, to specific queries from researchers, the management of their centre or the competent authority.
- If necessary, make decisions on behalf of the CIC, for example, in emergency situations or minor matters
- The obligation to inform the Occupational Health Commission of cases with a potential impact on workers' health.
- The procedure for submitting its opinions.
- The clear distinction between scientific responsibility and responsibility for occupational risk prevention, which lies with the company and its prevention bodies.
- Perform any other duties inherent to his position as CIC chairperson.

2.2.2 The Secretary shall have the following functions:

- The Secretary shall carry out all the functions assigned to him by the President, assuming the latter's duties in the event of his absence.
- Drafting and sending out notices of CIC meetings, in accordance with the instructions received from the President and with due notice.
- Draft the minutes of CIC meetings, stating the members in attendance, ensuring that they are copied, once approved, into the corresponding file, and signing them with the President.
- Receive and report on all requests and communications sent to the CIC.
- Issue, with the approval of the President, the documents authorising the procedures, certificates, reports, communications and resolutions agreed upon.
- Supervise the drafting of the Annual Report on activities on an annual basis.

2.2.3 The CIC may appoint a deputy secretary who shall perform the duties assigned or delegated by the Secretary and shall assume the duties of the Secretary in his absence and those of the chair in the absence of the Secretary and the chair if deemed necessary and circumstances so require.

2.2.4 The duties of the members (internal, ex officio or external) shall be:

- To receive the notice of meeting with the agenda for the corresponding session; information on the items on the agenda shall be made available to the members within the same minimum period.
- Attend meetings or justify their absence.

- Carry out the evaluations entrusted to them and draw up a detailed report on their resolutions, in accordance with these regulations.
- Participate in the debates during the sessions.
- Exercise their right to vote and formulate individual votes, as well as express the meaning of their vote and the reasons for it.
- Make requests and ask questions.
- Obtain the information necessary to perform their duties.
- Any other duties inherent to their status as CIC members.

2.2.5 The FIBHGM representative will be responsible for supervising the preservation of the paper archive of reports, attending meetings and may participate, but does not have the right to vote or make assessments.

2.2.6 In the absence of the chair, the secretary shall assume the duties of chair, and in the absence of the secretary, the deputy secretary or a person chosen from among those present shall perform the duties of secretary.

2.2.7 In each case, two coordinators shall be appointed from among the members of the CIC to manage communication, follow-up and discussion at CIC meetings.

2.3. Duties, Rights and Grounds for Termination of Membership

Once the CIC has been established and for subsequent renewals of its members, the CIC itself shall decide on their appointment and dismissal.

2.3.1 Duties of CIC members: Attend meetings, prepare, participate actively, maintain confidentiality when appropriate.

2.3.2 Rights of CIC members: To be convened, to have a voice and a vote, to receive information, to propose topics. Persons appointed as CIC members shall receive a document of appointment that they may use for their merit assessment.

2.3.3 Causes for dismissal or resignation:

All CIC members shall lose their status for any of the following reasons:

- Resignation, with the exception of that submitted by ex officio members.
- Final court ruling.
- Retirement.
- Death.
- Expiry of the term for which they were appointed, where applicable.
- Cessation of active status in any of the institutions comprising the IISGM.
- Repeated and unjustified absence from CIC sessions. Repeated absence shall be understood to mean absence without just cause from one-third of the sessions during the same academic year.

CIC members who hold office by virtue of their previous position (ex officio members) shall lose that status upon leaving office.

2.3.4 After four years of membership, members may request re-election (except those who are members by virtue of their position), ensuring that no more than 50% of the members are renewed, not including ex officio members. Likewise, if the CIC deems it appropriate, certain members may be re-elected in order to maintain the experience accumulated in the committee or in the absence of qualified candidates.

To encourage the entry of new members, outgoing members may not apply for re-entry to the CIC in the next call for applications.

External members of the CIC shall be elected, upon proposal by CIC members, based on their merits and experience. Renewal shall take place every two years, with members eligible for re-election for a further two-year term, up to a maximum of six terms. In all cases, consideration shall be given to the need to maintain the accumulated experience within the committee.

Article 3. Functions of the CIC.

3.1 To be a confidential channel: It acts as a first point of contact on a confidential, advisory and neutral basis so that researchers, students, technicians and other staff can discuss concerns related to scientific conduct informally and without initiating formal proceedings.

3.2 Advice and Guidance: Provides information and advice to members of the research community on:

- Standards of good scientific practice (research integrity).
- Internal policies internal of the institute on conduct responsible of research.
- Ethical and regulatory protocols (e.g., animal research ethics committees - AREC-).
- How to address dilemmas or conflicts related to authorship, intellectual property, data analysis, etc.
- The limits of internal and external conflicts of interest and how to resolve them.

3.3 Informal Conflict Resolution: Mediates conflicts between researchers (e.g., disputes over authorship, use of resources, supervision) informally, facilitating communication between the parties to find a solution before the conflict escalates.

3.4 Information on Formal Procedures: Informs the person making the inquiry about the formal channels available for filing a complaint or report if the situation requires it (e.g., animal mistreatment would be referred to the CEEA). The CIC does not conduct formal investigations or impose sanctions.

3.5 Protection Against Retaliation: Advises and guides individuals who fear retaliation for raising a concern in good faith, informing them of their rights and protection mechanisms.

3.6 Detection of Systemic Problems: Identifies recurring trends or problems within the institution that may affect the integrity of research (e.g., lack of training in scientific integrity, pressure to publish) and, while maintaining confidentiality, may make general recommendations to the IISGM Management to improve policies and the research environment.

3.7 Training and Promotion of a Culture of Integrity: Participates in the organisation of workshops and training sessions to raise awareness among the research community about the importance of responsible conduct in research.

Article 4. Functioning of the CIC.

The functioning of the CIC shall be subject to the provisions of these Regulations and the legislation in force on the legal regime of public administrations.

4.1 The Chair shall convene the CIC at least once every quarter. The schedule of ordinary meetings for the following year shall be proposed and agreed upon at the last annual meeting of the committee, thus establishing a tentative schedule with dates that may be altered, only for justified reasons, at the request of one or more members and provided that there is a quorum of all committee members.

The number of extraordinary meetings will be determined by the number of files to be evaluated and their deadlines, and will be set at least 10 days in advance, at the proposal of the management.

4.2 Each meeting notice shall provide the means for CIC members to carry out their review work and, if required, report on any procedures.

The venue and agenda for the meetings shall be communicated in the notice of meeting, with meetings being held in person, virtually or in a hybrid format.

The draft minutes of the previous meeting will be sent by email together with the notice of meeting, for review. Comments from members will also be sent by email or on the day of the meeting.

4.3 For the CIC Plenary to be constituted, at least one third of its members must be present in person or online. No member may delegate their functions or be replaced at CIC meetings. Delegated voting will not be permitted. CIC decisions will be adopted by simple majority.

4.4 The CIC may work in plenary sessions and in committees. The CIC may set up committees to study procedures when the number, deadlines or nature of the reports to be produced so require. The committees shall be made up of

at least two members and shall perform whatever functions are delegated to them by the plenary session. The plenary session may request information on any matter.

4.5 Confidentiality and conflict of interest in proceedings.

CIC members shall be bound by the principle of confidentiality, both in terms of debates and reports.

CIC members must abstain from proceedings affecting researchers with whom they have any kind of relationship or in cases where conflicts of interest may arise.

Minutes shall be taken of each session held. These shall include: those in attendance, the agenda of the meeting, the place and time of the meeting, the main points of discussion and the agreements reached. The minutes shall be approved at the following session.

The minutes must be drafted in such a way as to maintain the anonymity of the researchers involved, as required by the procedure initiated.

4.6 When the CIC deems it appropriate, it may seek the opinion of external experts, who shall also be subject to the principle of confidentiality.

4.7 Archiving and documentation:

The CIC archive shall be kept in the custody of the FIBHGM. This archive shall contain the originals of the minutes, a copy of all reports, and any other documentation generated in the information and evaluation process. This archive may be consulted by any member of the CIC upon express request and approval by the Plenary.

To facilitate archiving and documentation, all procedures will be assigned an identification number. The code must include the start date of the process (year/month/day) and a keyword (20250101keyword).

The file shall be kept for a minimum of 5 years from the expiry date of its authorisation period within the institution's network and only the chair and secretary of the CIC shall have access to the file.

Committee members shall be obliged to maintain the utmost confidentiality in their communications with each other and to send files via official email.

Article 5. Scope of Action

5.1 Consideration: Problems, issues or conflicts that may violate or deviate from the provisions of the IISGM Code of Good Scientific Practice are considered Bad Scientific Practice.

5.2 Scope: The liSGM Code of Good Scientific Practice applies to all its research staff, including those in training and those performing research-related functions (technical and support staff), regardless of the nature of their relationship with the liSGM and whether they are permanent or temporary, without prejudice to their subjection to the regulations on incompatibilities of personnel in the service of the Public Administrations and other applicable regulations. Likewise, this Code also applies to personnel outside the Institution, including interns or trainees who carry out scientific activity at the liSGM.

5.3 The following cases shall be considered:

Serious offences: Fabrication, falsification and plagiarism.

Questionable practices: Self-plagiarism, unjustified authorship ("gift" of authorship), omission of conflicts of interest, negligent data management, duplicate publication, manipulated peer review, etc.

5.4 Non-admissible matters: The committee will not admit questions relating to the validity of scientific hypotheses or the quality of the work, but rather the integrity of the process. Nor will it admit questions that exceed the liSGM's Code of Good Scientific Practice.

Disputes over authorship will be dealt with in accordance with the provisions of the liSGM Code of Good Scientific Practice, although the provisions of the publication's editors regarding the authorship of scientific work and the provisions of the procedures for the exploitation of specific results of each research project will also be taken into account.

5.5 Education and Prevention: The CIC is proactively committed to promoting the organisation of workshops, disseminating good practice guidelines and advising researchers.

Article 6. Regulation of the CIC's procedure for action

6.1 Incident reporting procedure.

These regulations govern the CIC's procedures and operating rules. The procedure for reporting possible cases of malpractice is set out in another document.

Reports of complaints or issues related to the CIC shall be made through the liSGM communication channel. In the case of in-person consultations, for informal and confidential assessment, an appointment shall be made via the CIC email address (cic@iisgm.com).

All researchers belonging to the liSGM or collaborators are obliged to report any cases of malpractice they know of or suspect.

Individuals are expected to act in good faith when raising a query or complaint about malpractice or when cooperating with the procedures for its clarification. In the event that they are made in bad faith, or any member of the institution, including the person making the enquiry and the person involved, obstructs the investigation, the FIBHGM may take the measures it deems appropriate. Likewise, if the conflict affects HGUGM staff, the management of Gregorio Marañón Hospital will be informed.

All consultations or complaints about malpractice originating from within or outside the institution will be assessed by the CIC and, if they fall within the scope of the CIC, will be taken into account.

Communications must be based on facts and provide documentary information or specific evidence. Investigation notebooks will be used as documentary evidence if necessary (it is recommended to follow the instructions explained in ANNEX I).

Complaints cannot be anonymous, but enquiries can be. The complainant must provide a reliable channel of communication in order to receive a response or additional requests for information. In all cases, the CIC will guarantee the anonymity of those involved in the enquiries until mediation or dispute proceedings are initiated.

6.2 Incident reporting procedure Stages and procedures:

FIRST. Initiation of the procedure through the IISGM communication channel or, in the case of enquiries or requests for enquiries in person, an appointment will be made via the CIC email (cic@iisgm.com).

SECOND. After receiving the communication by email from the CIC, the case will be assigned to the coordinators within a maximum period of seven calendar days. The CIC will acknowledge receipt of the communication, identify it with a code and open an entry in the CIC file.

The coordinators will evaluate it to decide whether it falls within the definition of malpractice and is sufficiently credible and specific to identify evidence of malpractice.

The Coordinators shall inform the CIC and the communicator whether or not the committee is competent to assess the dispute, and may also make recommendations as to other bodies to which the matter should be referred. If it is competent, it shall convene an extraordinary meeting of the CIC within 10 days to assess the communication.

If they consider the consultation to be insubstantial, they may request further information from the parties for evaluation at the CIC meeting. The Coordinators shall take all reasonable measures necessary to obtain all original evidence (physical and/or electronic) relevant to the analysis. This includes, among other documents, research proposals, laboratory data, protocols, images, samples, equipment, abstracts, theses, oral presentations, internal reports, published articles, and correspondence. All available material

available that is identified as relevant to the evaluation of the case must be submitted.

If it does not constitute a potential case within the scope of the CIC or is a matter that concerns another area, the procedure will not be initiated and, if appropriate, the interested party will be referred to the relevant department.

THIRD. The case will be discussed at the extraordinary meeting of the CIC, all the evidence will be examined, and it may be dismissed, a mediation procedure may be initiated, or a procedure involving the activation of a request for intervention due to internal conflict may be initiated. The CIC will issue a report in which anonymity will be respected if deemed appropriate, and which will be sent to the person responsible for communication, the liSGM Management and the FIBHGM Management so that the appropriate administrative actions can be considered.

If the report considers that there is an occupational risk (harassment, internal conflicts, internal violence and/or psychological harassment), the case will be referred to the FIBHGM Management, as well as communicated to the Occupational Health and Safety Committee (CSS) to initiate administrative procedures and, if necessary, activate the FIBHGM conflict procedure. Likewise, if the conflict affects HGUGM staff, the management of Gregorio Marañón Hospital will be informed.

The CIC will carefully assess the scope/range of the communication and whether there is evidence of malpractice in other investigations in which the person involved is participating.

6.3 Decision-making process

Decision-making mechanisms: The CIC shall decide by majority vote, although not necessarily unanimously, and in the event of a tie, the chair shall have the casting vote (casting vote).

The following have voting rights: the Chair (who has the casting vote in the event of a tie), the Secretary, the Deputy Secretary and all members. The representative of the FIBHGM and any advisors or persons from outside the CIC who may be requested during the process do not have voting rights.

Types of resolution: Based on the preponderance of evidence, the CIC will issue an evaluation report:

- **Request for investigation:** A possible case of malpractice is considered, recommending the activation of the protocol for processing a request for intervention due to internal conflict or administrative proceedings, where appropriate.
- **Communication dismissed:** The consultation is dismissed as a case of malpractice.
- **Communication in bad faith:** The liSGM Management will be informed so that it may take the measures it deems appropriate in this regard.
- **Request for mediation:** The CIC will appoint a representative to meet with the parties to reach an agreement.

A **final report** will be drawn up indicating the CIC's decision, which will be communicated to the parties and the FIBHGM Management.

The request for mediation may lead to an agreement between the parties and the resolution of the process. The Coordinators will inform the CIC of the initial agreement and the CIC will issue a report with the necessary considerations and recommendations for each case, which will be communicated to the complainant and the person(s) affected within the established three-month period. The interested parties will have a period of 10 working days from receipt of the agreement to make the appropriate allegations. The committee has a maximum period of 30 calendar days from the acknowledgement of receipt to respond to them. Once the final agreement has been adopted, the CIC will issue a final report which will be submitted to the parties and the Management of the FIBHGM, which is the executive body, so that it can take the appropriate measures. The files will be closed and must be duly archived and kept in safe custody. All emails will be sent with acknowledgement of receipt to confirm receipt.

Informal communications, whether through the communication channel or in person, do not require a CIC report, but a file must be created that will be presented at the CIC meeting and must be duly archived and safeguarded. In the event of a potential impact on workers' health or occupational risks, the CIC chair shall notify the FIBHGM Management and the CSS, either ex officio or through a CIC report, so that the facts can be investigated in a timely manner and the necessary actions can be taken to minimise any possible impacts, while respecting the anonymity of the communicator, until it is decided whether or not to proceed with the dispute. Likewise, if the dispute affects HGUGM staff, the management of Gregorio Marañón Hospital will be informed.

The minutes of the meeting must record the procedure, the evidence provided, discussions, agreements and decisions. They must include who drafts them, who approves them and how they are filed and distributed. In the case of anonymous processes, consultation or mediation, the minutes must maintain the anonymity of the persons involved in the process.

The language of the minutes and the report must be **neutral and objective**, avoiding assessments or prejudgements. It must include only verified information that is relevant to institutional or public interest. The ongoing process and the rights of all parties must be respected. Privacy must be respected and data protection regulations (General Data Protection Regulation - GDPR) and the presumption of innocence must be complied with. Details that could lead to parallel judgements may not be disclosed. **Personal data** should only **be disclosed** when there is a legitimate and proportionate public interest.

6.4. Confidentiality, Protection and Communication

Strict Confidentiality: All CIC members have an absolute obligation of confidentiality and, in the event of a breach, the IISGM Management and FIBHGM Management will be notified so that they may take the measures they deem appropriate.

The result will only be communicated to those who need to know (institutional authorities, affected parties).

The CIC must protect the complainant and witnesses, ensure that there is no retaliation, harassment or discrimination, and report and promote sanctions for those who engage in such behaviour.

Article 7. Regulatory framework

- Law 14/2011, of 1 June, on Science, Technology and Innovation (Spain):
- National Declaration on Scientific Integrity
https://www.csic.es/sites/www.csic.es/files/declaracion_nacional_sobre_integridad_cientifica_castellano-ingles.pdf
- Manual of Conflicts of Interests of the CSIC
https://www.csic.es/sites/www.csic.es/files/manual_de_conflictos_de_intereses_del_csic_version_espanol-ingles.pdf
- Singapore Statement on Research Integrity
<https://wcrif.org/guidance/singapore-statement>
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013) <https://wcrif.org/montreal-statement/file>
- European Code of Conduct for Research Integrity
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf
- Research Integrity: What it means, why it is important and how we might protect it (Science Europe. Briefing Paper)
https://www.scienceeurope.org/media/dnwbwaux/briefing_paper_research_integrity_web.pdf
- Seven Reasons to Care about Integrity in Research (Science Europe)
https://www.scienceeurope.org/media/42sphgqt/20150617_seven-reasons_web2_final.pdf
- The European Charter for Researchers and The Code of Conduct for the Recruitment of Researchers
https://euraxess.ec.europa.eu/sites/default/files/am509774cee_en_e4.pdf
- The San Francisco Declaration on Research Assessment (DORA)
<https://sfedora.org/read/>
- Commission Recommendation (EU) 2018/790 of 25 April 2018 on access to and preservation of scientific information <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018H0790&from=EN> CSIC Code of Good Scientific Practice Revised edition, March 2021

Article 8. Final Provisions

8.1 Amendment of the regulations. Amendments to these regulations must be approved unanimously by the CIC and will be reviewed approximately every 5 years.

8.2 Regulatory Gaps: In the event of a situation not covered by these regulations, the committee shall act in accordance with the general principles of law, applicable regulations, and decisions adopted by a simple majority of its members.

8.3 These Regulations shall enter into force on the day of their approval by the CIC.

ANNEX I

Research notebook (basic or clinical) as documentary evidence.

The Research Notebook is the official way to keep a complete record of a researcher's activity for any matter relating to intellectual/industrial property. The notebook is key documented evidence of the researcher's role in the work they are doing. The FIBHGM shall have ownership of the laboratory notebook. Therefore, the research notebook is a key element in determining the authorship of an experiment (who the inventors are) and the percentages of ownership thereof.

The Research Notebook and the information it contains are the property of the FIBHGM, and the PI is the custodian of the notebook and responsible for its filing and preservation.

Instructions for the correct use of the research notebook:

A Research Notebook is a medium for recording research and is therefore used to document hypotheses, experiments and analysis or interpretation of results.

The research notebook should be conceived as a diary in which each and every experiment carried out is recorded, along with any incidents of any kind that may have occurred.

The primary characteristic of a research notebook is that it must clearly and unequivocally state what was done, how it was done, who did it, and when it was done. In addition, it must contain all the information necessary to reproduce the experiment.

Use of research notebooks:

The research notebook must have a permanent binding, i.e. it must be hardback with stitched pages, as this is the only way to remove a page without cutting it out. The pages must be numbered and care must be taken to ensure that each page is correctly dated and signed. The institution must make the notebooks available to researchers.

In general, the notebook must be kept carefully and diligently so that, at any later time, the author or another scientist can repeat any experiment or operation using only the notebook as a guide.

What information should be recorded and how:

- The experimental design must clearly identify and quantify the materials used and their origin, whether commercial, internal or from third parties.
- All results or data observed must be recorded, including negative ones.

Storage and safekeeping of notebooks:

- The notebook must be kept in a secure location (with restricted access to persons not involved in the research) and its safekeeping shall be the responsibility of the PI/group leader or a person delegated by them.
- The PI must keep a record of the notebooks.
- The notebook may be stored for a minimum of 5 years, although it is best to keep it for an unlimited period of time so that it can be used at any time, bearing in mind that the date of validity in terms of protection will be that which appears in the records.
- The information generated must be stored on the FIBHGM network and on a dated, write-protected disc, preferably non-rewritable CDs or DVDs. The disc must be kept in a safe place and referenced in the laboratory notebook. If possible, the disc should be sealed, dated and protected against possible reading by unauthorised persons.