

**INL Research Ethics Committee
STATUTES**

Approved by the plenary session of the INL Research Ethics Committee on 24/02/2022

Article 1. Research Ethics Committee

The Research Ethics Committee ('REC') is a collegiate, permanent, multidisciplinary, independent and consultative body which aims to promote research integrity and to give advice on the ethical, social and legal aspects of research developed in, or supported by, the International Iberian Nanotechnology Laboratory ('INL'), in order to ensure the respect and protection of dignity, fundamental rights, safety, and well-being of the research participants and researchers.

Article 2. Scope of action

The REC exercises its functions with respect to the research developed in the groups of the INL, in research commissioned by Third Parties or in which it participates (European, Spanish or Portuguese funded projects), as well as regarding the activities of the researchers linked to any of these research practices.

Article 3. Affiliation

1. Established at institutional level, the REC is built into the INL, which has to provide technical and administrative support to ensure its functioning.
2. The REC has to provide sufficient information to the INL by issuing regular reports on its activity, at least on an annual basis.
3. In spite of its institutional affiliation, the REC performs its functions with independence and impartiality.
4. The INL should provide the conditions to guarantee the independence of the REC.

Article 4. Composition

1. The REC will have a maximum of nine members who should have scientific expertise or a degree in Social, Health or Natural Sciences or in other disciplines related to research. At least one quarter of them must have professional expertise or specific training on bioethics or research ethics.
2. The composition of the Committee will be multidisciplinary and has to reflect different and complementary backgrounds and, if possible, will include a balanced number of women and men.
3. The REC was created by INL's Council and shall be formed by:
 - five internal members (Research Group Leaders from INL and the Director-General or the Deputy-Director General);
 - three external members appointed by the Specialist entity invited - University of A Coruña;
 - one external member appointed by INL.

Article 5. Functions

1. The REC will perform its functions with independence, autonomy and impartiality.

2. These are functions of the REC:

- a) Report on the ethical correctness of research projects and outcomes.
- b) Prepare reports, proposals and recommendations on ethical issues on request or by its own initiative.
- c) Advise the competent bodies on the ethical aspects related to research.
- d) Promote scientific integrity and respect for research ethics as quality criteria and good professional practice.
- e) Any other related to its purposes that are expressly entrusted to it by the INL.

3. The REC is involved before, during and after the research activity through the evaluation and supervision of the ethical dimension of research, the identification of issues that deserve a specific monitoring, and the approval of the research proposal. In order to implement this, Research Groups must report to the REC a questionnaire that will allow the identification of those aspects that need supervision by REC.

4. The REC should offer a report assessing whether the research proposal is ethically acceptable, it needs some minor amendments or changes, or that it should not be performed without having introduced substantial changes.

5. The report of the REC is mandatory and binding for the performance of any research project within the INL that involves human beings, human embryos, biological samples of human origin, or animals.

6. The REC will base its ethics review of research proposals on widely accepted ethical principles and internal and international human rights hard and soft laws related to biomedical research. Its goal shall be to ensure that the interests, rights, safety and welfare of participants in research prevail over the sole interest of society, science or the institution.

7. While performing the approved research, the researcher has to provide a report if new developments merit a re-evaluation by the Ethics Committee. When the Ethics Committee has determined that regular supervision is necessary, the researcher shall facilitate further supervision and subsequent monitoring.

8. On completion of the research project, the Ethics Committee will check whether the duties of researcher have been fulfilled, especially those related to personal data disclosure and the provision of the expected benefits and guarantees offered to the research subjects.

9. The REC will prepare reports on relevant regulatory and ethical issues related to nanotechnology research and innovation.

10. The REC will assume an educational role and undertake complementary activities to improve the culture of research ethics, such as, training courses, conferences, forums, seminars and workshops, among others.

Article 6. Organic structure

1. The REC is composed of a chairman, a deputy chair and the ordinary members. It also has a secretary, who will attend the meetings as a non-voting external member.

2. The Chair of the Committee will be elected by its members in the plenary session. To be appointed as the chairman, the proposed candidate must have the support of at least two thirds of the members of the Committee.

3. The chairman leads the REC, coordinates and directs the Plenary and the Permanent Commission meetings and arranges their convocation. Both the REC budget and the balance sheet have to be submitted to the INL by the chairman.
4. The deputy chair will be appointed by the Chairman among the REC members. The deputy chair could be commissioned by the chairman to perform specific tasks and will replace him in case of vacancy, absence, illness or any other justified reason.
5. The secretary assumes the registry functions and is responsible for the practical organization of the Committee meetings and its written records. The secretary is appointed by the INL with the consent of the chairman.

Article 7. Appointing and term of office

1. The members of the REC will be appointed and dismissed by the INL for a term of office of three years, which is renewable for one additional term.
2. Committee membership will come to its end on the grounds of resignation, repeated failure of a committee member to fulfil their duties and the completion of the term of office.
3. The status of a REC member is personal and non-transferable.

Article 8. Conflict of interest

REC members should make explicit the activities undertaken by them as well as any circumstances which may create a conflict of interest or could interfere with the performance of their duties in any other way.

Article 9. Confidentiality

REC members ought to maintain as confidential all the matters discussed during the meetings. That duty extends to both the votes cast and the content of the discussion and deliberation process.

Article 10. Convening, discussion and voting

1. The REC meetings will be held through a free deliberative process within a framework of dialogue, open discussion, good faith, confidence and transparency.
2. The REC meetings shall be convened by through the sending of the correspondent Agenda upon at least ten days' notice before the date of the meeting.
3. The REC meetings may be held in in-person meetings, by conference telephone call, video-conference or through similar communications equipment by means of which all members participating in the meeting can communicate with each other, or be of a hybrid nature, meaning some members may be present and other using the electronic means mentioned above.
4. In the case foreseen in the previous paragraph, the resolutions shall be considered as taken in the location in which the Chair is present.
5. The REC will adopt its resolutions at a plenary session, regularly convened, without prejudice to the possibility to adopt unanimous written decisions of its members.
6. The plenary sessions must be held at least on a quarterly basis.
7. Special meetings can be called by the Chair or by the request of five members. At least five (5) days' notice shall be given to all members.

8. Fifty (50) percent of the members shall constitute a quorum for the meeting to be held.
9. If a general agreement has not been achieved, voting shall be the final step of the decision-making process of the REC. The final decision shall be taken by a simple majority of the votes cast of those who are present. The vote of the chairman shall be decisive in case of parity.

Article 11. Working groups

In the plenary sessions, the REC may set up working groups to study specific subjects. In such a case, the composition of the group, its functions and goals must be clearly established.

Article 12. External consultants

External consultants and advisers in a specific area of expertise or for specific matters may be appointed by the REC. They will act as collaborating experts, with voice but without voting rights.

Article 13. Approval and modifications to the Statutes

The approval and subsequent modification of these Statutes must be made by the REC in a plenary session. These decisions must be taken by a majority of 2/3 of the votes cast.

Article 14. Entry into force

The REC Statutes will enter into force the day they are approved by the REC plenary session.