



COMFUTURO ETHICS HANDBOOK

All ComFuturo participants will respect the fundamental ethical principles established by Horizon 2020 (REGULATION (EU) No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC). Specifically, those included in Article 19-Ethical principles: “All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the [Charter of Fundamental Rights of the European Union](#) and the [European Convention on Human Rights and its Supplementary Protocols](#).”

The Spanish National Research Council (CSIC), the organism that hires and hosts the ComFuturo Experienced Researchers, has an **Ethics Committee** with the following functions: reflecting, issuing reports and formulating recommendations about ethical and deontological principles related to research activity. Moreover, due to its assessment function regarding the ethical aspects of research within the CSIC framework, the Ethics Committee plays a very significant role ensuring the warranties tracking and controlling requested within the scientific research activity. Additionally, the Research Ethics Department is the technical and support of the CSIC Ethics Committee and contributes to enhance ethics as a fundamental element of the organizational culture, participating in the design, protocols, dissemination and appliance of tools oriented to reinforce integrity and good practices within the Institution.

Fundación General CSIC (FGCSIC), as the coordinating entity of ComFuturo, will follow a fair ethics management for ensuring that no ethical risks may occur within ComFuturo. Specific procedures and protocols will be followed for each of the phases framed under the project, according to the following project cycle.

FELLOW APPLICATION PHASE:

ComFuturo candidates will have to demonstrate proactively in their proposal that they are aware of, and will comply with, ethical principles and applicable international, European and national law. In order to do so, they will have to point out those ethical issues that will be involved in the development of their proposal. Specifically, candidates must fill in an **Ethics self-assessment form (ANNEX I)** that will be an



integral part of their application. It is the candidates' responsibility to identify any potential ethical issue in order to handle the ethical aspects of the proposal. General guidance to make the proposal ethically compliant can be found at https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf. This guide can help identify ethical issues that may arise from projects, but it is not necessary to provide additional information or documents at this stage.

In the event that the proposal contains sensitive ethics issues (as specified by checking any of the boxes in the 'ethics self-assessment form'), candidates must also sign a **Declaration of responsibility (ANNEX II)**, by which they acquire the commitment that, in the case of resulting proposed as ComFuturo fellows, they must submit, within 10 calendar days of receiving the communication, a formal request to the CSIC Ethics Committee for an ethical evaluation of their proposed project. The procedure for this request and the evaluation will be duly delivered to the selected fellows.

FELLOW SELECTION & EVALUATION PHASE:

During this phase, it will be verified that the candidates have correctly filled out the ethics self-assessment form and, where appropriate, the Declaration of responsibility mentioned previously. These aspects will be mandatory to consider eligible proposals to go through the evaluation and selection process. Later, after these mandatory phases, those candidatures proposed for funding as ComFuturo projects must comply with what was signed in the Declaration of responsibility: that is, within 10 calendar days after the communication by FGCSIC of having been selected for funding, they must request the ethical evaluation of their projects, according to the procedure that will be indicated to them at that time and which is summarized as follows:

- The CSIC Ethics Committee will provide specific instructions for the application for ethical assessment of research carried out within the CSIC. These instructions indicate, first of all, that "all research activity carried out in the scope of CSIC that involves the participation of human beings, the handling of their samples or data that require protection, the use of animals, Genetically Modified Organisms or biological agents of risk for humans, animals, plants and / or the environment, must be favorably evaluated by CSIC's Ethics Committee prior to its start,



regardless of the framework in which it is carried out (project, research contract, collaboration agreement, ...) and regardless of whether or not it is a funded activity”.

- Regarding the ethics evaluation procedure, ComFuturo candidates must send to the Research Ethics Department, as a support unit of CSIC Ethics Committee, the evaluation request form corresponding to the specific characteristics of their research, according to the models provided for CSIC (two models are available: a specific one for the request for evaluation of animal experimentation projects and another one for the request for bioethics / biosafety evaluation - Research with humans, samples and / or human data that require protection / Genetically Modified Organisms / Biological risk agents).
- Once the Ethics Department receives the request, it conducts an exhaustive formal and content review, in order to verify that the applicant has duly completed the request form, provided the information and accompanied the documentation required in the institutional instructions, depending on the research category in question. Once the application has been reviewed, and prior to submitting it for evaluation to the evaluators who collaborate with CSIC Ethics Committee, the Department verifies that, indeed, the applicant has met all the requirements and, if so, formalizes the acknowledgment of receipt of the evaluation request, which is signed by the secretary of CSIC Ethics Committee.
- Subsequently, once all the necessary information and documentation required in the instructions issued for the ethical evaluation of the CSIC research is available, the evaluators (specializing in the subject of the research whose evaluation is requested) are selected. All the evaluators have previously signed a confidentiality commitment and a declaration of responsibility for the absence of conflicts of interest and for not being involved in any of the abstention or objection causes. If the evaluators give a favourable opinion (there are projects that include research of a different nature and require evaluation by different experts, in cases, up to 5 different ones), CSIC Ethics Committee issues the corresponding favourable evaluation report, which is signed by the President of the Committee, and transfers it to the applicant. However, if necessary, the applicant is required to attend to the observations and comments made by the evaluators and when the Department receives the modified documentation, it is sent back to the evaluators. This scheme is repeated as many times as necessary until everything is satisfied and the favourable evaluation report is issued.



In conclusion, no research involving any ethics issue will be initiated before having obtained the corresponding approval from the CSIC's Ethics Committee and any additional authorisations that might be applicable to the particular case considered. Copies of the corresponding documents will be kept on file and made available upon request.

In the event any research project selected for funding may involve the use of human embryonic stem cells (hESC) or human embryos (hE), the FGCSIC shall inform the Research Executive Agency (REA) and relevant procedure involving European Commission Ethics review will be initiated. That project will not be able to start before that clearance.

Regarding the issue of protection of Personal Data, the corresponding research activities will be performed in full compliance with the General Data Protection Regulation and related national legislation. Details on the CSIC's Data Protection Officer will be made available to all data subjects involved in the corresponding research.

PROJECT IMPLEMENTATION & MONITORING PHASE:

For the entire project duration, CSIC Ethics Committee will be overseeing the ethics management process. However, it is important to note that once CSIC Ethics Committee issues the favourable evaluation report, the applicant is indicated as a fundamental issue that the ethics evaluation has been carried out in accordance with the information and documentation provided, so that he/she must commit to communicate to CSIC Ethics Committee, without delay, any significant modification in the research work programme that might require a new evaluation.

Any questions or queries that candidates may have in any of these phases, may be sent to the email comitedetica@csic.es. Likewise, in this link, <https://www.csic.es/en/csic/scientific-integrity-and-ethics-csic/csic-ethics-committee> the contact persons of the CSIC Research Ethics Department are identified, which is the technical and legal support unit of the Committee, together with their contact telephone numbers.



FELLOW TRAINING PHASE:

Once the ComFuturo projects have started, FGCSIC will offer all fellows 12 hours of training on responsible conduct of research, which includes topics such as *Research Ethics*, *Research Integrity* and *Research misconduct and other unacceptable research practices*. In addition, CSIC Ethics Committee offers two annual editions of a course on scientific integrity and research ethics.

ADDITIONAL INFORMATION

This document is completed with important additional information such as

- Documentary production of the CSIC Ethics Committee can be found in this link <https://www.csic.es/en/csic/scientific-integrity-and-ethics-csic/scientific-integrity-and-good-practises>, such as CSIC Code of Good Scientific Practices, the CSIC Manual of Conflicts of Interest and the National Statement on Scientific Integrity.
- This link <https://www.csic.es/en/csic/scientific-integrity-and-ethics-csic/ethics-in-research> includes the areas of action of the Committee in matters of ethics evaluation and all the applicable regulations.
- Once the ComFuturo fellows are hired by CSIC, they will be able to find, on the CSIC intranet, the procedure for the treatment of deviations from good scientific practices and violations of scientific integrity, defined and approved in plenary session by CSIC Ethics Committee.



ANNEX I

Ethics self-assessment form

1_HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO	
Does your activity involve Human Embryonic Stem Cells (hESCs)?		<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Will they be directly derived from embryos within this project?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they previously established cells lines?	<input type="checkbox"/>	<input type="checkbox"/>
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve the use of human embryos?		<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Will the activity lead to their destruction?	<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve the use of other human embryonic or foetal tissues / cells?		<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		<input type="checkbox"/>	<input type="checkbox"/>
2_HUMANS		YES/NO	
Does your activity involve human participants?		<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Are they volunteers?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they healthy volunteers for medical studies?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they patients for medical studies?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they potentially vulnerable individuals or groups?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they children/minors?	<input type="checkbox"/>	<input type="checkbox"/>
	Are there other persons unable to give informed consent?	<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?		<input type="checkbox"/>	<input type="checkbox"/>



If YES:	Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)?		<input type="checkbox"/>	<input type="checkbox"/>
	Does it involve collection of biological samples?		<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)?			<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Is it a clinical trial?		<input type="checkbox"/>	<input type="checkbox"/>
	Is it a low-intervention clinical trial?		<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			<input type="checkbox"/>	
3_HUMAN CELLS / TISSUES			YES/NO	
Does your activity involve the use of human cells or tissues?			<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Are they human embryonic or foetal cells or tissues?		<input type="checkbox"/>	<input type="checkbox"/>
	Are they available commercially?		<input type="checkbox"/>	<input type="checkbox"/>
	Are they obtained within this project?		<input type="checkbox"/>	<input type="checkbox"/>
	Are they obtained from another project, laboratory or institution?		<input type="checkbox"/>	<input type="checkbox"/>
	Are they obtained from a biobank?		<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			<input type="checkbox"/>	
4_PROTECTION OF PERSONAL DATA			YES/NO	
Does your activity involve processing of personal data?			<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Does it involve the processing of special categories of personal data (e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?		<input type="checkbox"/>	<input type="checkbox"/>
	If YES:	Does it involve processing of genetic, biometric or health data?	<input type="checkbox"/>	<input type="checkbox"/>
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?		<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)?			<input type="checkbox"/>	<input type="checkbox"/>



Is it planned to export personal data (data transfer) from the EU to non-EU countries? <i>Specify the type of personal data and countries involved:</i>		<input type="checkbox"/>	<input type="checkbox"/>
Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non- EU country to another non-EU country? <i>Specify the type of personal data and countries involved:</i>		<input type="checkbox"/>	<input type="checkbox"/>
Does your activity involve the processing of personal data related to criminal convictions or offences?		<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		<input type="checkbox"/>	<input type="checkbox"/>
5_ANIMALS			YES/NO
Does your activity involve animals?		<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Are they vertebrates?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they genetically modified?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they cloned farm animals?	<input type="checkbox"/>	<input type="checkbox"/>
	Are they an endangered species?	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		<input type="checkbox"/>	<input type="checkbox"/>
6_THIRD COUNTRIES			YES/NO
Will some of the activities be carried out in non-EU countries? <i>Specify the countries:</i>		<input type="checkbox"/>	<input type="checkbox"/>
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? <i>Specify the countries:</i>		<input type="checkbox"/>	<input type="checkbox"/>



I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		<input type="checkbox"/>	
7_ENVIRONMENT, HEALTH AND SAFETY		YES/NO	
Does this activity involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?		<input type="checkbox"/>	<input type="checkbox"/>
Does this activity deal with endangered fauna and/or flora / protected areas?		<input type="checkbox"/>	<input type="checkbox"/>
Does this activity involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, or the deployment of the technology as a possible impact)?		<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		<input type="checkbox"/>	
8_ARTIFICIAL INTELLIGENCE		YES/NO	
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?		<input type="checkbox"/>	<input type="checkbox"/>
Could the AI based system/technique potentially stigmatise or discriminate against people (e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)?		<input type="checkbox"/>	<input type="checkbox"/>
Does the AI system/technique interact, replace or influence human decision-making processes (e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)?		<input type="checkbox"/>	<input type="checkbox"/>
Does the AI system/technique have the potential to lead to negative social (e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance) and/or environmental impacts either through intended applications or plausible alternative uses?		<input type="checkbox"/>	<input type="checkbox"/>
Does this activity involve the use of AI in a weapon system?		<input type="checkbox"/>	<input type="checkbox"/>
If YES:	Is it possible to establish which specific function/functions are automated/autonomous in the weapon system?	<input type="checkbox"/>	<input type="checkbox"/>
	If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate?	<input type="checkbox"/>	<input type="checkbox"/>
	Does the design include the possibility of an autonomous mode for self-protection? If yes, can the system reliably distinguish between targets (threats) and non-targets?	<input type="checkbox"/>	<input type="checkbox"/>
	If YES:	Can the system reliably distinguish between targets (threats) and non-targets?	<input type="checkbox"/>



Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above (e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	<input type="checkbox"/>	
9_OTHER ETHICS ISSUES	YES/NO	
Are there any other ethics issues that should be taken into consideration? <i>Please specify:</i>	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	<input type="checkbox"/>	
10_CROSSCUTTING ISSUE: POTENTIAL MISUSE OF RESULTS		
Does your research have activities that involve or generate materials, methods, technologies or knowledge that could be misused for unethical purposes?	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	<input type="checkbox"/>	
11_DUAL USE	YES/NO	
Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	<input type="checkbox"/>	
12_EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	YES/NO	
Could your research raise concerns regarding the exclusive focus on civil applications?	<input type="checkbox"/>	<input type="checkbox"/>
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	<input type="checkbox"/>	



ANNEX II

Declaration of responsibility

Mr. / Mrs. (applicant's name and surname) with Identification Number (Passport / ID), as an applicant for the ComFuturo third edition call (ComFuturo-COFUND Fellowship Programme) declares that:

Related to his/her proposed research proposal (title of proposed project), he/she has **filled in the Ethics Self-Assessment template for ComFuturo, having checked as YES ethical issues concerning (select those applicable):**

- | | |
|---|--------------------------|
| 1. Human embryonic stem cells (hESCs) and human embryos | <input type="checkbox"/> |
| 2. Humans | <input type="checkbox"/> |
| 3. Human cells or tissues | <input type="checkbox"/> |
| 4. Personal data | <input type="checkbox"/> |
| 5. Animals | <input type="checkbox"/> |
| 6. Non-EU countries | <input type="checkbox"/> |
| 7. Environment, health and safety | <input type="checkbox"/> |
| 8. Artificial intelligence | <input type="checkbox"/> |
| 9. Other ethics issues | <input type="checkbox"/> |
| 10. Crosscutting issue: potential misuse of results | <input type="checkbox"/> |
| 11. Dual use | <input type="checkbox"/> |

He/she undertakes, in case of resulting proposed as a ComFuturo fellow, to submit, within 10 calendar days of receiving the communication, **a formal request to CSIC Ethics Committee (comitedeetica@csic.es) for an ethical evaluation of his/her proposed project.** No research involving any ethics issue will be initiated before having obtained the corresponding approval from the CSIC Ethics Committee and any additional authorisations that might be applicable to the particular case considered.

Date:

The contact persons of the CSIC Research Ethics Department, which is the technical and support unit of the Committee, are identified in this [link](#), together with their contact telephone numbers.

The digital signature of the applicant must be included in the PDF file to be uploaded in the application online form.