ComFuturo iAGE (IV Edition) Call
Ethics Handbook

All ComFuturo participants will respect the fundamental ethical principles established by the HE Framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19) and the HE Specific Programme Decision 2021/764. Accordingly, (Article 19), 'Actions carried out under the COMFUTURO iAGE shall comply with ethical principles and relevant Union, national 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 legal support unit of the CSIC Ethics Committee and contributes to enhance the strengthening of 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 iAGE, will follow a fair ethics management for ensuring that no ethical risks may occur within ComFuturo iAGE. 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 iAGE candidates must proactively demonstrate 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 undertake that, if they are selected as ComFuturo Fellows, they will submit a formal request —by sending an email to the CSIC Ethics Committee (comitedeetica@csic.es)— for an ethical evaluation of their proposed project within 10 calendar days of receiving the notification.

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 applicable, the Declaration of responsibility mentioned above. These aspects will be mandatory in order to consider the proposals eligible to go through the evaluation and selection process. Subsequently, 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 of the communication by the FGCSIC that they have 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 their commence, regardless of the framework in which it is carried out (project, research contract, collaboration agreement, ...) and regardless of whether they are funded or not".

- 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 evaluation of ethics / biosafety - research involving humans, samples and / or human data that require protection / genetically modified organisms / biological risk agents). Models of informed consent forms are also available.
- Upon receipt of the application, the Ethics Department carries out a thorough, formal and substantive review to verify that the applicant has duly completed the application form, provided the information and attached the documents required by the institutional instructions, depending on the category of research in question. After reviewing the application and before submitting it for evaluation to the experts collaborating with the 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 application for evaluation, signed by the Secretary of the CSIC Ethics Committee.
- Then, once all the necessary information and documents required in the instructions issued for the ethical evaluation of the CSIC research is available, the evaluators (specialized 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 grounds of abstention or objection. If the evaluators give a favourable opinion (there are projects that include research of a different nature and require evaluation by different experts, in some cases up to 5 different ones), the CSIC Ethics Committee issues the corresponding favourable evaluation report, which is signed by the Chairman of the Committee, and sends it to the applicant. However, if necessary, the applicant is obliged to attend to the observations and comments made by the evaluators and when the Department receives the amended documentation, it is sent back to the evaluators. This

procedure is repeated as many times as necessary until everything is satisfactory 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 under consideration. 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:

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

Any questions or requests that candidates may have during any of these phases, can be sent to the e-mail address comitedeetica@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 13 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, the CSIC Ethics Committee offers two annual editions of a course on scientific integrity and research ethics.

ADDITIONAL INFORMATION

This document is supplemented with important additional information such as

- Documents produced by the CSIC Ethics Committee can be found at this link https://www.csic.es/en/csic/research-integrity-and-ethics-at-the-csic/research-integrity-and-good-scientific-practices, such as the 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 employed by the 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, as defined and approved in plenary session by the 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)?		☐	☐
If **YES:**	Will they be directly derived from embryos within this project?	☐	☐
	Are they previously established cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines?	☐	☐
Does your activity involve the use of human embryos?		☐	☐
If **YES:**	Will the activity lead to their destruction?	☐	☐
Does your activity involve the use of other human embryonic or foetal tissues / cells?		☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		☐	
2_HUMANS		**YES/NO**	
Does your activity involve human participants?		☐	☐
If **YES:**	Are they volunteers?	☐	☐
	Are they healthy volunteers for medical studies?	☐	☐
	Are they patients for medical studies?	☐	☐
	Are they potentially vulnerable individuals or groups?	☐	☐
	Are they children/minors?	☐	☐
	Are there other persons unable to give informed consent?	☐	☐
Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?		☐	☐

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.)?	☐	☐
	Does it involve collection of biological samples?	☐	☐
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)?		☐	☐
If **YES:**	Is it a clinical trial?	☐	☐
	Is it a low-intervention clinical trial?	☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		☐	
3_HUMAN CELLS / TISSUES		**YES/NO**	
Does your activity involve the use of human cells or tissues?		☐	☐
If **YES:**	Are they human embryonic or foetal cells or tissues?	☐	☐
	Are they available commercially?	☐	☐
	Are they obtained within this project?	☐	☐
	Are they obtained from another project, laboratory or institution?	☐	☐
	Are they obtained from a biobank?	☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		☐	
4_PROTECTION OF PERSONAL DATA		**YES/NO**	
Does your activity involve processing of personal data?		☐	☐
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)?	☐	☐
	If **YES:** Does it involve processing of genetic, biometric or health data?	☐	☐
	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.)?	☐	☐
Does your activity involve further processing of previously collected		☐	☐

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

It is planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	☐	☐
Is it planned to import any material (other than data) from non-EU countries into the or from a non-EU country to another non-EU country? For data imports, see section 4	☐	☐
Is it planned to export any material (other than data) from the EU to non-EU countries? For data imports, see section 4	☐	☐
Does this activity involve low and/or lower middle income countries?	☐	☐
Could the situation in the country put the individuals taking part in the activity at risk?	☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	☐	
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**)?**	☐	☐
Does this activity deal with endangered fauna and/or flora / protected areas?	☐	☐
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**)?**	☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	☐	
8_ARTIFICIAL INTELLIGENCE	**YES/NO**	
Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?	☐	☐
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**)?**	☐	☐
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**)?**	☐	☐
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?**				
Does this activity involve the use of AI in a weapon system?			☐	☐
If **YES:**	Is it possible to establish which specific function/functions are automated/autonomous in the weapon system?		☐	☐
	If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate?		☐	☐
	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?		☐	☐
	If **YES:**	Can the system reliably distinguish between targets (threats) and non-targets?	☐	☐
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.**)?**			☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			☐	
9_OTHER ETHICS ISSUES			**YES/NO**	
Are there any other ethics issues that should be taken into consideration? *Please specify:*			☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			☐	
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?			☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL			☐	
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?			☐	☐

I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	☐	
12_EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	**YES/NO**	
Could your research raise concerns regarding the exclusive focus on civil applications?	☐	☐
I CONFIRM THAT **NONE** OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	☐	

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ANNEX II
Ethics Declaration of Responsibility

Mr. / Mrs. …… (applicant's name and surname) with Identification Number …… (Passport / ID), as an applicant for the ComFuturo iAGE call (ComFuturo iAGE-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 Form for ComFuturo iAGE, having marked YES for the following ethical issues concerning** *(as applicable):*

1. Human embryonic stem cells (hESCs) and human embryos	☐
2. Humans	☐
3. Human cells or tissues	☐
4. Personal data	☐
5. Animals	☐
6. Third countries	☐
7. Environment, health and safety	☐
8. Artificial intelligence	☐
9. Other ethics issues	☐
10. Crosscutting issue: potential misuse of results	☐
11. Dual use	☐
12. Exclusive focus on civil applications	☐

He/she undertakes, if selected 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.

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