Research Integrity Committees Organoid Proposal checking (RicOCheck)

Checklist for
Research integrity offices (RIOs)
Research integrity committes (RICs) and
Research ethical committees (RECs)

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Table of shared values

	Researcher	Evaluator	institution	Citizen/patient
Researcher / Physician	Reliability Honesty Transparency	Honesty Reliability Transparency Respect Responsibility	Honesty Reliability Transparency Respect responsibility	Physical, moral and Social well-being Respect for privacy Honesty
Evaluator	Equity (fairness) Transparency Respect Responsibility	**shared principles for evaluation** Benevolence Non-malevolence Autonomy Justice	Transparence Responsibility respect	Honesty
Institution	**Commitment of the institution** Transparency honesty Responsibility	Respect Responsibility Transpareny	Openness	Physical, moral and social well-being Honesty
Citizen & Patients	Consent	Consent	Consent	Consent Honesty

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Definitions

- **Transparency :**
  - *From Evaluator to institution*: evaluation procedures proposed by the evaluator and validated by the Institution.
  - *From Institution to evaluator*: feedback to the evaluator on the use of the evaluation work
  - *From Institution to researcher*: the rules of governance are clearly defined so that researchers can assess their constraints on freedom of research and expression, and know the scientific arbitration procedures (choice of priority themes), within a constrained budget
  - *From researcher to institution*: the aims of the research are clearly stated

- **Respect**:
  - *From Institution to evaluator*: acceptance and use of evaluation results
  - *From Institution to researcher*: clear statement of the rules in force,

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Definitions

- **Responsibility (accountability)**
  - *From the evaluator to the institution*: anticipating the impacts of the evaluation on the functioning of the institution (e.g., suffering at work)
  - *From the institution to the evaluator*: provide the means to carry out the evaluation according to the defined principles, avoid paradoxical injunctions (DORA versus bibliometric index).
  - *From the institution to the researcher*: working conditions that allow researchers to develop honest, loyal and responsible research, in a collaborative rather than competitive framework.

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Definitions

- **Openness**:
  - *From institution to institution*: commitment to open science (open access, open data -FAIR- open methodologies and protocols) and promotion of interdisciplinarity, multidisciplinarity and transdisciplinarity

- **Honesty:**
  - *From institution to researcher* (equity/fairness): independence from any relationship or conflict of interest. Procedure for managing referees is made explicit. Procedure for managing links and conflicts of interest are defined

- **Reliability** :
  - *From the researcher to the institution*/citizen: commitment to publish raw data in an open access FAIR mode

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Elements for Review by international boards (RECs, RIOs …)

Horizon 2020 Programme Guidance: How to complete your ethics self-assessment

10 sections	
1: Human embryos and foetuses	**6: Dual use**
2: Human subjects	**7: Third countries (non EU)**
3: Human cells, tissues, organoids	**8: Exclusive focus on civil applications**
4: **Personal data**	**9: Misuse**
5: Animals / Chimeras	**10: other ethics issues**

https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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Elements for Review by international boards (RECs, RIOs …)

Horizon 2020 Programme Guidance: How to complete your ethics self-assessment

10 sections	
1: Human embryos and foetuses 2 questions, 4 subquestions, 4 answers on plain paper requested	**6: Dual use** 1 question, 3 subquestions, 3 answers on plain paper requested
2: Human subjects 2 questions, 8 subquestions, up to 13 documents requested: 1 legal document and 12 answers on plain paper	**7: Third countries (non EU)** 6 questions, 5 subquestions, 4 answers on plain paper requested
3: Human cells, tissues, organoids 4 questions, 10 subquestions, up to 7 documents requested: 4 legal documents and 3 answers on plain paper	**8: Exclusive focus on civil applications** 1 question no subquestions (should there be one?)
4: **Personal data** 2 questions, 10 subquestions, up to 10 answers on plain paper requested	**9: Misuse** 1 question, 3 subquestions, three documents :2 answers on plain paper, one legal document requested
5: Animals / Chimeras 10 questions, 12 subquestions, up to 13 answers on plain paper requested	**10: other ethics issues** 1 question, 1 answer on plain paper requested (if yes)

Q2: do we need all the requested documents?

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Open questions

- **The original ethics self-assessment from contain 11 sections. N°11 deals with evironmental issues**
  - Does your research involve the use of elements that may cause harm to the environment, to animals or plants?
  - Does your research deal with endangered fauna and/or flora /protected areas?
- **How to make the questionnaire less of a chore i.e.**
  - **Are all RicOCheck items required?**
  - **What are the essential items?**
  - **Are all RicOCheck requested documents necessary**
- **Should recommendations be attached?**
- **Should examples be presented?**

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Project title		
Global purpose of the project		Summarize
Are there ethical issues raised by your expected results?	Yes/No	Explain

Section 1: HUMAN EMBRYOS / FOETUSES		Yes/No
Does your research involve the use of human embryos?		Yes/No
If yes	Provide origin of the embryos.	
	Provide details of the recruitment, of the inclusion and exclusion criteria, of the procedure for obtaining informed consent.	
	Confirm that oral information has been provided and that informed consent has been obtained.	
	Will the research lead to the destruction of the embryo?	
Does your research involve the use of human fetal tissues/cells?		Yes/No
If yes	Provide the origin of human fetal tissues/cells.	
	Provide details of the procedure for obtaining informed consent.	
	Confirm that oral information has been provided and that informed consent has been obtained.	
Compliance: brief description of compliance procedures, upload requested documents.		

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Sections 2: HUMAN SUBJECTS		Yes/No
Does your research involve human subjects?		Yes/No
If yes	Are they volunteers for social or human sciences research?	
	Are they healthy volunteers for medical studies?	
	Are they patients?	
	Are they vulnerable individuals or groups?	
	Are they persons unable to give informed consent?	
	Are they children/minors?	
	Provide details of the procedure for obtaining informed consent.	
	Confirm that oral information has been provided and that informed consent has been obtained.	
Does the research involve physical interventions on the study participants?		Yes/No
If yes	Does it involve invasive techniques?	
	Does it involve collection of biological samples?	
	Please describe risk assessment for each technique and overall.	
	What type of samples will be collected?	
	What are the procedures for collecting samples?	
	Please add copies of ethics approval.	
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Section 3: HUMAN CELLS/TISSUES/ORGANOIDS		Yes/No
Does the research involve human cells or tissues or organoids (other than from human embryos/fetuses, i.e. section above)?		Yes/No
If yes	Provide details of the cells, tissue type	
	Provide copies of relevant ethics approval	
	Provide accreditation/designation/authorization/licensing for using cells or tissues (if required).	
	Are they available commercially?	Yes/No
If yes	Details of the provider.	
	Are they obtained within this project?	Yes/No
	Copies of import license.	
If yes	Details on the source of material and procedure of collection.	
	Details on the duration of storage and of what you will do with the material at the end of the project.	
	Confirm that oral information has been provided and that informed consent has been obtained.	
	Are they obtained from another project, laboratory, institution or biobank?	Yes/No
If yes	Country where the material is stored.	
	Details of the legislation under which material is stored.	
	Details on the duration of storage and of what you will do with the material at the end of the project.	
	Name and country of the laboratory/institution/biobank.	
	Confirmation that the material is anonymized.	
	Confirmation that a secondary use is obtained in the consent.	
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Section 4: PERSONAL DATA		Yes/No
Does the research involve personal data collection and/or processing?		Yes/No
If yes	Details on the technical organizational measures to safeguard the rights of the research participants (protection policy).	
	Details of the procedure for obtaining informed consent.	
	Details of the security measures to prevent unauthorized access to personal data.	
	How is the processed data relevant and limited to the purposes of the project (data minimization principle)?	
	Details of the anonymization/pseudonymization techniques.	
	Justification if research data will not be anonymized/pseudonymized (if relevant).	
	Details or data transfers and countries to which they are transferred.	
Does the research involve further processing of previously collected personal data (secondary use)?		Yes/No
If yes	Details of the database used or source of data.	
	Details of the data processing operations.	
	How will the rights of the participants be safeguarded? Please explain.	
	How is the processed data relevant and limited to the purposes of the project (data minimization principle)?	
	Justification if the research data will not be anonymized/pseudonymized (if relevant).	
Compliance: brief description of compliance procedures, upload requested documents.		

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Section 5: ANIMALS/ CHIMERAS		Yes/No
Does the research involve animals?		Yes/No
If yes	Details of the species and rationale for their use, number of animals, nature of the experiments, procedures and techniques.	
	Justification of animal use (including the kind of animals) and why alternatives cannot be used.	
Are the animal vertebrates?		Yes/No
Are they non-human primates (NHP)?		Yes/No
If yes	Why are the NHPs the only research subjects suitable for achieving the scientific objectives?	
	What is the purpose of the animal testing? Please give details	
	Where do the animals come from?	
Are they genetically modified or cloned animals?		Yes/No
If yes	Details of the phenotype and any inherent suffering expected.	
	What scientific justification is there for producing such animals?	
	What measurement will you take to minimize suffering in breeding, maintaining colonies and using the GOMs?	
Are they endangered species?		Yes/No
If yes	Why is there no alternative to using this species?	
	What is the purpose of the research?	
Does the research involve chimeras?		Yes/No
Are the chimera human-animal?		Yes/No
If yes	What scientific justifications are there for producing such chimeric animals?	
Are the recipient non-human primates?		Yes/No
If yes	Why are the NHPs the only research subjects suitable for achieving the scientific objectives?	
Are the recipient genetically modified or cloned animals?		Yes/No
If yes	What scientific justification is there for producing such animals?	
Are the recipient endangered species?		Yes/No
Compliance: brief description of compliance procedures, upload requested documents.		

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Section 6: DUAL USE		Yes/No
Does the research involve dual use items in the sense of regulation 2021/821 or other items for which au authorization is required?		Yes/No
If yes	What goods and information used and produced in the research will need export license?	
	How exactly will you ensure compliance?	
	How exactly will you avoid negative implications?	
Compliance: brief description of compliance procedures, upload requested documents.		

Council Regulation (EC) No 428/2009 has been abrogated and replaced by regulation 2021/821 in 2021 control of the export, transfer, transit and brokering of dual-use items

Dual-use goods are goods and technologies that can be used for both civilian and military purposes

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Section 7: THIRD COUNTRIES		Yes/No
In case of non-EU countries are involved, do the research-related activities undertaken in these countries raise potential ethics issues?		Yes/No
If yes	Risk-benefit analysis?	
	What activities are carried out in non-EU countries?	
Are local resources planned to be used (animals, tissue samples, genetic material, endangered fauna)?		Yes/No
If yes	What type of local resources will be used and how exactly?	
Do you plan to import any material -including personal data- from non-EU countries?		
If yes	What type of materials will you import?	
Do you plan to export any material -including personal data- from EU-contries to non-EU countries?		Yes/No
In case the research involves low- or middle-income countries, are any benefits-sharing actions planed?		Yes/No
Could the situation in the country put the individuals taking part in the research at risk?		Yes/No
Compliance: brief description of compliance procedures, upload requested documents.		

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Section 8: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS		
Could the research raise concerns regarding the exclusive focus on civil applications?		Yes/No
Section 9: MISUSE		
Does the research have the potential for misuse of research results?		Yes/No
	Risk assessment	
	Details of the applicable legal requirements	
	Details of the measures to prevent misuse	
Compliance: brief description of compliance procedures, upload requested documents.		
Section 10: OTHER ETHICS ISSUES		
Are there any other ethics issues that should be taken into consideration? Please specify.		Yes/No
Compliance: brief description of compliance procedures, upload requested documents.		

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