Research Integrity Committees Organoid Proposal checking (RicOCheck)

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

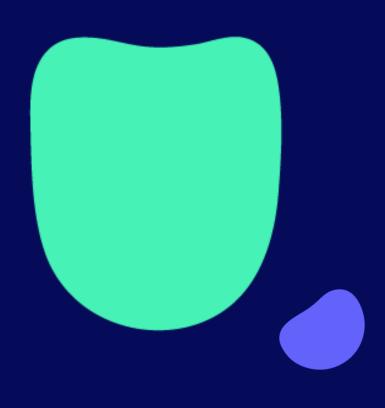






Table of shared values

	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





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,





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.





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





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





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

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

6: Dual use 1 question, 3 subquestions, 3 answers on plain paper requested
7: Third countries (non EU) 6 questions, 5 subquestions, 4 answers on plain paper requested
8: Exclusive focus on civil applications 1 question no subquestions (should there be one?)
9: Misuse 1 question, 3 subquestions, three documents :2 answers on plain paper, one legal document requested
10: other ethics issues 1 question, 1 answer on plain paper requested (if yes)

Q2: do we need all the requested documents?





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?

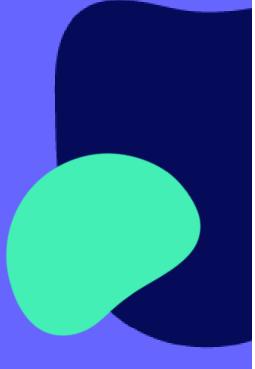
Should examples be presented?





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

oes your res	earch involve the use of human embryos?	Yes/No
	Provide origin of the embryos.	
	Provide details of the recruitment, of the inclusion and exclusion	
If yes	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?	
oes your res	earch involve the use of human fetal tissues/cells?	Yes/No
	Provide the origin of human fetal tissues/cells.	
If yes	Provide details of the procedure for obtaining informed consent.	
	Confirm that oral information has been provided and that informed consent has been obtained.	





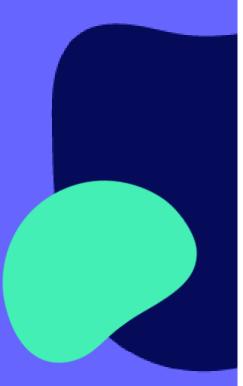


	MAN SUBJECTS	Yes/No
Does your rese	earch involve human subjects?	Yes/No
	Are they volunteers for social or human sciences research?	
	Are they healthy volunteers for medical studies?	
	Are they patients?	
If yes	Are they vulnerable individuals or groups?	
	Are they persons unable to give informed consent?	
	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 resea	arch involve physical interventions on the study participants?	Yes/No
	Does it involve invasive techniques?	
	Does it involve collection of biological samples?	
	Please describe risk assessment for each technique and overall.	
If yes	What type of samples will be collected?	
	What are the procedures for collecting samples?	
	Please add copies of ethics approval.	





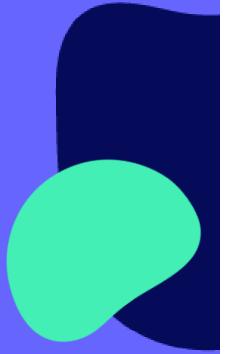
Section 3: HUN	MAN CELLS/TISSUES/ORGANOIDS	Yes/No
Does the resea	arch involve human cells or tissues or organoids (other than from	Yes/No
human embry	os/fetuses, i.e. section above)?	
	Provide details of the cells, tissue type	
If yes	Provide copies of relevant ethics approval	
	Provide accreditation/designation/authorization/licensing 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.	
	Details on the source of material and procedure of collection.	
If yes	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	Yes/No
	or biobank?	
	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	
lf yes	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.	







ection 4: PER	SONAL DATA	Yes/No
oes the resea	arch involve personal data collection and/or processing?	Yes/No
	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)?	
If yes	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.	
oes the resea econdary us	arch involve further processing of previously collected personal data e)?	Yes/No
	Details of the database used or source of data.	
If yes	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	







Section 5: ANIN	/IALS/ CHIMERAS	Yes/No
Does the resea	rch involve animals?	Yes/No
	Details of the species and rationale for their use, number of	
	animals, nature of the experiments, procedures and techniques.	
If yes	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
	Why are the NHPs the only research subjects suitable for	
	achieving the scientific objectives?	
If yes	What is the purpose of the animal testing? Please give details	
	Where do the animals come from?	
Are they genet	ically modified or cloned animals?	Yes/No
	Details of the phenotype and any inherent suffering expected.	
	What scientific justification is there for producing such animals?	
If yes	What measurement will you take to minimize suffering in	
	breeding, maintaining colonies and using the GOMs?	
Are they endar	ngered species?	Yes/No
If yes	Why is there no alternative to using this species?	
	What is the purpose of the research?	6
Does the resea	rch involve chimeras?	Yes/No
Are the <mark>chimer</mark>	a human-animal <mark>?</mark>	Yes/No
lf y <mark>e</mark> s	What scientific justifications are there for producing such chimeric animals?	
Are the recipie	nt non-human primates?	Yes/No
If yes	Why are the NHPs the only research subjects suitable for	
	achieving the scientific objectives?	
Are the recipie	nt genetically modified or cloned animals?	Yes/No
If yes	What scientific justification is there for producing such animals?	
Are the recipie	nt endangered species?	Yes/No
Compliance: br	ief description of compliance procedures, upload requested documents	s.







oes the resea	arch involve dual use items in the sense of regulation 2021/821 or	Yes/No
other items fo	r which au authorization is required?	
	What goods and information used and produced in the research	
If yes	will need export license?	
	How exactly will you ensure compliance?	
	How exactly will you avoid negative implications?	

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





Section 7: THIR	D COUNTRIES	Yes/No
	EU countries are involved, do the research-related activities 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 countries?	import any material -including personal data- from non-EU	
If yes	What type of materials will you import?	
Do you plan to non-EU countr	export any material -including personal data- from EU- <u>contries</u> to ies?	Yes/No
In case the reso sharing actions	earch involves low- or middle-income countries, are any benefits- s planed?	Yes/No
Could the situa risk?	ntion in the country put the individuals taking part in the research at	Yes/No





application	esearch raise concerns regarding the exclusive focus on civil s?	Yes/No
Section 9: N		
Does the re	esearch 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	e: brief description of compliance procedures, upload requested document	ts.
Section 10:	OTHER ETHICS ISSUES	
Are there a	ny other ethics issues that should be taken into consideration? Please	Yes/No



