







RESEARCH & INNOVATION

PROGRAMME 2021 – 27



Session 7: Horizontal Issues – IPR, RRI, Ethics, Open Science



Intellectual Property Rights - IPR





Intellectual Property rules

The IP rules in Horizon Europe can be found in:

- the Rules for Participation
- the (model) Grant Agreement
- the applicable work programme
- Online Manual(IP section is a work in progress)

How to find them: Funding & Tenders Portal

https://ec.europa.eu/info/fundingtenders/opportunities/portal/screen/how-to-participate/referencedocuments



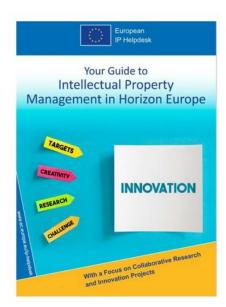
Intellectual Property Guide – by IPR Helpdesk

https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/ip-guides_en



IP guides

Our IP Guides provide you with comprehensive overviews on specific fields of intellectual property rights (IPR) and IP management, including practical tips and further resources.



Your Guide to Intellectual Property Management in Horizon Europe

This guide aims to spotlight critical aspects and novelties related to Intellectual Property (IP) management in the context of collaborative research and innovation projects funded under the European Union's current Framework Programme for Research and Innovation "Horizon Europe" (2021-2027). It does not claim to be exhaustive. The IP rules of Horizon Europe are built to a large extent on the regulations established by the previous Framework Programme "Horizon 2020". Consequently, there are only a few novelties and strategic shifts concerning IP management and its role in the exploitation and valorisation of research results. Therefore, this guide complements the existing guide "Your Guide to IP in Horizon 2020".

Download



Intellectual Property rules

Background

- Tangible or intangible input (data, knowhow, information) which is held by the project partners prior to their accession to the GA. Includes IP such as copyright, patents /patent applications (filed prior to access to GA).
- Rule: taking part in Horizon projects does not have any influence upon the ownership of background = your background remains yours!

Results

All results which are generated under the project – whether or not protectable.
 Such results may include copyright, design or patent rights, trademarks or others, and belong to the partners who have generated them.



Intellectual Property rules

Access rights

User rights (incl. licences) to results or background of project partners.

Exploitation

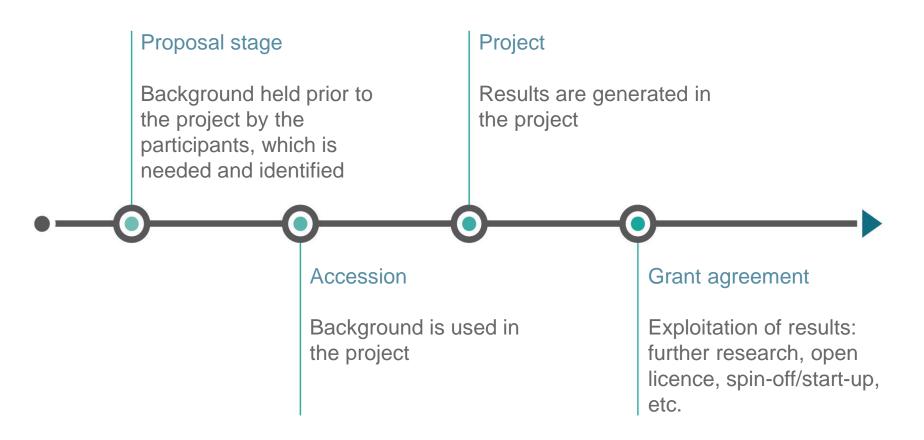
 Utilisation (direct /indirect) of results in research activities, which are not part of the project, as well as utilisation for further development, creation and commercialisation of a product or service.

Dissemination

 Public disclosure and transfer of project results with the aim to enable others to use and take up results, thus maximising the impact of EU-funded research.
 Targeted audiences that may take an interest in the potential USE of the results (e.g. scientific community commercial partner, policy makers).



IP management in Horizon Europe - Process





IP management in Horizon Europe – what to remember

- Background: The consortium partners identify and agree on the background for the project and how to use this in the project
- Ownership of the results: In Horizon Europe, generally the Grant Agreement establishes that the results of the project belong to the participant generating them
- General obligation to exploit: Each beneficiary must take measures to ensure the exploitation of its results, in particular through transfer or licensing, for up to four years after project completion
- Costs of IP protection are Horizon Europe project eligible costs: Costs related to intellectual property which occurred during the project implementation, can be eligible for reimbursement. Include them in the proposal budget!



https://intellectual-property-helpdesk.ec.europa.eu/index_en

European IP Helpdesk

- Service initiative of the European Commission
- Addressing current and potential beneficiaries of EUfunded projects, researchers and EU SMEs
- Free-of-charge first-line support on intellectual property (IP)
- Hands-on IP and innovation management support
- International pool of IP experts from various thematic fields
- Unique cooperation scheme with the Enterprise Europe
 Network: 48 ambassadors from 28 EU countries















Responsible Research and Innovation - RRI





Responsible Research and Innovation - RRI

RRI is an approach which intends to bridge gaps between science, research and innovation communities and society at large by fostering more inclusive, anticipatory, open and responsive research and innovation systems.

six key elements of RRI:

- ethics,
- gender equality,
- governance,
- public engagement,
- science education,
- and open access



Ethics





The Ethics Issues

- Human embryonic stem cells & human embryos
- 2. Humans
- 3. Human cells/tissues
- 4. Personal data
- 5. Animals

- 6. Non-EU countries
- 7. Environment, health & safety
- 8. Artificial Intelligence
- 9. Other ethics issues
- 10. Crosscutting issue: Misuse



Ethics

Examine

- Part A of the proposal: the Ethics Issues Table, the Ethics Self Assessment, list of participants
- Part B of the proposal: containing the proposed activities, workplan, ethics annexes (if necessary)



Part A

Ethics Issues Table

4 - Ethics and Security

Ethics issues table

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- Indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and
- provide additional information on that ethics issue in the Ethics Self-Assessment section.

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines 'How to Complete your Ethics Self-Assessment'.

1. HUMAN	EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		Page
Does this activity involve Human Embryonic Stem Cells (hESCs)?		○ Yes ○ No	
If YES:	Will they be directly derived from embryos within this project?	○ Yes ⊘ No	
	Are they previously established cells lines?	⊘Yes ○ No	
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	O Yes O No	
Does this a	ctivity involve the use of human embryos?	○ Yes ○ No	
If YES:	Will the activity lead to their destruction?	○ Yes ○ No	
2. HUMANS			Page
Does this a	ctivity involve human participants?	○Yes ○No	
If YES:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	○ Yes ○ No	
	Are they healthy volunteers for medical studies?	○Yes ○No	
	Are they patients for medical studies?	OYes O No	
	Are they potentially vulnerable individuals or groups?	○Yes ○No	
	Are they children/minors?	○Yes ○No	
	Are they other persons unable to give informed consent?	○Yes ○No	
Does this activity involve interventions (physical also including imaging technology, behavioural reatments, etc.) on the study participants?		○ Yes ○ No	
If YES:	Does it involve invasive techniques?	○Yes ○No	
	Does it involve collection of biological samples?	○ Yes ○ No	



ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines "How to Complete your Ethics Self-Assessment" and complete the table below.

Part A

Ethics Self Assessment

Ethical dimension of the objectives, methodology and likely impact

Explain in detail the identified issues in relation to:

- objectives of the activities (e.g. study of vulnerable populations, etc.)
- methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.)
- the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)

Compliance with ethical principles and relevant legislations

Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

How to complete your Ethics Self-Assessment

- Guide with information and advice on how to address ethics in research /
 Horizon Europe
 https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf
- For ALL applicants (NOT only medical research)
- Fill-in the Ethics issues table and sections for ethics self-assessment in Part A of the submission system
- If necessary, an annex to Part B on ethics can be added, e.g. Additional information on clinical studies as Annex in Part B



The Ethics Screening of Proposals

Which proposals?	ALL shortlisted proposals Except those cleared at pre-screening (no ethics issues) or directly referred to Ethics Assessment (for proposals involving hE/hESC)	
By whom?	2 ethics experts	
	 Identification of the ethics issues raised by the proposal Identification of proposals that raise serious/complex ethics issues and needs to undergo Ethics Assessment 	
What?	For 'cleared' proposals: - Decision on Ethics Advisor / Board mandate, reporting needs - Advice on Ethics Check / Review during project implementation	



Open Science



"Open science" means an approach to the scientific process based on open cooperative work, tools and diffusing knowledge

(Horizon Europe Regulation and Model Grant Agreement)



Open Science Practices in Horizon Europe

- early and open sharing of research (for example through preregistration, registered reports, pre-prints, or crowd-sourcing)
- research output management including research data management (RDM)
- measures to ensure reproducibility of research outputs
- providing open access to research outputs (e.g. publications, data, software, models, algorithms, and workflows) through deposition in trusted repositories
- participation in open peer-review
- involving all relevant knowledge actors including citizens, civil society and end users in the co-creation of R&I agendas and contents (such as citizen science)



Open Science – Open access to scientific publications

- Beneficiaries must ensure Open Access (OA) to peer-reviewed scientific publications relating to their results;
- Immediate open access through trusted repository (at the latest at the time of publication);
- information via the repository about any research output/tools/instruments needed to validate the conclusions of the scientific publication
- Only publication fees (if any) in full open access venues for peer-reviewed scientific publications are eligible for reimbursement
- Metadata must be open in line with the FAIR principles (Findable, Accessible, Interoperable and Re-usable)



Open Science – Research Data Management (RDM)

- Beneficiaries must manage the research data generated in the action responsibly, in line with the FAIR principles
- establish + regularly update a data management plan ('DMP') for generated (and/or collected) data; by M6 of project;
- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository;
- follow the principle 'as open as possible as closed as necessary', i.e. there can be exceptions to open access to research data.
- Costs for RDM (for example data storage, processing and preservation) are eligible



Open Research Europe:

A high-quality, reliable and efficient open access publishing venue for EU-funded research

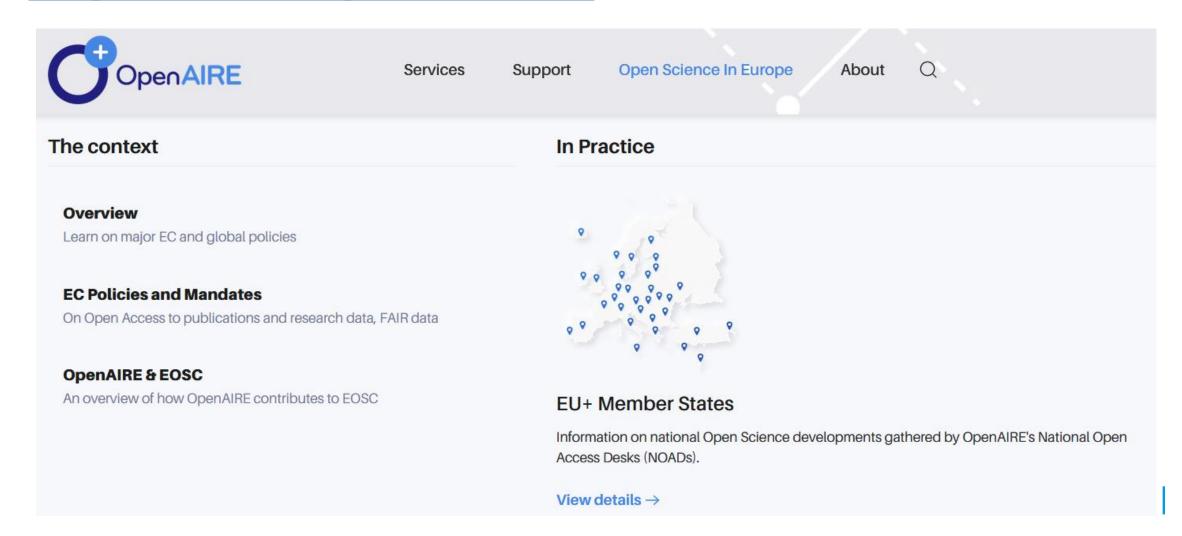
- Launched in March 2021 for H2020 and HE beneficiaries
- High scientific standards (e.g. editorial policies+guidelines), expert
 Scientific Advisory Board across all fields of science
- Swift publication times and transparent processes (e.g. open peer-review)
 No cost to authors/beneficiaries (publication fees paid by the Commission)
- Optional: no obligation to publish there: but if you do, you comply with HE policy

Submit your

article for publication

• https://open-research-europe.ec.europa.eu/

OpenAIRE - Services for Open Science https://www.openaire.eu/



Horizontal Issues - Group Work





Identify for your proposal key aspects of...

- IPR Intellectual property rights
- RRI Responsible Research and Innovation
- Ethics
- Open science
 - Challenges you see?
 - Opportunities created by action?
 - What needs to be done to integrate the issues adequately in your project?



Contact us!

- Trainer 1
- Trainer 2





Thank you!

#HorizonEU

http://ec.europa.eu/horizon-europe

