Horizon Europe

Programme Guide

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1.0	17.06.2021	▪ Initial version
1.1	19.07.2021	▪ Updated section 'Other third countries'

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Abbreviations and acronyms

AC	Associated country/countries associated to Horizon Europe
ERA	European Research Area
ERC	European Research Council
EIC	European Innovation Council
EIT	European Institute of Innovation and Technology
FP	HE Framework Programme
FR	EU Financial Regulation
GA	Grant agreement
HE	Horizon Europe Programme
IP(R)	Intellectual property (rights)
JRC	European Commission Joint Research Centre
KIC	Knowledge and innovation community
MFF	EU's Multi-annual financial framework
MS	EU Member State(s)
MSCA	Marie Skłodowska-Curie Actions
OS	Open science
NCP	National contact point
PCP	Pre-commercial procurement
PPI	Public procurement of innovative solutions
RRI	Responsible research and innovation
SMEs	Small and medium-sized enterprises
SP	HE Specific Programme
SSH	Social sciences and humanities
WP	EU work programme

Introduction

This Programme Guide contains detailed guidance on the structure, budget and political priorities of Horizon Europe. It also includes details on how to prepare proposals.

The purpose of this document is to help users understand the programme and its calls and prepare their proposals, by avoiding technical vocabulary, legal references and jargon, and seeking to help readers find answers to any practical questions they may have about particular parts of the proposal.

The guide will be periodically updated with new guidance and explanations, based on practical experience and on-going developments.

Potential applicants are invited to read the call documentation on the topic page in the Funding & Tenders Portal ('Portal') carefully, and in particular this Horizon Europe Programme Guide, the General Annexes, the EU Funding & Tenders Portal Online Manual and the EU Grants AGA — Annotated Grant Agreement. These documents provide clarifications and answers to questions relating to preparing the proposal:

- the Programme Guide provides:
    - detailed guidance on the structure, budget and political priorities and other relevant background of the Horizon Europe programme relevant for preparing the proposal
- the General Annexes outline the:
    - admissibility and eligibility conditions, and the criteria for financial and operational capacity and exclusion (Annexes A-C)
    - award criteria, mandatory documents and evaluation procedure (Annexes D-F)
    - legal and financial set-up of the grant agreements (Annex G)
    - specific conditions applying to actions which include pre-commercial procurement or procurement of innovative solutions (Annex H)
- the Online Manual outlines the:
    - procedures to register and submit proposals online via the EU Funding & Tenders Portal and recommendations on preparing the proposal
- the AGA — Annotated Grant Agreement contains:
    - detailed annotations on all the provisions in the grant agreement to be signed to obtain the grant.

Please note that calls launched by the European Research Council (ERC), the European Innovation Council (EIC), the European Institute of Innovation and Technology (EIT), the Institutionalised European Partnerships based on Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU), calls under the Euratom Research and Training Programme and the activities of the European Commission Joint Research Centre (JRC) are subject to separate work programmes and thus not entirely covered by this Programme Guide. This also applies to Marie Skłodowska-Curie Actions (MSCA).

For calls launched by EIC, please consult https://eic.ec.europa.eu/ for specific guidance.

For calls launched by EIT, please consult https://eit.europa.eu/ for specific guidance.

For calls launched by ERC, please consult https://erc.europa.eu/ for specific guidance.

For calls launched under the MSCA WP part, please find specific guidance under the relevant call topic pages on the Portal.

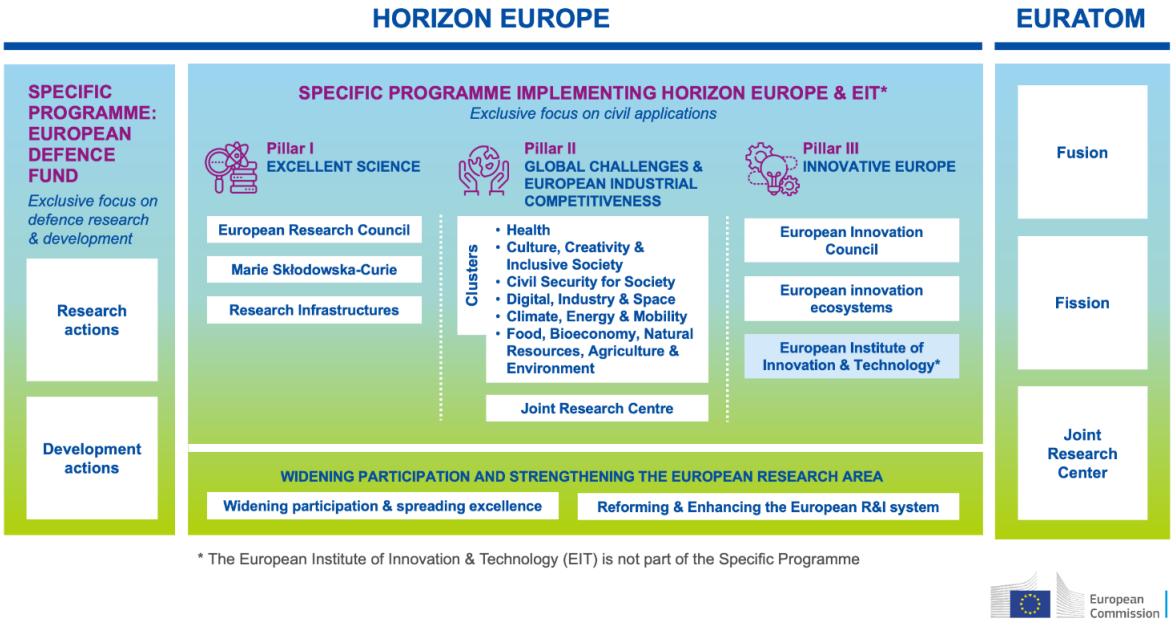
For calls launched by the other programme components and parts listed above, guidance will be published on dedicated websites together with the calls.

Terminology explained

Critical risk	A critical risk is a plausible event or issue that could have a high adverse impact on the ability of the project to achieve its objectives. Level of likelihood to occur (Low/medium/high): The likelihood is the estimated probability that the risk will materialise even after taking account of the mitigating measures put in place. Level of severity (Low/medium/high): The relative seriousness of the risk and the significance of its effect.
Deliverable	A report that is sent to the Commission or Agency providing information to ensure effective monitoring of the project. There are different types of deliverables *(e.g. a report on specific activities or results, data management plans, ethics or security requirements)*.
Impacts	Wider long term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments (long term). It refers to the specific contribution of the project to the work programme expected impacts described in the destination. Impacts generally occur some time after the end of the project. Example: *The deployment of the advanced forecasting system enables each airport to increase maximum passenger capacity by 15% and passenger average throughput by 10%, leading to a 28% reduction in infrastructure expansion costs.*
Milestone	Control points in the project that help to chart progress. Milestones may correspond to the achievement of a key result, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development. The achievement of a milestone should be verifiable.
Objectives	The goals of the work performed within the project, in terms of its research and innovation content. This will be translated into the project's activities. These may range from tackling specific research questions, demonstrating the feasibility of an innovation, sharing knowledge among stakeholders on specific issues. The nature of the objectives will depend on the type of action, and the scope of the topic.
Outcomes	The expected effects, over the medium term, of projects supported under a given topic. The results of a project should contribute to these outcomes, fostered in particular by the dissemination and exploitation measures (including the uptake, diffusion, deployment, and/or use of the project's results by direct target groups). Outcomes generally occur during or shortly after the end of the project. Example: *9 European airports adopt the advanced forecasting system demonstrated during the project.*
Pathway to impact	Logical steps towards the achievement of the expected impacts of the project over time, in particular beyond the duration of a project. A pathway begins with the projects' results, to their dissemination, exploitation and communication, contributing to the expected outcomes in the work programme topic, and ultimately to the wider scientific, economic and societal impacts of the work programme destination.
Research	Results generated by the action to which access can be given in the form of

output	scientific publications, data or other engineered outcomes and processes such as software, algorithms, protocols and electronic notebooks.
Results	What is generated during the project implementation. This may include, for example, know-how, innovative solutions, algorithms, proof of feasibility, new business models, policy recommendations, guidelines, prototypes, demonstrators, databases and datasets, trained researchers, new infrastructures, networks, etc. Most project results *(inventions, scientific works, etc)* are 'Intellectual Property', which may, if appropriate, be protected by formal 'Intellectual Property Rights'. Example: *Successful large-scale demonstrator: trial with 3 airports of an advanced forecasting system for proactive airport passenger flow management.*

Structure and budget



Horizon Europe is divided into three pillars and one part, corresponding to its main priorities

- The Excellent Science pillar aims to increase the EU's global scientific competitiveness. It supports frontier research projects defined and driven by top researchers themselves through the European Research Council, funds fellowships for postdoctoral researchers, doctoral training networks and exchanges for researchers through Marie Skłodowska-Curie Actions, and invests in world-class research infrastructures.

- The Global Challenges and European Industrial Competiveness pillar supports research relating to societal challenges and reinforces technological and industrial capacities through clusters. It sets EU-missions with ambitious goals tackling some of our biggest problems. It also includes activities pursued by the Joint Research Centre which supports EU and national policymakers with independent scientific evidence and technical support.

- The Innovative Europe pillar aims to make Europe a frontrunner in market-creating innovation via the European Innovation Council. It also helps to develop

the overall European innovation landscape through the European Institute of Innovation and Technology (EIT) which fosters the integration of the knowledge triangle of education, research and innovation.

- The part Widening Participation and Strengthening the European Research Area (ERA) increase support to EU Member States in their efforts to make the most of their national research and innovation potential.

Finally, Horizon Europe will be implemented also through the European Defence Fund and complemented by the Euratom Research and Training Programme.

Horizon Europe will have a budget of around €95.5 billion for 2021-2027 (current prices). This includes €5.4 billion (current prices) from NextGenerationEU to boost recovery and make the EU more resilient for the future, as well as an additional reinforcement (i.e. in addition to the MFF agreement in July 2020) of €4.6 billion (current prices).

What is the Strategic Plan and why is it important?

The Horizon Europe strategic plan sets out overarching strategic orientations for EU research and innovation investments over the period 2021-2024. Focusing on the second pillar of Horizon Europe, 'Global challenges and European industrial competitiveness', it also covers relevant activities in the first pillar, 'Excellent Science', and the third pillar, 'Innovative Europe', and the 'Widening Participation and Strengthening the European Research Area' part.

Overall, the aim of the strategic plan is to ensure an effective interface between EU policy priorities, and programme activities and ultimately, the research and innovation projects funded by Horizon Europe. The intention is to stimulate research and innovation investments where they are particularly needed to address the challenges we are facing, and, most importantly, deliver results.

The Horizon Europe strategic plan defines four **key strategic orientations:**

- **Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains** to accelerate and steer the digital and green transitions through human-centred technologies and innovations.

- **Restoring Europe's ecosystems and biodiversity, and managing sustainably natural resources** to ensure food security and a clean and healthy environment.

- **Making Europe the first digitally enabled circular, climate-neutral and sustainable economy** through the transformation of its mobility, energy, construction and production systems.

- **Creating a more resilient, inclusive and democratic European society**, prepared and responsive to threats and disasters, addressing inequalities and providing high-quality health care, and empowering all citizens to act in the green and digital transitions.

Each of the key strategic orientations encompasses three to four cross-cutting **impact areas**, which in turn link to a number of **expected impacts**. The key strategic orientations and impact areas are formulated on the basis of the expected impacts, which have been defined with input from stakeholders, largely bottom-up, during the strategic planning process. The expected impacts are structured by the six **clusters** that make up Horizon Europe's second Pillar, 'Global Challenges and European Industrial

Competitiveness'. The expected impacts define the wider effects on society, the economy and science to be targeted by research and innovation activities, but not the manner in which to achieve them. This is up to the applicants when designing their project proposals. In total, the strategic plan defines 32 expected impacts that cover a wide range of social, economic, ecological and scientific aspirations. Each expected impact serves as the foundation for a corresponding destination in the relevant work programme parts.

Furthermore, the strategic plan identifies European co-programmed and co-funded partnerships, as well as the EU missions and contains orientations regarding cross-cutting elements of Horizon Europe related to **areas for international cooperation**, and key **specific issues**, such as **gender, social sciences and humanities integration, key enabling technologies**, **ethics**, **open science practices**, as well as **social innovation** and the **EU taxonomy.**

The Horizon Europe strategic plan is the product of a series of intense co-creation activities among Commission services and **co-design** activities with Member States, members of the European Parliament, stakeholders and citizens at large. This has taken place through successive rounds of public consultations, web surveys and interactive workshops, in particular during the annual Research and Innovation Days.

Horizon Europe, an impact-driven framework progamme

The impact-driven design of Horizon Europe[1] aims at maximising the effects of Research and Innovation investments, ensuring their contribution to the Commission's policy priorities.

It marks a paradigm change in the design of the EU R&I Framework Programmes from an activity-driven to an impact-driven programme.

One of the novelties in the implementation of the Horizon Europe programme which facilitates such an impact-driven approach is the strategic planning process (as described above), which identifies the expected impacts of the first four years of Horizon Europe.

This represents a paradigm change also for the work programmes, that henceforth builds on this strategic planning. The structure of Horizon Europe work programmes translates this impact-driven nature: they are organised around 'Destinations', describing the expected impacts identified in the Strategic Planning, and 'topics', describing the related expected outcomes critical to the achievement of such impacts.

This impact design is also translated at project level, with revamped proposal and reporting templates, allowing for a straightforward monitoring that aims at providing close-to-real-time information.

Horizon Europe ground breaking approach to monitoring, the Key Impact Pathways[2], aims at capturing and communicating impact around 9 key story lines during and after the Framework Programme implementation. Its objective is to allow policy makers and the wider public to get regular insights regarding the effects and benefits of the framework programme on European science, the economy and wider society[3].

1 See Horizon Europe Regulation, Article 50 and Annex V.
2 https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/evaluation-impact-assessment-and-monitoring/horizon-europe_en#monitoring-horizon-europe.
3 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/horizon-dashboard.

European Partnerships

European Partnerships bring the Commission and private and/or public partners together to address some of Europe's most pressing challenges through concerted research and innovation initiatives. They are a key implementation tool of Horizon Europe, and contribute significantly to achieving the EU's political priorities.

By bringing private and public partners together, European Partnerships help to avoid the duplication of investments and contribute to reducing the fragmentation of the research and innovation landscape in the EU.

Find out more about European Partnerships in our infographic.

The aim of European partnerships with EU and associated countries, the private sector, foundations and other stakeholders is to deliver on global challenges and modernise industry.

The Horizon Europe proposal lays down the conditions and principles for establishing European Partnerships. There are 3 types:

- **European Co-programme Partnerships**

  These are partnerships between the Commission and private and/or public partners. They are based on memoranda of understanding.

- **European Co-funded Partnerships**

  Partnerships involving EU countries, with research funders and other public authorities at the core of the consortium.

- **European Institutionalised Partnerships**

  These are partnerships in the field of research and innovation between the Union, EU member states and/or industry. These partnerships require legislative proposals from the Commission and are based on a Council Regulation (on the basis of Article 187 TFEU) or a Decision by the European Parliament and Council (on the basis of Article 185 TFEU). They are implemented by dedicated structures created for that purpose. Institutionalised partnerships will only be implemented where other parts of the Horizon Europe programme, including other types of partnership, would not achieve the desired objectives or expected impacts. EIT Knowledge and Innovation Communities (KICs) are also institutionalised partnerships. EIT KICs aim to address skills shortages and are already established under Horizon 2020. Key partners in EIT KICs are higher education institutions, research organisations, companies and other stakeholders.

Read more about the European partnerships in Horizon Europe here.

Missions

EU missions are commitments to solve some of the greatest challenges facing our world like fighting cancer, adapting to climate change, protecting our oceans, living in greener cities and ensuring soil health and food. They are an integral part of Horizon Europe.

Each mission will operate as a portfolio of actions – such as research projects, policy measures or even legislative initiatives - to achieve a measurable goal that could not be achieved through individual actions. EU missions will contribute to the goals of the

European Green Deal, Europe's Beating Cancer Plan as well as the Sustainable Development Goals. A wide range of studies and reports informed this approach.

EU missions will

- be bold, inspirational and widely relevant to society
- be clearly framed: targeted, measurable and time-bound
- establish impact-driven but realistic goals
- mobilise resources on EU, national and local levels
- link activities across different disciplines and different types of research and innovation
- make it easier for citizens to understand the value of investments in research and innovation

Areas where there will be missions

- Cancer
- Adaptation to climate change including societal transformation
- Healthy oceans, seas coastal and inland waters
- Climate-neutral and smart cities
- Soil health and food

Read more about the EU Missions in Horizon Europe here.

International cooperation and association

In the context of Horizon Europe, international cooperation is about cooperation with legal entities established in non-EU countries (third countries). A non-EU country is any country or territory that is neither an EU Member State nor an overseas country or territory linked to an EU Member State. Non-EU countries are either associated or not associated to the Horizon Europe programme.

Overseas countries and territories (OCTs) linked to Member States

Legal entities from OCTs can participate and receive funding under equivalent conditions as legal entities from Member States.

The OCTs (and their linked Member States) are:

> Aruba (NL), Bonaire (NL), Curação (NL), French Polynesia (FR), French Southern and Antarctic Territories (FR), Greenland (DK), New Caledonia (FR), Saba (NL), Saint Barthélemy (FR), Sint Eustatius (NL), Sint Maarten (NL), St. Pierre and Miquelon (FR), Wallis and Futuna Islands (FR).

Third countries associated to Horizon Europe

Association to Horizon Europe is governed by the Horizon Europe Regulation 2021/695[4]. Legal entities from Associated Countries can participate under equivalent conditions as legal entities from the EU Member States, unless specific limitations or conditions are laid down in the work programme and/or call/topic text. Such measures could include the limitation of participation in certain actions to legal entities established in the EU alone, or in the EU and specified non-EU countries, in order to safeguard the EU's strategic assets, interests, autonomy or security. Limitations or conditions may also be attached to the participation of legal entities established in an eligible country but which are controlled directly or indirectly by an ineligible country[5]. The eligibility will be clearly defined in the work programme. There could also be criteria on the place of establishment of the legal entity to take into account specific policy requirements or the nature and objectives of the action[6].

Association to Horizon Europe takes place through the conclusion of an international agreement between the EU and the non-EU country. All sixteen third countries associated to the previous programme, Horizon 2020, have also expressed interest to become associated to Horizon Europe. Other third countries have also expressed an interest in association.

Until association agreements start producing legal effects either through provisional application or their entry into force, the transitional arrangements set out in the General Annexes to the Horizon Europe Work Programme 2021-2022 is applicable (for the entire Programme, including ERC, EIC, EIT and the institutionalised European partnerships[7]) with regard to the following countries and legal entities established in these countries, with which association negotiations are being processed or where association is imminent (*listed in the alphabetical order*):

1. Albania
2. Armenia
3. Bosnia and Herzegovina
4. Faroe Islands
5. Georgia
6. Iceland
7. Israel
8. Kosovo[8]
9. Moldova
10. Montenegro
11. Morocco
12. North Macedonia
13. Norway
14. Serbia
15. Tunisia
16. Turkey
17. Ukraine
18. United Kingdom[9]

[4] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ 12.5.2021 L 170/1).

[5] Based on Horizon Europe regulation article 22(5).

[6] Based on Horizon Europe regulation article 22(6).

[7] Subject to the adoption of the basic acts.

[8] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Legal entities established in Switzerland are currently not covered by these transitional arrangements.

Liechtenstein does not intend to associate to Horizon Europe.

This list will be updated to reflect the status of the negotiations for association.

For the Euratom Research and Training Programme, Ukraine and United Kingdom are expected to become associated to Euratom. The transitional arrangement described above applies to legal entities established in these countries.

Other third countries

Most Horizon Europe calls are also open to participants from non-associated countries, unless specific limitations or conditions are laid down in the work programme and/or the call/topic text, such as those described for associated countries above.

Moreover, some Horizon Europe calls are particularly relevant for international cooperation, encouraging or even requiring the participation of entities from non-associated non-EU countries in the funded actions.

Participants from non-associated non-EU countries can take part in Horizon Europe actions — but not always with funding.

Participants from the following low to middle income countries are **automatically eligible** for funding:

- Afghanistan, Algeria, Angola, Argentina, Azerbaijan
- Bangladesh, Belarus, Belize, Benin, Bhutan, Bolivia, Botswana, Burkina Faso, Burundi
- Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Colombia, Comoros, Congo (Democratic Republic), Congo (Republic), Costa Rica, Côte d'Ivoire, Cuba
- Djibouti, Dominica, Dominican Republic
- Ecuador, Egypt (Arab Republic), El Salvador, Equatorial Guinea, Eritrea, Eswatini, Ethiopia
- Fiji
- Gabon, Gambia, Ghana, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana
- Haiti, Honduras
- Indonesia, Iran (Islamic Republic), Iraq
- Jamaica, Jordan
- Kazakhstan, Kenya, Kiribati, Korea (Democratic People's Republic), Kyrgyz Republic
- Lao (People’s Democratic Republic), Lebanon, Lesotho, Liberia, Libya
- Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Mauritania, Mauritius, Micronesia (Federated States), Mongolia, Mozambique, Myanmar
- Namibia, Nepal, Nicaragua, Niger, Nigeria

[9] The UK is associating to the full Horizon Europe programme with the only exception of the EIC Fund (which is the loan/equity instrument of the EIC).

- Pakistan, Palestine[10], Papua New Guinea, Panama, Paraguay, Peru, Philippines
- Rwanda
- Samoa, São Tomé and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Africa, South Sudan, Sri Lanka, St. Lucia, St. Vincent and the Grenadines, Sudan, Suriname, Syrian Arab Republic
- Tajikistan, Tanzania, Thailand, Timor-Leste, Togo, Tonga, Turkmenistan, Tuvalu
- Uganda, Uzbekistan
- Vanuatu, Venezuela (Bolivarian Republic), Vietnam
- Yemen Republic
- Zambia, Zimbabwe.

Participants from other countries (i.e. countries that are not EU Member States, countries associated to Horizon Europe, or countries listed above) are not automatically eligible for funding and therefore by deafult have to participate at their own cost. These participants should explain in the proposal how their funding will be secured.

They can however receive exceptional funding, if:

- their country is explicitly identified in the Horizon Europe work programme and call for proposals as being eligible for funding
- the granting authority considers that their participation as a beneficiary is essential for implementing the project, for example in view of their:
    - outstanding competence/expertise
    - access to particular research infrastructures
    - access to particular geographical environments
    - access to particular data.

⚠ Please note that entities subject to EU restrictive measures under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)[11] and entities covered by Commission Guidelines No 2013/C 205/05[12] are NOT eligible to participate in any capacity in Horizon Europe actions (including as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties, if any).

International organisations

International European research organisations are automatically eligible to receive funding from Horizon Europe. International European research organisations are defined as international organisations, the majority of whose members are EU Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

[10] This designation is not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of the Member States on this issue.

[11] Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the EU Sanctions Map.

[12] Commission guidelines No 2013/C 205/05 on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards (OJEU C 205 of 19.07.2013, pp. 9-11).

For what concerns participation in Horizon Europe actions, international European research organisations are deemed to be established in a Member State other than the ones in which the other legal entities participating in the action are established.

As regards all other international organisations:

- For European Research Council frontier research actions, training and mobility actions and when provided for in the work programme, international organisations with headquarters in a Member State or associated country are deemed to be established in that Member State or associated country, and thus automatically eligible for funding from Horizon Europe.
- In all other cases, international organisations are not automatically eligible for funding from Horizon Europe, and they may exceptionally receive funding only if:
    - they are identified in the relevant Horizon Europe work programme as being eligible for funding or
    - the granting authority considers that their participation is deemed essential for implementing the action, for example in view of their:
        - outstanding competence/expertise
        - access to particular research infrastructures
        - access to particular geographical environments
        - access to particular data.

Gender equality and inclusiveness

Horizon Europe sets **gender equality as a cross-cutting principle** and **aims to eliminate gender inequality and intersecting socio-economic inequalities** throughout research and innovation systems, including by addressing unconscious bias and systemic structural barriers.

The strengthened provisions for gender equality under Horizon Europe address three different levels and include the following:

- A **new eligibility criterion** to get access to Horizon Europe funding: public bodies, research organisations and higher education establishments from Member States and Associated Countries are required, as of calls with deadlines in 2022, to have in place a **gender equality plan (GEP)**. Details on this requirement are specified in the General Annexes to the Work Programme (B— Eligibility, section 'Gender equality plans and gender mainstreaming') and additional guidance is available through this webpage, including a link to Frequently Asked Questions accessible through the Funding & Tenders Portal.
- The **integration of the gender dimension into research and innovation content** across the Programme is an operational objective for Horizon Europe, and **becomes a requirement by default.**
- Particular attention is being paid to ensuring **gender balance**, with a target of 50% women in Horizon Europe related advisory bodies such as boards and expert groups, as well as in evaluation panels. **Gender balance among researchers involved in projects** is strongly encouraged as well, and will be taken into account as a ranking criterion for ex aequo proposals.

- Researchers have the possibility to self-identify in proposals and project reporting according to three gender categories: woman, man, or non-binary.

In addition:

- Specific funding will be made available for actions supporting the development of inclusive gender equality plans in research and innovation organisations across Member States and associated countries, under the **Widening Participation and Strengthening the European Research Area** Programme Part.

- Specific funding will also be allocated to **gender studies and intersectional research**, in particular under Pillar II, Cluster 2 - Culture, Creativity and Inclusive Society.

- Flagship measures and activities for promoting gender equality are introduced under Pillar III, in particular through the **European Innovation Council** (EIC), including a target of 40% women-led companies invited to pitch their projects in the Accelerator instrument, a target of 50% women among members of EIC advisory structures, a dedicated initiative to support women-led deep-tech start-ups, and the continuation of the EU prize for women innovators.

These strenghtened provisions are also detailed on the Commission's Gender equality in research and innovation policy webpage, and summarised in the factsheet Gender equality: a strengthened commitment in Horizon Europe with a special focus on the new Gender Equality Plan (GEP) eligibility criterion.

In this Programme Guide, we focus more specifically on the integration of the gender dimension into research and innovation (R&I) content, and refer the reader to the links provided above and to the following webinar for further guidance on the other gender equality aspects addressed in Horizon Europe and to be taken into account by applicants.

Integration of the gender dimension into R&I content: a requirement under Horizon Europe

The integration of the gender dimension into R&I content is mandatory. It is a requirement set by default across all Work Programmes, destinations and topics, unless its non-relevance for a specific topic is specified in the topic description, e.g. by the mention *"In this topic the integration of the gender dimension (sex and gender analysis) in research and innovation content is not a mandatory requirement".*

This new requirement to integrate the gender dimension by default in R&I content in projects is recalled in the General Introduction to the Horizon Europe Work Programme, and in the General Annex D on Award Criteria (for Research and innovation actions, Innovation actions and Programme co-fund actions) and it is thus reflected in the corresponding application forms (proposal template) for Research and Innovation Actions, Innovation Actions and Programme Co-fund Actions under the *Excellence* evaluation criterion (under *Methodology*).

In the proposal template, applicants are invited to describe how the gender dimension (i.e. sex and/or gender analysis) is taken into account in the project's R&I content. If applicants do not consider such a gender dimension to be relevant in their specific project, they should provide a sound justification, which will be taken into account during evaluation of the proposal, *e.g. with appropriate scientific references*.

What does integrating the gender dimension in R&I content mean?

It is an umbrella term covering the integration of sex and/or gender analysis through the entire R&I cycle, from the setting of research priorities through defining concepts,

formulating research questions, developing methodologies, gathering and analysing sex/gender disaggregated data, to evaluating and reporting results and transferring them to markets into products and innovations which will benefit all citizens and promote gender equality. Addressing **the gender dimension in research and innovation** thus entails **taking into account sex and gender** in the **whole R&I process**. It is different from addressing issues of gender balance and equal opportunities among the project's team members or among participants to events *(e.g. conferences)* organised by the project.

Definitions of key related terms:

- *Sex* refers to biology. Sex is determined by several biological features, according to functions that derive from the chromosomal complement, reproductive organs, or specific hormones or environmental factors that affect the expression of phenotypic traits (morphology) in sexually reproducing organisms. *In humans*, sex refers to the biological attributes that distinguish male, female, or intersex. *In non-human animals*, sex refers to biological attributes that distinguish male, female, or hermaphrodite. *In engineering & product design research*, sex includes anatomical and physiological characteristics that may impact the design of products, systems, and processes. Sex differences may be relevant for many R&I projects.

- *Gender* refers to sociocultural norms, identities and relations that categorise people, structure societies and organisations, and shape behaviours, products, technologies, environments, and knowledge. Gender attitudes and behaviours are complex and change across time and place, as cultural norms and values change. How we speak, our mannerisms, the things we use and our behaviours all signal who we are and establish rules for interaction. Gender is an organising principle that structures behaviours, attitudes, physical appearance and habits. We generally consider three related dimensions of gender: *gender norms* (socio-cultural expectations of what is appropriate for women, men or gender-diverse individuals, often relying on gender stereotypes), *gender identities* (how individuals or groups perceive and present themselves in relation to gender norms, with most commonly used categories including: woman, man, and non-binary or gender-diverse) and *gender relations* (how sex and gender shape social interactions in families, schools, workplaces and public settings, often involving power relations). As such, gender can be an important aspect of research and design.

- *Intersectionality* describes overlapping or intersecting categories such as gender, ethnicity/racial origin, age, socioeconomic status, sexual orientation and geographic location, that compound to determine the identities and experiences of individuals. Researchers and innovators should not consider gender in isolation. Gender identities, norms and relations both shape and are shaped by other social attributes.

Why is the gender dimension important?

An increasing body of studies shows that the quality, reproducibility and accountability of research and innovation are affected by not taking into account sex and gender analysis. And in many fields, it is crucial to explore whether research outcomes may affect women and men differently. For instance:

- Why do we observe differences between women and men in infection levels and mortality rates in the COVID-19 pandemic? Does it make sense to study cardiovascular diseases only on male animals and on men, or osteoporosis only on women? And did you know that pheromones given off by men experimenters, but not women, induce a stress response in laboratory mice sufficient to trigger pain relief?

- Did you know that many aspects of taxation have a substantial effect on gender-related socioeconomic inequalities, but that when designing tax laws, policymakers still rarely consider gender inequalities?
- Does it make sense to design car safety equipment only on the basis of male body standards?
- Did you know that almost 3/4 of women Internet users worldwide have experienced some form of cyberviolence?
- Why do household travel surveys, and thus mobility analysis and transport planning, underrate trips performed as part of caring work, which are predominantly undertaken by women?
- Is it ethical to develop AI products that could spread gender and racial biases due to a lack of diversity in the data used in training AI applications?
- Did you know that climate change is affecting sex determination in a number of marine species and that certain populations are now at risk of extinction?

Integrating sex and gender analysis into R&I content **improves the scientific quality and societal relevance of the produced knowledge, technologies and innovation.** It:

- adds value to research and innovation in terms of excellence, creativity, rigor, reproducibility and business opportunities
- helps researchers and innovators question gender norms and stereotypes, and rethink standards and reference models
- leads to an in-depth understanding of all people's needs, behaviours, and attitudes
- contributes to the production of goods and services better suited to new markets
- is crucial to secure Europe's leadership in science & technology and support inclusive and sustainable growth.

Therefore, when drafting a proposal, you should in particular:

- **Reflect on why sex and/or gender could matter**: Think about and present the ways in which taking into account the gender dimension will provide added value in terms of creativity, excellence, and return on investment, both from public and private perspectives.
- **Consider the production of new knowledge on gender**: Consider what is already known in your area in terms of the gender dimension *(e.g. related scientific literature)* and identify what is missing. In many areas, gender knowledge still needs to be generated.
- **Include sex and gender aspects as part of a multidisciplinary approach**: Reflecting on sex and gender considerations in relation to health, transport, energy, security, etc. is a great opportunity to foster cooperation between scientists with gender expertise and others. It helps concepts cross the borders of scientific fields and encourages research methods to evolve.
- **Consider social categories/factors intersecting with sex and gender**: the way a research problem is formulated will determine which intersecting variables are relevant for analysis. Intersectional research should be designed to

illuminate the multiplicative effects of different, but interdependent, categories and factors.

Guidance and concrete examples (including those mentioned above) on how to better integrate sex and gender based analyses into R&I content under Horizon Europe have been developed by the Commission's Expert Group on Gendered Innovations under the coordination of DG R&I's Gender Sector.

A full policy report has been prepared and is available to support applicants. Entitled *Gendered Innovations 2: How inclusive analysis contributes to research and innovation* and publicly released by the European Commission on 25 November 2020, it is available here, through the Europa website dedicated to gender equality policy in R&I.

The report contains: full definitions of terms; both general and field-specific methods for sex analysis, gender analysis and intersectional approaches; fifteen case studies covering health, climate change, energy, agriculture, urban planning, waste management, transport, artificial intelligence (AI) and digital technologies, taxation, venture funding, as well as COVID-19; and policy recommendations to address the global challenges, targeted impacts and key R&I orientations of the six Horizon Europe Clusters, as well as Mission Areas, and European partnerships.

More information and examples on how to integrate the gender dimension into R&I content in different fields of research and innovation may be found here:

- Website developed by the EU-supported Expert Group on Gendered Innovations, featuring latest material presented in the 2020 EC policy report *Gendered Innovations 2: How inclusive analysis contributes to research and innovation*, as well as previous case studies developed through EC support
- Factsheets:
    - factsheet summarising the EC policy report's contents
    - factsheet on the impact of sex and gender in the COVID-19 pandemic
    - factsheet on gender and intersectional bias in AI
    - factsheet on general provisions for gender equality under Horizon Europe
- MSCA-developed video on Understanding the gender dimension for MSCA projects
- GENDER-NET ERA-NET's online tool for integrating gender analysis into research (IGAR Tool)
- ERC seminar on Sex and gender dimension in frontier research (16/11/2020)
- Interview of Commissioner Mariya Gabriel on the release of the new EC policy report on Gendered Innovations, in the Norwegian KILDEN online news magazine (25/11/2020)
- *Nature* magazine editorial on the release of the new EC policy report on Gendered Innovations and the new Horizon Europe requirements on the integration of sex and/or gender analysis (09/12/2020)
- See also: Tannenbaum, C., Ellis, R. P., Eyssel, F., Zou, J., & Schiebinger, L. (2019). Sex and gender analysis improves science and engineering. *Nature*, 575(7781), 137-146.

Social Science and Humanities (SSH)

SSH in the R&I chain

Under Horizon Europe, the effective integration of social SSH in all clusters, including all Missions and European partnerships, is a principle throughout the programme. The aim of SSH integration is to improve our assessment of and response to complex societal issues. Thus, SSH are a key constituent of research and innovation, especially regarding the twin green and digital transitions.

Therefore, where relevant, the R&I chain should **include contributions from SSH disciplines** such as sociology, economics, psychology, political science, history, cultural sciences or/and the arts. *See the list of SSH disciplines below*.

Project requirements - SSH flagged topics

Many topics invite contributions from the SSH, often in collaboration with non-SSH disciplines such as natural and physical sciences, health sciences or technology. These topics have been 'flagged' and can be found on the Funding & Tenders Portal.

Proposals under these topics are expected to integrate the SSH perspective (social, economic, behavioural, institutional, historical and/or cultural dimensions etc), as appropriate. Applicants should therefore ensure that:

- contributions from SSH disciplines are integrated throughout their proposed project, and
- the actions required, participants and disciplines involved as well as the added value of SSH contributions are clearly stated in the proposal.

The SSH methodologies used in the projects should be described, or if the applicant consortium considers that SSH is not relevant to their particular proposal, they should explain why.

Where relevant, applicants are also encouraged to include contributions from the SSH in a project proposal under any call, even if it is not SSH-flagged.

Evaluation

When evaluating a proposal submitted to a topic that was 'flagged' for SSH contributions, experts will first refer to the topic description to identify what the expected contributions are. With this in mind, they will evaluate the contributions from SSH in the proposal, according to the criteria.

Experts should be mindful that a successful contribution from SSH, depending on the topic, may require collaboration among various SSH disciplines and/or between SSH and non-SSH disciplines.

A proposal without a sufficient contribution/integration of SSH research and competences will receive a lower evaluation score.

Even if proposals do not belong to a topic 'flagged' for SSH contributions, they may contain contributions from the SSH disciplines, which should be evaluated with other relevant aspects of the proposal.

List of SSH disciplines

Social sciences, education, business and law

Social and behavioural sciences: economics, economic history, political science, sociology, demography, anthropology (except physical anthropology), ethnology, futurology, psychology, geography (except physical geography), peace and conflict studies, human rights.

Education science: curriculum development in non-vocational and vocational subjects, educational policy and assessment, educational research.

Journalism and information: journalism, library and museum sciences, documentation techniques, archival sciences.

Business and administration: retailing, marketing, sales, public relations, real estate, finance, banking, insurance, investment analysis, accounting, auditing, management, public and institutional administration.

Law: law, jurisprudence, history of law.

Humanities and the arts

Humanities: religion and theology, foreign languages and cultures, living or dead languages and their literature, area studies, native languages, current or vernacular language and its literature, interpretation and translation, linguistics, comparative literature, history, archaeology, philosophy, ethics.

Arts: fine arts, performing arts, graphic and audio-visual arts, design, crafts.

The list is adapted from the UNESCO International Standard Classification of Education (ISCED 2011).

Social Innovation

Innovations originate from many sources. They stem not only from advances in science and technology, but also from creative uses of existing knowledge and technologies as well as inventiveness in the non-technical and social spheres.

Social innovation concerns the development of new products, methods, and services for and with society involving citizens, public authorities, business and industry, and academia — the Quadruple Helix — in their design, development, and implementation. Social innovation engages and empowers citizens, enhances the resilience of communities, increases the relevance, acceptance and uptake of innovation, and helps foster lasting changes in social practices, therefore acting as a system changer.

It thus helps answering societal and environmental challenges, connecting society with innovation.

Social Innovation in Horizon Europe

Social innovation has been identified as a cross-cutting specific issue in Horizon Europe and concerns all programme parts. Indeed, it holds potential to develop solutions answering at once multiple interconnected challenges. Moreover, embedding social innovation into the scope of a topic enhances the chances of uptake of the results of the project by involving intended users from the beginning of the project to listen to them, understand their needs, and benefit from their knowledge and creativity. Therefore, it increases the delivery of the outcomes and impact expected from the project.

In Horizon Europe, social innovation will serve the environmental, economic, digital, cultural, sovereignty, and democratic priorities set by the von der Leyen Commission. In particular, social innovation will support changes towards socially, environmentally, and economically sustainable social practices. More specifically, the integration of social

innovation on Horizon Europe is relevant to address global challenges – including in areas such as health and care, also in the light of the COVID-19 pandemic, the twin green and digital transitions, climate change mitigation and adaptation or citizen engagement and deliberative democracy.

The above has been reflected by flagging specific topics and encouraging applicants to consider social innovation as a way to meet the topic's objectives, and by dedicating topics to social innovation.

Reference Documents

- Bureau of European Policy Advisors, Empowering people, driving change, 2011, p. 9.
- Oslo Manual, 2018, p. 252.

Ethics and integrity

For all activities funded by the EU, the ethical dimension is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. There is a clear need to make a thorough ethical evaluation from the conceptual stage of the proposal not only to respect the legal framework but also to enhance the quality of the research. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. This includes the adherence to the highest standards of research integrity as described in the European Code of Conduct for Research Integrity.

The process to assess and address the ethical dimension of activities funded under Horizon Europe is called the **Ethics Appraisal Procedure**.

Objectives

In addition to the scientific evaluation focusing on the scientific merit, the quality of the management and the potential impact, the Ethics Appraisal ensures that all research activities carried out under Horizon Europe are conducted in compliance with fundamental ethical principles.

Ethics Appraisal Procedure

The Ethics Appraisal Procedure concerns all activities funded in Horizon Europe and includes the Ethics Review Procedure, conducted before the start of the project, as well as Ethics Checks, Reviews and Audits conducted during the project.

When preparing a proposal, it is required to conduct an Ethics Self-assessment starting with the completion of an **Ethics Issues Table**. You can read further practicalities in the How to complete your ethics self-assessment guide.

Ethics Review Procedure

All proposals above threshold and considered for funding will undergo an Ethics Review carried out by independent ethics experts. The Review starts with the Ethics Screening which can include, in the cases where there is no ethics issue identified in the proposal, a pre-screening to confirm or not the absence of ethics issues (this check can be conducted by qualified staff). If appropriate a further analysis called the **Ethics Assessment** is conducted. The Ethics Assessment can lead to **ethics requirements** that become **contractual obligations.**

The Ethics Review Procedure focusses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations,

national authorisations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research.

The ethics review covers issues as:

- human rights and protection of human beings
- animal protection and welfare
- data protection and privacy
- health and safety
- environmental protection
- artificial intelligence

It may also cover issues of research integrity, including, fabrication, falsification and plagiarism in proposing, performing, or reviewing research or in reporting research results; this includes misrepresenting credentials and improprieties of authorship.

Ethics Screening

The Ethics Screening is carried out during the scientific evaluation or soon after. The ethics experts are asked to flag the proposals that have serious or complex issues (on the basis of the Guidelines on serious and complex ethics issues) that will be the subject of a more in-depth analysis (Ethics assessment). Proposals involving the use of human Embryonic Stems Cells (hESCs) or human Embryos (hE) automatically proceed to the second step, the Ethics Assessment.

Further to the Ethics screening, the proposals that will be funded and are not flagged as serious or complex must handle the ethics issues in the proposed activities in line with National and European legislation and practice and the How to complete your ethics self-assessment guide. The ethics summary report will list the main ethics issues identified in your proposal. Ethics screening will not issue ethics requirements but can lead to the obligation to nominate an external independent ethics advisor or board to assist the project in adhering to the relevant ethical and legal standards.

Ethics Assessment

For the limited number of proposals flagged as serious or complex and for all the proposals involving the use of hESCs or hE, the Ethics Screening is followed by an Ethics Assessment prior to the signature of the grant agreement.

The Ethics Assessment is an in-depth analysis of the ethical issues of the proposals, taking into account the analysis made during the Ethics screening. The Ethics Assessment can lead to ethics requirements that are inserted as obligations in the grant agreement.

If the proposal undergoes an Ethics Assessment, you will receive an ethics summary report with an ethics opinion on your proposal. The possible outcomes of the ethics assessment are:

1. **Ethics clearance**

   The ethics issues are appropriately addressed. The ethics section in the proposal can be transferred mostly unchanged to the ethics section in Part B of the description of the action (DoA).

2. **Conditional ethics clearance**

   In this case clearance is subject to conditions. Your ethics summary report will list one or more 'ethics requirements'. These may include:

   - regular reporting to the Commission or the agency concerned
   - appointing an independent ethics advisor or ethics board (possibly with a task to report on compliance with ethics requirements)
   - supplying further information/documents
   - adjusting methodology so as to comply with ethical principles and relevant legislation

   Ethics requirements must be implemented during grant preparation or during the grant implementation.

   - Ethics requirements **due before grant signature** normally require that you update the ethics section in the narrative part (Part B) of the DoA (Annex 1). However, other parts of Annex 1 may also be affected. Exceptionally, additional supporting documents may be required before the grant agreement can be signed.
   - Ethics requirements **due after project start** are automatically included in the grant agreement in the form of 'ethics deliverables'.

   Tasks of the coordinator or sole applicant:

   - update the DoA whenever appropriate to address the ethics requirements and describe how they are to be met in the course of the project
   - provide supporting documents if exceptionally requested before grant signature
   - take into account any recommendations set out in the ethics summary report.

3. **Request for additional information (intermediate outcome)**

   You may be asked to provide additional information if this is needed to complete the ethics assessment *(e.g. in case of serious or complex ethics issues or missing information)*.

4. **No ethics clearance**

   After the second ethics assessment, if your proposal is not given ethics clearance, it is not eligible for funding and will be rejected.

   You will be informed of

   - the decision to reject your proposal
   - the reasons for the decision
   - how you can appeal against it.

Ethics requirements and ethics work package

Ethics deliverables: All ethics requirements due after project start are automatically included in the grant agreement in the form of deliverables. These deliverables are

known as 'ethics deliverables' and will be placed in an automatically generated work package called 'ethics requirements'.

Work package 'ethics requirements' - if applicable - is added to your grant agreement as soon as the ethics assessment has been completed. At this point in time it will appear as the last work package in the list of work packages (WP). During grant preparation you can move this WP to any other position in the list by drag & drop. It is recommended to keep the 'ethics requirements' WP at the end of the list where it will not affect the numbering of the other work packages.

Ethics checks, reviews and audits

During the Ethics Screening or the Ethics Assessment, the experts identify the projects that need an Ethics Check or Review, which are executed during the course of the research project. The procedure can also be initiated by the Commission services.

The objective of the procedure is to assist the beneficiaries to deal with the ethics issues raised by their research and if necessary to take preventive or/and corrective measures. The Ethics check is an internal check by the project officer or ethics officer who may be supported by ethics experts and the Ethics Review is an elaborate review and in-depth procedure carried out by up to 5 external ethics experts. They are both conducted on the basis of the information provided by the concerned beneficiaries, who may be invited to a meeting in Brussels to discuss the issues at stake. Onsite visits can also be organised during the Ethics Reviews.

In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can carry out an Ethics Audit following the provisions and procedures laid down in the grant agreement.

The checks, post-grant reviews and audits can result in an amendment of the grant agreement. In severe cases, it can lead, upon the decision of the Commission services to a reduction of the grant, its termination or any other appropriate measures, in accordance with the provisions of the grant agreement.

Summary of the Ethics appraisal steps

Activity	**Who?**	**When?**	**How?**
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Screening	Ethics experts (and/or qualified staff in case a pre-screening is conducted)	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC/hE or flagged as serious or complex)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics check/review/audit	Project Officer and/or Ethics officer and/or	Implementation phase	Review of project deliverables/interview with applicants/onsite

	Ethics experts		visit

For assistance please contact us at the Ethics Review Helpdesk (select subject 13. Ethics in the enquiry form).

Reference documents

Rules & codes of conduct

- HE Framework Programme Regulation 2021/695: Eligible actions and ethical principles (Article 18) and Ethics (Article 19)
- HE Model Grant Agreement: Ethics (Article 14 and Annex 5)
- Statement by the Commission on research activities involving human embryos or human embryonic stem cells
- EU Charter of Fundamental Rights
- ALLEA European Code of Conduct for Research Integrity
- Global Code of Conduct for Research in Resource-poor Settings

General guidance

- How to complete your ethics self-assessment
- Guidelines on serious and complex ethics issues

Standard operating procedures

- Guidelines for Promoting Research Integrity in Research Performing Organisation
- Standard Operating Procedures for Research Integrity
- Data Protection Decision Tree

Domain-specific guidance

- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications
- Guidance note on research on refugees, asylum seekers and migrants
- Ethics and data protection
- Ethics in Social Science and Humanities
- Position of the European Network of Research Ethics Committees (EUREC) on the Responsibility of Research Ethics Committees during the COVID-19 Pandemic
- Functional Magnetic Resonance Imaging
- Research Ethics in Ethnography/Anthropology
- Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

- SIENNA Ethical guidance for research with a potential for human enhancement
- Guidelines on ethics by design/operational use for Artificial Intelligence

Ethics and Research Integrity Networks

- European Network of Research Ethics Committees – EUREC
- European Network of Research Ethics and Research Integrity – ENERI
- The Embassy of Good Science
- The European Network of Research Integrity Offices – ENRIO

Security

Activities carried out under the programme must comply with the applicable security rules and in particular, rules on the protection of classified information against unauthorised disclosure, including compliance with any relevant Union and national law. Where appropriate, the actions carried out under the Horizon Europe Programme must comply with Commission Decision (EU, Euratom) 2015/444, and its implementing rules. The Horizon Europe Model Grant Agreement includes specific security related obligations (Article 13 and Annex 5). The Horizon Europe Programme Security Instruction (PSI) has to be followed in case a proposal selected for funding will lead to a project that involves classified information.

The process to assess and address the security dimension of activities funded under Horizon Europe is called the **Security Appraisal Procedure.**

Security Appraisal Procedure

The Security Appraisal Procedure concerns all activities funded under Horizon Europe and includes three main steps: the Security Self-assessment, performed by the applicants at the proposal preparation stage, the Security Review Procedure, conducted before the start of the project, as well as the Security checks, conducted during or after the life of the project.

Security Self-assessment

When preparing a proposal to be submitted under any of the Horizon Europe calls, the applicant is required to conduct a Security Self-assessment starting with the completion of a Security Issues Table. In case the proposal is submitted under a call or topic, which is a priori flagged by the Commission as security sensitive, the applicant is also required to complete a Security Section. Further information and guidance can be found in the *How to handle security-sensitive projects* guide.

Security Review

Only proposals above threshold and considered for funding will undergo a Security Review carried out by granting authority and Commission qualified staff, as well as by national security experts.

The Security Review includes three steps: the Security Pre-screening performed by the granting authority, the Security Screening performed by the Commission and the Security Scrutiny conducted by national security experts. The Security Review is organised based on whether the call or topic, under which a proposal is submitted, is security sensitive or not and it can lead to security requirements that become contractual obligations.

The Security Review Procedure focusses on the compliance with security rules and in particular, on the protection of sensitive and classified information against unauthorised disclosure. The objective of the Security Review is to identify and address security issues that could emerge from the research by adopting appropriate mitigation measures.

Security Pre-screening

The first phase of the Security Review Procedure, the Security Pre-Screening, is carried out by qualified staff of the granting authority, during the scientific evaluation or soon after, in the following cases:

- If the proposal has been submitted under a call or topic not flagged as security sensitive and the applicant has replied positively to at least one of the questions in the Security Issues table.
- If the proposal has been submitted under a call or topic not flagged as security sensitive and the applicant has replied negatively to all the questions in the Security Issues table, but the granting authority has, nevertheless, detected security issues.

Security Screening

The Security Screening is performed by qualified staff of the Commission. All the proposals that have gone through the Security Pre-screening will be automatically sent to the second phase of the Security Review. During this phase, the Commission (DG HOME) will assess the results of the pre-screening and decide whether the launch of the third phase of the procedure, the Security Scrutiny, is needed.

Security Scrutiny

The Security Scrutiny is the last phase of the Security Review and it is conducted by the Security Scrutiny Group, comprised of national security experts appointed in close cooperation with the relevant Programme Committee and the competent National Security Authorities. It is chaired by the Commission. The Security Scrutiny will be carried out prior to the signature of the grant agreement in the following cases:

- Automatically, if the proposal has been submitted under a call or topic flagged as security sensitive.
- In other cases, if the Security Screening has concluded that the proposal is very likely to raise security issues for which mitigation measures should be proposed.

The **objective of the Security Scrutiny** is to identify security concerns in a certain proposal, assess if sensitive or classified information will be used or produced by a certain project, verify whether the security issues have been properly addressed by the applicant and propose recommendations in order to properly address the identified security issues. The purpose of the Security Scrutiny is to address potential misuse of project results *(e.g. results that could be channelled into crime or terrorism or results that could adversely affect critical infrastructure)*. For additional information, *see the Guidance note on potential misuse of research*. The information is classified according to the *Guidelines on the classification of information in Horizon Europe projects*.

The Security Scrutiny may result in **security requirements** that, in principle, will have to be fulfilled by the beneficiaries before the signature of the Grant Agreement. The security requirements may include limiting the dissemination level of certain deliverables for security reasons, classifying certain deliverables or other security recommendations. Other security recommendations may include appointing a Project Security Officer, establishing a Security Advisory Board, ensuring that personnel has

followed security trainings, limiting the level of detail, using a fake scenario, excluding the use of classified information, adjusting the scope of a certain work package etc.

As the result of the Security Scrutiny a security summary report will be produced. It will contain the security opinion and security recommendations. It will be provided to the applicants at the stage of the grant preparation in order to implement the security requirements.

The possible outcomes of the Security Scrutiny are:

a) No security concern

No security issues were identified in the proposal. No need for the Grant Agreement to include a security section.

b) Security recommendations and/or security classification

The security summary report will list one or more security requirements. These requirements should be set out in the security section of Part B of the DoA of the Grant Agreement and may include:

- security recommendation to limit the dissemination level of certain deliverables for security reasons
- classification of certain deliverables at a certain level (the classification levels applied in Horizon Europe research projects are RESTREINT UE/EU RESTRICTED, CONFIDENTIEL UE/EU CONFIDENTIAL and SECRET UE/EU SECRET)
- appointment of a Project Security Officer in case of classified deliverables
- establishment of a Security Advisory Board
- other security recommendations.

The security requirements must be **implemented** during grant preparation and **before grant signature.** You will be required to update the security section in the narrative part (Part B) of the DoA (Annex 1). In certain exceptional cases, security requirements will be implemented during the grant implementation, *e.g. issue of Personnel Security Clearance*.

c) Proposal too sensitive to be funded

The Security Scrutiny may reveal that the information to be used or generated by the project is too sensitive, or that the applicants lack the right experience, skills or authorisations to handle classified information at the appropriate level. In such cases, funding is refused and the proposal is rejected.

If this happens, your report will contain the following information:

- the decision to reject your proposal;
- the reasons for the rejection, except if they are classified;
- the way to appeal against it.

Security Checks

Where appropriate, the Commission or the relevant funding body may carry out security checks.

Reference documents

Rules

- HE Framework Programme Regulation 2021/695: Security (Article 20)
- HE Model Grant Agreement: Confidentiality and security (Article 13 and Annex 5)
- Commission Decision 444/2015 on the security rules for protecting EU classified information
- Commission Decision 2021/259 on implementing rules for classified grants
- Commission Recommendation on internal compliance programmes for controls of research involving dual-use items *(— coming soon)*

Guidance

- How to handle security-sensitive projects
- Guidelines on the classification of information in Horizon Europe projects
- HE Programme security instruction (PSI)
- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications

Dissemination and exploitation of research results

Under Horizon Europe, beneficiaries must engage in dissemination and exploitation activities regarding their results.

Dissemination means the public disclosure of the results by appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium.

Exploitation means the use of results in further research and innovation activities other than those covered by the action concerned, including inter alia, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities.

Experience shows it is not always easy to meet these goals. As an applicant, it is useful to keep in mind the following:

- At the stage of forming the consortium, before submitting your proposal, attention should already be paid to eventual and expected results, ownership issues and the associated intellectual property rights (IPR) with a view to disseminating and exploiting the results efficiently.
    - The consortium agreement sets the framework for successful project implementation and results exploitation including intellectual property management, and is meant to settle where already possible all issues that might hamper the smooth and seamless cooperation of the different actors for the different parts of the project.
    - Having a consortium agreement with clear IPR management and ownership rights between the consortium members can maximise the exploitation potential of the project's results.

- The consortium agreement should in principle be negotiated and concluded before signing the grant agreement, and should complement the grant agreement but must not contain any provision contrary to it.
- The consortium agreement is a private agreement between the beneficiaries setting out the rights and obligations amongst themselves, and does not involve the Commission/Agency.

- The implementation of Horizon 2020 programme showed that beneficiaries often confused the concepts as dissemination, communication and exploitation. The guidelines below clarify the differences and can help the beneficiaries to apply the concepts in practice. In addition the EU offers a wide range of services to assist beneficiaries in dissemination and exploitation activities.

Guidelines for your dissemination, exploitation and communication activities

We suggest you take a step-by-step approach to dissemination, exploitation and communcation when developing your proposals for an application. These guidelines are not compulsory.

The dissemination and exploitation part

1. Prepare your planned summary for exploitation and dissemination activities carefully.

This must be a distinct part of your proposal (unless excluded by the call conditions). As it is too early to know what kind of results you will have, at this stage we only expect a planned summary for Dissemination and Exploitation (D&E) activities. Unless otherwise specified in the call conditions, you will be asked to submit a detailed D&E plan along with a plan for communication activities at the latest 6 months after the date of signature of your grant agreement.

In order to give you an idea of how these recommendations could be described in your proposal, we have devised an example of a project involved in water treatment:

1) Identify the problem/need to address

Example: in a context of pandemic, the current sand water treatment does not filter against viruses. It requires the use of iodine and chlorine which in large quantity may have an impact on health and the environment. Chlorine also has a taste that makes it unpleasant for the consumer who then resorts to bottled water.

2) Check what is the current offer *(e.g. competition)*

Example: The market usually offers:

- Reverse Osmosis (R.O.) Membranes
- Ultrafiltration (U.F.) Membranes
- Micro-Filtration (M.F.) Membrane
- Nano-Filtration (N.F.) Membrane

3) What is the added value of your research/technology/methodology

Example: using techniques issued from biomimetics, to filter the water and combat the viruses like live organisms do in nature

4) Identify the Key Exploitation Result(s) (KER)

Example: our KER will be an eco-friendly biomimetic membrane for filtering water thereby removing 99% of viruses in water treatment plants.

5) Explain what the outcome is (do not confuse it with the expected impact to be addressed in the canvas of the application)

Example of the outcome: We would like to create a filtering membrane to treat tap water. At the end of the project, the technology should be used by 10 water treatment plants.

The expected impact will be: For companies and water treatment plants, our technology is expected to reduce the costs in the long run (after the initial investment) and the use of chemical product to treat the water. We plan on testing the technology in X region(s) of the EU and this environmental friendly technology should encourage help reducing the use of plastic bottles by consumers who would then drink tap water.

6) Identify the target groups (early adopters)

Example:

Target group: water treatment equipment manufacturers (filter manufacturers)

End users: water treatment plants that have been approached by the consortium and agreed to test the technology

7) Describe some dissemination measures and channels to reach out to your target audience

Example of dissemination measures:

Organising visits for potential investors and/or B2B to the demo plant

Participation in events such as trade fair dissemination to increase awareness of our project amongst target user base, including international conferences on water management & environment

8) Describe some exploitation measures

- Realize a Demo plant to show the UVP (Unique Value Proposition) of the novel solution
- Establish contacts with industry (B2B) *e.g. scan main players in the water treatment and gather information about the dynamics of each of the target markets*
- Reach out to end-users (regional water authorities, consumers) identified during the dissemination activities to redefine/improve features of the product
- Organise testbeds with end users (public authorities, companies in water treatment, citizens)

9) How your results can feed back to policy making and how it contributes to EU priorities

Example:

Water treatment would contribute to higher quality of tap water at a lesser cost with a better taste and the guarantee of a safer product (free of viruses), thereby encouraging

citizens to drink tap water instead of bottled water, and reducing the impact on the environment, thereby contributing to the green deal. We will reach out to the local authorities to raise their awareness and get their support. We will implement a mapping of stakeholders at the local governmental level. For that we can rely on indicators as level of interest in water management but also Go-to-market service from Horizon Results Booster. We will create a white paper to be distributed to regional water authorities from the region of A and B (where we intend to run the tests)

2. Involve potential end-users and stakeholders in your proposal.

If they're committed from early on, they may help guide your work towards specific qualities and applications of your results. End-users could come from the regional, national and international networks of the partners in your consortium, or from the value chains they operate in. They could be involved as partners in the project, or, throughout its duration, as members of an advisory board or user group tasked with co-creating and testing the results and providing feedback. In the case your project aims at providing policy recommendations, you may want to approach policy makers from local/regional/national authorities, or regulatory bodies in order to design your research project bearing in mind their needs from the start, and to actively involve them during the project to integrate their feedback and know their potentially evolving policy needs.

3. Say how you expect the results of your project to be exploited/further developed and give the main advantages of the new solution(s) you expect to emerge.

The results could befor example: a manual, test, model, new therapy, better product or process, or improved understanding of mechanisms **and advantages** for reduced material or energy usage, improved safety, or better-trained staff.

Explain how you expect results like these to be exploited. This could also depend on progress elsewhere in an innovation chain, in related projects or in adjacent fields - so outline these dependencies and any progress to be made in these areas.

4. Link your proposal to the policy context of the call for proposals.

Think of how your project’s results will contribute to the outcomes specified in the calls and topics and how they are linked with the wider impact, in the longer term, specified in the respective destinations in the work programe. Consider the following questions:

- What are the objectives of your project?
- Why and how they can be important in view of work programme?
- What target audience (user communities? Parts of the society?) would benefit?
- Is it clear how the effects of your project can contribute to the outcomes or wider impact?

5. Implement open science practices

Think of use, ownership and access rights.

Open science practices are addressed and evaluated under ‘excellence’ as they are considered a part of the methodology. However, open access in particular also results in the broad dissemination of knowledge and is relevant in the context of dissemination.

Providing open access to peer-reviewed publications is mandatory in Horizon Europe, when peer-reviewed publications are produced. Open access to generated research data is required under the premise ‘as open as possible as closed as necessary’, meaning that there can be exceptions to this. Data management plans are mandatory for all

projects generating or reusing data and should be aligned with the D&E plan. Additionally, we recommend that you provide open access to research outputs beyond publications and data *(e.g. software tools, models, apps, etc)* and share them as early and openly as possible providing guidance for potentially interested users. Costs for providing open access to publications and data are eligible and should be budgeted in the proposal.

Please consult the relevant sections under 'open science' for guidance on all of the above and the Annotated Grant Agreement for further guidance regarding the requirements.

6. Show you understand the barriers to any exploitation of your results. How will you tackle them? Possible obstacles may include:

- inadequate financing
- skills shortages
- other R&I work within and beyond Horizon Europe
- regulation that hinders innovation[13]
- intellectual property right issues
- traditional value chains that are less keen to innovate
- incompatibility between parts of systems (lack of standards)
- mismatch between market needs and the solution
- user behaviour

Your proposal should show you understand these impediments and how you will tackle them. You may involve in your projct experts in economics, business, marketing and public administration that could help to overcome barriers.

7. Think ahead. Once your research and innovation is complete, will you need to take further steps to apply it in actual practice?

Examples of further steps: standards to be agreed on, financing the testing and prototyping, scaling up or production, promoting acceptance by consumers or other partners in a value chain. Policymakers may also establish follow-up steps to integrate the results into policies.

You could also consider support schemes for follow-up steps, *e.g. national programmes, EIC, InnovFin and Invest EU schemes Regional Funds, Enterprise Europe Network (EEN), European IPR Helpdesk, European exploitation support schemes (more on ESIC in the Work Programme), Horizon Results Platform, or Horizon Results Booster services*.

The communication part:

Since EU grants are financed by public funds, beneficiaries are generally expected to actively engage in communication activities, to promote the projects.

Communicating and promoting the project

What does communication involve?

[13] See Innovation Principle, a tool to ensure that EU policies and legislation support innovation

Communication activities must already be part of the proposal and be described in the draft Dissemination and exploitation plan including communication activities which is an admissibility criterion.

A good communication plan should define clear objectives (adapted to various relevant target audiences) and set out a description and timing for each activity.

With your communication activities you should draw the attention of general and specialised audiences to the EU policy area addressed by the call.

Good communication

- Starts at the outset of the action and continues throughout its entire lifetime.
- Is strategically planned and not just ad-hoc efforts.
- Identifies and sets clear communication objectives *(e.g. have final and intermediate communication aims been specified? What impact is intended? What reaction or change is expected from the target audience?)*.
- Is targeted and adapted to audiences that go beyond the project's own community, including the media and the public.
- Chooses relevant messages *(e.g. how does the action's work relate to our everyday lives? Why does the target audience need to know about the action?).*
- Uses the right medium and means (*e.g. working at the right level — local, regional, national, EU-wide; using the right ways to communicate — one-way exchange (website, press release, brochure, etc) or two-way exchange (exhibition, school visit, internet debate, et.); where relevant, include measures for public/societal engagement on issues related to the action)*.
- Is proportionate to the scale of the action.

Strategy for intellectual property management

Applicants must outline their strategy for the management of intellectual property (IP), including intended protection measures (if relevant) and how these would be used to support exploitation in the proposal (section on impact).

Particularly in the case of projects aimed at economic and societal exploitation, the strategy for IP management must be commensurate with the desired outcomes and impacts. Hence, a weakness or failure to submit such a strategy would also need to be reflected in the proposal evaluation (scoring) with view to the 'credibility' of the envisaged impact pathways.

Results ownership

What is the ownership of results?

The owner of results is the natural or legal entity that has generated the results.

Results are defined as any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

When do you have to address the ownership of your results?

The ownership of potential results should be addressed very early by the consortium members when preparing the proposal.

Why does the results ownership matter?

Horizon Europe has the specific objective to strengthen the deployment and exploitation of innovative solutions. This objective calls for transparency and clarity in terms of results ownership.

The lack of clarity on the ownership of results can be one of the main obstacles for exploitation and commercialisation, especially for SMEs. Clarity of results ownership is a critical factor for attracting investors. Beneficiaries should also clarify their freedom to operate without infringing on intellectual property owned by third parties that might require specific action *(e.g. licencing)* to fully exploit the own intellectual property.

More practically speaking, it is important that potential future consortium members decide on the ownership of results when drafting the proposal to simplify their lives as beneficiaries. Indeed, beneficiaries must indicate the owner(s) of the results in the final periodic report of the Horizon Europe project in the so called Results Ownership List. If the ownership of results has not been carefully thought through at the proposal phase, beneficiaries may face difficulties in filling in the Results Ownership List at the reporting stage. Knowing that failure to fill in the Results Ownership List will block the submission of the final periodic report and hence the payment, dedicating sufficient time on the allocation of the ownership of results at the proposal phase will avoid hurdles at the end of the project.

Standardisation

What is standardisation?

A standard is a document that sets the technical requirements of a product, service or process and its use. Standards are adopted by recognised standardisation bodies (such as ISO, CEN, CENELEC, ETSI, and many more). In these organisations, representatives from industry, research, governments and civil society, discuss and agree on what should be a standard. Once a standard is published, its use is normally voluntary but in some cases certain specific standards can be made mandatory by law.

In other words, standards form a common language that allows researchers, people, public institutions and industry to communicate, produce and commercialise products and services in a harmonised manner. This is especially important in the European single market.

Why is it important to consider standardisation when drafting a proposal?

Standards play an important role in the valorisation of research & innovation results:

They help researchers bring their innovation to the market and spread technological advances by making their results transparent. In spreading the diffusion of new technologies, standards provide both economic opportunities, facilitate realisation of SDGs and give confidence to consumers that an innovative technology is safe.

They codify the technology requirements and inform both manufacturers and consumers on what to expect.

They allow technologies and materials to be interoperable: since a standard provides details on the use and content of a technology or a material, it is much easier to know when and how it can be used in combination with other technologies.

In other words, by codifying information on the state of the art of a particular technology, standards enable dissemination of knowledge (both within and outside the relevant industry community). Moreover, standards bridge the gap between research and products or services allowing the diffusion of the technology in the market and

increasing the probabilities of its take-up. Standardisation facilitates the deployment of new technologies, interoperability between new products and services. Innovations can more easily gain market acceptance and consumer trust if they comply with existing standards for safety, quality, performance and sustainability.

If the project is relevant for standardisation it is advised for applicants to involve standard development organisations in the consortium in order to facilitate the valorisation of project results through standardisation.

The Do No Significant Harm principle

What is meant by the Do No Significant Harm principle in the context of Horizon Europe?

The Commission Communication on the European Green Deal[14] introduced green oath to 'do no harm'. The 'Do not Significant Harm' (DNSH) principle has been further specified in the EU Regulation on the establishment of a framework to facilitate sustainable investments[15], commonly defined as the 'EU Taxonomy Regulation'. Six environmental objectives are listed in Article 9[16] of the EU Taxonomy and Article 17 specifies what can constitute a 'significant harm' for these objectives:

1. An economic activity is considered to do significant harm to **climate change mitigation** if it leads to significant greenhouse gas (GHG) emissions;

2. An economic activity is considered to do significant harm to **climate change adaptation** if it leads to an increased adverse impact of the current climate and the expected future climate, on the activity itself or on people, nature or assets;

3. An economic activity is considered to do significant harm to the **sustainable use and protection of water and marine resources** if it is detrimental to the good status or the good ecological potential of bodies of water, including surface water and groundwater, or to the good environmental status of marine waters;

4. An economic activity is considered to do significant harm to the **circular economy**, including waste prevention and recycling, if it leads to significant inefficiencies in the use of materials or in the direct or indirect use of natural resources, or if it significantly increases the generation, incineration or disposal of waste, or if the long-term disposal of waste may cause significant and long-term environmental harm;

5. An economic activity is considered to do significant harm to **pollution prevention and control** if it leads to a significant increase in emissions of pollutants into air, water or land;

6. An economic activity is considered to do significant harm to the **protection and restoration of biodiversity and ecosystems** if it is significantly detrimental to the good condition and resilience of ecosystems, or detrimental to the conservation status of habitats and species, including those of Union interest.

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14 COM (2019) 640, The European Green Deal.

15 The 'EU Taxonomy Regulation' refers to Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment, by setting out a classification system (or 'taxonomy') for environmentally sustainable economic activities.

16 Climate change mitigation; climate change adaptation; sustainable and protection of water and marine resources; transition to a circular economy; pollution prevention and control; protection and restoration of biodiversity and ecosystems.

References on the DNSH principle are included in the General Introduction of the Work Programme 2021-2022 of Horizon Europe Pillar II and in Cluster 4 (Digital, Industry and Space), Cluster 5 (Climate, Energy and Mobility), and Cluster 6 (Food, Bioeconomy, Natural Resources, Agriculture and Environment) because of their particular relevance for environmental outcomes and impacts.

At programming stage, the Horizon Europe work programme has been co-created to support research and innovation activities that respect climate and environmental priorities of the Union and cause no significant harm to them.

At project level, the reference to the DNSH principle in the Horizon Europe Work Programme is included in the application form (proposal part B template) to offer researchers the possibility to present the credential of their projects in relation to the DNSH principle. Applicants can refer to the DNSH principle when presenting their research methodology and the expected impacts of the project, to show that their project will not carry out activities that make a significant harm to any of the six environmental objectives of the EU Taxonomy Regulation listed above.

However, **evaluators will not score applications in relation to their compliance with the DNSH principle** unless explicitly stated in the work programme (currently, this is the case only for actions in the European Innovation Council Work Programme 2021).

Open science

Open science in Horizon Europe

Open science is an approach based on open cooperative work and systematic sharing of knowledge and tools as early and widely as possible in the process. It has the potential to increase the quality and efficiency of research and accelerate the advancement of knowledge and innovation by sharing results, making them more reusable and improving their reproducibility. It entails the involvement of all relevant knowledge actors.

Horizon Europe moves beyond open access to open science for which it features a comprehensive policy implemented from the proposal stage to project reporting. The Horizon Europe Regulation sets the legal basis for the open science obligations and incentives that apply to Horizon Europe beneficiaries. The Annotated Grant Agreement provides guidance on how to comply with the open science obligations required in the Model Grant Agreement. **The present guide complements the information provided in the Annotated Grant Agreement, with a particular focus on the preparation of proposals.**

In Horizon Europe, open science practices are considered in the evaluation of proposals, under 'excellence' and under the 'quality and efficiency of implementation'.[17] There are mandatory open science practices, which are required for all projects through the Model Grant Agreement and/or through the work programme or call conditions, and recommended practices (all open science practices that are not mandatory). Recommended open science practices are incentivised through their the evaluation at the proposal stage. Proposers should be aware of both mandatory and recommended practices and integrate them into their proposals.

[17] This does not apply to the ERC programme that does not include open science in the evaluation. It also does not include EIC transition calls for the WP 2021-2022 where open science practices are exceptionally evaluated under 'impact'.

Open science practices include early and open sharing of research (for example through preregistration, registered reports, pre-prints, or crowd-sourcing); research output[18] management; measures to ensure reproducibility of research outputs; providing open access to research outputs (such as publications, data, software, models, algorithms, and workflows); participation in open peer-review; and 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).

These practices are explained and relevant resources provided in a separate section further below (open science practices and resources).

Mandatory open science practices

- Some open science practices are **mandatory for all beneficiaries per the grant agreement.** They concern:
    - open access to scientific publications under the conditions required by the grant agreement;
    - responsible management of research data in line with the FAIR principles of 'Findability', 'Accessibility', 'Interoperability' and 'Reusability', notably through the generalised use of data management plans, and open access to research data under the principle 'as open as possible, as closed as necessary', under the conditions required by the grant agreement;
    - information about the research outputs/tools/instruments needed to validate the conclusions of scientific publications or to validate/re-use research data;
    - digital or physical access to the results needed to validate the conclusions of scientific publications, unless exceptions apply;
    - in cases of public emergency, if requested by the granting authority, immediate open access to all research outputs under open licenses or, if exceptions apply, access under fair and reasonable conditions to legal entities that need the research outputs to address the public emergency[19].

These obligations are described in the Model Grant Agreement (Article 17) and detailed guidelines on complying with them are provided in the Annotated Grant Agreement (Article 17).

- Some open science practices are **mandatory per specific work programmes or call conditions,** which may provide for additional obligations to adhere to open science practices.

Recommended open science practices

These are open science practices beyond the mandatory ones, such as involving all relevant knowledge actors, including citizens, early and open sharing of research, output management beyond research data, open peer-review. This is a non-exhaustive list of practices that proposers are expected to adopt when possible and appropriate for their projects. Finally, certain work programme topics or call conditions may encourage specific additional open science practices.

Evaluation of open science practices

[18] These are results generated by the action to which online access can be given in the form of scientific publications, data or other engineered outcomes and processes such as software, algorithms, protocols and electronic notebooks.

[19] The additional provision on access in cases of public emergency does not apply to the ERC.

Open science practices are evaluated under the **'Excellence**' criterion (in particular under methodology) and under the '**Quality and efficiency of implementation'** award criterion. Proposers should address open science practices in the relevant section on open science under methodology[20].

Proposers will have to provide concrete information on **how** they plan to comply with the **mandatory open science** practices. Failure to sufficiently address this, will result in a lower evaluation score.

A clear explanation of how they will adopt **recommended practices**, as appropriate for their projects, will result in a higher evaluation score.

If proposers believe that none of the open science practices (mandatory or recommended) apply to their project, then they have to provide a **justification**.

Under the 'excellence' part of their proposals, in the section on methodology, proposers should describe how open science practices (mandatory and recommended, as appropriate) are implemented as an integral part of the methodology and show how their implementation is adapted to the nature of their work, therefore increasing the chances of the project delivering on its objectives. Information relevant to the specific area of the proposal should be provided in no more than one page. If open science practices are not applicable to the proposal, justifications should be provided sp that, if evaluators agree, open science will not be taken into consideration in the evaluation. Additionally, proposers generating or reusing data should outline in a maximum of one (additional) page their plans for data management.

Under 'capacity of participants and consortium as a whole', proposers should describe how the consortium brings together the necessary disciplinary and inter-disciplinary knowledge. Proposers should show how this includes expertise and/or track record in open science practices, relevant to what is planned for the project. If justification has been provided that open science practices are not relevant for their projects, it is not necessary to demonstrate track record and expertise.

Finally, in **part A of their proposals**, proposers are asked to list up to five relevant publications, widely used datasets or other achievements of consortium members that they consider significant for the action proposed. Open access is expected for publications, in particular journal articles, while datasets are expected to be FAIR and 'as open as possible, as closed as necessary'. If publications are not open access, proposers are strongly encouraged to deposit them retroactively in repositories and provide open access to them when possible. The significance of publications will not be evaluated on the basis of the Journal Impact Factor of the venue they are published in, but on the basis of a qualitative assessment provided by the proposers for each publication.

How should you address open science practices in your proposal?

Make sure to read the Annotated Grant Agreement on the mandatory open science practices in combination with this guide[21].

Early and open sharing: Provide specific information on whether and how you will implement early and open sharing and for which part of your expected output. For example, you may mention what type of early and open sharing is appropriate for your

[20] The information in this section does not apply to the ERC programme, which does not include open science in the evaluation.

[21] The information in this section does not apply to the ERC programme, which does not include open science in the evaluation.

discipline and project, such as preprints or preregistration/registration reports, and which platforms you plan to use.

Research data management (RDM): RDM is mandatory in Horizon Europe for projects generating or reusing data. If you expect to generate or reuse data and/or other research outputs (except for publications), you are required to outline in a maximum of one page how these will be managed. Further details on this are provided in the proposal template in the relevant section on open science. A full data management plan (DMP) is not required at submission stage. For those work programmes that require the use of the European Open Science Cloud (EOSC) federated repositories, proposers should explicitly discuss the use of such repositories in their proposals. By exception, in cases of a public emergency and if the work programme requires so, you should submit a full DMP already with submission of proposals or at the latest by the signature of the grant agreement. A template for a DMP is provided under the reporting templates in the reference documents of the Funding and Tenders portal of the European Commission.

Reproducibility of research outputs: you should outline the measures planned in the project that tend to increase reproducibility. Such measures may already be interweaved in other parts of the methodology of a proposal (such as transparent research design, the robustness of statistical analyses, addressing negative results, etc) or in mandatory/non-mandatory open science practices *(e.g. the DMP, early sharing through preregistration and preprints, open access to software, workflows, tools, etc)* to be implemented. More detailed suggestions on good practices for enhancing reproducibility and resources in the relevant section below.

Horizon Europe requires information via the repository where publications and data have been deposited on any research output or any other tools and instruments - *data, software, algorithms, protocols, models, workflows, electronic notebooks and others* - needed for the re-use or validation of the conclusions of scientific publications and the validation and reuse of research data. Further, beneficiaries must provide digital or physical access to data or other results needed for the validation of the conclusions of scientific publications, to the extent that their legitimate interests or constraints are safeguarded[22]. More details on these requirements for reproducibility and guidance on how to meet them are provided in the AGA (article 17).

Open access: Offer specific information on how you will meet the open access requirements, that is deposition and immediate open access to publications and open access to data (the latter with some exceptions and within the deadlines set in the DMP) through a trusted repository, and under open licenses. You may elaborate on the (subscription-based or open access) publishing venues that you will use. You may also elaborate on the trusted repository/repositories through which open access to publications and research data will be provided (article 17). Open access to research data and other research outputs should be addressed in the section on research data management of your proposal. Research data should be open as a default, unless there are legitimate reasons for keeping them closed. On open access to data and the legitimate reasons for restricting access, consult the AGA (article 17).

As a general rule, open access to other research outputs such as software, models, algorithms, workflows, protocols, simulations, electronic notebooks and others is not required but strongly recommended. Access to 'physical' results like cell lines, biospecimens, compounds, materials, etc. is also strongly encouraged.

Open peer review: Anytime it is possible, you are invited to prefer open peer review for your publications over traditional ('blind' or 'closed') peer review. When the case,

[22] This does not apply to ERC calls.

you should provide specific information regarding the publishing venues you envisage to make use of, and highlight the venues that would qualify as providing open peer review.

Citizen, civil society and end-user engagement: Provide clear and succinct information on how citizen, civil society and end-user engagement will be implemented in your project, where/if appropriate. The kinds of engagement activities will depend on the type of R&I activity envisaged and on the disciplines and sectors implicated.

This may include: *co-design activities* (such as workshops, focus groups or other means to develop R&I agendas, roadmaps and policies) often including deep discussion on the implications, the ethics, the benefits and the challenges related to R&I courses of action or technology development; *co-creation activities (*involving citizens and/or end-users directly in the development of new knowledge or innovation, for instance through citizen science and user-led innovation); and *co-assessment activities* (such as assisting in the monitoring, evaluation and feedback to governance of a project, projects, policies or programmes on an iterative or even continual basis).

The extent of engagement in the proposal could range from one-off activities alongside other methodological approaches to being the primary focus or methodological approach of the project itself. Engagement will require resources and expertise and is therefore often conducted by dedicated interlocutor organisations or staff with relevant expertise. More detailed information on these activities and useful resources developed over the course of Horizon 2020 can be found in the relevant section below.

Open science practices and relevant resources

Early and open sharing of research

'Early and open sharing' means making research work, methodologies, outputs, such as data and software, among others, and findings available as soon as possible in the research process. Examples of such early sharing include preregistration, registered reports and pre-prints. Early-sharing practices support reproducibility in the research and helps researchers secure precedence over their findings and/or conclusions.

Preregistration of the research plan in a public repository makes available the research hypothesis, study design and planned analysis before data is collected. Preregistration is assisted by dedicated platforms; it increases the transparency, credibility and reproducibility of the results and helps addressing publication bias toward positive findings.

Registered reports are research articles that are peer-reviewed and published in two stages. The study design and analysis plan including hypothesis and methodology undergo peer-review of the quality and suitability of the research question and protocol. If accepted, research protocols are preregistered *(see preregistration)* and the final research article is provisionally accepted for publication. After the research is conducted, an article containing the results and discussion as well as any changes is submitted and undergoes a second round of peer-reviewing. Registered reports reduce publishing bias for positive results as the acceptance for publication is based on the quality of the research, regardless of the outcome.

Preprints are scientific manuscripts that are publicly shared prior to peer-review and journal publication via preprint platforms. An increasing number of journals accepts sharing of preprints prior to publication, but there are exceptions. Beneficiaries have to check the policy of their target journal to clear that a preprint will not pre-empt its publication.

Resources

ORION open science factsheets on preregistration, preprints and crowd science: https://www.orion-openscience.eu/public/2019-02/201810-VA-Orion-FactSheets-V5.pdf

The Centre for open science offers a wealth of resources on Registered Reports, including a list of journals that support them: https://www.cos.io/initiatives/registered-reports

Sherpa Romeo can be used to check the journal submission policy and if the posting of a preprint is considered as prior publication: https://v2.sherpa.ac.uk/romeo/

Preregistration repositories (examples)

- OSF (domain-general preregistration repository service with multiple formats for preregistration)
- AsPredicted (domain-general registry service providing standardised preregistration template)
- Preclinicaltrials.eu (preclinical animal study protocols)
- PROSPERO (health and social care)
- Evidence in Governance and Politics (EGAP) (political sciences)
- Registry for International Development Impact Evaluations (RIDIE) (social sciences)

Preprint servers (examples)

- Zenodo – multidisciplinary;
- Preprints - multidisciplinary
- bioRxiv - Life sciences;
- medRxiv – Medicine and health sciences;
- PsyArxiv - Behavioural sciences;
- SocArXiv - Social sciences and humanities;
- LawArXiv – Law;
- ArXiv - o.a. physics, mathematics, computer science;

Research data management and management of other research outputs

Research data management (RDM) is the process within the research lifecycle that includes the data collection or acquisition, organisation, curation, storage, (long-term) preservation, security, quality assurance, allocation of persistent identifiers (PIDs), provision of metadata in line with disciplinary requirements, licencing, and rules and procedures for sharing of data. RDM is an essential element in any project that generates, collects or re-uses data. Planning ahead to data needs that proposers are likely to encounter during the project is a best practice. For example, provisions need to be in place to ensure that data is managed responsibly *(e.g. the right venue is chosen for deposition, adequate are issued, legal provisions such as General Data Protection Regulation (GDPR) are respected, etc)*. Further, data management should be in line

with the FAIR principles[23], to ensure that researchers can find, access and re-use each other's data, maximising the effectiveness and reproducibility of the research undertaken.

RDM, in line with the FAIR principles is a requirement that should be carried out regardless of whether the data generated and re-used in the project is intended to be openly accessible, or if access restrictions are foreseen. FAIR data is not equivalent to open data (publicly available to everyone to access and reuse). Data can, and should be FAIR even when access is restricted.

RDM and the FAIR principles can be applied to research outputs other than data *(i.e. workflows, protocols, software, samples, etc)*. Proposers are recommended to consider robust management practices for data and other research outputs as early as the proposal stage of their project.

Below are important elements and resources for RDM useful already at proposal stage.

Persistent identifiers (PIDs) are key in ensuring the findability of research outputs, including data. They are globally unique and long-lasting references to digital objects *(such as data, publications and other research outputs)* or non-digital objects such as researchers, research institutions, grants, etc. Frequently used persistent identifiers include digital object identifiers (DOIs), Handles, and others. For further reading on PID types, please refer to https://www.dpconline.org/handbook/technical-solutions-and-tools/persistent-identifiers.

To enhance the findability of research outputs, and their potential reuse, **standardised metadata frameworks** are essential, ensuring that data and other research outputs are accompanied by rich metadata that provides them with context.

To enhance the re-usability of research data, they must be licenced. For more information on the licences required for data under Horizon Europe, please refer to the AGA (article 17).

Trusted repositories assume a central role in the Horizon Europe for the deposition of and access to publications and research data. For a definition of trusted repositories in Horizon Europe please refer to the AGA (article 17). Proposers, with the help of data and research support staff *(e.g. data stewards, data librarians, etc)*, should check whether the repositories that they plan to deposit their data have the features of trusted repositories, and justify this accordingly in their Data Management Plans.

Data management plans (DMPs) are a cornerstone for responsible management of research outputs, notably data and are mandatory in Horizon Europe for projects generating and/or reusing data (on requirements and the frequency of DMPs as deliverables consult the AGA article 17). A template for a DMP is provided under the reporting templates in the reference documents of the Funding and Tenders portal of the European Commission. Its use is recommended but not mandatory. DMPs are formal documents that outline from the start of the project all aspects of the research data lifecycle, which includes its organisation and curation, and adequate provisions for its access, preservation, sharing, and eventual deletion, both during and after a project. Writing a DMP is part of the methodology of the project, since good data management makes the work more efficient, saves time, contributes to safeguarding information and to increasing the value of the data among the beneficiaries themselves and others, during and after the research. DMPs are thus a key means of support when planning and conducting a research project, and, ideally, filling in a DMP should be started prior to the beginning of the project.

[23] FAIR data are data that are curated to satisfy the principles of findability, accessibility, interoperability, and reusability. For further reading: https://www.go-fair.org/fair-principles/

DMPs play a key role in helping researchers to adequately manage research outputs other than data and publications, also in line with the FAIR principles. Such research outputs may be physical or digital, and include original software created during the project, workflows, protocols, new materials such as samples, cell-lines, antibodies, among many others. DMPs should reflect an adequate management strategy for such outputs as well.

A DMP should be a living document, which is updated and enriched as the project evolves. Such updates might occur after attaining milestones related e.g. to the generation of new data or to reflect changes related to the original planning, changes in data/output access provisions or curation policies, changes in consortium practices *(e.g. new innovation potential, decision to file for a patent)*, changes in consortium composition, etc.

A good practice regarding DMPs is to register them as a non-restricted public deliverables to make them openly accessible, unless legitimate reasons exist to keep them confidential. An additional good practice is to publish the DMP in specialised journals or publishing platforms such as RIO etc., or to deposit them in DMP-specific public repositories such as DMPOnline and others.

As practices with regard to data management, storage, and sharing differ widely across disciplines, the DMPs should reflect common disciplinary practices. In addition to domain specificities, DMPs across the board should address an overarching set of data-related requirements including those aspects related to making the data FAIR. Common aspects that need to be addressed in all DMPs include[24]:

- **Data set description**: a sufficiently detailed description of the data generated or re-used, including the scientific focus and technical approach to allow association of their data sets with specific research as well as information on data types and an estimate of the data set's size.

- **Standards and metadata**: the protocols and standards used to structure the data (i.e. fully reference the metadata) so that other scientists can make an assessment and reproduce the dataset. If available, a reference to the community data standards with which their data conform and that make them interoperable with other data sets of similar type.

- **Name and persistent identifier for the data-sets**: a unique and persistent identification (an identifier) of the data sets and a stable resolvable link to where the data sets can be directly accessed. Submission to a public repository normally provides this; many institutional repositories provide similar services.

- **Curation and preservation methodology**: information on the standards that will be used to ensure the integrity of the data sets and the period during which they will be maintained, as well as how they will be preserved and kept accessible in the longer term. A reference to the public data repository in which the data will be/is deposited with relevant consideration on whether the chosen repository meets the requirements of a trusted repository.

- **Data sharing methodology**: information on how the data sets can be accessed, including the terms-of-use or the license under which they can be accessed and re-used, and information on any restrictions that may apply or relevant security and privacy considerations. It is also important to specify and

[24] These aspects are broadly in line with the requirements set forth in Science Europe's Practical Guide to the International Alignment of Research Data Management: https://www.scienceeurope.org/media/4brkxxe5/se_rdm_practical_guide_extended_final.pdf

justify the timing of data sharing. On open access to research data *see below relevant section on open access*.

- **Output management, for research outputs other than data and publications**: The section on output management should show efforts to manage outputs in line with the FAIR principles, including a detailed description of the output, consider relevant metadata standards and the provision of PIDs when depositing the output, or its digital representation if it is physical. The plan should further detail the deposition, curation and preservation methodology foreseen, identifying the right home for the output, and it should set out an approach likely to maximise the re-use and adoption of the output by the wider research community. If the output is physical, the plan should indicate how it would be made available to potential users.

- **Costs and personnel related to RDM**: An estimation of costs related to RDM such as costs for data collection, data documentation, data storage, data access and security, data preservation, data availability and reuse as well as the person/team responsible for data management and quality assurance processes.

The European Open Science Cloud

The European Open Science Cloud (EOSC) aims to deploy and consolidate an open, trusted virtual environment to enable circa 2 million European researchers to store, share, process, analyse, and reuse research digital objects including data, publications and software across disciplines and borders. A European co-programmed Partnership approach for EOSC has been proposed for the period 2021-2030 (https://eosc.eu/). It will bring together institutional, national and European initiatives and engage all relevant stakeholders to deploy a European Research Data Commons where data are Findable, Accessible, Interoperable, Reusable (FAIR). This European contribution to a Web of FAIR Data and Related Services for Science will support open science in a deepened European Research Area and provide the basis for the research and innovation data space foreseen in the European Strategy for Data.

Certain work programmes may require the use of trusted repositories that are federated in EOSC for depositing research data. In that case, data must be deposited in repositories which are registered to the EOSC and support (implicitly or explicitly) the FAIR principles. An initial offering of EOSC resources and services can be found from the EOSC Portal. This offering is expected to continue growing in function of the EOSC rules of participation.

Resources

Metadata standards and Research Data Management guidelines

- The FAIRsharing portal with information and resources on data standards, databases, and policies in the life sciences and other scientific disciplines.

- DM guidelines and good practices for the Life Sciences, the Social Sciences and the Humanities provided by relevant research infrastructures, ELIXIR, CESSDA and DARIAH, respectively along with relevant data resources and repositories/databases.

- For more information on disciplinary metadata standards, visit Digital Curation Centre and Research Data Alliance Metadata Standards Directory.

DMP

- A template for the Horizon Europe DMP is provided A template for a DMP is provided under the reporting templates in the reference documents of the Funding and Tenders portal of the European Commission.

- The RDA FAIR Data Maturity Model Working Group delivers a detailed annotated list of indicators to address when increasing the FAIRness of data.

- For developing DMPs: The DMPONLINE tool (supports the development of project DMPs); ARGOS (online tool); the Data Stewardship Wizard, a joint ELIXIR CZ and ELIXIR NL tool, helps researchers understand what is needed for FAIR-oriented data stewardship, and build their own Data Management Plans.

- The Science Europe Practical Guide to the International Alignment of Research Data Management contains detailed guidance for drafting and evaluating DMPs.

Repositories

See resources under 'open access to research outputs' section below.

Measures to ensure reproducibility of results

Reproducibility is the possibility for the scientific community to obtain the same results as the originators of specific findings. Reproducibility of some or all results is important as it increases the performance of research & innovation (wider use of research results); it limits waste of resources (less duplication and fewer false baselines); it increases the quality and the reliability of research (stronger methods, controls and reporting); and, as a result, it may increase the trust of citizens in science. Therefore, reproducibility is integral part of 'Excellence'; we expect the results of Horizon Europe to be reproducible, and planning should start at proposal stage to make results reusable and reproducible.

Below is a list of practices which tend to increase reproducibility. Some of them may already be required by the MGA (for example DMP, FAIR) or by specific calls and proposers may interweave such practices in various parts of the methodology section as appropriate:

- Specify with precision and no ambiguities the research design and the methodologies that you will be applying.

- Specify how you will deal with negative results, if any, so that others can lean from your project regarding of its outcomes.

- Make prior searches and checks on existing results and data to ensure you are not duplicating unnecessarily.

- Specify how you are making use of pre-prints, preregistration of protocols and registered reports *(see above, 'Early sharing of research results')*, to ensure that your method and research questions are accountable, if applicable.

- Detail the steps you will take to make your research process and tools (software, materials, protocols, flows, ...) transparent and available during and after the research.

- Mention the steps, if any, that you will take to ensure the validity and the quality of the project's process and results *(e.g. peer review, knowledge sharing, independent testing, supervision, quality control mechanisms)*.

- Plan to use the DMP to the full extent possible to detail the assets and materials underlying your data collection and analysis *(see above, 'DMP')*.

- Ensure that your data are FAIR so that others can find them and re-use them to reproduce your results *(see above, 'FAIR')*.
- Specify how you will ensure robust statistical analysis, that can be repeated (power of sample, robust experimental techniques, open software, ...).
- Specify what 'common assets' for research & innovation your project will be building, if any, including knowledge bases, methodologies, evaluation frameworks, ontologies, open repositories, etc.
- Make provisions to validate, demonstrate, make interoperable, scale-up and overall make replicable the results of your R&I activities.
- Consider whether your project will produce digital copies of your results, *e.g. Digital Twins, virtual bodies, digital blueprints, that increase the likelihood of re-use and reproducibility*.

Resources

- An extensive list of resources is provided by the Centre for open science
- Information and resources provided by networks focusing on reproducibility, for example in the UK, Germany, Switzerland
- Guidelines and toolkits on reproducibility, especially specific to your field *(e.g. in biomedical research)*.

Open access to research outputs

Open access is online access at no cost for the end user of research outputs such as scientific publications, data or other engineered outcomes and processes *(e.g. software, models, algorithms, protocols and electronic notebooks)*. Open access often carries less restrictive copyright and licensing barriers than traditionally published works, for both the users and the authors.

Open access enables increased quality and efficiency of research and accelerates the advancement of knowledge and innovation by making results reusable and by improving their reproducibility. It also offers the means for more creativity, more trust in science and greater impacts by building on collective intelligence, facilitating cross-disciplinary research and involvement of all relevant knowledge actors, including citizens.

Horizon Europe requires deposition of scientific peer-reviewed publications and research data and open access (with exceptions for research data) following specific requirements. For guidance on this consult the AGA (article 17).

While it is not mandatory to publish (if a project intends to exploit its results, it may decide not to publish), if **scientific peer-reviewed publications** are produced then they must be open access immediately at publication time under open licenses (such as Creative Commons), providing specific minimum sets of rights of reuse (CC BY for articles and book chapters in edited books and CC BY, CC BY-NC, CC BY-ND, CC BY-NC-ND or equivalent for long-text formats. The following checklist shows what users can do with publications and other outputs licensed under the following Creative Commons licenses.

	YOU CAN			**YOU MUST**	**YOU MAINTAIN**
	Share	**Use for**	**Adapt**	**Attribute**	**Copyright,**

	(copy and redistribute the material in any medium or format)	**commercial purposes**	**(remix, transform and build upon the material)**	**Give appropriate credit, provide a link to the license, and indicate if changes were made.**	**database rights**
CC BY	Yes	Yes	Yes	Yes	Yes
CC BY NC	Yes	No	Yes	Yes	Yes
CC BY ND	Yes	Yes	No If you remix, transform, or build upon the material, you may not distribute the modified material.	Yes	Yes
CC BY NC ND	Yes	No	No	Yes	Yes
CC0	Yes	Yes	Yes	No	No: Waived

It is important to be aware that Horizon Europe requires that enough intellectual property rights are maintained by beneficiaries or authors to ensure the required open access to scientific publications.

Proposers should be aware that beneficiaries are required to retain sufficient intellectual property rights (IPR) to comply with their open access obligations. Authors may need to interact with prospective publishers, in particular when they publish in venues that are not open access. To facilitate compliance with their open access obligations, beneficiaries/researchers are encouraged to notify publishers of their grant agreement obligations (including the licensing requirements) already at manuscript submission. For example, by adding the following statement to their manuscript: "*This work was funded by the European Union under the Horizon Europe grant [grant number]. As set out in the Grant Agreement, beneficiaries must ensure that at the latest at the time of publication, open access is provided via a trusted repository to the published version or the final peer-reviewed manuscript accepted for publication under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights. CC BY-NC, CC BY-ND, CC BY-NC-ND or equivalent licenses could be applied to long-text formats."* If the publishing agreement is contrary to the grant agreement obligations, authors should negotiate its terms and, alternatively, look for a different publishing venue/options.

Data should be deposited in a trusted repository as soon as possible after data production and at the latest by the end of the project. Data underpinning a scientific publication should be deposited at the latest at the time of publication and in line with standard community practices. Beneficiaries of Horizon Europe have to ensure open access to research data generated in their projects under the principle 'as open as possible and as closed as necessary'. This means that data is in principle open, unless beneficiaries decide to restrict access to some or all their research data for legitimate reasons. On open access to data and the legitimate reasons for restricting access consult the AGA (article 17) and section above on research data management.

Open access to other research outputs, such as software, workflows and others, will ensure that these outputs that have been generated by Horizon Europe actions are also freely accessible to all. This will promote transparency, efficiency and reproducibility, as well as trust in science, and will facilitate access for citizens. Proposers/beneficiaries are also encouraged to license research outputs other than publications and data under appropriate licenses. With regard to software, it should be noted that with the exception of CC0 (i.e. public domain dedication) CC licenses are not appropriate (although they can be used for software documentation). Instead, the use of appropriate software licenses, such as those listed as free by the Free Software Foundation and listed as open source by the Open Source Initiative, is strongly recommended.

Resources

Publishing

- Open Research Europe (ORE), the open access publishing platform of the European Commmission for all disciplines, for research stemming from Horizon Europe https://open-research-europe.ec.europa.eu/
- Locate trustworthy open access journals in your field of work in the Directory of Open Access Journals www.doaj.org
- Check whether a journal has an open access policy that is aligned to the Horizon Europe requirements with the Journal Checker Tool https://journalcheckertool.org/ (tool to become available toward the end of 2021).
- Locate trustworthy open access publishers and open access monographs in the Directory of Open Access Books https://www.doabooks.org/

Repositories

Search for open repositories in www.opendoar.org

www.re3data.org offers a Repository Finder to facilitate the search for a suitable general or discipline-specific repository for various kinds of research outputs.

The general-purpose repositories for multidisciplinary research results including data, software and publications:

- www.zenodo.org - general-purpose repository for data, software and publications
- https://figshare.com/ – repository for any research outputs of all file formats
- open science Framework (OSF) - open source project management tool and repository

Repositories for Software:

- GitHub is development platform to host and review code, manage projects, and build software
- Savannah hosts free projects that run on free operating systems, with a focus on GNU software
- SourceForge is an Open Source software community and hosting platform
- Launchpad is a software collaboration and hosting platform

Repositories for experimental workflows and protocols:

- Protocol Exchange (open repository for sharing scientific research protocols) and
- Protocols (Platform for data management and protocol sharing

Discipline-specific repositories:

- ELIXIR Deposition Databases and ELIXIR Core Data Resources (repositories recommended for the deposition of life sciences experimental data)

Publishing using open peer-review

Open peer review is an umbrella term for various alternative review methods that seek to make classical peer review more transparent and accountable. It has neither a standardised definition, nor an agreed schema of its features and implementations. Open peer review refers to a peer review process that contains one or more of these elements[25]:

- Authors and reviewers are aware of each other's identity during or after the review process.
- Review reports are published alongside the relevant article.
- The wider community is able to contribute to the review process (peer researcher or even general public).
- Manuscripts are made immediately available in advance of the formal peer review procedure.
- Review or commenting on the final 'version of record' is made possible.
- Direct, reciprocal discussion between authors and reviewers and/or between reviewers is allowed and encouraged.
- Review can be decoupled from publishing when facilitated by a different organisational entity than the venue of publication *(e.g. publishing platforms)*.

Some journals and scholarly publishers apply open peer review. Some platforms, including preprint servers, may also facilitate open peer review of preprints. For example, Open Research Europe, the open access publishing platform of the European Commission uses the open peer review model, where both names of authors and reviewers are public, and the review report is open access.

Open peer review is an important aspect of open science. Opening up what has traditionally been a closed process increases opportunities to spot errors, validate findings and to increase the overall trust in published outputs. Open peer-review is considered by some among the measures that increase the quality of the peer review process (by making it more constructive), and the transparency of research (with 'openness' applying to all processes in the scientific workflow). Another argument to engage in open peer review is that it ensures reviewers to get credit for their efforts.

Resources

Ross-Hellauer T. What is open peer review? A systematic review. *F1000Research* 2017, 6:588 (https://doi.org/10.12688/f1000research.11369.2)

[25] Taxonomy of open peer review elements based on Ross-Hellauer T. What is open peer-review? A systematic review listed under 'Resources'.

FOSTER proposes a module to learn basics on open peer review (https://www.fosteropenscience.eu/learning/open-peer-review)

Open Research Europe (https://open-research-europe.ec.europa.eu) supports open peer review in all scientific fields for all Horizon Europe publications.

Some discipline-specific venues support open peer review and are suitable for the life sciences *(e.g. eLIFE, Bio Med Central, BMJ, GIGA science and BioRxiv, ASAPbio)*, the social sciences *(e.g. SAGE open, Wiley and SocArXiv)* and the arts and humanities (SAGE open, Wiley and digitalculturebooks).

Citizen, civil society and end-user engagement

Citizen and civil society engagement is a programme principle and operational objective that refers to the opening up of R&I processes to society to develop better, more innovative and more relevant outcomes, and to increase societal trust in the processes and outcomes of R&I.

Opening up the R&I system towards society and supporting citizens, civil society and end-users to participate in R&I – as sources of ideas, knowledge and/or data, as data collectors and/or analysers, and/or as testers and/or end users – enlarges the collective intelligence, capabilities and scope of the R&I and is likely to lead to greater creativity and robustness of the outcomes and reduced time-to-market of the innovative products and services. It also increases the relevance and responsiveness of R&I, ensuring that its outcomes align with the needs, expectations and values of society. Moreover, it is a key element for improving the transparency, co-ownership and trust of society in the process and outcomes of R&I. Conducting R&I openly, responsibly, transparently, and in adherence to the highest standards of research integrity and ethics is also important for responding to increased science denial.

Engagement can range from the identification and conceptualisation of R&I priorities *(e.g. through deliberative or other participatory processes)*, to the implementation, utilisation and assessment of R&I results *(e.g. through data collection, data analysis, discussion and publication or presenting scientific results, working in fab-labs to develop new innovations, testing innovations and solutions, and evidence-based advocacy)*.

The following are activities that proposers may consider including in their proposal:

Co-design activities could involve workshops, focus groups or other means to develop R&I agendas, roadmaps or policies. These could be one-off activities in one or several different localities or repeated consultations with the same or varying groups. They could involve citizens and/or one or many organisation types at the same time. Co-design activities often include deep discussion on the implications, the ethics, the benefits and the challenges related to R&I courses of action or technology development. Co-design could be the overall focus of a project *(e.g. to develop a roadmap for a certain technology)*, a Work Package within a project that uses the outcomes of the co-design in subsequent Work Packages, or a supporting Work Package that provides continual feedback on project activities throughout the project cycle.

Co-creation activities, such as citizen science or user-led innovation, involve citizens or end-users directly in the development of new knowledge or innovations, through a range of different levels of participation. These could include identifying R&I questions to be tackled by the project, developing a methodology, observing, gathering and processing data, right up to the publication and presentation of results. The co-creation activities could be the focus of a proposal, or could be one of the methodological approaches taken alongside others.

Co-assessment activities, such as assisting in the monitoring and evaluation of the progress of the project, portfolio of projects, policies or programmes, help ensure an

iterative or even continual process of interaction with citizens, civil society and end-users throughout the project cycle on the quality, utilisation and (potential) impact of project outputs.

In certain cases, citizens, civil society and end-users may be involved across different stages of the R&I and/or policy cycle, by deciding on the research to be conducted, conducting that research, analysing and interpreting the data, and engaging in related advocacy or policy activities.

An important aspect to consider in many cases is the *inclusivity* of the engagement and ensuring diversity of participation. The challenge of sustaining engagement should not be underestimated and different forms of compensation or rewards could be considered, as well as measures for two-way learning between scientists or innovators and the co-creators.

Engagement requires *resources and expertise*. Often, engagement is conducted by dedicated interlocutor organisations that already have the reach, trust, and expertise to successfully carry out the engagement exercises. The integration of the engagement activities, and their outcomes within the project design, should aim to ensure use of the outcomes (i.e. they are not 'window dressing' or unimportant side-activities), and that there is appropriate feedback and acknowledgement to the engaged. If the call conditions allow it, the launch of calls for small grants or prizes can be useful (or in some other cases even essential) for reaching and engaging local communities and small associations, civil society organisations, social enterprises, or small businesses.

Generally, the greater the interaction from across the quadruple helix (academia-industry-government-civil), the more the R&I results will be reliable, trusted and taken up by society. Different organisation types, and different societal perspectives, help ensure that the processes and the outcomes of the R&I align with the needs, values and expectations of society. In many cases, the body of knowledge and practice built up in Horizon 2020 on Responsible Research and Innovation will be relevant.

Co-design, co-creation, and co-assessment, as (sometimes) radical departures from more traditional forms of R&I, could imply changes to the institutional governance of the participating beneficiaries that last beyond the lifetime of project funding.

Terminology:

- 'Citizens' should be understood as individuals acting on their own initiative and not on behalf of their employer or sectoral interests. It does not refer to any legal citizenship(s) that people may or may not hold.
- 'Civil society' refers to the ensemble of citizens and civil society organisations that are active in the public sphere but distinct from government and business.
- 'Civil society organisations (CSOs)' include all non-state, not-for-profit structures, such as citizens' associations, patient groups, professional societies or groups, consumer groups, humanitarian organisations, non-governmental organisations (NGOs), foundations and charities.
- 'End-users' are public, private or civil (i.e. civil society, *see above*) organisations that constitute potential *users* of the R&I outputs.
- 'Engagement' means the involvement of citizens and civil society in co-designing R&I agendas, in co-creating R&I contents, and/or in co-assessing R&I outcomes.

Resources

The Responsible Research and Innovation (RRI) toolkit

Action catalogue of inclusive research methods

Methods to engage the public

The societal readiness Thinking Tool

Innovation Compass Self-check Tool for SMEs

Living innovation co-creation tool-kit for responsible innovation

Resources to open up research and innovation actors to society

Models and guidelines to increase patient engagement in health research

RRI Practice Handbook for research organisations

EU portal for citizen science projects, initiatives, networks, organisations, and training courses

Innovation Procurement

What is innovation procurement and how is it relevant for Horizon Europe?

Innovation procurement happens when public procurement is used to drive innovation from the demand side. This enables the public sector to speed up the development and adoption of innovative solutions that can improve the quality and efficiency of public services or address wider societal challenges while opening concrete business opportunities for companies in Europe to bring innovations to the market.

Innovation procurement is therefore a topic of **cross-cutting importance for all pillars of the Horizon Europe programme**:

- Under the *Excellence Science pillar*, innovation procurement can help increase the EU's global scientific competitiveness in the field of research infrastructures. In the field of supercomputing for example, innovation procurement actions financed under FP7 and Horizon 2020 have paved the way for stronger European cooperation and competitiveness through the joint undertaking for High Performance Computing (HPC).

- Under the *Global Challenges and European Industrial Competiveness pillar* innovation procurement can trigger new research and development (R&D) and deployment of innovative solutions to address societal challenges *(e.g. in health, security, energy, environment, transport…)* and reinforce technological and industrial capacities. For EU-missions, innovation procurement can also play a key role to bring to the market solutions that can tackle big problems. This online brochure bundles examples of innovation procurement funded by the EU research and innovation programme that successfully tackled societal challenges in several sectors.

- Under *the Innovative Europe pillar*, innovation procurement links to SME support via the European Innovation Council.

Finally, innovation procurement is also central to the European Defence Fund and may also be used in the context of the Euratom Programme.

What is the strategic importance for Europe?

Benchmarking shows that in Europe investments on innovation procurement are 2 times lower compared to other leading global economies. Underinvestment is the

biggest in R&D procurement (5 times lower) and in adoption of ICT based solutions (3 times lower). As innovation procurement is crucial for public sector modernisation and business growth, **mainstreaming innovation procurement is of strategic importance to strenghten Europe's global competitiveness**. By closing the gap between supply and demand in a way that reinforces EU strategic autonomy, innovation procurement can make a key contribution to economic recovery[26]. It can increase resilience in the supply chain by opening up opportunities for innovative companies, including also SMEs and Startups, to access the public procurement market, attract financial investment and scale up their business.

How does Horizon Europe support innovation procurement?

Horizon Europe provides EU funding to start innovation procurement. A key difference to other research and innovation actions is that funding for innovation procurement is not targeted at potential 'providers' but at potential 'buyers' of innovative solutions: public procurers, possibly in cooperation with private and NGO buyers.

Two complementary types of innovation procurement are supported**:**

- **Public Procurement of Innovative solutions (PPI)** can be used by procurers when challenges of public interest can be addressed by innovative solutions that are nearly or already in small quantities on the market. PPI can thus be used when there is no need for procurement of new R&D to bring solutions to the market, but as a clear signal from a sizeable amount of early adopters/launch customers that they are willing to purchase/deploy the innovative solutions if those can be delivered with the desired quality and price by a specific moment in time. PPI may still involve conformance testing before deployment.

- **Pre-Commercial Procurement (PCP)** can be used by procurers when there are no near-to-the-market solutions that meet all the procurers' requirements and new R&D is needed to get new solutions developed and tested to address the procurement need. PCP can then compare the pros and cons of alternative approaches to address the challenge and eliminate risk from promising innovations step-by-step via solution design, prototyping, development and first product testing. PCP is a public procurement of R&D services that does not include the deployment of commercial volumes of end-products *(see PPI for the latter)*.

In several areas, there is a need for European cross-border cooperation on innovation procurement to address challenges that require cross-border interoperability or interconnection, to pool resources for problems that cannot be financed from only national funding, to obtain higher quality and lower cost solutions and to reduce fragmentation of demand so that companies can sell their solutions to a wide European market.

Therefore, **Horizon Europe provides different types of support for buyers from different countries** that want to collaborate together on innovation procurement**:**

- **Coordination and Support actions (CSA)** support coordination and networking activities for groups of procurers to investigate the feasibility and/or prepare the ground for concrete future innovation procurement. CSA grants do not provide EU co-financing for a procurement action.

[26] Impacts of EU funded PCP show 20%-30% efficiency and quality improvements in public services, doubling of the amount of public procurement directly awarded to startups/SMEs, a factor 20 increase in the amount of cross-border contract award to startups/SMEs and a factor 4 additional financing secured by startups/SMEs. The use of place of performance and IPR/commercialisation conditions that fuel commercialisation in Europe, also contributes to EU strategic autonomy.

- **PCP or PPI actions** co-finance both the procurement cost for groups of procurers to buy the research, development, validation and possible first deployment (PCP) or wider scale deployment (PPI) of innovative solutions as well as additional related costs to prepare, manage and follow up such procurement. A minimum of two public procurers from two different EU Member States or associated countries are required in the buyers' group. One of them will act as lead procurer to coordinate and lead one joint PCP or PPI action or several separate but coordinated PPI actions for the buyers' group. In addition other procurers, e.g. private procurers or NGO procurers, can be part of the buyers' group. Both in PCP actions, PPI actions and CSAs that prepare PCP or PPI procurements, other entities *(e.g. experts, certification bodies)* can also participate in the additional activities of the action, except entities that are potential suppliers of solutions for the procurement action or have another potential conflict of interest with the procurement action. In total there must be minimum three participants from three different Member States or countries associated to Horizon Europe in the action. Entities formed by several public procurers from different countries can also apply for this type of funding *(e.g. European Groupings of Territorial Cooperation- EGTCs, European Research Infrastructure Consortia – ERICs, Central Purchasing Bodies, etc)*.

For more information about the CSA and PCP and PPI action instruments, refer to General Annex H of the Horizon Europe Work Programme.

The EU itself can also implement innovation procurement from the Horizon Europe budget, either alone or together with public buyers from Member States. An example funded by Horizon Europe is the EU blockchain PCP implemented by the European Commission.

It is also possible for one single buyer to implement PCP and PPI actions on its own, under the subcontracting activities of a regular research and innovation grant.

Examples of projects and achievable impacts?

Examples of ongoing PCP and PPI projects funded by previous FP7 and CIP programs can be found here. Showcase success stories are bundled here. More information about the impacts achieved by past projects is also available here.

How to find and apply for relevant calls?

If you are a public buyer and you are looking for an overview of all actions that support innovation procurement, you can search all calls on the Funding and Tenders portal via the keywords 'innovation/innovative procurement', 'PCP', 'PPI'.

Where to find support to prepare a proposal?

Looking for partners? Participate in info days and EU events on innovation procurement in preparation of calls for proposals. Get connected with other procurers and experts from around Europe that are interested and active on innovation procurement via the European Procurement Forum.

National Contact Points (NCPs) in every Member State offer information and guidance in your own language on how to apply for Horizon Europe funding and may help with partner search.

Check if there is an innovation procurement competence/support center in your country where you could find information and support. This European network of national innovation procurement competence centers can be a starting point.

Is my organisation a public procurer?

Public procurers are organisations that are contracting authorities or contracting entities according to the definition of those terms in the EU public procurement directives 2014/24/EU, 2004/25/EU, 2009/81/EC.

'**Contracting authority**' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law (for the full definition, *see Article 2(1)(1) of Directive 2014/24/EU*). Bodies governed by public law also include entities financed mostly by the State, regional or local authorities, or other bodies governed by public law and entities controlled by those bodies (for the full definition, *see Article 2(1)(4) of Directive 2014/24/EU*). This includes for example ministries, regions, cities, road management authorities, public hospitals, central purchasing bodies etc.

'**Contracting entities**' refers to entities operating in specific sectors (such as utilities for water, energy, transport, postal services covered by Directive 2014/25/EU and contracting entities in the field of security covered by Directive 2009/81/EC). They may be contracting authorities, public undertakings or entities operating on the basis of special or exclusive rights (for the full definition, *see Article 4 of Directive 2014/25/EU*).

Under Horizon Europe, public procurers also include entities that are contracting authorities/entities according to the above definition but to which the EU public procurement Directives itself do not apply *(e.g. international organisations such as ERICs - European Research Infrastructure Consortia)*.

Related links

- Overview and links to EU policy initiatives on PCP and PPI
- Subscribe to the innovation procurement newsletter to stay up-to-date with latest EU policy initiatives, workshops, call news and more.
- Topics supporting Innovation Procurement
- In order to help procurers implement PCP and PPI, the EU also developed specific guidance in the Annotated Model Grant Agreement and example template tender documents for Horizon funded PCP actions and for PPI actions.

Key Digital Technologies

Due diligence is required regarding the trustworthiness of all artificial intelligence-based systems or techniques used or developed in projects funded under the Horizon Europe Framework Programme. Wherever appropriate, AI-based systems or techniques must be developed in a safe, secure and responsible manner, with a clear identification of and preventative approach to risks.

To a degree matching the type of research being proposed (from basic to precompetitive) and as appropriate, AI-based systems or techniques should be, or be developed to become (implicitly or explicitly contributing to one or several of the following objectives):

- technically robust, accurate and reproducible, and able to deal with and inform about possible failures, inaccuracies and errors, proportionate to the assessed risk posed by the AI-based system or technique
- socially robust, in that they duly consider the context and environment in which they operate

- reliable and to function as intended, minimising unintentional and unexpected harm, preventing unacceptable harm and safeguarding the physical and mental integrity of humans

- able to provide a suitable explanation of its decision-making process, whenever an AI-based system can have a significant impact on people's lives.