Horizon Europe Programme

Standard Application Form (EIT)

Application form (Part A)

Version 2.0
21 January 2022

Disclaimer
This document is aimed at informing potential applicants for Horizon Europe funding. It serves only as an example. The actual Web forms and templates, provided in the online submission system under the Funding and Tenders Portal, might differ from this example.

Structure of the Proposal

The proposal contains two parts:

- **Part A** of the proposal **is generated by the IT system. It is based on the information entered by the participants through the submission system in the Funding & Tenders Portal.** The participants can update the information in the submission system at any time before final submission.

- **Part B** of the proposal is the narrative part that includes three sections that each correspond to an evaluation criterion. Part B needs to be uploaded as a PDF document following the templates downloaded by the applicants in the submission system for the specific call or topic. The templates for a specific call may slightly differ from the example provided in this document.

The electronic submission system is an online wizard that guides you step-by-step through the preparation of your proposal. The submission process consists of 6 steps:

- Step 1: Logging in the Portal
- Step 2: Select the call, topic and type of action in the Portal
- Step 3: Create a draft proposal: Title, acronym, summary, main organisation and contact details
- Step 4: Manage your parties and contact details: add your partner organisations and contact details.
- Step 5: Edit and complete web forms for proposal part A and upload proposal part B
- Step 6: Submit the proposal

- **Instructions and footnotes in green will not appear in the text generated by the IT system.**
- **For options *[*in square brackets*]*: the option that applies will be automatically shown in the IT system (Part A) or included in the template of Part B offered by the IT system or you must select the appropriate value from a predefined list.**
- **For fields in [grey in square brackets] (even if they are part of an option as specified in the previous item): enter the appropriate data in the IT system.**
- **Data in coloured fields will be prefilled by the IT tool.**

HISTORY OF CHANGES		
Version	**Publication date**	**Changes**
1.0	10.03.2021	▪ Initial version
1.1	19.04.2021	▪ Formatting and alignment
2.0	21.01.2022	▪ Added definitions for role of participants

Application Forms

Please check our wiki for help on navigating the form.

Horizon Europe

Application forms (Part A)

Topic:

Type of action:

Type of Model Grant Agreement:

Proposal number:

Proposal acronym:

Table of contents

The forms must be filled in for each proposal using the templates available in the Submission System. Some data fields in the forms are pre-filled based on the previous steps in the Submission wizard.

1 – General information

Section 1 provides basic data on the proposal. It can be filled in by contacts of the coordinator. Other participants may view this section only. Read-only parts are marked in blue.

Topic	Type of action
Call	Type of Model Grant Agreement

Acronym	*Acronym is mandatory*
Proposal title	*Max 200 characters (with spaces). Must be understandable for non-specialists in your field.*

Note that for technical reasons, the following characters are not accepted in the Proposal Title and will be removed: < > " &

Duration in months	*Estimated duration of the project in full months.*
Fixed keyword	
Fixed keyword	
Free keywords	*Enter any words you think give extra detail of the scope of your proposal (max 200 characters with spaces).*

Abstract

The abstract should provide the reader with a clear understanding of the objectives of the proposal, how they will be achieved, and their relevance to the Work Programme. This summary will be used as the short description of the proposal in the evaluation process and in communications to the programme management committees and other interested parties. It must therefore be short and precise and should not contain confidential information. Use plain typed text, avoiding formulas and other special characters. If the proposal is written in a language other than English, please include an English version of this abstract in the Part B (technical description) of the proposal.

Has this proposal (or a very similar one) been submitted in the past 2 years in response to a call for proposals under any EU programme, including the current call? *A `similar' proposal or contract is one that differs from the current one in minor ways, and in which some of the present consortium members are involved.*	○ Yes	○ No
Please give the proposal reference or contract number	XXXXX-X	

Declarations

These declarations can be filled in by any coordinator contact(s). All declarations are mandatory.

1) We declare to have the explicit consent of all applicants on their participation and on the content of this proposal.	☐
2) We confirm that the information contained in this proposal is correct and complete and that none of the project activities have started before the proposal was submitted (unless explicitly authorised in the call conditions).	☐
3) We declare: – to be fully compliant with the eligibility criteria set out in the call – not to be subject to any exclusion grounds under the EU Financial Regulation 2018/1046 – to have the financial and operational capacity to carry out the proposed project.	☐
4) We acknowledge that all communication will be made through the Funding & Tenders Portal electronic exchange system and that access and use of this system is subject to the Funding & Tenders Portal Terms & Conditions.	☐
5) We have read, understood and accepted the Funding & Tenders Portal Terms & Conditions and Privacy Statement that set out the conditions of use of the Portal and the scope, purposes, retention periods, etc. for the processing of personal data of all data subjects whose data we communicate for the purpose of the application, evaluation, award and subsequent management of our grant, prizes and contracts (including financial transactions and audits).	☐
6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.	☐
7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 2021/821, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used).	☐
8) We confirm that the activities proposed do not – aim at human cloning for reproductive purposes; – intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or – intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer. – lead to the destruction of human embryos (for example, for obtaining stem cells) These activities are excluded from funding.	☐
9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State	☐
10) *[Additional option for LUMP SUM Grants:* For Lump Sum Grants with a detailed budget table: We understand and accept that the EU lump sum grants must be reliable proxies for the actual costs of a project and confirm that the detailed budget for the proposal has been established in accordance with our usual cost accounting practices and in compliance with the basic eligibility conditions for EU actual cost grants (see *AGA — Annotated Grant Agreement, art 6*) and exclude costs that are	☐

ineligible under the Programme. Purchases and subcontracting costs must be done taking into account best value for money and must be free of conflict of interest.]	

The coordinator is only responsible for the information relating to their own organisation. Each applicant remains responsible for the information declared for their organisation. If the proposal is retained for EU funding, they will all be required to sign a declaration of honour.

False statements or incorrect information may lead to administrative sanctions under the EU Financial Regulation.

2 – Participants

List of participating organisations

#	Participating Organisation Legal Name	Country
1		
2		
3		

Coordinator contacts have the rights to:

- *add, delete, edit and re-order partners in the consortium*
- *add, delete, edit and re-order contact points for those organisations*
- *edit all sections of the administrative forms*
- *upload, delete, view and download Part B and Annexes (when required for the call)*
- *submit the proposal*

Participant contacts may:

- *view all the information in this screen, but not edit it*
- *edit only the section for their organisation in the administrative forms (including budget)*
- *view the entire administrative forms*
- *view/download the Part B and other Annexes*

You can manage the list of organisations and access rights of persons at Step 4 of the submission process. You may identify and give access to as many contact persons of the selected organisations as you wish. The identification is based upon the e-mail address of the person. When you add a contact person, you will be prompted to supply the contact details: name, e-mail, phone.

Person in charge of the proposal (main contact person): Each organisation needs to have one main contact person identified; the main contact person will have to fill in full contact details in the administrative form. The 'Main Contact Person' for the coordinating organisation (Participant no. 1) will become the primary contact person for the Services. Other contact persons may also be identified and may receive read-only or full access rights. Contact persons with full access rights of the coordinator (Participant no. 1) will be called 'Coordinator contacts' in the Funding & Tenders Portal, while for the other participants 'Participant Contacts'; contact persons with read-only rights will be called 'Team Members'. Other contact persons are listed with basic details in the administrative form.

Access rights: The main contact person and contact persons of the coordinator with full access rights have the same level of rights: they can manage the list of participants and contacts, edit any part of the administrative part of the proposal and upload any attachments (eg. Part B - technical description), and submit the proposal. Contact persons with read-only rights can only view/download the information. Participant contacts with full access rights can only edit their section of the administrative form and view all proposal data.
Access rights can be revoked by the Coordinating Organisation contacts. The person who created the proposal cannot be deleted.

Invitation: All contacts will receive an e-mail and a notification to the Portal about the invitation to the proposal upon saving the data at Step 4 of the submission process.

Organisation data

The section shows the administrative data of the participating organisation as registered and/or validated in the central registry of organisations of the European Commission, linked to the given PIC number. Data in blue is read-only, modification is not possible in the proposal forms. For more information on how to modify this information, please visit the online manual on the participant register.

PIC ***Legal name***

Short name

Address of the organisation

Street

Town

Postcode

Country

Webpage

Specific legal statuses

Read more about legal statuses.

Public ..... unknown

Legal person ..... unknown

Non-profit ..... unknown

International organisation..... unknown

International organisation of European interest..... unknown

Secondary or Higher education establishment..... unknown

Research organisation..... unknown

SME status

The enterprise data of the organisation is taken from the Participant Register. Changes to the self-declared or self-assessed SME data can be performed by the self-registrant or by the LEAR (Legal Entity Appointed Representative) in the Participant Register.

SME self declared status ..... unknown

SME self-assessment ..... unknown

SME validation sme ..... unknown

Based on the above details of the Participant Registry the organisation is not an SME (small- and medium-sized enterprise) for the call.

Departments carrying out the proposed work

The information serves mainly statistical purposes. For determining the eligibility of the proposal, the official address of the organisation is taken into account.

Department 1

Department name		☐ not applicable
	☐ Same as organisation address	
Street	*Please enter street name and number*	
Town		
Postcode		
Country		

Links with other participants

Please indicate if there are dependencies with other participants of the proposal.
Two participants (legal entities) are dependent on each other where there is a controlling relationship between them:
** A legal entity is under the same direct or indirect control as another legal entity;or*
** A legal entity directly or indirectly controls another legal entity;or*
** A legal entity is directly or indirectly controlled by another legal entity.Control:*

Legal entity A controls legal entity B if:
** A, directly or indirectly, holds more than 50% of the nominal value of the issued share capital or a majority of the voting rights of the shareholders or associates of B, or*
** A, directly or indirectly, holds in fact or in law the decision-making powers in B.*

The following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50 % of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

Type of link	***Participant***	
*[*Same group*]* *[*Controls*]* *[*Is controlled by*]*	*Select one participant from the list of participants*	

Main contact person

This will be the person the EU services will contact concerning this proposal (e.g. for additional information, invitation to hearings, sending of evaluation results, convocation to start grant preparation). The data in blue is read-only. Details (name, first name and e-mail) of Main Contact persons should be edited in step 'Participants' of the submission wizard.

Title Gender ○ Woman ○ Man ○ Non binary

First name Last name

E-mail

Position in org. *Please indicate the position of the person*

Department ☐ Same as organisation

☐ Same as organisation address

Street

Town Post code

Country

Website

Phone 1 Phone 2

Other contact persons

First name	Last name	e-mail	Phone

Researchers involved in the proposal

Include only the researchers involved in the proposal, (see below definition of 'researcher'). You do not need to include in the table the identity of other persons involved in the proposal who are not researchers.

'Researchers are professionals engaged in the conception or creation of new knowledge. They conduct research and improve or develop concepts, theories, models, techniques instrumentation, software or operational methods. (Frascati Manual 2015)'

Include also person in charge of the proposal if a researcher.

Title	First Name	Last Name	Gender	Nationality	E-mail	Career stage[1]	Role of researcher (in the project)	Reference Identifier	Type of identifier
			*[*Woman*]* *[*Man*]* *[*Non-binary*]*			*[*Category A – Top grade researcher*]* *[*Category B – Senior researcher*]* *[*Category C – Recognised researcher*]* *[*Category D – First stage researcher*]*	*[*Leading*]* *[*Team member*]*		*[*ORCID*]* *[*Researcher Id*]* *[*Other - specify*]*

[1] Career stages as defined in Frascati 2015 manual:
Category A – Top grade researcher: the single highest grade/post at which research is normally conducted. Example: 'Full professor' or 'Director of research'.
Category B – Senior researcher: Researchers working in positions not as senior as top position but more senior than newly qualified doctoral graduates (IsCED level 8). Examples: 'associate professor' or 'senior researcher' or 'principal investigator'.
Category C – Recognised researcher: the first grade/post into which a newly qualified doctoral graduate would normally be recruited. Examples: 'assistant professor', 'investigator' or 'post-doctoral fellow'.
Category D – First stage researcher: Either doctoral students at the IsCED level 8 who are engaged as researchers, or researchers working in posts that do not normally require a doctorate degree. Examples: 'PhD students' or 'junior researchers' (without a PhD).

Role of participating organisation in the project *Applicants may select more than one option.*		*Definitions*
Project management	☐	*Click if your organisation will do project management activities (i.e. assigning the tasks, reporting and interface with the EC). These tasks are normally carried out by the coordinator, but other participants can also contribute.*
Communication, dissemination and engagement	☐	*Click if your organisation will be in charge of communication, dissemination and engagement. This can be centralised by one partner or split across the partners.*
Provision of research and technology infrastructure	☐	*Click if your organisation is providing a research facility or research equipment.*
Co-definition of research and market needs	☐	*Click if your organisation will be involved in the co-defining the research and market needs. Usually it is a company that intends to later use the research results, or a NGO that will use the solution. This will help the project further tailor its results to respond to specific needs of the end user.*
Civil society representative	☐	*Click if your organisation belongs to civil society (NGO, association, organisation, consumer group, community group, charity, etc.).*
Policy maker or regulator, incl. standardisation body	☐	*Click if your organisation is a policy maker (local, regional, national, European level), regulator or a standardisation body.*
Research performer	☐	*Click if your organisation is in charge of performing the research during the project.*
Technology developer	☐	*Click if your organisation is in charge of developing the technology during or after the project.*
Testing/validation of approaches and ideas	☐	*Click if your organisation is in charge of testing/validating the approach and ideas.*
Prototyping and demonstration	☐	*Click if your organisation is in charge of developing the prototypes and performing demonstrations.*
IPR management incl. technology transfer	☐	*Click if your organisation is in charge of IPR management including technology transfer at the end of the grant.*
Public procurer of results	☐	*Click if your organisation (public authority, hospital, university, local government, etc) will be using the results afterwards.*
Private buyer of results	☐	*Click if your organisation (from the private sector) will be using the results afterwards.*
Finance provider (public or private)	☐	*Click if your organisation will be providing the financing for the exploitation during or after the end of the project.*
Education and training	☐	*Click if your organisation is in charge of educating and training researchers.*
Contributions from the social sciences or/and the humanities	☐	*Click if your organisation is in charge of contributing to the social sciences or/and the humanities dimension to the research projec.t*
Other Specify (50 character limit):	☐	

List of up to 5 publications, widely-used datasets, software, goods, services, or any other achievements relevant to the call content.

Type of achievement	**Short description**
*[*Publication*]* *[*Dataset*]* *[*Software*]* *[*Good*]* *[*Service*]*	Key elements of the achievement, including a short qualitative assessment of its impact and (where available) its digital object identifier (DOI) or other type of persistent identifier (PID). Publications, in particular journal articles, are expected to be open access. Datasets are expected to be FAIR and 'as open as possible, as closed as necessary'.

*[*Other achievement*]*	

List of up to 5 most relevant previous projects or activities, connected to the subject of this proposal

Name of Project or Activity	**Short description**

Description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work

Name of infrastructure or equipment	**Short description**

Gender equality plan

Having a gender equality plan is an eligibility criterion for Public bodies, Higher education establishments and Research organisations from Member States and Associated Countries. Be aware that if the proposal is selected, having a Gender Equality Plan will be necessary before the grant agreement signature (applicable on calls with deadlines in 2022 and beyond). Does the organisation have a Gender Equality Plan (GEP) covering the elements listed below? **Minimum process-related requirements (building blocks) for a GEP** – **Publication:** formal document published on the institution's website and signed by the top management – **Dedicated resources:** commitment of human resources and gender expertise to implement it. – **Data collection and monitoring:** sex/gender disaggregated data on personnel (and students for establishments concerned) and annual reporting based on indicators. – **Training:** Awareness raising/trainings on gender equality and unconscious gender biases for staff and decision-makers. **Content-wise, recommended areas** to be **covered** and addressed via concrete measures and targets are: ○ work-life balance and organisational culture; ○ gender balance in leadership and decision-making;	○ Yes	○ No

○ gender equality in recruitment and career progression; ○ integration of the gender dimension into research and teaching content; ○ measures against gender-based violence including sexual harassment.		

3 – Budget for the proposal

			Estimated expenditure								Estimated income					
											Requested EU contribution			Revenues	Other sources of financing		
			Estimated eligible costs								EU contribution to eligible costs						
No	Participant name	Country	A. Personnel costs/€ (a1)	B. Subcontracting costs/€ (b)	C. Purchase costs			D. Other cost categories	E. Indirect costs/€ (e) = 25% * [(a1) + (c1) + (c2) + (c3) + (d7)]	Total eligible costs (h) = (a1) + (b) + (c1) + (c2) + (c3) + (d) + (e)	Funding rate (U)	Maximum EU contribution to eligible costs (l) = (U) * (h)	Requested EU contribution to eligible costs/€ (Requested grant amount) (m) (n)	Income generated by the action (o)	Financial contributions (q)	Own resources (r)	Total estimated income (s)=(n)+(o)+(p)+(q) + (r)
					C.1 Travel and subsistence/€ (c1)	C.2 Equipment/€ (c2)	C.3 Other goods, works and services/€ (c3)	D.X [specific cost category] /€ (dx)									
1	Participant 1	NL															
2	Participant 2	LB															
	Affiliated Entity	LB															
3	Participant 3	DE															
	Associated Partner	AR															
Total																	

Possible 'Other cost categories' for Horizon Europe

			Estimated project expenditure									
			Estimated eligible costs									
			D. Other cost categories									
No	Participant name	Country	D.1 Financial support to third parties (Actual costs) (d1)	D.2 Internally invoiced goods and services (Unit costs - usual accounting practices) (d2)	[D.3 Transnational access to research infrastructures (Unit costs) (d3)]	[D.4 Virtual access to research infrastructures (Unit costs) (d4)]	[D.5 PCP/PPI procurement costs (Actual costs) (d5)]	[D.6 Euratom Cofund staff mobility costs (Unit costs) (d6)]	[D.7 ERC additional funding (Actual costs) (d7)]	[D.8 ERC additional funding (subcontracting, FSTP and internally invoiced goods and services) (Actual costs) (d8)]		
1	Participant 1	NL										
2	Participant 2	LB										
	Affiliated Entity	LB										
3	Participant 3	DE										
	Associated Partner	AR										
Total												

4 – Ethics and Security

Ethics issues table

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

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

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

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

Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		○ Yes ○ No	
If **YES**:	Is it a clinical trial?	○ Yes ○ No	
	Is it a low-intervention clinical trial?	○ Yes ○ No	
3. HUMAN CELLS / TISSUES (not covered by section 1)			Page
Does this activity involve the use of human cells or tissues?		○ Yes ○ No	
If **YES**:	Are they human embryonic or foetal cells or tissues?	○ Yes ○ No	
	Are they available commercially?	○ Yes ○ No	
	Are they obtained within this project?	○ Yes ○ No	
	Are they obtained from another project, laboratory or institution?	○ Yes ○ No	
	Are they obtained from biobank?	○ Yes ○ No	
4. PERSONAL DATA			Page
Does this activity involve processing of personal data?		○ Yes ○ No	
If **YES**:	Does it involve the processing of special categories of personal data (e.g.: sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?	○ Yes ○ No	
	If **YES**: Does it involve processing of genetic, biometric or health data?	○ Yes ○ No	
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	○ Yes ○ No	
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?		○ Yes ○ No	
Is it planned to export personal data from the EU to non-EU countries?		○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved:		
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?		○ Yes ○ No	
If **YES**:	Specify the type of personal data and countries involved		

Does this activity involve the processing of personal data related to criminal convictions or offences?		○ Yes ○ No	
5. ANIMALS			Page
Does this activity involve animals?		○ Yes ○ No	
If **YES**:	Are they vertebrates?	○ Yes ○ No	
	Are they non-human primates (NHP)?	○ Yes ○ No	
	Are they genetically modified?	○ Yes ○ No	
	Are they cloned farm animals?	○ Yes ○ No	
	Are they endangered species?	○ Yes ○ No	
6. NON-EU COUNTRIES			Page
Will some of the activities be carried out in non-EU countries?		○ Yes ○ No	
If **YES**:	Specify the countries:		
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?		○ Yes ○ No	
If **YES**:	Specify the countries:		
Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?		○ Yes ○ No	
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.		○ Yes ○ No	
If **YES**:	Specify material and countries involved:		
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.		○ Yes ○ No	
If **YES**:	Specify material and countries involved:		
Does this activity involves low and/or lower-middle income countries? (if yes, detail the benefit-sharing actions planned in the self-assessment)		○ Yes ○ No	
Could the situation in the country put the individuals taking part in the activity at risk?		○ Yes ○ No	
7. ENVIRONMENT, HEALTH and SAFETY			Page

Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?	○ Yes ○ No	
Does this activity deal with endangered fauna and/or flora / protected areas?	○ Yes ○ No	
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)?	○ Yes ○ No	
8. ARTIFICIAL INTELLIGENCE		Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	○ Yes ○ No	
9. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration?	○ Yes ○ No	
Please specify: (Maximum number of characters allowed: 1000)		

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines 'How to Complete your Ethics Self-Assessment'. ☐

ETHICS SELF-ASSESSMENT

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

Ethical dimension of the objectives, methodology and likely impact
Explain in detail the identified issues in relation to: – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)
Compliance with ethical principles and relevant legislations
Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the E U / national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

Security issues table

Please indicate, by answering Yes or No to all of the questions in the below table, if the proposed activity will use and/or generate information which might raise security concerns. If an answer is Yes, then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.

1. EU classified information (EUCI)[2]			Page
Does this activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)?		○ Yes ○ No	
If **YES**:	Is the activity going to use classified information as background[3] information?	○ Yes ○ No	
	Is the activity going to generate EU classified foreground[4] information as results?	○ Yes ○ No	
Does this activity involve non-EU countries?		○ Yes ○ No	
If **YES**:	Do participants from non-EU countries need to have access to EUCI?	○ Yes ○ No	
	Do the non-EU countries concerned have a security of information agreement with the EU	○ Yes ○ No	
2. MISUSE			Page
Does this activity have the potential for misuse of results?		○ Yes ○ No	
If **YES**:	Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism?	○ Yes ○ No	
	Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery?	○ Yes ○ No	
3. OTHER SECURITY ISSUES			Page
Does this activity involve information and/or materials subject to national security restrictions?		○ Yes ○ No	
If yes, please specify: *(Maximum number of characters allowed: 1000)*			
Are there any other security issues that should be taken into consideration?		○ Yes ○ No	

[2] According to the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information, "European Union classified information (EUCI) means any information or material designated by an EU security classification, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the European Union or of one or more of the Member States".

[3] Classified background information is information that is already classified by a country and/or international organisation and/or the EU and is going to be used by the project. In this case, the project must have in advance the authorisation from the originator of the classified information, which is the entity (EU institution, EU Member State, third state or international organisation) under whose authority the classified information has been generated.

[4] EU classified foreground information is information (documents/deliverables/materials) planned to be generated by the project and that needs to be protected from unauthorised disclosure. The originator of the EUCI generated by the project is the European Commission.

If yes, please specify: (Maximum number of characters allowed: 1000)	

5 – Other questions

Two-stage calls

The full stage-2 proposal must be consistent with the short outline proposal submitted to the stage 1 – in particular with respect to the proposal characteristics addressing the concepts of excellence and impact.

Are there substantial differences compared to the stage-1 proposal?	○ Yes	○ No

Questions showed only in answer is Yes:
Please list the substantial differences, and indicate the reasons

☐	Partnership	*List the substantial differences and indicate the reasons*
☐	Budget	*List the substantial differences and indicate the reasons*
☐	Approach	*List the substantial differences and indicate the reasons*

[Calls with clinical trials: Essential information to be provided for proposals including clinical trials / studies / investigations

Clinical study means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices.

Are clinical studies / trials / investigations included in the work plan of this project?	○ Yes	○ No

Please upload the dedicated annex 'Essential information for clinical studies / trials / investigations' (a Word template is provided under 'download templates' in the up-load section for Part B and Annexes).

This document should include the relevant information of each clinical study / trial / investigation included in the work plan of this project.

Please give a short title, an acronym or a unique identifier to each clinical study / trial / investigation, to be used as a reference / identifier in the other parts of the proposal	Add Remove

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