



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.

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Proposal ID XXXXXXXXX

Acronym XXXXXXX

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		
Proposal ID XXXXXXXXX	Acronym XXXXXXX	
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

Section	Title	Action
1	General information	
2	Participants	
3	Budget	
4	Ethics and security	
5	Other questions	

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.

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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.

rts are marked in blue	9. 		
Topic	Type of action		
Call	Type of Model Grant Agreemer	nt	
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			
L			
Fixed keyword			
Free keywords	Enter any words you think give extra detail of the scope of your proposal (max 20 spaces).	0 characte	ers with
Abstract			
the Work Programme programme managen information. Use plair	provide the reader with a clear understanding of the objectives of the proposal, how they will be achieved a. This summary will be used as the short description of the proposal in the evaluation process and in content committees and other interested parties. It must therefore be short and precise and should not content typed text, avoiding formulas and other special characters. If the proposal is written in a language other resion of this abstract in the Part B (technical description) of the proposal.	nmunications ain confident	s to the ial
for proposals u	sal (or a very similar one) been submitted in the past 2 years in response to a call under any EU programme, including the current call? A 'similar' proposal or contract is m the current one in minor ways, and in which some of the present consortium members are involved.	O Yes	○ No
	e proposal reference or contract number	XXXXX-	X

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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) The	 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) 	
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	

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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.

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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.

<u>Person in charge of the proposal (main contact person)</u>: 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.

<u>Invitation</u>: 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.

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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.

	Legal name
Short name	
Address of the organisation	
Street	
Town	
Postcode	
Country	
Webpage	
Specific legal statuses	
Read more about <u>legal statuses</u> .	
Publicunknown	unknown Legal person
Non-profit	unknown
International organisation	unknown
International organisation of Europe	an interest unknown
Secondary or Higher education esta	ıblishment unknown
Research organisation	unknown
SME status	
	is taken from the Participant Register. Changes to the self-declared or self-assessed SME data can be a LEAR (Legal Entity Appointed Representative) in the Participant Register.
SME self declared status	unknown
SME self-assessment	unknown
SME validation sme	unknown

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Departments carrying	out the proposed work
The information serves mainly sta	atistical 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	
Country	
Links with other particip	ants
Elliks with other particip	
· ·	lencies with other participants of the proposal.
	dependent on each other where there is a controlling relationship between them: lirect or indirect control as another legal entity;or
* A legal entity directly or indirectly	
* A legal entity is directly or indirect	tly controlled by another legal entity.Control:
Legal entity A controls legal entity I	3 if:
	e 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 of mairectly, noids in ta	act or in law the decision-making powers in B.
	n legal entities shall not in themselves be deemed to constitute controlling relationships:
i .	poration, institutional investor or venture-capital company has a direct or indirect holding of more than sued share capital or a majority of voting rights of the shareholders or associates;
	owned or supervised by the same public body.
Type of link	Participant
/Samo group ¹	Select one participant from the list of participants
[Same group]	
[Controls]	
[Is controlled by]	

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Main contact person				
This will be the person the EU services will contact evaluation results, convocation to start grant prepareurs persons should be edited in step 'Participants' of the	ration). The data in blue is read-or			
Title	Gender	O Woman	Man	Non binary
First name		Last name		
E-mail				
Position in org.	Please indicate the position	on of the person		
Department				☐ Same as organisation
Street	☐ Same as organisation	address		
Town		Post code		
Country				
Website				
Phone 1	Phone 2			
Other contact persons				
First name	Last name	e-mail		Phone

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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]

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).

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¹ Career stages as defined in Frascati 2015 manual:

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Role of participating organisation in the project Applicants may select more than one option.	ţ.	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]	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
[Dataset]	persistent identifier (PID).
[Software]	Publications, in particular journal articles, are expected to be open access. Datasets
[Good]	are expected to be FAIR and 'as open as possible, as closed as necessary'.
[Service]	

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[Other achievement]			
List of up to 5 most re	elevant previous projects or activities, connected to the subject of	this pro	posal
Name of Project or Activity	Short description		
Activity			
Description of any sig the proposed work	nificant infrastructure and/or any major items of technical equipn	nent, rele	evant to
Name of infrastructure or equipment	Short description		
Gender equality p	lan		
organisations from Member S	n is an eligibility criterion for Public bodies, Higher education establishments and Research states and Associated Countries. Be aware that if the proposal is selected, having a Gender by before the grant agreement signature (applicable on calls with deadlines in 2022 and		
	have a Gender Equality Plan (GEP) covering the elements listed below?	O Yes	O No
Minimum process-rel	ated requirements (building blocks) for a GEP		
•	document published on the institution's website and signed by the top		
 Dedicated resourc 	es: commitment of human resources and gender expertise to implement		
	d monitoring: sex/gender disaggregated data on personnel (and		
 Training: Awarenes 	shments concerned) and annual reporting based on indicators. ss raising/trainings on gender equality and unconscious gender biases for		
	nakers. nended areas to be covered and addressed via concrete measures and		
targets are:	lance and organisational culture;		
	ance in leadership and decision-making;		
o gender bala	and in readership and decision-making,		
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3 – Budget for the proposal

												_					
												Estimated income					
				Estimated expenditure								uested EU con	tribution	Revenues		ources of ncing	
			Estimated eligible costs						EU cor	tribution to eliç					Total estimate d income		
			A. Personnel costs/€	B. Subcontracti ng costs/€	C. I	Purchase co	osts	D. Other cost categories	E. Indirect costs/€ (e) = 25% *	Total eligible costs	Funding rate	Maximum EU contributio n to	Requeste d EU contributio n to	Income generated by the	Financial contributi ons	Own resource s	(s)=(n)
No	Participant name	Country	(a1)	(b)	C.1 Travel and subsiste nce/€	C.2 Equip ment/€	C.3 Other goods, works and services	D.X [specific cost category] /€ (dx)	[(a1) + (c1) + (c2) + (c3) + (d7)]	(h) = (a1) + (b) + (c1) + (c2) + (c3) + (d) + (e)	(U)	eligible costs (I) = (U) * (h)	eligible costs/€ (Requeste d grant amount)	action (o)	(p)	(r)	(s)=(n) +(o)+(p)+ (q) + (r)
					(c1)		/€						(m) (n)				
							(c3)										
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

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

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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)? If YES: Will they be directly derived from embryos within this project? Yes No			
If YES:	Will they be directly derived from embryos within this project?	O Yes O No	
	Are they previously established cells lines?	O Yes O No	
		O Yes O No	
Does this a	ctivity involve the use of human embryos?	O Yes O No	
If YES:	Will the activity lead to their destruction?	O Yes O No	
2. HUMAN	5		Page
Does this a	ctivity involve human participants?	O Yes O No	
If YES:		O Yes O No	
	Are they healthy volunteers for medical studies?	O Yes O No	
	Are they patients for medical studies?	CYes O No	
	Are they potentially vulnerable individuals or groups?	O Yes O No	
	Are they children/minors?	O Yes O No	
	Are they other persons unable to give informed consent?	O Yes O No	
	ctivity involve interventions (physical also including imaging technology, behavioural etc.) on the study participants?	O Yes O No	
If YES:	Does it involve invasive techniques?	O Yes O No	
	Does it involve collection of biological samples?	O Yes O No	

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Regulation	(EU 536/201	e conducting a clinical study as defined by the Clinical Trial 4)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or cinal products)	© Yes	○ No	
If YES:	Is it a clinic	al trial?	O Yes	O No	
	Is it a low-i	ntervention clinical trial?	O Yes	O No	
3. HUMAN	CELLS / TISS	UES (not covered by section 1)			Page
Does this a	ctivity involve	the use of human cells or tissues?	O Yes	O No	
If YES:	Are they hur	man embryonic or foetal cells or tissues?	O Yes	O No	
	Are they ava	ailable commercially?	O Yes	O No	
	Are they obt	ained within this project?	O Yes	O No	
	Are they obt	ained from another project, laboratory or institution?	© Yes	○ No	
	Are they obt	ained from biobank?	O Yes	O No	
4. PERSON	AL DATA				Page
Does this a	ctivity involve	processing of personal data?	O Yes	O No	
If YES:		lve the processing of special categories of personal data (e.g.: sexual nicity, genetic, biometric and health data, political opinion, religious or al beliefs)?	© Yes	O No	
	If YES:	Does it involve processing of genetic, biometric or health data?	© Yes	O No	
	large scale	lve profiling, systematic monitoring of individuals, or processing of of special categories of data or intrusive methods of data processing prveillance, geolocation tracking etc.)?	© Yes	O No	
		ther processing of previously collected personal data (including use of rces, merging existing data sets)?	O Yes	O No	
Is it planned	to export perso	nal data from the EU to non-EU countries?	O Yes	O No	
If YES:	Specify the typ	pe of personal data and countries involved:			
	to import perso -EU country?	nal data from non-EU countries into the EU or from a non-EU country to	© Yes	O No	
If YES:	Specify the typ	pe of personal data and countries involved			

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

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	abstances or processes that may cause harm to the ing the implementation of the activity or further to the use	© Yes	€ No	
Does this activity deal with endangere	d fauna and/or flora / protected areas?	© Yes	O No	
	abstances or processes that may cause harm to humans, (during the implementation of the activity or further to the act)?		○ No	
8. ARTIFICIAL INTELLIGENCE				Page
	nent, deployment and/or use of Artificial Intelligence? (if ther that could raise ethical concerns related to human vill be addressed).	O Yes	O No	
9. OTHER ETHICS ISSUES				Page
			0	
Are there any other ethics issues that	should be taken into consideration?	© Yes	© No	

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'.

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м	uu	IICa	เเดา	ΓUI	1115

Proposal ID XXXXXXXXX

Acronym XXXXXXX

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 EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for activities performed in a non-EU countries, they should also be allowed in at least one EU Member State.

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

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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.

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SECURITY SELF-ASSESSMENT

If you have answered YES for one or more of the questions indicated above, describe the measures you intend to take to solve/avoid them. For more information, see the guidelines Classification of information in Horizon Europe projects, Classification of information in EDF projects.

Please specify (Maximum number of characters allowed: 5000)

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5 – Other questions

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

Tw	o-stag	ge calls			
		e-2 proposal must be consistent racteristics addressing the cond	with the short outline proposal submitted to the stage 1 – in particular with respect septs of excellence and impact.	to the	
	Are the	ere substantial differences	compared to the stage-1 proposal?	© Yes	ON
		showed only in answer is Yes: t 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		
Clinic data preve clinic Regu	cal study obtained ention, dia al studies dation 20	rials / studies / investi means, for the purpose of this do from individual patients or health agnosis, monitoring or treatment of a sa defined by Regulation 536/20	ntial information to be provided for proposals including gations cument, any systematic prospective or retrospective collection and analysis of health or persons in order to address scientific questions related to the understanding, of a disease, mental illness, or physical condition. It includes but it is not limited to 114 (on medicinal products), clinical investigation and clinical evaluation as defined by formance study and performance evaluation as defined by Regulation 2017/746 (on in		
Are	clinica	l studies / trials / investigat	ions included in the work plan of this project?	O Yes	O No
		If the dedicated annex 'Essential in the up-load section for Part B and	nformation for clinical studies / trials / investigations' (a Word template is provided under Annexes).	'download	
This proje		nt should include the relevant infor	rmation of each clinical study / trial / investigation included in the work plan of this		
	Pleas		onym or a unique identifier to each clinical study / trial / investigation a reference / identifier in the other parts of the proposal	n,	nove

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