**Annex 4 - Template Outline Proposal**

**Administrative forms (Part A)**

**1 - General information**

**Call: GP/EFSA/ED/2022/01 – “ NAM projects in the areas of AOP development and transcriptomics for risk assessment”**

**Lot for which you are applying:**

**For Lot 1, specific area for which you are applying (A, B, C, D):**

**Proposal title:**

**Abstract (2000 characters)**

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|  |

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?

Yes or no.

If yes, provide proposal reference or contract number:

**2 –** **INFORMATION ON THE APPLICANT AND IN CASE OF CONSORTIUM OF THE LEADER AND PARTNER/S**

**APPLICANT / (in case of consortium: LEADER)**

Official name in full:

Short name or acronym:

Legal form:

Address:

* Street:
* Number:
* Post code:
* City:
* Country:

Organisation`s contact details:

* Telephone:
* Fax:
* E-mail address:
* Internet site:

Legal representative of the applicant (he/she will sign the grant agreement in case of award):

Administrative contact point for project implementation in the case of grant award:

* Position:
* Telephone:
* Fax:
* E-mail address:

Contact person responsible for this application (if different from the above):

* Position:
* Telephone:
* Fax:
* E-mail address:

**Partners**

**Partner 1[[1]](#footnote-2):**

Official name in full:

Short name or acronym:

Legal form:

Address:

* Street:
* Number:
* Post code:
* City:
* Country:

Organisation`s contact details:

* Telephone:
* Fax:
* E-mail address:
* Internet site:

Legal representative of the partner (he/she will sign the Mandate (Power of Attorney) to the applicant to sign the grant agreement on behalf of this partner):

**3 - DECLARATIONS**

1) In case of consortium, we declare to have the explicit consent of all partners on their participation and on the content of this proposal.

2) We confirm that the information contained in this proposal is correct and complete.

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 Article 136 of the EU Financial Regulation 2018/1046, as detailed in the Declaration on Honour (section A) available here (to be submitted with the full application in step 2)

to have the financial and operational capacity to carry out the proposed project.

4) By submitting a proposal, we and in case of consortium also partner/s accept/s the procedures and conditions described in the Call for proposal GP/EFSA/ED/2022/01 and in the documents referred to in it.

5) 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[[2]](#footnote-3), as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union[[3]](#footnote-4) and the European Convention on Human Rights and its Supplementary Protocols[[4]](#footnote-5). 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.

6) We confirm having provided information under section 5 “ethics” below.

7) We confirm that for activities carried out outside the European Union, the same activities comply with point 5 and 6 above and would have been allowed in at least one EU Member State.

Each applicant remains responsible for the information declared for their organisation. In case of joint outline proposal from a consortium the coordinator is responsible for the information relating to the consortium partners. If the proposal is retained for EFSA funding, each consortium partners be required to sign a declaration of honour.

False statements or incorrect information may lead to to rejection from this procedure and to administrative sanctions (exclusion or financial penalty).

Signature and date

**4. ESTIMATED BUDGET (only indicative at this stage. The final estimated budget will be submitted and assessed in the step 2 in order to determine the EFSA grant contribution)**

|  |  |  |  |
| --- | --- | --- | --- |
| No | Name of Beneficiary | Country | Requested grant amount (€) |
| 1 |  |  | 0.00 |
|  | Total | | 0.00 |

**5 - ETHICS**

Ethics Issues Table

|  |  |
| --- | --- |
| 1. **Human Embryonic Stem Cells and Human Embryos** | |
| Does this activity involve Human Embryonic Stem Cells (hESCs)? | Yes No |
| 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 |
| Will the activity lead to their destruction? | Yes No |

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| --- | --- |
| **2. Humans** | |
| Does this activity involve human participants? | Yes No |
| Are they volunteers for non medical 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 |
| Does it involve invasive techniques? | Yes No |
| Does it involve collection of biological samples? | Yes No |

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| --- | --- |
| **3. Human Cells/Tissues (not covered by section 1)** | |
| Does this activity involve the use of human cells or tissues? | Yes No |
| 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 |

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| --- | --- |
| **4. Personal Data** | |
| Does this activity involve processing of personal data? | Yes  No |
| Does it involve processing of genetic, biometric or health data? | Yes  No |
| Does this activity involve further processing of previously collected personal data (including use of pre-existing 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 |

Specify the type of personal data and countries involved

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| 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 |

Specify the type of personal data and countries involved

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| **5. Animals Page** | |
| Does this activity involve animals? | Yes  No |
| 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 |

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| --- | --- |
| **6. Non-EU Countries** | |
| Will some of the activities be carried out in non-EU countries? | Yes  No |

Specify the countries involved

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| --- | --- |
| In case non-UE countries are involved, do the activities undertaken in these countries raise potential ethics issues? | 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? | Yes  No |

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| **7. Environment, Health and Safety** | |
| Does this activity involve the use of substances or processes that may cause harm to humans (including those performing the activity), the environment, to animals or plants? | Yes  No |

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| --- | --- |
| **8. Artificial Intelligence** | |
| 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 |
| 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 below. | Yes  No |

**Ethics Self-Assessment**

|  |
| --- |
| Ethical dimension of the objectives, methodology and likely impact |
| Explain in detail (maximum 5000 characters) 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.) |

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| 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 (maximum 5000 characters). It is reminded that for activities performed in a non-EU country, they should also be allowed in at least one EU Member State. |

**Outline Proposal (Part B)**

Please respect the following formatting constraints: Times New Roman, Arial or similar, at least font size 11, margins (2.0 cm side and 1.5 cm top and bottom), single line spacing. Please respect the overall page limit (recommended max 5 pages excluding references).

The **outline proposal** must provide a “**Description of the project to address the objectives of the relevant lot”** following the two sections (1 2) and the instructions provided below, in line with the award criteria specified for step 1 (see section 3.4 of the Call for proposals)

**Section 1:**

**Outline how the proposal (recommended max 4 pages) addresses the objectives of lot 1 (specific areas A-D) or lot 2** by:

1. Describing the problem or the need that the proposed work is aiming to solve or alleviate in regulatory science[[5]](#footnote-6)) (the problem);
2. Explaining how the proposed work will address EFSA’s needs, solve or alleviate the problem (the solution: scope of proposal);
3. Outlining the approach and methodology for the proposed work to address the problem. Describe the activities to be undertaken to demonstrate regulatory impact through appropriate case studies (the solution: approach and methodology);
4. Outlining the potential impact and acceptance of the proposed work on regulatory science (e.g. use of AOPs or in vitro transcriptomics for regulatory purposes) (the impact);
5. Outlining how the project outcomes will be innovative or distinctive for risk assessment, will ensure scientific quality and excellence, and improve the speed, precision and predictability of chemical risk assessment related to food safety. This entails an outline on what is the expected project outcome (e.g. databases, methods, tools, etc.) (the impact).

**Section 2: Capacity and commitment of the** **Applicant/Leader) (recommended max 1 page)**

**The Applicant/Leader**

- To describe their role in the project, including how they will take the strategic lead of it.

- In case of a consortium, to explain the role and expected contributions of the individual partner organisations.

**Project Management:**

- General overview of the organisational structure and the decision-making process.

1. Repeat this section as many times as there are the partners [↑](#footnote-ref-2)
2. <https://allea.org/code-of-conduct/> [↑](#footnote-ref-3)
3. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN> [↑](#footnote-ref-4)
4. <https://www.echr.coe.int/documents/convention_eng.pdf> [↑](#footnote-ref-5)
5. Regulatory Science: Transdisciplinary scientific information, including risk/safety assessments, methods, tools, models and scientific advice, to support sound and transparent science-based policies. [↑](#footnote-ref-6)