**ERINHA-Advance**

**Transnational Access (TNA) Application**

**Please complete the following application for each project to be considered**

**APPLICATIONS ARE DUE 15 DECEMBER 2019**

**Text in *blue* is intended for guidance and should be deleted from the final application submission.**

**All applications should include *(please check the relevant boxes)*:**

**This Application Form, **fully completed** (Century Gothic, font size 10, single spacing)

**CV of all User-Group members **(*please use CV template in this document*)**

**ERINHA­­‑Advance Data Protection Policy, **signed** ***(one form from each team member; available at***[***https://www.erinha.eu/erinha-advance/***](https://www.erinha.eu/erinha-advance/)***)***

**TNA Animal Use Form, **signed** ***(if applicable)***

Detailed information regarding ERINHA‑Advance Transnational Access Programme can be found in the TNA Guidelines ([**https://www.erinha.eu/erinha-advance/**](https://www.erinha.eu/erinha-advance/)).

**Please submit your application as a single PDF file by 15 December 2019, 18.00 CEST at** [**contact@erinha.eu**](mailto:contact@erinha.eu)

**If you have any questions or concerns, please do not hesitate to contact**

**the ERINHA Central Coordinating Unit (CCU) at** [**contact@erinha.eu**](mailto:contact@erinha.eu)

**We are looking forward to receiving your application!**

**APPLICATION FORM**

**Are you also applying to the TRANSVAC2 TNA programme?**

**(the European network of vaccine research & development)**

|  |
| --- |
| **YES** |
|  |
| **NO** |

**GENERAL INFORMATION**

1. **USER-GROUP DETAILS**

|  |
| --- |
| *Please indicate if this proposal is submitted by:* |
| **An individual** |
|  |
| **A group** |

* **Principal Investigator (User-Group leader)**

|  |  |
| --- | --- |
| **First and last name** |  |
| **Nationality** |  |
| **Gender** |  |
| **Job Title** |  |
| **Institution** |  |
| **Address** |  |
| **Country** |  |
| **Email address** |  |
| **Telephone** |  |

* **User‑group members (if relevant)**

***Member # 1 (duplicate below for each member of the user group)***

|  |  |
| --- | --- |
| **First and last name** |  |
| **Nationality** |  |
| **Gender** |  |
| **Job Title** |  |
| **Institution** |  |
| **Address** |  |
| **Country** |  |
| **Email address** |  |
| **Telephone** |  |

1. **PROJECT IDENTIFICATION**

|  |  |
| --- | --- |
| **Title of the project** |  |
| **Acronym** |  |
| **Principle Investigator (PI) Name:** |  |
| **PI Institution:** |  |
| **Email address** |  |
| **Telephone** |  |

1. **PROJECT ABSTRACT**

***Please give a short description of your planned work, your main objectives, the expected outcomes and the expected benefit of accessing ERINHA-Advance services. Please limit to 250 words.***

1. **PUBLICATIONS**

***Please list here your publications relevant to this application (maximum 5) with authors, title, full reference and date.***

1. **FUNDING**

|  |
| --- |
| *Please indicate if your institution has other funding for this project:* |
| **YES; details:** |
|  |
| **NO** |

**DETAILED PROJECT DESCRIPTION**

***NOTE: For the purpose of this application, project refers to the tasks, experiments or investigation to be carried out at an ERINHA Facility.***

***The project description should clearly summarise the aim of the project, the scientific background, and the overall methodological approaches (including statistics where appropriate) proposed to solve the main scientific problems.***

***For a competitive evaluation, it is important that the description of the objectives and the methodological approach can be easily evaluated.***

1. **SCIENTIFIC RATIONALE**

***Please limit to 1000 words.***

1. **RESEARCH STRATEGY, METHODOLOGY & ASSOCIATED WORKPLAN**

***Please present here the detailed research strategy and experimental design of your project including:***

* ***Nature and form of the experiments to be performed.***
* ***If you are requesting TNA for animal studies (mice only during this TNA programme), clearly justify the necessity to perform in vivo experiments in your project. This information is essential to obtain ethical approval from national authorities on animal experimentation and/or animal welfare bodies.***

***Please limit to 1000 words.***

1. **GAP ANALYSIS**

***Clearly state why the service is required and describe why the work cannot be performed in your institution. Please limit to 500 words.***

1. **OBJECTIVES & GOALS OF THE PROJECT**

***Please describe the objectives and goals of your project. Please limit to 500 words.***

1. **EXPECTED OUTCOMES & IMPACT**

***Describe the expected outcomes and the impact of your project in relation to the topic in question. Mention the steps that will be needed to bring about these impacts. Mention any assumptions and external factors that may determine whether the impacts will be achieved. Please limit to 750 words.***

1. **RISKS, CONTINGENCIES & MITIGATION MEASURES**

***Describe below the potential risks and contingencies that might occur during the project and how you plan to avoid, mitigate or resolve them.***

|  |  |
| --- | --- |
| **Risk / contingency** | **Prevention / mitigation / corrective action** |
|  |  |
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1. **ETHICAL CONSIDERATIONS**

|  |  |
| --- | --- |
| **HUMANS** |  |
| 1. Does your research involve human participants? **If yes, answer b-g.** | |  | | --- | | **YES NO** | |  | |
| 1. Are they volunteers for social or human sciences research? | |  | | --- | | **YES NO** | |  | |
| 1. Are they persons unable to give informed consent? | |  | | --- | | **YES NO** | |  | |
| 1. Are they vulnerable individuals or groups? | |  | | --- | | **YES NO** | |  | |
| 1. Are they children/ minors? | |  | | --- | | **YES NO** | |  | |
| 1. Are they patients? | |  | | --- | | **YES NO** | |  | |
| 1. Are they healthy volunteers for medical studies? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve physical interventions on the study participants? **If yes, answer i and j.** | |  | | --- | | **YES NO** | |  | |
| 1. Does it involve invasive techniques? | |  | | --- | | **YES NO** | |  | |
| 1. Does it involve collection of biological samples? | |  | | --- | | **YES NO** | |  | |
| **HUMAN CELLS/TISSUES** |  |
| 1. Does your research involve human cells or tissues? | |  | | --- | | **YES NO** | |  | |
| 1. Are they available commercially? | |  | | --- | | **YES NO** | |  | |
| 1. Are they obtained within this project? | |  | | --- | | **YES NO** | |  | |
| 1. Are they obtained from another project, laboratory or institution? | |  | | --- | | **YES NO** | |  | |
| 1. Are they obtained from a biobank? | |  | | --- | | **YES NO** | |  | |
| **PERSONAL DATA** |  |
| 1. Does your research involve personal data collection and/or processing? | |  | | --- | | **YES NO** | |  | |
| 1. Does it involve the collection and/or processing of sensitive personal data?   (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical  conviction)? | |  | | --- | | **YES NO** | |  | |
| 1. Does it involve processing of genetic information? | |  | | --- | | **YES NO** | |  | |
| 1. Does it involve tracking or observation of participants? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve further processing of previously collected personal data (secondary use)? | |  | | --- | | **YES NO** | |  | |
| **NON-EUROPEAN UNION (EU) COUNTRIES** |  |
| 1. In which non-EU countries will the research take place? | |  | | --- | | **YES NO** | |  | |
| 1. Do the research related activities undertaken in these countries raise potential ethics issues? | |  | | --- | | **YES NO** | |  | |
| 1. Do you plan 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** | |  | |
| 1. Do you plan to import any material – including personal data – from non-EU countries into the EU? | |  | | --- | | **YES NO** | |  | |
| 1. Do you plan to export any material – including personal data – from the EU into non-EU countries? | |  | | --- | | **YES NO** | |  | |
| 1. If your research involves low and/or middle‑income countries, are benefits sharing actions planned? | |  | | --- | | **YES NO** | |  | |
| 1. Could the situation in the country put the individuals taking part in the research at risk? | |  | | --- | | **YES NO** | |  | |
| **ENVIRONMENT & HEALTH AND SAFETY** |  |
| 1. Does your research involve the use of elements that may cause harm to the environment, to animals or plants? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research deal with endangered fauna and/or flora and/or protected areas? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve the use of elements that may cause harm to humans, including research staff? | |  | | --- | | **YES NO** | |  | |
| **DUAL USE, CIVIL APPLICATIONS, MISUSE** |  |
| 1. Does your research involve dual-use items in the sense of Regulations 428/2009, or other items for which an authorisation is required? | |  | | --- | | **YES NO** | |  | |
| 1. Could your research raise concerns regarding the exclusive focus on civil applications? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research have the potential for misuse of research results? | |  | | --- | | **YES NO** | |  | |
| **HUMAN EMBRYOS, FOETUSES** |  |
| 1. Does your research involve Human Embryonic Stem Cells (hESCs)? | |  | | --- | | **YES NO** | |  | |
| 1. Will they be directly derived from embryos within this project? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve the use of human embryos? | |  | | --- | | **YES NO** | |  | |
| 1. Are they previously established cells lines? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve the use of human foetal tissues/cells? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve the use of human embryos? | |  | | --- | | **YES NO** | |  | |
| 1. Can you confirm that your research will not destroy those embryos? | |  | | --- | | **YES NO** | |  | |
| 1. Does your research involve the use of human foetal tissues / cells? | |  | | --- | | **YES NO** | |  | |
| **SECURITY** |  |
| 1. Will your project involve activities or results raising security issues? | |  | | --- | | **YES NO** | |  | |
| 1. Will your project involve 'EU-classified information' as background or results | |  | | --- | | **YES NO** | |  | |

*Are there any other ethics issues that should be taken into consideration? Please specify.*

**CV TEMPLATE**

***Please provide a CV for all individuals listed on the application.***

1. **DETAILS**

**Title:**

**Name:**

**Gender:**

**Nationality:**

**Organization name:**

**Organization address:**

**Tel:**

**Email:**

1. **SCIENTIFIC PROFILE**

***Briefly state your main areas of expertise and professional activity. Please limit to 250 words.***

1. **EDUCATION & DEGREES AT UNIVERSITY LEVEL**

|  |  |  |  |
| --- | --- | --- | --- |
| **Degree** | **Subject** | **Granting Institution** | **Year of graduation\*** |
|  |  |  |  |
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***\*Start the list from the most recent graduation***

1. **PRESENT & SCIENTIFIC EMPLOYMENT**

|  |  |  |
| --- | --- | --- |
| **Start year\*** | **End year** | **Descriptive job title** |
|  |  |  |
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***\*Start the list from the most recent position***

1. **MOST RELEVANT PUBLICATIONS**

***Please start with the most recent publication and highlight your name in bold. Only those relevant to the application are required, although additional publications can be cited if you consider they would help the selection panel to assess your prior experience***

1. **PROJECT FUNDING**

***If you have an extensive list of project funding, you may enter only those within the last 3 years.***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Project name** | **Start year** | **End year** | **Funder** | **Your budget\*** | **Your role** |
|  |  |  |  |  |  |
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***\* Amount of funding to your organisation***

1. **PRIZES & AWARDS**

***Other academic and professional awards***

**TNA ANIMAL USE FORM (Optional)**

Please note that if a proposal is selected by the ERINHA‑Advance TNA Programme, the animal experiments will still require approval by the respective local ethics committee (from the country where the experiments are to be conducted). Providing a letter of support from your own institution’s ethical / animal welfare board may facilitate this process.

**IMPORTANT:**

**Please note that, due to time constraints, such letter does not have to be provided at the time of application.**

**If the approval is not granted, the ERINHA‑Advance consortium cannot be deemed responsible, and the applicant cannot make any claim for compensation.**

**Only experiments involving mice will be carried out during this TNA programme.**

Per ERINHA-Advance guidelines, TNA access for handling live or dead animals must be considered '**remote**' access. In such, a highly experienced individual from the host ERINHA facility will conduct **ALL HANDLING** of any live or dead animal. In this context, one half-day of work by the host facility staff will count as one (1) Access Unit (see TNA Guidelines).

|  |
| --- |
|  |
| ***I intend to try and obtain a letter of support from my institution’s ethical board regarding animal studies (optional)*** |
|  |
| ***I, \_\_ User-Group leader name\_\_\_\_, agree with the terms and conditions regarding TNA Access requiring animal experiments (mandatory).*** |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**User-Group leader signature**