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SPECIAL CALL
FOR COVID-19 / SARS-CoV-2 Research

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European Research Infrastructure
on Highly Pathogenic Agents

TNA GUIDELINES

This project has received funding from the EU Horizon 2020 research and innovation programme under grant agreement No 824061

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SPECIAL CALL
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PAN-EUROPEAN DISTRIBUTED RESEARCH INFRASTRUCTURE

RESEARCH ON HIGHLY PATHOGENIC AGENTS

HIGH-CONTAINMENT FACILITIES & NATIONAL RESEARCH INSTITUTES

EXCELLENCE & INNOVATION

1 INTRODUCTION

Officially started in July 2017, **ERINHA-AISBL (European Research Infrastructure on Highly Pathogenic Agents – Non-profit international association)** is a pan-European research infrastructure dedicated to the study of high-consequence pathogens. It brings together leading European high-containment facilities and national research institutes with longstanding experience of research in this field. ERINHA-AISBL is currently the only research infrastructure of its kind in the European scientific landscape and therefore meets a critical need to bring the European Research Area to the forefront of research excellence, competitiveness, innovation and preparedness in the field of highly infectious diseases.

The current pandemic of COVID-19 is unprecedented in modern times, and has caused a global crisis with considerable health, economic and social consequences. With no medical countermeasures available to fight SARS-CoV-2, it has also ignited a major scientific momentum to better understand this new virus, limit its spread and eventually control the pandemic.
ERINHA and its Members have come forward in this time of emergency and taken part in multiple European projects and initiatives to advance COVID-19 / SARS-CoV-2 research and accelerate the development of therapeutic and prophylactic solutions against the virus.
However, ERINHA was not only created to lead excellence-driven research but also to benefit the whole scientific community. **One of the most important missions of the infrastructure is to give academia and industry the opportunity to access Europe's top high-containment research facilities to develop medical countermeasures against highly pathogenic viruses.**

Therefore, we now want to extend our commitment to the current scientific effort by launching our second call for proposals, fully dedicated to COVID-19 / SARS-CoV-2 research. With the support of the EU-funded H2020 project ERINHA-Advance, we will be offering the selected scientists and their projects **free of charge* transnational access (TNA)** to our cutting-edge high-containment facilities.
** Free of charge transnational access includes administrative & logistical support, free use of the installations, in accordance with all applicable national laws, local safety and health regulations, and technical & scientific support. The User-Group will be in charge of procuring consumables & animals (when applicable). Routine consumables may be covered to some extent. These aspects will be discussed during project implementation.*

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2 SERVICE OFFER

REMOTE ACCESS TO HIGH-CONTAINMENT FACILITIES

IN VIVO & IN VITRO STUDIES

SCIENTIFIC PROJECT MANAGEMENT

This special call gives access to the ERINHA services listed below:

❖ **Remote access to high-containment and complementary facilities**

- *Remote access to high-containment installations for in vitro studies*: wide range of facilities, equipment, collections of microorganisms, reference materials and expertise for the in vitro study of highly pathogenic agents
- *Remote access to high-containment installations for in vivo and preclinical studies*: small animals (mice & hamsters)*

**Please note that Non-Human Primates (NHP) models are available at ERINHA Facilities but cannot be offered under this call. Do not hesitate to contact the CCU for more information* (contact@erinha.eu).

- *Remote access to connecting facilities*: proteomics, genomics, sequencing, electron microscopy, toxicology, pre-GMP facilities…

Please note that for management and coordination purposes, Users will not choose the facility(ies) where their project will be conducted. The ERINHA-CCU will be in charge of assigning Users projects to the available and technically relevant Access Provider(s).

❖ **High-quality scientific project management**

The ERINHA-CCU and its full-time staff will ensure high-quality coordination of the scientific programmes.

❖ **Scientific advice and expertise**

Large scope of multidisciplinary expertise and advice.

Please note that due to the current situation, training and in-person access to the facilities will not be possible in the frame of this call. All experiments will be conducted by the expert staff of ERINHA facilities ("Remote Access").

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CONDITIONS FOR ACCESS & ELIGIBILITY

FREE OF CHARGE ACCESS

TRANSNATIONAL ACCESS

OPEN TO ALL

In accordance with **Article 16 of Horizon 2020 Grant Agreement No 824061** and the **European Charter for Access to Research Infrastructures**, potential users must satisfy the following:

- ERINHA and the ERINHA-Advance project will provide **free of charge* transnational access to the partner facilities (Access Providers)** for **selected User-Groups**, i.e teams of one or more researchers (users) led by a User-Group Leader.

** Free of charge transnational access includes administrative & logistical support, free use of the installations, in accordance with all applicable national laws, local safety and health regulations, and technical and scientific support. It does not include any other costs (travel and/or subsistence costs; consumables; animals; etc…).*

- The Users should have an **adequate background and training in biology** as determined by the ERINHA-Advance selection committee. Since training for handling pathogens at high-containment facilities is included in the TNA, potential users should demonstrate a history of biological research excellence and commitment to biosafety and biosecurity.

- The access must be transnational, i.e if the User-Group Leader and the majority of the Users work in a **country where one of the Access Providers is located, the Users will not have access to this specific Access Provider.**

***Note:** The CCU will be in charge of directing the Users to the Access Providers that best suit their needs.*

- The institution where the User-Group Leader is affiliated should be located in the **European Union or an associated country.**

***Note:** TNA can be granted to Users from institutions based outside the EU or its associated countries but cannot represent more than **20% of the total access** that will be provided by the ERINHA-Advance project under this call.*

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CONDITIONS FOR ACCESS & ELIGIBILITY (cont.)

- **TNA will be exceptionally only provided through remote services to selected Users.**

The access will include the **logistical, technological, and scientific support** usually provided to external researchers performing experiments in the facilities.

- Only User-Groups that are allowed to disseminate the results they have generated under the action may benefit from TNA, unless the Users are working for Small to Medium Enterprises (SMEs).

In addition to these general conditions and given the sensitive nature of the activities conducted under this programme, ERINHA and its partner facilities reserve the right to limit access due to, among others but not limited to:

- **National security and defense matters,**
- **Applicable laws,**
- **Ethical considerations**
- **Inadequate background of the Users.**

REMOTE ACCESS

USERS FROM ACADEMIA & INDUSTRY

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SPECIAL CALL FOR COVID-19 / SARS-CoV-2 RESEARCH

ACCESS UNITS

TNA is quantified as Unit Costs, **with 1 (one) Unit Cost** defined as **one access per user for half a day**, which includes:

- Administrative and logistical support
- Free use of the installations, in accordance with all applicable national laws, local safety and health regulations
- Technical and scientific support

Due to the current situation, **all experiments will be carried out by the highly experienced host facility staff but will still count as an access**. For example, a rodent-based experiment that requires 4 half-days' worth of animal handling will count as 4 Unit Costs.

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APPLICATION & SELECTION PROCESS

ELIGIBILITY ASSESSMENT

TECHNICAL FEASIBILITY ASSESSMENT

SCIENTIFIC EVALUATION

FINAL SELECTION

TNA to ERINHA services will be granted **based on the quality of the proposed research project** and will rely on a peer-review procedure.
In addition, **priority will be given to**:

- Proposals that clearly demonstrate the potential impact of the research on health with regards to the current COVID-19 pandemic
- Proposals aiming at providing the research community with efficient and optimal tools for the study of SARS-CoV-2
- Proposals aiming at developing pan anti-coronavirus medical countermeasures or tools

The fast-track evaluation of the Applications will be divided into 4 major steps:

- **Eligibility assessment:** The ERINHA CCU ensures that the proposals comply with the eligibility criteria as defined by Sections 3 & 7 of this document and the **European Commission's Transnational Access rules**.
- **Feasibility assessment:** the ERINHA-CCU and infrastructure managers assess the technical and ethical feasibility of the eligible projects.
- **Scientific evaluation:** experts evaluate and rank the feasible proposals according to their scientific content, originality / innovation, relevance of the outcome, impact on the community. Potential connection / collaboration with industry will also be considered.
- **Final decision & notification:** The awarded applicants will be notified by email by the CCU. The selected projects will be implemented and coordinated by the CCU.

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6 TOPICS OF INTEREST

FOSTERING RESEARCH

COVID-19

SARS-CoV-2

DIAGNOSTICS & THERAPEUTICS

VACCINE

Pre-GMP

We will prioritize applications falling into one of the following scientific sections. The subtopics listed below each section are given as examples.

- **SECTION 1: Diagnosis tools & Immunological Tests for COVID-19 / SARS-CoV-2**
  - Development of innovative technologies for COVID-19 diagnosis
  - Development of serological tests
  - Development of innovative alternatives for antibodies production for COVID-19 diagnosis purposes
  - Any other topic related to the development of diagnosis tools for COVID-19 / SARS-CoV-2

- **SECTION 2: Therapeutics against COVID-19 / SARS-CoV-2**
  - Development of innovative COVID-19 therapeutic tools
  - Development of innovative alternatives for antibodies production for COVID-19 therapeutic purposes
  - Drug repurposing
    - In vivo anti-COVID-19 / SARS-CoV-2 efficacy of known drugs
    - In vitro anti-COVID-19 / SARS-CoV-2 efficacy of known drugs, including high throughput SARS-CoV-2 antiviral or therapeutic screening assays
  - Drug development
    - In vivo anti-COVID-19 / SARS-CoV-2 efficacy of newly developed drugs
    - In vitro anti-COVID-19 / SARS-CoV-2 efficacy of newly developed drugs, including high throughput SARS-CoV-2 antiviral or therapeutic screening assays
    - Any other topic related to the development of therapeutics against COVID-19 / SARS-CoV-2

- **SECTION 3: Vaccine against SARS-CoV-2**
  - Development of a vaccine against SARS-CoV-2
  - Development of new methods to improve immunogenicity of anti-SARS-CoV-2 vaccines
  - Any other topic related to the development of vaccines against COVID-19 / SARS-CoV-2

- **SECTION 4: Process development – Pre-GMP projects**

Proposals in this section may include any COVID-19 / SARS-CoV-2-related project progressing into GMP production and aiming to set standard operating procedures for production of plasmids, cells, gene-modified cells, viruses, etc.

- **SECTION 5: Other Tools & Methods related to COVID-19 / SARS-CoV-2**
  - Development & optimization of alternative technologies to animal models for the study of COVID-19 and/or SARS-CoV-2
  - Development of new decontamination procedures against SARS-CoV-2
  - Any other topic related to the development of tools and methods related to COVID-19 / SARS-CoV-2

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SPECIAL LAUNCH
FOR COVID-19 / SARS-CoV-2 RESEARCH

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DATA MANAGEMENT POLICY

PERSONAL DATA

TRANSPARENCY & CONSENT

INTELLECTUAL PROPERTY

USER CONTRACT

PERSONAL DATA

For the purpose of managing the programme, ERINHA will collect and process certain **personal data** concerning individuals who apply for free TNA in the frame of ERINHA-Advance.

These data must be held in order to process and evaluate applications, to liaise effectively with applicants, and report to the European Commission.

It is the obligation and responsibility of ERINHA to clearly inform and collect the consent of Applicants regarding the processing of their personal data, and their right to control them.

All persons involved in the processing of the applications are bound to respect the confidentiality of the information collected.

Personal data will not be disclosed in any case outside the frame of ERINHA-Advance TNA programme without permission of those involved.

Applications lacking the consent of ALL Users listed in the User-Group to processing personal data will be considered ineligible.

SCIENTIFIC DATA

Successful Applicants must sign a **User Access Contract** prior to the start of their project.

The Applicants become Users as soon as the contract is signed.

The User Access Contract is a legally binding document defining the rules and obligations of the Users, the Access Providers, and ERINHA, including the framework of intellectual property rights related to the scientific outcomes of the TNA projects. It sets a frame for the activities to be performed during TNA.

Each User assigned to a single TNA project must sign a separate contract.

ERINHA will provide TNA Users with a contract outlining roles and responsibilities, intellectual property rights, liability, among other issues. Suggestions or changes asked by the TNA User may significantly delay the time to Access Provision. **Should a TNA User not sign the User Access Contract, the related TNA activities will be cancelled and no compensation will be granted under any circumstances.**

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ETHICS POLICY

ERINHA-Advance activities will be conducted according to the highest standards of Good Laboratory, Clinical and Manufacturing Practices and Ethics that are applied in Europe.
Most importantly and considering the sensitive nature of the research that will be conducted under this TNA programme,
Users must commit to scrupulously adhere to any recommendation and / or instruction made by the Access Providers.

EUROPEAN & INTERNATIONAL FRAMEWORK

Please refer to Annex 2 for details about the applicable legislation & relevant recommendations & guidelines

RESEARCH INTEGRITY

In accordance with the European Charter for Access to Research Infrastructures, Users will adhere, as the Access Providers do, to the standard codes of conduct and ethical behavior in scientific research and to research integrity, as drafted by the European Science Foundation (ESF) and the European Federation of National Academies of Sciences and Humanities (ALLEA):

- Honesty in communication
- Reliability in performing research
- Objectivity
- Impartiality and independence
- Openness and accessibility
- Duty of care
- Fairness in providing references and giving credit
- Responsibility for the scientists and researchers of the future

FUNDAMENTAL ETHICAL PRINCIPLES

All research supported by the ERINHA-Advance project will be conducted in adherence with:

· The principle of respect for human dignity and the principles of non-exploitation, non-discrimination and non-instrumentalisation

· The principle of individual autonomy (entailing the giving of free and informed consent, and respect for privacy and confidentiality of personal data)

· The principle of justice and the principle of beneficence and non-maleficence, namely with regard to the improvement and protection of health

· The principle of proportionality (including that research methods are necessary to the aims pursued and that no alternative more acceptable methods are available)

HONESTY

RELIABILITY

OBJECTIVITY

IMPARTIALITY

INDEPENDENCE

OPENNESS

FAIRNESS

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ETHICS POLICY (cont.)

REPLACEMENT

REDUCTION

REFINEMENT

ETHICAL PRINCIPLES IN ANIMAL EXPERIMENTATION

When in vivo experimentation is required, the model to be used as well as the exact number of animals will be determined after the projects have been selected for TNA. However, **ERINHA and the Access Providers are highly committed to reducing the number of animal experiments without compromising scientific excellence**. Therefore, the design of studies requiring animal experimentation will be under close scrutiny, especially to **comply with the principles of the 3Rs**:

Replacement

Given the issues that this TNA programme will focus on, no other acceptable alternative method will be suitable to fully replace animal experimentation. However, appropriate in vitro methods will be used in parallel to reduce the number of animal experiments.

Reduction

The minimum number of animals required for statistical analysis of the results and robust conclusions will be used. Also, animal experimentation will be coordinated in order to reduce the number of experiences.

Refinement

In accordance with the "Amsterdam Protocol on Animal Protection and Welfare", best practices which alleviate potential pain, suffering and distress and which enhance the animals' well-being will be applied. Early, humane endpoints will be determined to reduce suffering, regardless of the value of the scientific output that pursuing the experiment could produce.

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OTHER USERS' OBLIGATIONS

In accordance with Articles 16, 35, 36, 38 and 46 of Horizon 2020 Grant Agreement No 824061, Users will agree to:

- Avoid conflict of interest
- Maintain confidentiality
- Be liable for damages
- Promote the action and give visibility to the EU funding.

Outcomes resulting from this TNA programme must acknowledge the ERINHA-Advance project as follows: "The research leading to these results received [partial] funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No824061, ERINHA-Advance project".

Users will also agree to provide ERINHA with a post-access activity report and to fill out a survey to help ERINHA improve the quality of the services.

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ANNEX

ETHICS POLICY

Applicable Legislation & Recommendations

EU LEGISLATION & RECOMMENDATIONS

- The Charter of Fundamental Rights of the EU
- The European Convention of Human Rights
- Recommendations of the European Group on Ethics in Science & New Technologies on the Ethical Aspects of Clinical Research in Developing Countries (Opinion n°17 presented to the European Commission on 4th February 2003)
- Directive 2005/28/ECC of the European Parliament and of the Council of 8 April 2005, laying down principles and detailed guidelines for good practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
- Directive 2001/20/EEC of the European Parliament and of the Council of 4th April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, as well as the Guidelines as suggested by the European Science foundation, in European science foundation policy briefing May 2001, on Controlled clinical trials (consolidated version on 7 August 2009)
- Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified microorganisms
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (consolidated version on 26 July 2019)
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
- Directive 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (consolidated version on 4 May 2016)

To carry out their duties, ERINHA and its Members will also use the Principles on Good Laboratory Practice published by the Paris Organisation for Economic Co-operation and Development (OECD) (ENV/MC/CHEM (98) 17), as well as the "Guideline on the Clinical Evaluation of Diagnostic Agents" developed by the Committee for Medicinal Use Products for Human Use of the European Medicines Agency (CMPM/EWP/1119/98/Rev).

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ANNEX

ETHICS POLICY

Applicable Legislation & Recommendations (cont.)

INTERNATIONAL CONVENTIONS, DECLARATIONS & RECOMMENDATIONS

- The Nuremberg Code (1947)
- The Universal Declaration of Human Rights (1948)
- The United Nations Convention on the Rights of the Child (1989)
- The revised Helsinki declaration on Ethical Principles for Medical Research involving Human Subjects as adopted by the 64th WMA General Assembly in 2013
- The Convention on the Protection of Human Rights and the Dignity of Human Beings with regard to the Application of Biology and Medicine, also known as the Convention on Human Rights and Biomedicine (Council of Europe, 1997)
- The International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002 version) prepared by the CIOMS
- The International Ethical Guidelines for Epidemiological Studies (2009 version) prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)
- The Additional Protocol on the Prohibition of Cloning Human Beings (1998)
- The Guideline for Good Clinical Practice E6 (R1) developed during the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (1996) (Last updated 2016)
- The Ethics of Research in Global Health Emergencies developed by the Nuffield Council on Bioethics (2020)
- The background paper on Pandemics commissioned by the Nuffield Council on Bioethics (2011)
- The background paper on Dual Use in Biology and Biomedicine commissioned by the Nuffield Council on Bioethics (2016)
- The background paper on Scientific Research Integrity commissioned by the Nuffield Council on Bioethics (2013)
- The Ethics of Research Involving Animals developed by the Nuffield Council on Bioethics (2005)
- The Ethical Review of Genome Editing by the Nuffield Council on Bioethics (2016)
- The Ethics and Social Issues of Genome Editing and Human Reproduction developed by the Nuffield Council on Bioethics (2018)
- The Ethics of Research Related to Healthcare in Developing Countries developed by the Nuffield Council on Bioethics (2002)
- The Ethics of the Collection, Linking and Use of Data in Biomedical Research and Health Care developed by the Nuffield Council on Bioethics (2015).

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