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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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PAN-EUROPEAN DISTRIBUTED RESEARCH INFRASTRUCTURE

RESEARCH ON HIGHLY PATHOGENIC AGENTS

HIGH-CONTAINMENT FACILITIES & NATIONAL RESEARCH INSTITUTES

ESFRI LANDMARK SINCE 2018

1 INTRODUCTION

In 2008, the European Strategy Forum on Research Infrastructures (ESFRI) identified a critical need for a relevant and coordinated European Bio-Safety Level 4 (BSL4) capacity to enable the European Union to rise to the challenge posed by the emergence, re-emergence and globalization of highly pathogenic agents. During two preparatory phases funded by the FP7 and H2020 programmes, the ERINHA and ERINHA2 projects respectively have laid the foundations for the set-up of ERINHA Research Infrastructure (RI) by developing its concept, vision and approach.

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.

ERINHA-AISBL is currently coordinating the ERINHA-Advance project, which received funding from the European Union's Horizon 2020 Research and Innovation programme under grant agreement No 824061. Through ERINHA-Advance, ERINHA is now launching its first call for applications to offer scientists free Transnational Access (TNA) to the infrastructure's full catalog of services, including access to cutting-edge, high-containment facilities, training, as well as expertise and advice to perform top-level research in the field of highly pathogenic agents.

This first call will particularly focus on:

- Development of innovative animal models for highly infectious agents
- Innovative therapeutic approaches against RG4 pathogens

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2 SERVICE OFFER

ACCESS TO HIGH-CONTAINMENT FACILITIES

SCIENTIFIC PROJECT MANAGEMENT

EXPERTISE IN BIOSAFETY & BIOSECURITY

TRAINING

This call gives access to the full spectrum of services provided by ERINHA:

❖ Access to high-containment (BSL3 and BSL4) and complementary facilities (from BSL1 to BSL4, genomics, proteomics…)

- *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
- *Access to high-containment installations for in vivo and preclinical studies*: small animals (mice, rats, ferrets, guinea pigs, hamsters) and Non-Human Primates (NHP)*

** Please note that only experiments involving mice will be conducted during this TNA programme. For information on experimentation requiring the use of other species, please contact the Central Coordinating Unit (CCU).*

- *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 – including high-consequence pathogens research, construction of containment facilities, biosafety and biosecurity, transport of samples – for international organizations, states, public and private institutions.

❖ Training

Given the nature of the agents to be manipulated in the framework of ERINHA, training in conducting experiments in high-containment conditions, but also in bio-risk and biosafety management, will be one of the key services provided by ERINHA.

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3

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 either:
- In person, and provided to selected Users that visit the facilities, on the necessary condition that the users successfully complete the required training
- Remote, through the provision of remote scientific services to selected Users

Note: Under this programme, remote access will systematically apply for experiments requiring the manipulation of animals.

The access will include the logistical, technological, scientific support and training usually provided to external researchers performing experiments in the facilities. In case of in-person access, no travel expenses of the User will be covered by ERINHA-Advance.

❖ 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, or inability to satisfactorily complete the training.

REMOTE ACCESS

IN-PERSON ACCESS

TRAINING

4 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 specific nature of handling live animals in high-containment facilities, all in vivo 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. Therefore, all access to ERINHA's infrastructures, whether for specific training, in vitro experiments or remotely performed animal experimentations will be declared as TNA.

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5 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 projects on health
- Large-scale research programmes aiming to provide the research community with efficient and optimal tools for the study of highly infectious diseases
- Proposals building an effective collaboration on a common interdisciplinary research based on complementarities and sharing experience
- Users coming from countries where such infrastructures are not available

The selection process 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.
- Technical feasibility assessment: the ERINHA-CCU and infrastructure managers assess the technical and ethical feasibility of the eligible projects.
- Scientific Evaluation: a panel of experts (*ERINHA's Independent Advisory Board*) evaluates and ranks 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 selection: a selection committee, composed by ERINHA-Advance coordinator and WP leaders, will give the final decision, based on feedback provided by the panel of experts, the ERINHA-CCU, the infrastructure managers as well as criteria related to allocated access time and general project management.

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6 TOPICS OF INTEREST

We will prioritize applications falling into one of the two following scientific sections and sub-topics:

❖ SECTION 1: Innovative therapeutics, vaccines or diagnosis approaches for RG4 pathogens

- Development of RG4 pathogens' standards for diagnosis
- Development of innovative technologies for diagnosis
- Development of innovative alternatives for antibodies production for diagnosis and therapeutics purpose
- Development of innovative therapeutics tools/ immunotherapy
- Development of new synthetic methods to improve immunogenicity of vaccines
- Development of new approach for the design of antiviral drugs
- Development of vaccines against RG4 pathogens

❖ SECTION 2: Innovative approaches in animal experimentation to study highly infectious viruses

- Optimization/ adaptation of rodent models
- Development of telemetry technics/ biochemistry technics for animal experimentation
- Development and optimization of alternative technologies to animal models
- Development of innovative real-time imaging capacity in BSL-4 conditions

ERINHA-Advance TNA programme is a unique opportunity to avail of ERINHA services and expertise if your project requires:

- A final step of validation (proof of concept);
- A preliminary study;
- Adaptation of methods & approaches to study highly pathogenic viruses.

HIGHLY PATHOGENIC VIRUSES PRIORITIZED BY ERINHA

EBOLA VIRUS

MARBURG VIRUS

CRIMEAN CONGO HEMORRHAGIC FEVER VIRUS

NIPAH VIRUS

LASSA VIRUS

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7 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 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.
The User Access Contract cannot be negotiated and must be signed as is. Should a successful Applicant 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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8 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.

LEGAL FRAMEWORK

Please refer to Annex 2 for details about the applicable legislation

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.

9 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

EU LEGISLATION

- The Charter of Fundamental Rights of the EU
- Council Directive 83/570/EEC of 26 October 1983, amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products
- Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Human tissue banking, when necessary, will follow the opinions given to the European Commission by the "European Group on Ethics in Science and New Technologies" on "ethical aspects of human tissue banking" (N° 11, 21 July, 1998)
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
- 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
- Directive 2005/28/ECC of the European Parliament and of the Council of 8th April, 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 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes
- Protocol on animal protection and welfare annexed to the Treaty of Amsterdam
- 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
- http, ://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_121/l_12120010501en00340044.pdf www.esf.org/publication/90/ESPB13.pdf
- Participants will take into account the opinions of the European Group of Advisers on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).
- OECD Principles on Good Laboratory Practice (as revised in 1997). Paris Organisation for Economic Co-operation and Development, Environment Directorate, Chemical Group and Management Committee 1998 (ENV/MC/CHEM (98)17)
- "Points to consider in the evaluation of diagnostic agents" Committee for Proprietary Medicinal Products, EMEA (CMPM/EWP/1119/98)

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ETHICS POLICY

Applicable legislation (cont.)

INTERNATIONAL CONVENTIONS & DECLARATIONS

- The Nuremberg Code (1947)
- Universal Declaration of Human Rights (1948)
- The revised Helsinki declaration as adopted on the 59th WMA General Assembly in October 2008
- Council for International Organizations of Medical Sciences (CIOMS) International guidelines for ethical review of epidemiological studies (1991)
- Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998
- CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (1996) Guideline for good clinical practice E6 (R1)
- Nuffield Council on Bioethics (2002) The ethics of research related to healthcare in developing countries
- UN Convention on the Rights of the Child (1989)
- The convention on the protection of human rights and the dignity of human beings with regard to the application of biology and medicine, or "Convention on Human Rights and Biomedicine" (Council of Europe, 1997)

In other aspects, in each country, each Access Provider will comply with the relevant national legal and ethical requirements.

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