ERINHA USER HANDBOOK

CONTENTS

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824061.

The **E**uropean **R**esearch **I**nfrastructure on **HI**ghly pathogenic **A**gents (ERINHA) is a pan-European research infrastructure and Non-profit International Association with its registered offices located in Brussels, a Central Coordinating Unit (CCU) located in Paris and distributed Member facilities, located across Europe. ERINHA strengthens European research and development capacities by offering high containment services to researchers and coordinating research on highly infectious emerging and re-emerging pathogens.

This document describes the guidelines and access procedures for Users of ERINHA. These guidelines apply to any User wishing to utilize ERINHA Paying Services, Collaborative Projects, or TransNational Access (TNA).

1. Introduction to ERINHA

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 set up 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 offers services in training, laboratory expertise, laboratory experiment services, and other services. Please refer to Section 3 for more information.

Users may access ERINHA Services through a variety of mechanisms, detailed in Sections 4, 5 and 6.

The Ethics and Data Management Policies, which apply to all ERINHA services, are described in Sections 7 and 8.

All Users should refer to this document for detailed information to access ERINHA Services and direct any questions to the Central Coordinating Unit at contact@erinha.eu.

2. Important Definitions regarding ERINHA Services

ERINHA Member: A national or international research institute, or network of institutes, that has paid a Membership fee to join the ERINHA Research Infrastructure.

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ERINHA Node: A national or international research institute, or network of institutes, located in a Member country that has agreed to provide services for ERINHA.

In-person access: When a User uses a ERINHA service by being physically present at the ERINHA Member location. In order to complete in-person access, Users must complete all necessary security checks and complete all required training.

Remote Access: When a User uses an ERINHA service without being physically present at an ERINHA Member location. Typically, an ERINHA Node will perform any proposed experiments and send data, results and samples (when appropriate) to the User.

Service: The act of an ERINHA Node conducting an agreed upon experiment, protocol, training or otherwise for a User. Services will be defined using appropriate contracting mechanisms.

TransNational Access (TNA): Access provided to a Node located outside of the user's country. The EU-funding TNA mechanism through European projects enables free of charge Transnational Access.
**Special conditions apply. See Section 4.3.*

User: Any public or private researcher or group of researchers which has requested access or services through ERINHA

3. Services offered through ERINHA

ERINHA's mission is to protect human health by increasing Europe's preparedness and capacity to respond to existing high consequence infectious disease or a newly emerged infectious disease threat. To fulfil this mission, ERINHA offers several services.

The Ethics and Data Management Policies, found in Sections 7 and 8, apply to all ERINHA services.

3.1 Access to ERINHA Facility's Services

ERINHA Members have biocontainment facilities capable of conducting research on highly pathogenic agents. Most ERINHA Nodes can support in-person and remote access for research purposes.

3.1.1 In-Person Access for Service Requests

In person access allows Users to perform experiments themselves in an ERINHA Member facility, as long as training, biosafety, and biosecurity requirements of ERINHA and the Member facility are fulfilled. In person access is permissible for select experiments.

3.1.2 Remote Access for Service Requests

In the case that 'In Person' access is not available or not requested by a user, ERINHA Member laboratories may conduct 'remote' access in which the ERINHA Member facility staff conducts the experiment according to protocols discussed with the User. All data and results are then provided to the User.

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3.2 Training

ERINHA Member facilities have significant experience in operating and maintaining high containment facilities and research programmes. ERINHA Members provide training for:

- Safely operating in high containment laboratories
- Operating and maintaining a high containment laboratory
- Establishing and running a biosafety program

3.3 Expertise

ERINHA Member facilities have significant experience conducting research on highly pathogenic agents, working in high containment facilities, biosafety / biosecurity risk assessment, and project management. ERINHA Members are available to answer questions and provide recommendations regarding:

- Developing risk assessments
- Building and operating a high containment facility
- Designing and implementing a biosafety program
- Development of a quality management system within high containment laboratories
- Development of research programs on high-consequence pathogens
- Other expertise related to high containment research facilities
- Expertise on protocols and handling of pathogenic agents
- Project management expertise

4. Guidelines for Paying Services

4.1 Conditions of Access and Eligibility

Any individual researcher or group of researchers requiring access to ERINHA's capacities is eligible regardless of geographical location or institute affiliation, as long as the request fits the scientific scope and ethical policy of ERINHA. Any request may be subject to ERINHA Executive Board approval.

Please note that due to the sensitive nature of the research meant to be conducted at Member facilities, ERINHA reserves the right to decline any request based on security considerations.

All Users will be required to sign an ERINHA Service Provision Contract provided by the ERINHA Legal and Financial team. This contract addresses all financial and legal matters, including but not limited to: intellectual property ownership, provision of services from ERINHA, and expectations of all parties.

4.2 Access Costs

Access costs will be determined by a cost estimation performed by an ERINHA Node. This estimation will be based on the cost of performing the work at this specific ERINHA Node and may not be transferable to a different ERINHA Node. While cost estimations are calculated in good faith with all known requirements, changes may occur.

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4.3 Access Approval and Selection Process

Potential Users may submit requests for access to the CCU through email to contact@erinha.eu. Scientific Project Managers at the CCU are responsible for responding to all requests, gathering information necessary and determining which capacities are required.

5. Guidelines for Collaborations

5.1 Conditions of Access and Eligibility

ERINHA capacities are available for use within collaborative projects. For groups that wish to enter into a collaborative project with ERINHA, an approval process will apply and is detailed in Section 5.3.

For collaborative services, the CCU will be the contact point of the Coordinator of the Consortium. The CCU will then coordinate the participation of ERINHA Nodes willing to enter the Consortium, including writing the proposal and establishing the budget.

For the purpose of applying to EU funding, please note that ERINHA will be the beneficiary and the ERINHA Nodes willing to enter the Consortium will be linked-third parties.

5.2 Budget

Access costs will be determined by a cost estimation. This estimation will be based on the cost of performing the work at a specific ERINHA Node and may not be transferable to a different ERINHA Node. While cost estimations are calculated in good faith with all known requirements, changes may occur.

The CCU will work with the ERINHA Nodes willing to enter the collaboration to estimate the budget necessary to perform the work. The total estimated budget will include the budget that should be allocated to the CCU for coordinating the collaborative activities.

5.3 Access Approval and Selection Process

Potential Coordinators may submit requests for collaboration to the CCU through email to contact@erinha.eu. Scientific Project Managers at the CCU are responsible for responding to all requests, gathering information necessary and determining what capacities are required.

For all collaborative projects, the Executive Board of ERINHA must approve the collaboration. The Executive Board will take into account:
1. Compatibility of the project with ERINHA Scientific Strategy
2. Benefits and risks to ERINHA,
3. Ethical considerations,
4. Overall capacity usage at ERINHA,
5. Financial aspects of the project.

Upon approval by the Executive Board, the Central Coordinating Unit team will work with all parties to ensure that ERINHA interests are represented, financial, legal and

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management aspects are addressed and ERINHA Nodes are capable of handling all proposed work.

6. Guidelines for TransNational Access (TNA)

6.1 Conditions for Access and Eligibility

ERINHA 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 offers scientists free* TNA to the infrastructure's full catalog of services.

To facilitate TNA to ERINHA Nodes, ERINHA will periodically open a call for applications. These calls will be widely disseminated through ERINHA's network, mailing list, Twitter, ERINHA Members and partner's communication networks.

Any individual or group interested in the TNA programme should consult the relevant information under the call for applications. Calls may be restricted to projects focused on specific pathogens or research aims; this information will be clearly stated in the application and all supporting information. Please refer to section 6.2 for more information on the evaluation process.

TNA will be either:

- In person, and provided to selected Users that visit the facilities, on the necessary conditions that the users have appropriate background and successfully complete the required training
- Remote, through the provision of remote scientific services to selected Users

Note: Remote access will systematically apply for experiments requiring the manipulation of animals.

** 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. In case of in-person access, no travel expenses of the User will be covered by ERINHA-Advance. In addition, 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.*

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 defence matters, applicable laws, ethical considerations, inadequate background of the Users, or inability to satisfactorily complete the training.

TNA Guidelines will be made available online each time a call is launched.

6.2 Access Approval and Selection Process

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

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- 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:

1. Eligibility assessment: The ERINHA CCU ensures that the proposals comply with the eligibility criteria as defined by Section 6.1 of this document, the European Commission's Transnational Access rules and the specific TNA Guidelines that will be made available online each time a call is launched.
2. Technical feasibility assessment: the ERINHA-CCU and infrastructure managers assess the technical and ethical feasibility of the eligible projects.
3. 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.
4. Final selection: a selection committee, composed by ERINHA-Advance coordinator and WP leaders ("TNA Selection Committee"), 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.

A fast-track selection procedure may be applied in specific circumstances.

7. Data Management

ERINHA is developing a data management plan for all ERINHA Services. This document will be updated as necessary.

PERSONAL DATA

ERINHA may collect personal data to fulfil service requests. This data is necessary to liaise effectively with Users.

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

All persons involved in the processing User Requests are bound to respect the confidentiality of the information collected. Personal data will not be disclosed in any way outside of ERINHA without the prior consent of those involved.

ERINHA's Data Protection Policy is available at erinha.eu.

SCIENTIFIC DATA

All Users must sign a Service Provision Contract prior to the start of Services.
The Service Provision Contract is a legally binding document, which defines the rules and obligations of the Users, the ERINHA Nodes in charge of the work, and ERINHA, including the framework of intellectual property rights related to the scientific outcomes of the Service.

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8. Ethical Guidelines

For any request received by ERINHA, the ERINHA Executive Board may vote to determine whether ERINHA accepts and fulfils the request. As part of the decision-making process, the Board may ask for detailed information on the Ethics requirements for the project.

ERINHA expects to maintain strict ethics in all projects. Key ethics principles are listed below. A detailed Ethics Policy, available at erinha.eu, has been developed and should be referred to for information.

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 behaviour 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)

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. 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 as defined below according to the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs):

- **REPLACEMENT:**
  - *Standard definition*: Methods that avoid or replace the use of animals

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- *Contemporary definition*: Accelerating the development and use of models & tools, based on the latest science & technologies, to address important scientific questions without the use of animals

- **REDUCTION:**
  - *Standard definition*: Methods that minimise the number of animals used per experiment
  - *Contemporary definition*: Appropriately designed and analysed animal experiments that are robust and reproducible, and truly add to the knowledge base

- **REFINEMENT:**
  - *Standard definition*: Methods that minimise animal suffering and improve welfare
  - *Contemporary definition*: Advancing research into animal welfare by exploiting the latest in vivo technologies and by improving understanding of the impact of welfare on scientific outcomes.

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