HUMAN TECHNOPOLE NATIONAL FACILITIES ACCESS RULES
Access regulated by Convenzione

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1. SCOPE

The present document aims to illustrate the rules regulating Access to Human Technopole National Facilities (NFs) and related services by Researchers affiliated with Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities (as regulated by the *Convenzione* between the Ministry of Economy and Finance, the Ministry of Health, the Ministry of University and Research and HT).

In addition to these general rules, specific requirements may be defined for each NF.

These rules adhere to the principles and guidelines defined by the European Charter for Access to Research Infrastructures (link).

2. INTRODUCTION

Human Technopole Foundation (HT) promotes innovation in the healthcare sector through an interdisciplinary approach based on the creation and sharing of knowledge. Supported by public funds from the Italian State budget, HT carries out frontier research in biomedicine and offers state-of-the-art technologies and services, available to HT Researchers as well as to Italian Researchers, who can Access them through open, merit-based selection procedures.

As defined by the *Convenzione* by applying to the national context the definition of 'research infrastructure' introduced by the European Strategy Forum for Research Infrastructures, National Facilities (NFs) are facilities, resources and related services used by the Italian scientific community to conduct top-level research in their respective fields, regardless of institutional affiliation. Specific operational units, called Infrastructural Units (IUs), defined as the set of people, tools, resources, technological procedures and cutting-edge experimental protocols necessary for a specific thematic line of research, form each NF.

Below the list of the first NFs and relevant IUs:

- NF for Genomics - IU1 High Throughput Sequencing, IU2 Multi-Omics Technologies, IU3 Computational Genomics, IU4 Technology Development

- NF for Genome Engineering and Disease Modelling - IU1 Pluripotent Stem Cells and Advanced Cell Cultures, IU2 Gene Editing Technologies, IU3 Validation, IU4 Technology Development

- NF for Structural Biology - IU1 Cryo-Electron Microscopy, IU2 Biomass Production, IU3 Biophysics, IU4 Structural Proteomics, IU5 Dynamic Single-molecule, IU6 Technology Development

- NF for Light Imaging - IU1 Imaging, IU2 Tissue Processing, IU3 Flow Cytometry, IU4 High-content Imaging, IU5 Ion Imaging, IU6 Technology Development - Customized Microscopy

- NF for Data Handling and Analysis - IU1 Bioimage Analysis, IU2 Omics Analysis, IU3 Technology Development - DevOps and Web Development

More information on HT NFs and a detailed list of services can be found on the dedicated webpage (link).

2.1. Access modalities

Three different Access modalities can be requested. Their availability will vary, based on the service specifics of each NF:

- **"Simple" Access to NF or individual instruments thereof**: this modality is intended for Users involved in projects requiring technologies that are available at the NF for direct Access by User. This Access modality requires prior expertise with the technology of interest. After an initial introductory training aimed at defining the level of expertise of the User, the use of the instrument with limited supervision by NF staff is authorised. For defined NFs/ instruments/ services this Access modality may be restricted or not available.

- **Access to NF services**: This procedure entails the provision of services performed by NF staff on behalf of the User. NF services may include both standard services as well as, when foreseen by the technology development specifics of each NF, bespoke services conceived and discussed with the User. To allow the NF staff to best align the experimental activity to the research objective, the User may be invited, if needed, to assist the NF staff while performing the project or aspects of it.

- **Access to NF services including training**: This procedure entails training by NF staff to provide Users, in addition to or alternatively to the services described in the previous modality, with training courses and/or programs, aimed at transferring the expertise necessary for the independent use of the specific technology. In this case, technical and/or experimental activities are conducted with the active participation of the User. This type of Access is also aimed at researchers who want to acquire expertise for subsequent independent use of a specific technology in other laboratories.

2.2. Application type

Applicants shall select the type of application they want to submit, choosing between two options:

a. **Standard** application for projects that are technically mature.

b. **Proof-of-concept** application for:

i. Projects with high scientific potential but with insufficient technical maturity or preliminary Data.

ii. Projects aimed at setting up the experimental conditions required for a standard project, including methods or technology development projects.

iii. Time-limited Access projects (e.g., to acquire Data to complete a manuscript, or preliminary Data needed for a grant application, or single microscopy session).

3. DEFINITIONS

3.1. Access

"Access" refers to the authorized use of the NF and of the services offered. Such Access can be granted for sample preparation, set-up, execution and dismantling of experiments, education and training, expert support and analytical services, among others. Access to the NFs includes all infrastructural, logistical, technical and scientific support (including training) that is necessary to perform the aspects of the project approved for Access.

Law 160/2019, art. 1, co. 276, lett. b currently foresees that Access of external Users affiliated with Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities is supported by open calls for Access organized by HT, and is free of charge for the User for the project (or part of the project) approved for Access.

3.2. Applicant

"Applicant" is the Principal Investigator who applies to a NF open call for Access and who is responsible for the submitted project. They can be of any nationality and must be affiliated with an Italian University, *Istituto di Ricovero e Cura a Carattere Scientifico* (IRCCS) or Public Research Entity.

3.2.1. Physical Access (or in person Access)

"Physical Access" applies when a User accesses a NF or a service by being physically present at the selected NF. In order to obtain physical Access, the User must complete all necessary security and health, safety and environment (HSE) checks, complete all required training and be provided with all the necessary insurances. Physical Access is also required for on-site training.

3.2.2. Remote Access

"Remote Access" means Access to a NF or service without the User being physically present at the NF. Typically, NF staff perform the experimental protocols entailed by the service and return the Data and results produced to the User together with any resulting samples (when appropriate). If applicable, "remote Access" can also include remote analysis of the samples by the User after sending them to the NF.

3.3. National Facility

NFs are technological platforms used by both HT internal and external Researchers to conduct research and foster innovation in their respective fields. NFs include not only scientific equipment but also personnel (both scientific and administrative), resources (e.g., Data resources and analytical pipelines, collections, biobanks), technical knowledge and services that are essential to achieve excellence in research and innovation.

3.4. Principal Investigator

"Principal Investigator" (PI) is the Researcher affiliated to an eligible Institution with the role of independent Group Leader, who is responsible for coordinating the research activities conducted within the framework of the submitted project.

The PI shall hold a primary appointment as Group Leader at an eligible Institution, with the following requisites:

- Coordinate an independent research team.
- Have a supervisory role towards junior and/ or senior Researchers.
- Their Group has an autonomous budget sufficient to cover their current research expenses.
- Be the recipient of independent research funding as PI or co-PI.

Junior PI: Up to 6 years from their first appointment in an independent Group Leader position.

Established PI: More than 6 years from their first appointment in an independent Group Leader position.

3.5. Researcher

"Researcher" is a professional engaged in the conception or creation of scientific knowledge. They conduct research and improve or develop concepts, theories, models, techniques, instrumentation, software or operational methods.

3.6. User and User Institution

"User" of the NFs in general can be individuals, teams or institutions from academia, industry or any other public or private research conducting organisations. They are engaged in the conception or creation of new knowledge, products, processes, methods and systems and also in the management of projects. Teams can include Researchers, doctoral candidates, technical staff and students participating in research in the framework of their studies.

The Access of Users affiliated to Italian Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities is supported by open calls for Access as provided for in *Law 160/2019, art. 1, comma 276, letter b*. User can be the Principal Investigator or a member of their team.

If requested by the Applicant, the User of the NF can also be a member of their team. Applicants are encouraged to support NF Access by young Researchers (R1 and R2 profiles of the European Framework for Research Careers, link) who are part of their team.

"User Institution" is the institution to which the Users are affiliated.

3.7. User Access project

"User Access project" includes the objectives and the activities performed at the NF to achieve the scope of the Access.

4. ACCESS PROCEDURE FOR EXTERNAL USERS APPLYING TO OPEN CALLS FOR ACCESS

Law 160/2019, Art. 1, comma 276, lett. b foresees that Access of external Users affiliated to Italian Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities is supported by open calls for Access organized by HT and does not entail any charge for the User in connection with the project (or part of the project) approved for Access. Access for external Users through open calls is granted based on the principles of scientific excellence, with the aim of supporting high-quality research. Access requests are approved by the Standing Independent Evaluation Committee (SIEC) based on the evaluation of the submitted application. Such evaluation, based on scientific merit, originality and innovation potential is performed by a dedicated panel of independent experts (Review Panel) identified and appointed by the SIEC. Access to the NFs is approved by the SIEC, based on scientific merit and technical feasibility of the project, as well as capacity of the relevant NF. Detailed information on the evaluation criteria and the scoring system is available in each call for Access.

Once approved, Access is managed through a dedicated Access portal that allows the User to interact with the NF staff and to follow the status of the project as experiments are carried out.

A detailed description of the Access workflow is available on the NF webpage (link).

5. SCIENTIFIC REVIEW PANEL

NFs offer Access to a wide range of technologies that can be applied to different scientific fields. For the evaluation process to be efficient and of high-quality and following established international best practice, SIEC is supported by dedicated Review Panels composed of experts in the technological fields covered by the NF selected by the SIEC.

6. ACCESS AGREEMENT

The Access of external Users to the NFs is regulated by an Access Agreement covering technical and legal aspects such as mode of Access, rights, obligations, representation and warranties of the User, ethical clearances, intellectual property rights, Data protection, confidentiality, liability, and financial aspects, among others. A template of the Access Agreement is available at this link.

The Principal Investigator and the legal representative of the User Institution are required to sign the Access agreement.

When external User Access foresees co-development of protocols or technologies with the contribution of both the external User and HT staff, the Access is regulated by an additional dedicated Agreement.

7. COSTS

NFs are supported by public funds from the Italian Ministries of Health, of University and Research and of Economy and Finance.

Law 160/2019, Art. 1, comma 276, letter b foresees that Access of external Users affiliated to Italian Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities is supported by open calls for Access and is free of charge for the User for the project (or part of the project) approved for Access and described in the Project Plan. The costs for the activities to be performed at the NFs will be fully covered, including shipment of relevant material from and to the User's laboratory, as well as travel and accommodation for the User while accessing the NF. Project-related costs (personnel, consumables, and other costs) at the User laboratory are not funded.

8. DATA MANAGEMENT

NFs shall process any personal Data relating to the Access in accordance with the *Regulation (EU) 2016/679* and the Italian *d.lgs. 196/2003* and *d. lgs.102/2018* on the protection of natural persons with regard to the processing of personal Data and on the free movement of such Data.

The Input Data is temporarily made available by the User to HT for the execution of the approved Access and remains property of the User.

Research Data produced by the NFs as result of the activity performed for the Access project is processed in accordance with HT's Research Data Management Guidelines (link).

During the preparation of the Project Plan, User and NF staff agree on a Data Management Plan, regulating how research Data resulting from the NF service are handled. Data management shall refer to HT's Data Management Guidelines (link) that aims at making research Data findable, Accessible, interoperable and re-usable (FAIR), and includes information on:

- the handling of research Data during & after the end of the project

- what Data are collected, processed and/or generated

- which methodology & standards are applied

- whether Data are shared/made Open Access and

- how Data are curated & preserved (including after the end of the project).

NF staff is primarily responsible for Data production, quality control, and first-pass Data analysis. Users are responsible for further downstream Data analysis and interpretation.

At the end of the Access, the Output Data is made available to the User following the timeline and the conditions specified in the Access Agreement. The Output Data will be retained on HT server for the time indicated in the Access Agreement and then deleted.

9. CONFIDENTIALITY AND ETHICAL CONDUCT

Each User shall comply with the confidentiality requirements and adhere to the code of conduct and standard ethical behaviour in scientific research when conducting research and using/disseminating research Data and findings, as detailed in the European Code of Conduct for Research Integrity of the European Science Foundation ([link](#)).

When submitting an application, each Applicant shall confirm that all relevant authorisations, declarations, and accreditation from the competent authorities have been obtained in order to perform the proposed activity. In particular, Users shall ensure compliance of the proposed work with the ethical obligations as requested by European and National laws (e.g., ethical clearance), providing specific representations and warranties in this regard.

10. INTELLECTUAL PROPERTY RIGHTS (IPR)

10.1. Definitions

10.1.1. Intellectual Property

Intellectual Property means trade-marks, service marks, certification marks, official marks, trade names, trade dress, distinguishing guises and other distinguishing features used in association with wares or services, whether or not registered or the subject of an application for registration and whether or not registrable, and associated goodwill; inventions, processes, articles of manufacture, compositions of matter, business methods, formulae, developments and improvements, whether or not patented or the subject of an application for patent and whether or not patentable, methods and processes for making any of them, and related documentation (whether in written or electronic form) and know-how; software in source code or object code form, documentation, literary works, artistic works, pictorial works, graphic works, musical works, dramatic works, audio visual works, performances, sound recordings and signals, including their content, and any compilations of any of them, whether or not registered or the subject of an application for registration and whether or not registrable; domain names, whether registered primary domain names or secondary or other higher level domain names; industrial designs and all variants of industrial designs, whether or not registered or the subject of an application for registration and whether or not registrable; and trade secrets, technical expertise, and research Data and other confidential information. Background Intellectual Property means any and all Intellectual Property conceived, developed, reduced to

practice or otherwise made or acquired by HT and/or the User before the Access and that was not developed or conceived during the Access. Foreground Intellectual Property means any and all Intellectual Property that is conceived, developed, reduced to practice or otherwise made by HT personnel during the Access as part of the service, including improvements and enhancements to Background Intellectual Property.

10.2. IPR policy

Unless a dedicated collaboration agreement provides otherwise, all Intellectual Property Rights (IPR) deriving from the activities within the scope of the Project, including those consisting in the execution of the Service, shall belong to the User and/or the User Institution, depending on the agreements between them.

All IPR that are developed by HT while carrying out the Service but beyond the scope of the Project shall solely belong to HT. Shall the User contribute to the latter, the related IPR shall be shared between HT and the User on the basis of the User's actual contribution.

11. OWNERSHIP AND PUBLICATION OF RESULTS

The User shall own the results produced and have the right to publish or otherwise exploit findings and results produced during the Access. Since the NFs are subject to evaluation, they need to provide KPI to demonstrate success in providing support to the scientific community. Therefore, NFs shall be acknowledged for providing the service, and NF staff listed as co-authors in the case of co-development of part of the project.

HT shall be acknowledged as the Access provider in any publications or presentations of the Data and results provided by the NFs, using the following statement "*We acknowledge the Access and services provided by the National Facility for [GENOMICS / STRUCTURAL BIOLOGY – IU (specify number and name of the IU)/ GENOME ENGINEERING / LIGHT IMAGING - IU (specify number and name of the IU) / DATA HANDLING AND ANALYSIS – IU (specify number and name of the IU)], Fondazione Human Technopole, Milan, Italy".* Moreover, in scientific publications the statement "[Technique/analysis] was performed at National Facility for [GENOMICS / STRUCTURAL BIOLOGY - IU *(specify number and name of the IU)*/ GENOME ENGINEERING / LIGHT IMAGING - IU *(specify number and name of the IU)*/ DATA HANDLING AND ANALYSIS – IU *(specify number and name of the IU)*]], Fondazione Human Technopole, Milan, Italy" shall be indicated in the materials and methods section of the publication. "Publication" means any form of dissemination of the results such as manuscripts, pre-prints, abstracts, presentations, etc. All Users shall make their Data publicly available in the most appropriate and time-efficient way as required by the *Convenzion*e (link).

When NF staff critically contributes to the User's project while performing the service requested, co-authorship shall be discussed. Activities for which authorship is recommended are: design of project that includes critical input and/or original ideas (e.g., providing guidance for experimental design, solving technical problems, developing technology/ methods that make the project feasible); Data acquisition, analysis and/or interpretation beyond routine practices; critical drafting and/or revision of manuscript for intellectual content purposes.

12. ACCESS REPORT, FEEDBACK FORM AND SCIENTIFIC OUTPUT

At the end of the activities carried out at the NF, and not later than 3 months thereafter unless agreed

otherwise with the NF User Access Office, the User must submit (via email to national.facilities@fht.org) a short report on the results obtained and the impact of the service on their research, to be published on the NF website as required by the *Convenzione Art 6, comma 5.*

Moreover, the User will be required to fill in a brief survey regarding their experience, providing feedback and suggestions for further service improvement.

The User must communicate to the User Access Office (via email to national.facilities@fht.org) any publication acknowledging the NFs.

Research Data obtained during the Access shall be made available to the scientific community following the FAIR principles. Users must inform the User Access Office (via email to national.facilities@fht.org) when and how the Data are made public.

13. LIMITATION OF LIABILITY

HT does not guarantee:

- the suitability, with respect to the research purposes of the User, of its premises, equipment and personnel;

- the accuracy of the services provided by its NFs, nor that such services are free from errors or omissions.

In the absence of bad faith or willful misconduct, HT shall in no case be liable to the User and to the User Institution for any losses, liabilities, damages, costs or expenses arising out of inadequacy or malfunctioning of its laboratories or arising out of delays or negligence in the providing of the services.

14. REPRESENTATIONS AND WARRANTIES

The User and the User Institution represents and declares that the relevant research project has received full ethical clearance and that all biological samples and personal Data involved have been collected in accordance with applicable laws and regulations. In this regard, the User and the User Institution expressly undertake to indemnify and hold harmless HT, its regents, officers, agents and employees from any liability, loss or damage HT may suffer as a result of claims, demands, costs or judgments arising due to the breach of ethical protocols, privacy laws or biosafety regulations.

The User and the User Institution also expressly undertake to indemnify and hold harmless HT in connection with any loss or damage, direct or indirect, HT may suffer as a consequence of the User or the User Institution's own negligence or failure to comply with the instructions given, time by time, by HT's HSE Area or by NF staff.

15. GENERAL RULES FOR PHYSICAL ACCESS

HT strongly promotes remote Access to minimise costs and time as well as to limit travelling. In cases where remote Access is not possible, physical Access is used and the following rules applies:

15.1. Implementation

Physical Access to the NFs is in accordance with the rules and procedures of HT. This applies in particular to the granting of Access to User Access projects, entrance permits, length of stay, health

and safety, and security of Users at HT.

15.2. User instructions

HT provides Users with instructions for effective and efficient Access to the NFs. Instructions relevant to the use of the NF of interest are provided by the NF providing the Access.

15.3. User responsibilities

Users have to comply with all instructions given by NF staff within the NF and report any problems or safety relevant issues.

Users are obliged to notify the NF staff of any malfunction or damage to instruments without any delay.

15.4. Insurance

All external Users who physically Access NFs must ensure that they have comprehensive insurance coverage for accidents and third-party liability, encompassing all their activities during their stay at HT. The external User Institution or the external User shall provide the name of the insurance company, insurance policy number and expiration date, and ensure that HT is recognized as third party.

15.5. Coverage of costs during physical Access

Law 160/2019, Art. 1, comma 276, lett. b currently foresees that for external Users affiliated to Italian Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities the travel, food and lodging expenses during the period to be spent at HT during physical Access are covered by HT in accordance with HT's current applicable policies.

16. REVIEW AND UPDATE OF NF ACCESS RULES

These Access rules represent the current procedure and rules to Access HT NFs.

The first round of calls, planned for Q2 2024, is open in "trial modality" to survey the main needs of the Italian scientific community and to consequently inform and help define best practices for subsequent calls. To meet the requirements of the scientific community, User groups are created with the aim to collect feedback from external Researchers who Access the NF services. HT will periodically review the relevance, suitability and applicability of these Access rules and, whenever appropriate, update them accordingly. The most updated version of the rules is available on the NF website at the following link.

17. FURTHER INFORMATION

For general inquiries: NF User Access Office, national.facilities@fht.org