

HUMAN TECHNOPOLE NATIONAL FACILITIES USER ACCESS WORKFLOW

Access regulated by Convenzione

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1. INTRODUCTION

Services offered by Human Technopole (HT) National Facilities (NF) to researchers affiliated with Universities, *Istituti di Ricovero e Cura a Carattere Scientifico* (IRCCS), and Public Research Entities (Access regulated by the *Convenzione* between the Ministry of Economy and Finance, the Ministry of Health, the Ministry of University and Research and HT) are available through open calls for Access that are published regularly on the HT website (<u>link</u>), allowing applicants to submit their requests for access throughout the year For technical reasons, the online application system may be closed for short periods after each selection deadline for maintenance purposes and occasional downtimes may occur at any time. Candidates must take these potential issues into consideration during their application process.

Each call for Access includes the list of services and Access modalities offered by each NF, eligibility criteria, technical requirements, evaluation criteria and scoring system (<u>link</u>).

Moreover, a detailed description of the services offered by the NF, the available equipment and the technical requirements for Access, as well as terms and conditions are available on the dedicated NF webpage (link), which is updated regularly.

1.1. 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. ACCESS MANAGEMENT PORTALS

Access to NFs is managed through dedicated portals that include:

a. A dedicated webpage for the NFs (link), including:

- i. Description of the NFs.
- ii. List of available technologies.
- iii. List of open calls for Access including service list and technical requirements.
- iv. Contact form to allow Applicants to contact the NF Users Access Office in case of questions before or during the application process.
- v. Link to the application portal.
- vi. List of approved and completed projects.
- vii. List of closed calls.

b. An application portal available for:

- i. Applicants
- ii. Reviewers

3. DESCRIPTION OF THE ACCESS WORKFLOW

The User Access workflow comprises different steps, spanning from the initial submission of the application to evaluation and Access approval, Access to the performance of the service(s) and Access conclusion.

3.1. Application submission and evaluation

Figure 1 summarises the steps involved from submission of an application to Access approval.

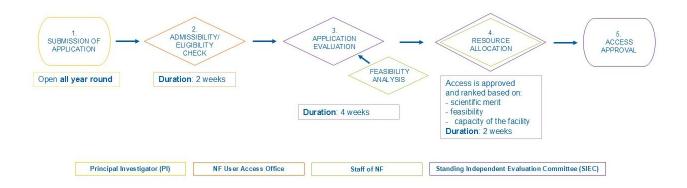


Figure 1: Schematic representation of the Application workflow, from application submission to Access approval.

Below is a detailed description of the procedure.

1. Application submission

A researcher (Principal Investigator, PI) interested in a service offered by a NF submits their application in response to a specific call for Access. The Applicant is the Principal Investigator who applies to a NF open call for Access and who is responsible for the submitted project. The Applicant shall hold a primary appointment as Group Leader in an eligible Institution. Applications from Researchers who are not independent should be submitted by their Group Leader. For details on eligibility, see the relevant call for Access (link).

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).

The Applicant is asked to fill out an online application form, specifying the type of application among the two available (i.e., Standard or Proof-of-Concept), the Access modality they need among the available ones, and a description of the project including any technical information necessary to define project feasibility.

Should the Applicant need support before or during the application process, a contact form is available in the dedicated NFs webpage (<u>link</u>).

2. Admissibility and eligibility check

The application is processed by the NF User Access Office, where a first administrative review is performed to ensure that all the requested components have been provided, and that all eligibility criteria have been met. If an application is deemed not admissible/eligible, the Applicant is informed immediately, along with a justification for the decision.

3. Evaluation of the application

The evaluation procedure is conducted by the Standing Independent Evaluation Committee (SIEC). SIEC is supported by a Panel of independent external Reviewers (Review Panel) selected by the SIEC on the basis of their scientific expertise.

Five Review Panels are appointed by the SIEC, one for each NF (i.e., Review Panel Genomics, Review Panel Structural Biology, Review Panel Genome Engineering, Review Panel Light Imaging, Review Panel Data Handling and Analysis). Each Review Panel is composed of 2 SIEC members, who act as Chairs, plus 10 appointed external Reviewers, with the relevant expertise.

The admissible/eligible applications are directed to an appropriate Review Panel for evaluation. Each application is assigned for independent evaluation to three Reviewers who are part of the relevant Review Panel.

Reviewers submit their scores and evaluations to the Chairs.

During this stage, the Reviewers as well as the Chairs receive feedback from the NF staff who performs a comprehensive analysis of the proposed project's technical feasibility. Technical feasibility also includes an evaluation of the fulfilment of the technical requirements in terms of capacity to receive and process the research data generated by the NF. This latter is performed in consultation with the NF for Data Handling and Analysis. Based on the technical maturity of the proposed project, the application can be categorised as Feasible / Not Feasible / Partially Feasible / Proof-of-Concept study required.

4/5. Resource allocation and Access approval

NF staff provides the SIEC with information on the resources needed (cost and time) to perform the highest ranked, technically feasible projects. Applications with the highest scientific score that fulfil all the requested technical requirements are approved for Access by SIEC, based on the capacity of the NF. A selected number of applications may be placed on a temporary waiting list (in case of cancellations).

Evaluation results – Access granted, Access conditionally granted, Access waitlisted, Access not granted – are communicated to the Applicant through the Access portal.

Applicants whose applications are placed on the waiting list will receive additional information advising whether the project can be Access approved or should be resubmitted within the subsequent application window.

3.2. User Access

A "User" is intended as a Researcher affiliated with an eligible Institution who accesses the NFs to perform the approved activities or to support the National Facility staff while performing the approved service. If requested by the Applicant, the User of the NF can also be a separate member of their research team.

After Access approval, PI and NF staff meet to define the experimental protocol and the project plan. Once the project plan has been agreed, the NF User Access Office coordinates the signature of the required formal agreements (e.g., Access Agreement, Collaboration Agreement, other), when applicable.

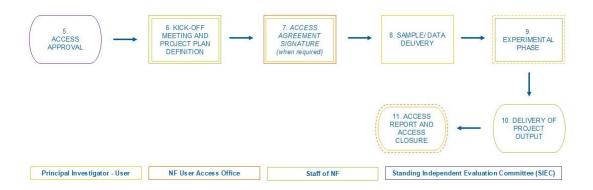


Figure 2: Schematic representation of the User Access workflow. The workflow described here represents a general overview of the User Access in terms of steps required for the User to Access the services offered by the NFs. A dedicated workflow is available by each NF and describes the specific steps required to Access the offered services. When required, NFs can develop ad hoc workflows for specific services.

6. Kick off meeting and project plan definition

After Access approval, a kick-off meeting is organized and the PI is invited to meet the NF staff to discuss the experimental design of the project, to exchange sample handling protocols and to draft a project plan with goals, tasks, timelines, milestones and data management plan. Shipping requirements are also discussed. Once the project plan is finalised and agreed by NF staff and PI, the project can start. The plan can be updated by the PI or by the NF staff as needed.

7. Access Agreement signature (when required)

When required or appropriate (e.g., projects that involve the use of data, samples, other material of human origin and derivatives thereof) an Access Agreement or other formal Agreement shall be signed by the PI and their Institution.

8. Sample/data delivery

Once the Access Agreement (or other formal Agreement) is signed, the PI prepares the samples/ data to be tested/ processed/ analysed and sends them to the NF. PI is required to provide the samples/ data as agreed upon with the NF staff and specified in the project plan. During the entire duration of the project, and based on technical requirements, multiple sample deliveries can be foreseen and detailed in the project plan.

9. Experimental phase

Once the NF receives the samples/ data the project can be initiated. At this stage, based on the type of service requested, the PI or PI's team member can visit the NF for training or to perform aspects of the project. Under these circumstances, the time to be spent by the User on HT premises and indicative dates are reported in the project plan. The NF User Access Office contacts the User for planning travel and accommodation arrangements.

10. Delivery of the project output

The last step of the service workflow is the delivery of the project output that can include processed samples or research data. Research data are handled by the NF for Data Handling and Analysis, that performs a quality control of the data and prepares them for subsequent analysis by the User.

11. Final report submission

At the end of the activities carried out at the NF, and not later than 3 months thereafter if not differently agreed with the NF User Access Office, the PI must submit a short report on the results obtained and the impact of the service on their research. Moreover, a final report to be published on the NF website and describing the impact of the Access to the NF on the research project for which the service has been requested shall be provided upon publication of the relevant results.