Infrastructure for the Production and Characterization of Nanomaterials,
Biomaterials and Systems in Biomedicine
www.nanbiosis.es

NANBIOSIS Access Protocol

NANBIOSIS is an Infrastructure that supports biomedical research for national and international companies and research institutions covering the entire development life cycle of a biomedical device, from the design of biomaterials to preclinical validation in large and small animal models. This includes the design of diagnostic devices (IVDs), medical devices, biosensors, regenerative medicine solutions, drug delivery systems, therapeutic agents, and MRI contrast agents.
NANBIOSIS forms part of the National Spanish Map of Unique Scientific and Technological Infrastructures (ICTS in Spanish) -large installations, resources, facilities, and services, unique in its kind, dedicated to cutting edge and high-quality research and technological development, as well as to promote exchange, transmission, and preservation of knowledge, technology transfer, and innovation.
NANBIOSIS is a distributed infrastructure integrated by three nodes -Centro de Investigación Biomédica en Red (CIBER) in the area of Bioengineering, Biomaterials an Nanomedicine (-BBN), Centro de Cirugía de Mínima Invsión Jésus Usón (CCMIJU) and IBIMA Plataforma Bionand (Bionand)- and composed of several Units that offer over 150 services under a centralized one-stop shop system (a single web access point), the access to which is hereby determined:

I. SCIENTIFIC AND TECHNICAL CONDITIONS:

All the applications for access to NANBIOSIS services must be submitted through the online tool by filling the Order request form available at: ***http://www.nanbiosis.es/order-request/***, or by clicking on the Order Request tool provided in different part of NANBIOSIS website.

Scientific and technical conditions concerning the access to ICTS of users are subject to the development of projects that require the use of equipment and processes for research on nanomaterials, biomaterials, and medical systems, including preclinical validation, or to facilitate the training to existing techniques in NANBIOSIS, and which have been previously approved by the Access Committee.

There are two kinds of access according to the applicant's experience, the scientific challenge of the proposals and the kind of service required: remote and on-site (self-service).

- **Remote service:**
  Once the application has been approved by the Access Committee, the project is performed by the NANBIOSIS' technical staff, under the supervision of the research staff. In general, the applicant's assistance is required, but not his presence. Many times, a previous discussion with researchers who coordinate the required units is needed to find the best strategy to implement the project.
  Generally, these are researchers, external users from companies, other research centres and hospitals who do not know the procedures or, knowing them, they do not work directly

with similar tools or seek techniques that supplement their own. It is also common that the user is only interested in the solution to a specific need or problem.

- **On-site service** is a scientific use available in some services of some units where it is possible to access as self-service. In this case, the equipment of the units is used by experienced users who do not have the facilities of NANBIOSIS in their own centres.
  For this modality, it is necessary to check the user's qualifications before allowing them to use the equipment. It is sometimes possible, in certain units and specific circumstances, to qualify them previously. Users are advised by our technical staff on the use of equipment to work independently.

Type of access depends also on the specific service. See details of the services offered by each Unit at the Catalogue of Services for each Unit at http://www.nanbiosis.es/nanbiosis-services.

Regarding user's required and accredited experience, there are two types of users.

- **Type 1: Non-doctor researchers,** usually working on their doctoral thesis. The proposal to develop and, when appropriate, PhD student's stay must provide him/her with useful knowledge in the context of the thesis.
- **Type 2: PhD or with a minimum of three years accredited research experience.**

Researcher users must belong to R&D institutions, public and private centres or companies, part of a research team or research group or, if applicable, part of a scientific department or similar unit. The access is open to both the national and international scientific community.

As for administrative requirements, first, the user must complete the online **'Access Application Form**' and confirm the compliance of the requirements specified there.

Once the project is accepted, all assistance needed for the execution of their experiment will be at users' availability. Specifically:

- Tips on project preparation.
- Advice and assistance in the preparation of the samples.
- Access to the use of facilities and instrumentation.
- Enabling training for the use of the methods.
- Support during the processes.
- Support for the assessment of results.
- Support during equipment maintenance.
- Support for the design of additional experiments.
- Backing in administrative matters, offered by administration managers of NANBIOSIS

Once the access requests are accepted, the Access Protocol, which is explained later, must be followed.

To access the services, the application must be submitted through the ***http://www.nanbiosis.es/order-request/*** tool.

II. COST OF THE ACCESS FOR THE FACILITY AND CONSEQUENCES FOR THE USERS WHERE RELEVANT

The user will assume the 100% of the service to cover maintenance and operation costs (except in the case that public funds for the use of the ICTS or discounts may apply). These costs will be calculated based on specific rates existing for the services provided by the different units, which can be found at the website for each Unit, by clicking on Services & Rates. In those rates, different costs depending on the type of access, for instance self-service mode, if available, are considered.

Once the proposal is approved, costs and deadlines are estimated and communicated to the user. The user will contact the Unit/s involved to know the estimated costs. Before starting the project, it is necessary that customer accepts the budget. Any deviation of the project will be considered, estimated and reported to the user.

In terms of billing, this could be made by the institution/s where the Units involved are located, through CIBER, through JUMISC and/or Bionand, always on basis on published rates.

III. ACCESS CRITERIA AND PROCEDURES

i. Description of the access Protocol

NANBIOSIS offer access to its services to all interested national and international users who may come either from the public or the private sector, and who can apply to them under the “Competitive Open Access” or “Access on Demand” modalities.

a. Competitive Open Access:

As an ICTS, NANBIOSIS offers at least 20% of the capacity of each outstanding facilities under a competitive open access scheme to the entire scientific and technological users community concerned. Under this modality, regular calls are launched for the scientific community to apply for access on basis on competitive criteria. Dates and details of the calls are explained and announced at http://www.nanbiosis.es/call/ and NANBIOSIS social media channels.

To access the NANBIOSIS services, the application must be submitted through ***http://www.nanbiosis.es/order-request/*** tool within the periods of the calls. The Access Application Form, “Order Request”, includes a section related to the evaluation criteria. To have their application granted under “competitive open access” modality, applicants must choose and explain the concurrence of one or more of the criteria provided, sufficiently argued and with the necessary details to allow their consideration. This evaluation is carried out by the NANBIOSIS Access Committee.

The Access Committee shall study the access proposals received, evaluating each of them based on the concurrence of the following criteria of scientific excellence and uniqueness and with the relevance indicated by the punctuation provided for each criterium:

1. Access to the Unit within the framework of a National, European or international granted competitive project. (Details of the project must be provided: official code, title, financing agency, call, and dates for its execution). (Score: 5 points)
2. The need to carry out one of the NANBIOSIS "cutting-edge biomedical solutions" (CEBS) that implies the interaction of several Units. (Applicants must apply for one of the CEBS and provide arguments supporting the scientific-technical relevance of the proposal, its quality and originality) (Score: 4 points)
3. Provide a unique service under GMP/GLP conditions or in a laboratory under ISO standards (Applicants must apply for specific services of NANBIOSIS Units under GMP/GLP conditions or under ISO standards and provide arguments supporting the scientific-technical relevance of the proposal, its quality and originality) (Score: 3 points)
4. Access to the Unit within the framework of a project granted in a competitive call of an entity of regional, local or institutional scope. (Details of the project must be provided: official code, title, financing agency, call, and dates for its execution). (Score: 2 points)
5. The need to periodically carry out a "continuous access under contract" service. (This criterium benefits the applicants that contract NANBIOSIS services on an ongoing basis, which demonstrates their confidence in the Unit). (Score: 1 points)
6. Need for special involvement and high-level knowledge and experience of the technical and scientific staff involved during the service (Applicants must provide arguments supporting the concurrence of this criterium in relation of the scientific-technical relevance of the proposal, its quality and originality). (Score: 1 points)
7. A special demand in the type of work to be carried out that is only offered by the NANBIOSIS Unit (Applicants must provide arguments supporting the concurrence of this criterium in relation of the scientific-technical relevance of the proposal, its quality and originality. The concurrence of this criterium demonstrates the singularity of the Unit). (Score: 1 points)
8. The need to make a complete report or perform an interpretation and discussion of the results by the technicians and scientists of the Unit given their previous experience. (Applicants must provide arguments supporting the concurrence of this criterium in relation of the scientific-technical relevance of the proposal, its quality and originality. The concurrence of this criterium demonstrates the singularity of the Unit) (Score: 1 points)
9. Development of a new material, process or active ingredient of great interest to the National Health System given its foreseeable future potential or its intellectual property. (Applicants must provide arguments supporting the concurrence of this criterium in relation of the scientific-technical relevance of the proposal, its quality and originality). (Score: 1 points)

The NANBIOSIS Access Committee will elaborate a report with a prioritization proposal of the accesses to the required Units. The Coordination Committee will study this report and issue the Access Prioritization Agreement that will be published on the NANBIOSIS website http://www.nanbiosis.es/call/ and disseminated through NANBIOSIS social networks and communication channels.

b. Access on Demand:

Access applications forms submitted after the Open Access Call deadlines or not prioritized by the Access Committee shall be considered as "access on demand".

In both modalities, after receiving the application, a preliminary administrative evaluation will be conducted to determine the compliance of the proposal requirements. If necessary, a period will be given to the applicant to make the corresponding corrections. This first evaluation will be carried out by the Coordinator of NANBIOSIS.

Once the application is approved under any of both modalities and the Unit/s involved is/are determined, the Scientific Coordinators of the Unit/s involved will contact the applicant for scheduling the access.

ii. Access Committee (members, functions)

The composition of the NANBIOSIS Access Committee includes experts in the scientific and technical field of NANBIOSIS, independent of the infrastructure, that do not belong to any of the Units of NANBIOSIS and are not users of the ICTS.

The **Access Committee members** (https://www.nanbiosis.es/nanbiosis-committees/) are proposed and named by the Coordination Committee every eight years, or when the members need to be replaced by their own request.

This Committee's function is to evaluate the applications submitted within the competitive calls to provide the NANBIOSIS Coordinating Committee with a prioritization proposal of the accesses to the NANBIOSIS Units in the **Competitive Open Access modality**.

Due to the high complexity and variability of the units and large number of services involved in NANBIOSIS, the Coordination Committee can be consulted by the Access Committee to determine the Units that better fit to develop the requested project, unless the user has previously selected the required Unit.

Furthermore, for solving specific technical issues, if necessary, the Access Committee may also consult the corresponding Scientific Directors and or Coordinators of the different Units involved. Also, these scientific Heads of the units can be consulted by the applicants before applying for competitive access (contact details at www.nanbiosis.es).

IV. ACCESS TO THE FACILITY

The details of the general access to facilities protocol are shown below, although specific conditions for each institution/Unit will be communicated to user accordingly. In case of selecting the self-service modality, once the proposals have been approved, access protocols for each of the units involved will be communicated to users by the corresponding Unit.

i. Access Schedule

- The equipment of the Units included in NANBIOSIS is available approximately 280 days per year, that is, every day except Sundays and national and regional holidays.
- Opening hours will be the same of the institution where the unit is located. However, it is possible to contact the management unit through www.nanbiosis.es
- For the corresponding Units, authorization from the Scientific responsible of the unit must be requested to access to the facility, outside the opening hours established by the institution where is located the infrastructure, except emergencies.
- Any person not included in the list of users can´t enter the facilities.

ii. Access to the facilities

- Each Scientific Director or Coordinator is able to deny access if any incompatibility with other works in progress is observed at the same time, e.g. an experiment is running. Access will need to be rescheduled according to the availability of the Unit.
- It is compulsory to be accredited to access the laboratories and, if required, show the corresponding card.

Access to other facilities throughout the different Units will be possible only with express permission given by the Scientific Director of the Unit and following the rules for access to the premises.

iii. Entrance and exit to facilities.

- Entrance and exit to facilities will follow the rules set by each Unit. Such rules must be available to users at its application's approval, once the applicant contacts the Unit.

iv. Access to materials and products

- It is not allowed to introduce any type of equipment, material and/or consumable product without express authorisation of the Scientist Responsible.
- It is forbidden to introduce cartons, boxes and packaging.
- It is forbidden to introduce food or drink.
- Any material (previously authorized) that enters to the facilities must be cleaned and, if applicable, sterilized before being used.
- Animals (previously authorized) that may be introduced will follow the established quarantine period.

V. RULES OF BEHAVIOUR

i. Behaviour in the facility

General rules of behaviour are aimed at guaranteeing the safety of people

- It is mandatory to use gowns and gloves in labs, and depending on the units, may be necessary to use hat, and mask.

- Do not touch any unsterile object with gloves to avoid contamination, if it occurs gloves should be changed.
- Do not run or make sudden movements or violent in the facilities.
- Regarding any problem with the equipment, decisions of the personnel that accompany the person must respect.
- If the facilities remain in the dark by a power failure, it is compulsory to go out of the place in the company of the personnel.
- In case of doubt, consult the Scientific Responsible.
- It is strictly forbidden to take pictures inside the facility without the authorisation of the management.
- It is forbidden access to places where other projects are developing.
- It is denied access to other computer terminals than those assigned.
- There could be chemicals and gases in the facilities that are particularly flammable. In case of fire or activation of any alarm or in any emergency situation, users must leave the facilities as fast as possible warning then the person responsible of maintenance.