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Norwegian Molecular Imaging Infrastructure (NORMOLIM)

Access and Data Management Policy

1 What is NORMOLIM?

NORMOLIM is a national infrastructure platform for molecular imaging and a node in Euro-BioImaging. NORMOLIM is a distributed node with three sites located in Oslo, Bergen and Trondheim that offer advanced and innovative biomedical imaging technologies for academic and industrial research purposes. NORMOLIM is specifically focused on *in vivo* imaging methods for animal model systems (experimental models of disease and transgenic mice/rats).

Updated information about the infrastructure, instruments/equipment and offered services can be found on the NORMOLIM website: http://normolim.no

2 Who can access?

NORMOLIM aims to provide access to a wide scientific community. Medical and biomedical research projects that have needs for molecular imaging to fulfill their project aims are welcome to apply for access. Applicants must be affiliated with a Norwegian academic or public institution or a Norwegian company. Access will also be provided to international scientist through Euro-BioImaging.

3 Access procedure

NORMOLIM strongly encourages potential applicants to contact one of the three NORMOLIM sites directly to discuss the feasibility and utility for the applicant's project to use the NORMOLIM infrastructure before the submission of an application for access. Contact information is found on the web site (http://normolim.no).

International projects must submit their application through the Euro-BioImaging web page (http://www.eurobioimaging.eu). The application will undergo a scientific review before a technical feasibility review will be performed by NORMOLIM. Further information on the access process via Euro-BioImaging can be found on the Euro-BioImaging web site.

NORMOLIM wants to encourage recruitment of new users through a policy of low threshold for first contact. The potential user is encouraged to fill out the short access enquiry form on the NORMOLIM web site (http://normolim.no). And after a first contact and discussion the user will be encouraged to submit a more comprehensive application.

The application must contain a project description that clearly describes the scientific content of the project (See box on the right for content)

Content of project description

- Background and status of knowledge in the field
- Clear research questions and hypothesis
- Expected results and potential impact
- Methods and experimental design
- Description of animal models, purchase and transfer of animals
- Planned use of the NORMOLIM infrastructure and its importance and added value to the project
- Plan for data analysis
- Progress plan
- Partners and collaborators
- Needed and available resources
- Budget and funding sources

After submission of the application, the NORMOLIM executive committee will evaluate the application according to the evaluation criteria (See table below).

Evaluation criteria for NORMOLIM project proposals	
A	1. The proposal must be a biomedical or medical research project.
B	1. The project must be of good scientific quality (clear hypothesis/research questions, proper experimental design) 2. The project description must describe the scientific content clearly 3. The part of the project to be performed at NORMOLIM must be scientifically realistic/feasible 4. The use of NORMOLIM must give added scientific value to the project compared to use of other technologies or use of similar technologies that are available locally to the applicant. 5. NORMOLIM must have the necessary equipment and competence to perform the proposed project. 6. NORMOLIM must have the necessary capacity to perform the project
C	1. The applicant must document the necessary financial resources 2. The proposed purchase or transfer of animals must be feasible 3. The proposed use of animals must be in accordance with Norwegian and EU laws and regulations

When an application for access has been evaluated to fulfil the criteria, access will be granted.

If the evaluation shows that the project does not fulfil the criteria, the applicant will be notified about the decision and the reason(s) for rejection. Some applicants may be encouraged to resubmit a revised application if NORMOLIM considers that changes or improvements to the project will make it fulfil the criteria. In such cases NORMOLIM will give advice on improvements to the project's planned use of the infrastructure.

A contract must be signed by the User and NORMOLIM before use of the infrastructure can commence. The contract will detail use of instruments and services, training, use of laboratory animals, ownership and rights of use to the research results/data, data management plan, the estimated costs of the project and the financial terms. The contract will also contain the terms of use; the user's responsibility to comply with local laws, rules and regulations; responsibilities related to accidents; and agreements on co-authorship and acknowledgement. The generated knowledge (including Intellectual Property Rights - IPR), and data storage and access will also be regulated through the contractual agreement between the NORMOLIM site and the user's institution.

4 User support related to access

After access has been granted, NORMOLIM will as quickly as possible decide on which one of the sites is most suitable to carry out the project, and the technical and scientific personnel at the chosen site will contact the applicant for detailed project planning and preparations prior to the physical access for the user. As a minimum, this will include a dialogue about the best choice of technologies and methods, plan for animal transfer/purchase, calculation of the estimated total price the user must pay for the project, booking of time slots on the instruments for the entire project and an agreement on time and scope for user training adapted to each user and project.

NORMOLIM will also aid in all necessary applications for use of animals and NORMOLIM staff will monitor and aid during all use of animals to ensure compliance with Norwegian laws and regulations.

NORMOLIM will contribute with their competence in planning of studies, development of protocols, procedures, experimental design, choice and optimization of image acquisition and analysis.

Users will receive training and instructions for the use of lab and the instruments they will be able to run themselves. For instruments that can only be run by the NORMOLIM staff, the staff will perform the image acquisition according to a project plan in collaboration with the user. Hourly fees for the use of NORMOLIM staff will apply.

5 Access restrictions and capacity

There are no specific access restrictions that apply to any of the instruments. However, some instruments can only be run by the NOMROLIM staff. There may also be restrictions on what animals and animal models that can be used and moved to the different sites. Each instrument has a specified capacity (hours per year). A maximum of 50% of instrument capacity will be allocated to users through Euro-BioImaging. When instruments have limited capacity, projects will be prioritized based on their need of a specific imaging technology and its added value to the project, and the overall quality of the project. Maximum 20% of an instrument's capacity can be used for economic activity according to the state aid rules.

6 Costs and fees for use of the infrastructure

The user fees for use of instruments and related services are calculated as hourly rates based on the full cost to commission, keep and maintain the instruments (service contracts, lab space rental, electricity, lab consumables, engineering staff etc.) and the its capacity. All calculations of costs are in accordance with laws and regulations for pricing of infrastructure and research infrastructure resources in the university and university college sector in Norway (TDI-model).

Additional costs for purchase of consumables, animals, animal housing etc that are specific for the project must be covered by the User.

Fees for use of the different instruments can be found on the web pages of the respective sites. For a full cost estimate for a given project, contact NORMOLIM.

7 Terms and conditions for use

7.1 Use of the instruments

Only properly trained users will be allowed to use equipment/instruments and other infrastructure. All use of infrastructure must be booked in advance. All users must pay for the use of the infrastructure and services according to the prevailing prices.

7.2 Health, safety, security and environment

All use of the NORMOLIM infrastructure must comply with all local health, safety and environmental regulations. This includes a risk assessment of the planned experiments before the start of the project. All new users must undergo lab training, including instructions in safe lab conduct, relevant protocols, and correct handling and reporting of incidents and discrepancies.

The User can be held responsible for damage or injury to property, instruments and personnel that is the consequence of deliberate action or gross negligence.

NORMOLIM or the host institutions cannot be held responsible for any loss or damage/injury to property or personnel, unless the damage or loss is due to deliberate action or gross negligence.

7.3 Use of animals

All work with laboratory animals that is performed at NORMOLIM is subject to Norwegian law and must be conducted in accordance with the Animal welfare act (LOV-2009-06-19-97), the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS 123) and the Norwegian Regulation on Animal Experimentation (FOR-2015-06-18-761), and be approved by the Norwegian authority on animal welfare (Forsøksdyrutvalget). Work involving genetically modified microorganisms (including bacteria, virus and viral vectors) and animals must be conducted in accordance with the Norwegian Regulation on Enclosed Use of Genetically Modified Microorganisms (FOR-2001-12-21-1600) and Regulation on Genetically Modified Animals (FOR-2001-12-21-1602), and must be reported to the Norwegian Directorate of Health.

8 Data management policy

8.1 Data management plan

A plan for data management, based on the NORMOLIM data management policy outline below, will be agreed upon for each project between the user and NORMOLIM and be part of the user contract. The Checklist for a Data Management Plan (v4.0) from the Digital Curation Centre (http://www.dcc.ac.uk/resources/data-management-plans/checklist) will be used as a template and aid to tailor the data management plan to each project.

8.2 Ownership to data and project results and IPR

Ownership rights to data, project results and Intellectual Property Rights (IPR) that has been generated through the use of NORMOLIM research infrastructure and related services will either be joint ownership between the NORMOLIM Site and the User, or exclusive User ownership depending on the nature of the project and user. The User contract will include details on the regulation of ownership rights, IPR and any specific agreements on how to exercise these rights.

8.3 Data storage

NORMOLIM will store digital data, results and reports safely on dedicated servers operated by the institutional IT departments. Data will be automatically backed up daily and stored as securely as possible for at least 10 years. NORMOLIM give advice and facilitate solutions for long term data storage (for instance through NORSTORE). Controlled access to use and downloading of the data will be given via a web interface for the user and trusted collaborators. NORMOLIM will not be liable for data that are lost or truncated e.g. due to server crash or lost network connection.

8.4 Data formats and metadata

All imaging data will be stored in their original native format along with the metadata files produced by the imaging instrument. In addition, image data will be converted and stored in one or more standard image formats (i.e. Dicom, Nifti, JPEG) along with necessary metadata to facilitate the postprocessing and analysis of images from multiple imaging modalities. NORMOLIM will provide tools for conversion between image formats as well as standards for storage of metadata both from the image acquisition and from experimental conditions. Metadata from the experimental conditions will include for example animal strain, genotype, age, experimental procedures, treatment conditions and groups.

8.5 Access to and re-use of data

NORMOLIM will abide to the FAIR guiding principles (Findability, Accessibility, Interoperability, and Reusability). Presently there are no available national or international platforms for storage and

re-use access for the type of imaging data NORMOLIM will produce. However, Euro-BioImaging has the goal of establishing such a platform and repository in collaboration with EMBL-EBI (https://www.ebi.ac.uk/). NORMOLIM plans to use this platform as soon as it is established.

In the meantime, NORMOLIM will encourage that the image data generated through use of NORMOLIM infrastructure should be made publically available, facilitate sharing of data through digital archiving solutions, and encourage Data owner(s) to enable re-use of the data.

Due to the nature of animal experiments where the results and data can only be trusted and interpreted with in-depth knowledge about the animal handling, experimental procedures and conditions, NORMOLIM considers it vital that re-use of openly accessible image data involves the researcher(s) that performed the experiments and generated the data, and/or the NORMOLIM site that was involved in the data generation. Any open access publication of image data will therefore include mechanisms to accommodate this.

8.6 Publication of data and results

The general rule shall be that scientific results from a project using NORMOLIM infrastructure shall be published as one or more full scientific articles in scientific journals with referee. Scientific results may also be presented by project team members from the user and/or NORMOLIM at professional meetings and conferences, in non-academic articles and the like.

All external dissemination of data and results must indicate the role of both NORMOLIM and the User in the research project. NORMOLIM and other research facilities that have provided services to the project must be acknowledged in publications.

If highly qualified technical personnel or scientific personnel from NORMOLIM have contributed with their scientific knowledge to solve the scientific questions, they should be co-authors according to the “ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals concerning Authorship and Contributor ship” (Vancouver rules, see: www.icmje.org/ethical_1author.html).

Rules for postponement of publications in cases where IPR protection in the form of patenting processes is relevant will be regulated by the User contract.