SymbNET

Research Grant:

the use of new methods in Metabolomics and Genomics

"This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 952537".

Content

1. About the Grant

1.1. This Grant aims to promote the **use of new technologies and approaches in Metabolomics, Genomics and Proteomics,** and the **interaction of FCG-IGC and ITQB-NOVA researchers with the SymbNET partner Institutions (CAU, UNIL, EMBL).** The purpose is for the researchers to use and identify techniques to be imported to FCG-IGC and ITQB NOVA facilities or to be used in the long-term as an external service in partner institutions or collaborations.

1.2. The Grant will cover **50% of services expenses or consumables in partner research groups**. The other 50% of the service costs must be covered from the research funds of the applicant.

1.3. Grants, up to **4,000 euros** each, will be funded in each call.

2. Eligibility rules and other provisions

2.1. Eligible researchers must be affiliated with FCG-IGC or ITQB-NOVA.

2.2. The project must include the use of services in research facilities or specialized techniques of research groups of the SymbNET partner institutions (CAU, UNIL, EMBL).

2.3. The project must be on Genomics, Metabolomics or Proteomics in host-microbe symbiosis.

2.4. The specific technique or service must not be available at the FCG-IGC or ITQB-NOVA.

2.5. The funds provided must be used on services or research expenses directly related to the specific technique being proposed (e.g. consumables and internal services). Any other costs (i.e.: indirect costs) are not eligible.

2. 6. SymbNET must be acknowledged in publications and communications that may arise from the research funded by this Grant by including the following text: “This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 952537 (SymbNET Genomics and Metabolomics in a Host-Microbe Symbiosis Network)”, together with the EU emblem.

2.7. Publications and research data that arise from work funded by this Grant must follow EU open access policy. For detailed information, see Annex 1.

2.8. Projects must comply with the relevant ethical and legal provisions in the laboratories where they are developed. For detailed information, see Annex 2.

2.9. The awardees should use all funds within 12 months, counting from the moment the result is communicated to the winner.

2.10. The awardees must provide an activity report, including a data management plan and expenses description, up to one month after completing the project.

2.11. One applicant may submit more than one proposal.

3. Procedure and Selection

3.1. Submission of proposals will be open: Sep-Nov 2021, Mar-April 2022, and Aug-Sep 2022.

3.2. The applicants must provide the following items:

a) **Name** and **Affiliation**;

b) **Project title** and the **state of the art** of their field of interest and the question(s) they want to address in their proposal (maximum of 3,000 characters, including spaces);

c) **Summary of the experiments** they want to perform and how the use of the new technique(s) will promote the development of their research project or lab research plans (maximum of 3,000 characters, including spaces);

d) A **quote** of the Research Facility or a detailed budget of expenses. This should be the full cost of the proposed experiments, of which SymbNET covers 50%, up to 4,000 Euros;

e) A **statement** (1 paragraph) from the **Head of the relevant Facility at FCG-IGC or ITQB-NOVA** about the novelty of the technique and local unavailability;

f) A **statement** from the **applicant*** confirming compliance with Ethics regulations. This letters should state the following:

" I [*applicant's name*] confirm that the research to be developed at [*Name of Institute*] within the scope of the SymbNET Research Grant complies with all national and European ethical and safety rules. The Laboratory / Facility where the project will be developed follows all national and European ethical and safety rules, and all licenses required for experimentation have been acquired. [*date*] and [*signature*]"

* If the applicant is not a Group Leader, the statement has to be filled and signed by the Group Leader.

g) A **letter** from the collaborative **Group Leader / Head of Facility** confirming their support, and the following statement:

" I [*name of Group Leader / Head of Facility*] confirm that the research to be developed at [Name of Institute] within the scope of the SymbNET Research Grant complies with all national and European ethical and safety rules. The Laboratory / Facility where the project will be developed follows all national and European ethical and safety rules, and all licenses required for experimentation have been acquired. [*date*] and [*signature*]".

The Ethics and Safety statements must be filled even if the project does not raise ethical questions or licenses are required.

3.3. Eligibility requirements will be verified by the task leader (Michael Zimmermann, EMBL) and contributors (Luís Moita and Luís Teixeira, FCG-IGC) with the support from the project manager (Mariana Simões, FCG-IGC).

3.4. Proposals will be evaluated by the SymbNET representatives of CAU, UNIL or EMBL.

3.5. If one of the SymbNET representatives has a conflict of interest in the evaluation of any of the proposals (e.g. is involved in the preparation of the proposal), a replacement will be proposed by the relevant partner institution.

3.6. Selection will be based on:

a) The innovative nature of the proposal;
b) The novelty of the method used and unavailability of similar methods at FCG-IGC or ITQB-NOVA;
c) The relevance of the question(s) being addressed within the scientific areas represented in SymbNET;
d) The scientific strength of the proposal;
e) The feasibility of the proposal;
f) Added value to the applicant's host institution in the development of the technique being used or the long-term use of the technique for the applicant.

Throughout the calls, selection will balance institutions, research groups, and topics covered in the awarded applications.

3.7. The reviewers will meet after performing an individual evaluation and ranking to discuss and select the applications.

3.8. The selected projects will be announced in December 2021 (1st call), May 2022 (2nd call), and October 2022 (3rd call).

This Regulation was updated on the **15th Aug 2022**. The following points have been modified:

1.3) ~~Three~~ Grants, up to 4,000 euros each, will be funded in each call ~~of totally three calls~~;

3.2 b) added "**Project title**";

3.6) Throughout the ~~three~~ calls, selection will balance institutions, research groups, and topics covered in the awarded applications.

3.7. The reviewers will meet after performing an individual evaluation and ranking to discuss and select the ~~three~~ applications.

ANNEX 1

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 Obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the Agency before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms “European Union (EU)” and “Horizon 2020”;
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

Regarding the digital research data generated in the action (‘**data**’), the beneficiaries must:

(a) deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate — free of charge for any user — the following:

(i) the data, including associated metadata, needed to validate the results presented in scientific publications, as soon as possible;

(ii) not applicable;

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the ‘data management plan’ (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

As an exception, the beneficiaries do not have to ensure open access to specific parts of their research data under Point (a)(i) and (iii), if the achievement of the action's main objective (as described in Annex 1) would be jeopardised by making those specific parts of the research data openly accessible. In this case, the data management plan must contain the reasons for not giving access.

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the Agency requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

“This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 952537”.

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the Agency.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding Agency responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ANNEX 2

ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

34.1 Obligation to comply with ethical and research integrity principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity)

and

(b) applicable international, EU and national law.

[23] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[24].

This implies compliance with the following fundamental principles:

- **reliability** in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;

- **honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;

- **respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;

- **accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, each beneficiary must have obtained:

(a) any ethics committee opinion required under national law and

[24] European Code of Conduct for Research Integrity of ALLEA (All European Academies) http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

(b) any notification or authorisation for activities raising ethical issues required under national and/or European law

needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the coordinator to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out, in addition to Article 34.1, only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the Agency (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

5. Ethics and Security

5.1 Ethics

The Twinning project SymbNET is considered a Coordination and Support Action (CSA) for capacity building and networking among partner institutions. SymbNET will involve some research collaborative projects (WP2, WP3 and WP4) between the partners and also some of the network activities may involve the gathering of personal data. In this document, we present an overall review of all ethical issues that may arise, however, since new collaborative research projects between the partner institutions are expected to be established during the project implementation, this document will be revised and updated to consider all possible scenarios.

Confirmation of Compliance with relevant EU and national legislation:

All SymbNET partners will comply with all the relevant ethical and legal provisions (single-out in Section 4 of Part A) from the beginning to the end of the project. Also, we will comply with, ethical principles and applicable International, European and national laws in the implementation of the research activities not originally envisaged. The Consortium confirms that any ethical concerns raised by those activities under SymbNET will be handled rigorously following the recommendations provided in the European Commission Ethics Self-Assesment Guidelines. The Project Manager (to be hired) will oversee all activities implemented under SymbNET, being the Project Coordinator responsible for the overall compliance with all legal and ethical provisions related to SymbNET. Moreover, SymbNET has included a WP7 to address ethical requirements (flagged in the Ethics Evaluation Report in Pre-Grant Requirements) and two deliverables.

Namely, concerning data protection laws and regulations, such as:

- the Directive on Data Protection (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data);
- the Portuguese Act on Data Protection (Law 67/98, 26.10.1998) which transposes the above-mentioned Directive;
- the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR- General Data Protection Regulation);
- the collection and processing of data will be done according to the Portuguese law "Lei n.º 58/2019, de 8 de Agosto" which transposes the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC;
- the principles of the European Convention of Human Rights, the rules of the Convention of the Council of Europe for the protection of individuals with regard to automatic processing of personal data and especially the European Directive 95/46/EC;
- the Universal Declaration of Human Rights and the Convention 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data
- directive 95/46/EC & Directive 2002/58/EC of the European Parliament regarding issues with privacy and protection of personal data and the free movement of such data;
- the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols

As an example of ethics compliance, we give the situation of the coordinating institution (and all partners declare to comply with the ethical provisions that apply at their institutions and countries, according to the research projects that will be implemented in their premises).

The host institution *Fundação Calouste Gulbenkian - Instituto Gulbenkian de Ciência* (FCG-IGC, Portugal) has established procedures to address ethical issues that might arise during the implementation of its research proposals, in compliance with European and Portuguese legislation. The IGC has an **Ethics Committee** (http://bit.ly/IGCEC2018) that oversees and maintains a standard of quality and integrity inherent to research projects, assuring the ethical conduct of scientific research related to Vertebrate Animals or Human Beings. The FCG-IGC also has an independent **Animal Welfare Committee** (*Órgão Responsável pelo Bem-Estar Animal* -

ORBEA), which specifically focuses on animal welfare and thoroughly evaluates all standard operating procedures before being applied on vertebrate animals. SymbNET collaborative projects implemented at the FCG-IGC will be submitted to the **Ethics Committee** and the **Animal Welfare Committee** (if applicable) before starting. Also, the **Biosafety Unit** is responsible not only for establishing "Good Laboratory Practices" but also to ensure that all activities comply both with the Portuguese and European health & safety legislation.

We confirm that all researchers will adhere to accepted procedures for ethical behaviour in scientific conduct. The FCG-IGC has established procedures for safety including the handling of chemicals and biological materials. The researchers at FCG-IGC are dedicated to excellence and high ethical standards in design, conduct, reporting, and exploitation of research results. All procedures and protocols are subject to risk assessments and all researchers performing high-risk work are trained accordingly. Therefore, only certified staff members will be allowed to participate in SymbNET research projects (when applicable).

In addition, all required institutional licenses and authorizations have already been obtained and will be kept on file at the coordinator premises.

Therefore, possible ethics requirements are envisioned in:
- the use of animal vertebrate models, namely wild-type and genetically modified mice (*Mus musculus*) of risk level 1;
- the collection and processing of personal data the collection and handling of personal data from the ESRs, staff members, other researchers and possibly from people engaged in outreach activities (trainings, staff exchanges and related activities).

<u>How ethical issues flagged will be addressed, in particular with regard to the objectives, methodology and impact of the research</u>

SymbNET hereby details the ethics governance procedures to be applied if any of these ethical requirements are verified for the objectives of the network to be accomplished. The SymbNET coordinator (Luís Teixeira) the Project Manager (to be hired), as well as all partners institutions will ensure compliance with the above legislation.

Justification for the use of vertebrate animals
The scientific activities highlighted in WP2, WP3, WP3, involve collaborations between FCG-IGC researchers and other SymbNET partners and are expected to involve the use of vertebrate animal models, namely mice (*Mus musculus*).

The IGC Animal Facility and experimental procedures have been approved by the Institutional Ethics Committee. The number of mice used per experiment is minimized and equal number of males and females will be used, such that the results are not biased by sex. Any suffering or other harmful effects experienced by the animals (i.e. gavage and antibiotic treatment) are reduced. During the experiments, mice will be monitored and any individual showing signs of untoward suffering or weight loss exceeding 20% will be euthanized (CO2 narcosis).

Research projects conducted at the host institution (FCG-IGC) using vertebrate animals are evaluated by both the institutional Ethics Committee and ORBEA, and subsequently submitted to the Portuguese National Authority for Animal Health (*Direcção Geral de Veterinária* - DGAV) for welfare licensing. This procedure ensures that, in accordance with the 3Rs rules (Replacement, Reduction and Refinement) guiding principles underpinning the humane use of animals in research, alternatives to animals are used whenever possible, the number of animals used per experiment is minimized and that any pain, stress or suffering caused to the mice as a result of experimentation will be kept to a minimum and have been weighed against the potential benefits of the research. All mice are bred and/or maintained in accordance with the European and institutional guidelines and FCG-IGC members working with vertebrate animals hold the necessary licenses from DGAV to carry out the work in compliance with the fundamental European and Portuguese ethical principles. The FCG-IGC Animal Facility is licensed by DGAV, comply with the Portuguese law, and follow the FELASA (Federation of European Laboratory Animal Science Associations; in attachment).

Isabel Gordo, Luis Moita, Miguel Soares, and Karina Xavier, have a long-standing and extensive experience in biomedical experimentation involving the production and analysis of genetically modified mice and hold all the necessary Accreditation, i.e. licenses and authorization from the Portuguese Official Veterinary Department (DGAV) to carry out the work in respect with the fundamental European ethical principles (will be provided to the EC). Team

members that will be working with animals also hold the necessary licenses from DGAV to carry out the work in compliance with European and Portuguese ethical principles.

Justification for the use of genetically modified organisms and microorganisms:
The genetically modified organisms (GMOs) to be used are mice (*Mus musculus*), *Drosophila melanogaster and E. coli*. The use of genetically modified mice and *D. melanogaster* are required for testing the function of genes in hosts in the interaction with microbes. The use of genetically modified bacteria is required for testing the function of bacterial genes in the interaction with the host. The bacteria to be studied will include non-pathogenic *E. coli* level 1, but also members of the microbiota which also include level 2 bacteria. Of these models only, mice are vertebrates.

The work with genetically modified organisms, in Portugal, is regulated by "Decreto-lei 55/2015, de 17 de Abril", transposing to the Portuguese legislation the Directive 2009/41/CE of the European Parliament and of the Council. The *Instituto Gulbenkian de Ciência* (coordinating Institute) complies with the mandatory good laboratory practices determined by the legislation and is authorised by the competent national agency, *Agência Portuguesa do Ambiente* (APA, I.P.) to work with genetically modified organisms (GMO) and microorganisms (GMM) of risk level 1 and 2 (license attached).

Ethics compliance in the rest of the beneficiaries
The research projects to be implemented during SymbNET will depend on the annual Competitive Prizes awarded to the PhD students (WP4). This means that *a priori* we cannot predict what will be the animals that will be used in all the research projects under SymbNET. To address the ethical requirements (flagged in the Ethics Evaluation Report in Pre-Grant Requirements) authorisations for animal experiments from all beneficiaries, also covering GMOs, have been obtained and are kept on a folder at FCG-IGC (coordinating institution). However, before the implementation of any research project under SymbNET, these authorizations will be reviewed and if required updated, in the folder by the project manager. This verification procedure also applies to training certificates and personal licenses of the staff involved in animal experiments which are also kept in a folder at the coordinating institute. This authorizations and certificates will be submitted to the EC upon request.

Personal data collection and/or processing
Data storage, processing and handling will be done following the European standards and in line with internal data privacy policies. Datasets will be stored in encrypted and password-locked files with appropriate ciber-security protection measures. Such dataset will be from voluntary self-report of ESRs/partners staff (WP1, WP2, WP3, WP4, WP6) to participate in the trainings and from general public for being involved in outreach activities (link to WP6). Dataset are expected to include 'special categories' of personal data like gender, location and employer and often contact, but given their public and volunteer nature, does not raise particular concerns. Whenever personal data is collected, the DPO contact details will be made available to all data subjects involved in SymbNET.

The collection and processing of data will be done according to "Lei n.º 58/2019, de 8 de Agosto" which transposes the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The data will not be openly neither publicly accessible. We will use protective measures to avoid unforeseen, usage or disclosure. The data will not involve sensitive personal data (for example: sexual lifestyle, ethnicity, political opinion, religious, philosophical conviction …).

Personal data collected will be treated in conformity to the:

- Charter of Fundamental Rights and the Treaty on the Functioning of the European Union as well the European Convention on Human Rights, specifically the article concerning the right to data protection and protection of personal data;
- the opinions of the European Group on Ethics in Science and New Technologies in their report "Citizens Rights and New Technologies: A European Challenge" on the Charter on Fundamental Rights related to technological innovation;
- the EU's ePrivacy Directive concerning the processing of personal data and the protection of privacy in the electronic communications sector;
- in particular, recommendations related to ICT concerning data protection and individual's freedom and autonomy

To sum up, the project data management plan will contain indications on how data will be collected, handled and storage (research data and personal data).

Activities that are not planned in the project

We confirm that the research presented in this proposal does not involve other specific ethical issues related to intervention on human beings, research on human cells/tissues or human embryos/fetus, and the use of non-human primates, cloned farm animals or endangered species.

Also, the work to be developed does not require samples previously collected (e.g., clinical studies conducted in previous projects). No clinical trials are expected to be conducted with the scope of SymbNET. The project does not envision the involvement of children or the processing of sensitive data.

Our activities will not involve third countries, dual use, civil applications, elements that may cause harm to the environment and/or health and safety, and it is not anticipated that any research could be misused with criminal intentions.

5.2 Security

The SymbNET project will not involve any activities or results raising security issues.
No EU-classified information will be used, neither as background, nor as results.