
GILEAD
Fellowship PROGRAM

INTRODUCTION

In view of the need to **acquire, report and apply scientific knowledge** to health care activities for the purpose of achieving progress and improving patients' lives, **GILEAD SCIENCES, S.L.U., (GILEAD) has actively implemented a policy to promote and support** key research projects and educational/scientific programs in therapeutic areas of interest (such as HIV/AIDS, serious respiratory or cardiovascular diseases, cancer and hemato-oncology diseases, chronic hepatitis B and C, fungal diseases and cystic fibrosis), as it considers that there are unmet needs in these health care areas.

Accordingly, the GILEAD Fellowship Program has announced the ***"Fifth Call for Research Projects on HIV, Hepatitis and Hemato-oncology"***, in order to foster the development of health care research in these areas within Spain.

The call is intended to promote **new research projects** that will benefit patients, society, and the scientific community through the award of funds to be used for the projects.

This financial grant initiative for research activities, which is sponsored by GILEAD, is in keeping with public policies to foster and promote scientific and technical research, particularly in the above biomedical areas, as well as to encourage collaboration and cooperation among the various players in the health sciences (private institutions, public research agencies, and National Health Service facilities), in order to **identify synergies among research groups that will allow the results to be used in improving public health**.

This call is also consistent with other investment efforts related to applied R&D in the health sciences promoted by the Spanish Ministry of Health, Social Policy and Equality.

Consequently, GILEAD intends to contribute, through this initiative, to the promotion and development of public and private cooperative instruments in health care research in the HIV, Hepatitis and Hemato-oncology areas.

Therefore, an agreement has been signed with the Instituto de Salud Carlos III management regarding their participation in the process to evaluate research projects submitted as part of this call, as well as regarding the support of the Ministry of Health, Social Policy and Equality.

General Terms and Conditions

One. Purpose

These terms and conditions are intended to establish the rules, requirements and specifications for GILEAD grants awarded as part of the ***"Fifth Call for Research Projects on HIV, Hepatitis and Hemato-oncology".***

These funds will be awarded through a competitive procedure that reviews all applications submitted, under terms that guarantee the principles of publicity, transparency, objectivity, equality and nondiscrimination in the grant procedure.

In this competitive procedure, the financial grants are awarded after comparing the applications submitted to establish the priorities thereof, in accordance with the objective review criteria defined in section 2.2 of the Grant Award and Notification document, in which the funds are awarded to the applications with the highest scores **(upper limit of 50,000 euros per project)** until all available financial resources are assigned under the terms described in Condition Four of this call.

The grant awards will be formalized by signing a Cooperative Agreement between GILEAD and the grant recipient under the terms set forth in the applicable legislation.

Two. Grant Recipient Requirements

1. The grants awarded hereunder are available to proposals regarding research projects to be conducted in Spanish health care centers and that originate at the nonprofit institutions and sponsored grant recipients listed in Articles 2 and 16 of Law 49/2002, of December 23, covered by the tax system for nonprofit organizations and the tax incentives for sponsor organizations, provided that the requirements of the provisions of Article 3 of this law are met. In particular, and taking into account the provisions stated in the aforementioned regulation as well as the scope of this grant program, the following institutions are included:

- Foundations.
- Associations declared of public usefulness
- Federations and associations of non-profit entities referenced in the paragraph above
- Public universities
- Public research agencies under the auspices of the central government

2. Likewise, the grants can be awarded to health research institutions and to public research consortiums under the auspices of public research agencies in the field of health

sciences. In such situations, the legislative or regulatory requirements that are applicable to such institutions shall be taken into account.

3. The grants may not be awarded to natural persons, but only to the institutions described above, which must submit the documentation listed in the grant procedure described in the Grant Award and Notification section hereof.

4. This Fourth Call excludes any projects submitted by the principal investigator or any of his/her co-investigators that may have obtained a project grant in the previous edition.

Third. Requirements for Research Project Proposals

a) Research lines allowed

Proposals submitted hereunder may only relate to research projects with an execution period not above 24 months. This period shall be counted from the date on which the business cooperative agreement for activities of general interest alluded to in the Grant Award and Notification section of this website are signed.

The projects must fall within one of the research lines defined below:

HIV:

- Research aiming the HIV **treatment cascade** in Spain: Early HIV diagnosis and treatment, role of treatment as prevention in the control of new infections, screening strategies, and early diagnosis in Primary Care and reduction of late diagnosis.

- Research on the characterization and clinical management of **aging** in the HIV-infected population. Research on the specific management of **comorbidities** in the HIV patient, including, but not limited to, characterization, prevention and treatment of cardiovascular disease, renal disease, neurocognitive degeneration, and bone disease, and their causal relationship with inflammation.

- Research on **inflammation** in HIV infection.

- Research on the **integrated care** of the HIV patient and **special populations**: children, adolescents, women, older patients with HIV/AIDS (>50 years).

Hepatitis:

- **Epidemiological studies** of chronic hepatitis C, and characterization of high-risk populations (PWID, MSM, and prisons) and of extra-hepatic manifestations of chronic hepatitis C virus infection.

- **Screening and linkage to care** projects to foster chronic hepatitis C diagnosis and **referral** in Primary Care and Addiction Centers.

- Impact of **early treatment** on disease burden.

- Use of new **decentralized medical care models in high-risk population, and digitalized systems** for diagnosis, referral, and treatment of hepatitis C patients.

Hemato-oncology:

Projects studying the following aspects of Chronic Lymphocytic Leukemia or Follicular Lymphoma:

- Clinical projects aimed at **improving the diagnosis** of Chronic Lymphocytic Leukemia. Assesment of diagnostic techniques for determining genetic prognostic markers of high risk. Assesment population of surrogate survival markers, including imaging techniques or laboratory tests.

- Studies assesing **rapidly progressing disease subgroups** or **mechanisms of disease transformation** to high-grade malignancy (Richter's syndrome).

- Improvement of treatment **adherence**.

- Studies aimed at determining the **optimal moment to start treatment.**

- Projects related with **comorbidities and aging** in this patient population. Geriatric assessment studies in patients with chronic lymphoproliferative diseases.

- **Preclinical basic translational studies** on intracellular signalling of the B cell receptor, including the significance of different PI3K subunits, how they interrelate with the TP53 pathway, the role of Syk and Btk and regulation of expression in physiological conditions or different types of lymphoproliferative disease. Role of epigenetic mechanisms in Chronic Lymphocytic Leukemia or Follicular Lymphoma.

b) Participation modalities

The research project proposals may be submitted in one of the following modalities:

a) **Single-center study**: project submitted by a single applicant, in accordance with the provisions in Term 2 hereunder, and that will be conducted at a single health care center. Such projects may be subcontracted, although the grant recipient must ensure that it is subcontracted in accordance with all applicable legislation and regulations.

b) **Multicenter study**: project requested by a single applicant, in accordance with the provisions in Term 2 hereunder, and that will be conducted at various health care centers. The coordinator center must report the participating centers in the application.

c) Excluded scopes

Proposals for research projects involved in directly **studying drugs from GILEAD or other pharmaceutical companies** will be excluded.

Proposals for clinical interventional research projects with one of the following objects will be excluded from this call:

- **Embryonic stem cells from humans or cell lines derived from them**, as well as research projects that involve the use of cells and tissues of human origin in the field of regenerative medicine

- Projects that involve the **use of biological agents**

- Projects that involve the use of **genetically modified organisms**

d) Ethical-legal aspects of research projects

Research projects applying for the grant must adhere to the fundamental principles established in the Declaration of Helsinki, the Convention on Human Rights and Biomedicine of the Council of Europe, and the Universal Declaration on the Human Genome and Human Rights, and must comply with the requirements established in the Spanish legislation on medical research, personal data protection and bioethics, in accordance with Law 14/2007, of July 3, on biomedical research and other requirements established in the Spanish legislation on these matters.

All projects must comply with the legal and regulatory provisions in effect and any provisions that modify or develop them, in particular:

a) Projects that involve human research or the use of biological samples of human origin must comply with the provisions of Law 14/2007, of July 3, on biomedical research and all other current legislation on the matter.

b) Projects that involve clinical trials must comply with the provisions of Royal Decree 1090/2015, of December 4.

c) Post-authorization observational studies on medicines for human use in accordance with the provisions of Order SAS/3470/2009, of December 16.

Four. Grant funding

The "***Fifth Call for Research Projects on HIV, Hepatitis and Hemato-oncology***" sponsored by GILEAD **consists of 900,000 euros to be used to fund research projects that meet the requirements and conditions described in these Terms and Conditions.**

The grant awarded hereunder shall consist of **financial contributions** with a variable amount not above 50,000 euros per project and which includes the costs of administrative management.

The award of this grant must be compatible with any other subsidies, grants, income or resources of a public or private nature used to fund the research project submitted hereunder, provided that the amount already received, whether itself, or in addition to the amount of grant proposed hereunder, does not exceed the total cost of the research activity under consideration. Precisely for this reason, the grant award will take into account the existence of other funding sources available to the applicant's research team, by virtue of the information provided on the Application Form.

In the project review and review process, the Instituto de Salud Carlos III Review Board shall be entitled to adjust the budget itemization listed in such projects to the standards defined in calls by such institution.

If sufficient funds are freed up due to waiver by one or more of the beneficiaries following a grant award, GILEAD may propose that the grant be awarded to another grant recipient based on the score order obtained in the final reports prepared by the Technical Review Boards, which must accept them under the same terms indicated herein.

Five. Items eligible for grant

Grants awarded hereunder must cover costs directly related to the execution of the activities of the research project submitted by the potential grant recipient, with the scope and limits set forth herein.

However, only activities considered consistent with the specific objective or purpose of the nonprofit organization applying for the grant will be considered eligible for funding.

In particular, the following project execution costs are considered eligible for grants:

a) Costs for instrumentation and depreciation of newly acquired scientific-technical equipment, to the extent and during the period in which it is used for the research project

b) Costs for consumables and supplies necessary for project execution

c) Costs for contract research

d) Travel and per diem for research team members, duly proven, including investigator visits and stays directly related to the project, etc.

e) General additional costs directly derived from the project or activity

f) Staff costs directly and exclusively related to performance of the subsidized research project (maximum of one year).

Under no circumstances may the amount of the grant received hereunder be used to directly fund research team staff in their health care activities and, therefore, the entities, institutions or agencies to which such staff reports professionally are responsible for payment of their compensation. Research team staff may be compensated with funds obtained hereunder in accordance with the time devoted exclusively to the project.

Likewise, costs to acquire scientific-technical equipment are also not considered eligible for funding.

GRANT AWARD AND NOTIFICATION

1. Application submission

All grant applications must be submitted online at www.fellowshipGilead.es.

In this fifth edition of the Call for Research Projects on HIV, Hepatitis and Hemato-oncology **all information must be submitted in English** and, therefore, no projects submitted in any other language will be reviewed.

Each **principal investigator may submit only one research project proposal**. Each grant applicant may submit a maximum of two projects per therapeutic area (HIV, Hepatitis and Hemato-oncology), such that only one project at most may be awarded per therapeutic area (HIV, Hepatitis and Hemato-oncology) per grant applicant site.

The decision on the projects to be submitted to the call shall lie with the management bodies of the grant recipient.

The information required for an application to be evaluated will be as follows:

- Research project report in accordance with the template provided
- Standard curriculum vitae for investigator, demonstrating his/her capacity to execute the project submitted
- Authorization from the director of the health care site where the project will be conducted, in accordance with the template.
- Articles of association of the grant applicant
- Power of attorney for the signer from the institution
- Registration of the institution in the respective registry
- Certificate of the Declaration of Public Utility in the case of associations

All applications and respective appendices must be submitted by the interested parties online within the deadline listed at www.fellowshipGilead.es..

Any application submitted after the deadline will be excluded from this procedure, and the grant applicant will be notified of such fact by certified means. If the applications are incomplete when submitted, such situation will be reported to the grant applicant and a

deadline of ten calendar days will be given to correct the application under the risk of being excluded from this call.

2. Review Procedure and Criteria and Competent Bodies for Review Proposal Review

2.1 Procedure

Projects received will be reviewed by the Instituto de Salud Carlos III, which will act independently and in accordance with the principles of transparency, objectivity and equality of treatment, in accordance with the following procedure.

For this fourth call for the Fellowship, the Instituto de Salud Carlos III has brought the review process to the international level, as in the previous edition, and will include international reviewers.

The research project proposals will undergo a two-phase review process.

The **first phase will consist of a scientific-technical review** of each project that will be carried out individually by at least two international experts.

These experts will be selected by the Instituto de Salud Carlos III and will confidentially and independently issue a review report on each proposal. Once the individual reports are analyzed, a scientific-technical synthesis report will be prepared by independent experts.

The **second phase will consist of a panel review process** for all proposals by a Technical Review Board.

The Technical Review Board appointed by the ISCIII **will prepare a final report** for each proposal describing the most relevant aspects of the reviews carried out in the first phase and issue, in a consensus manner, a list of the proposals in order according to the score obtained using the review criteria set forth in the terms and conditions for the call.

2.2 Scientific-technical review criteria for the proposals:

a) Research team review:

The following will be reviewed for both the principal investigator and the rest of the team: academic record; professional merits (publications, research project funding, experience, mobility, national and international collaborations, health care activity), and candidate suitability for the tasks to be performed.

b) Project assessment:

The project will be assessed with regard to the following: quality, viability, relevance, interest, applicability and transfer; project capacity to improve disease prevention, diagnosis and treatment; impact; technology and outcome dissemination and transfer plan.

The review process is expected to be carried out by three Technical Review Boards composed of national and international experts: one Technical Review Board will evaluate HIV projects, another will review Hepatitis projects, and a third will evaluate Hemato-oncology projects.

These boards will be composed of a chair and a number of experts that will vary according to the number of proposals. The chair of each board will assign each proposal to **two reviewers for scientific-technical review from among experts unrelated to the board** and will likewise appoint, from among the board members, those responsible for preparing the synthesis reports.

All synthesis reports will be prepared by board members, and each board member will be assigned a similar number of proposals.

A board will be created to manage the review of proposals affected by **conflicts of interest** as a means to ensure the neutrality, transparency and objectivity of the process ("Technical Conflict of Interest Board").

Proposals will be understood to have a conflict of interest and, therefore, will be managed by this board whenever a board member has a direct or indirect relationship or interest, whether personal (by virtue of a family bond), economic, scientific, educational-training, in particular the following:

- When the proposal is sponsored by a grant applicant in which the reviewer is involved, whether as a result of a professional dependent relationship, or by virtue of any other form of direct or indirect assistance.
- When the proposed award could have some kind of financial impact for the reviewer.
- When the proposal could interfere with the scientific interests of the reviewer in question.

In general, explicit or potential conflicts of interest will be identified by the chairs of the two Technical Review Boards prior to the reviewer assignment process.

In any case, for the purpose of safeguarding neutrality and independence in the review process, the Instituto de Salud Carlos III will ensure that experts participating in the proposal review process sign the "Ethical Review Commitment" requiring that they abstain from reviewing proposals in which there is a conflict of interest. Hereunder they also agree to

maintain absolute confidentiality of all information to which they have access and the entire review process.

3. Proposed award

Once the proposals have been reviewed by the panel, the result of the review and the prioritized lists of project proposals will be sent to the Selection Board, licensed body, composed of the following:

- Subdirector General for the Review and Promotion of Research or the person who substitutes him/her.
- An official from the Subdirectorate General for the Review and Promotion of Research who will act as secretary.
- Chairs of the Technical Review Boards.

The decisions made by the Technical Review Boards cannot be appealed.

The Selection Board will confirm that the review process has been properly executed and, in view of the prioritized list of research project proposals and the budget allocated in the conditions, will prepare a report listing all proposals considered eligible, in particular, listing the fundable budget, according to criteria of maximum efficiency in the assignment of available financial resources. This report will be sent to GILEAD along with the meeting minutes, under conditions to ensure its confidentiality.

4. Grant Award and Notification to Grant Applicants

The Selection Committee will prepare an individual report per project, with details on the acceptance/denial of the application as well as the key points from the evaluation. These reports will be sent by the ISCIII to GILEAD, the latter being responsible for posting them on the website of the Fellowship Program (www.FellowshipGilead.es). Each resulting report will be available to the respective investigator responsible for the project that applied for the grant. If the investigators request additional reasons from GILEAD, ISCIII will inform them of the details included in the report to the investigators. GILEAD will approve the grant award based on the content of the Report/Proposal prepared by the Selection Committee described above.

Interested parties who have been notified of the grant award will have a term of 15 calendar days to notify GILEAD by certified means of their acceptance of the grant awarded under the terms and in the amount proposed.

If the above procedure has not been completed within this deadline, it will be understood that the grant awarded has been waived.

5. Signing of the Cooperative Agreement between GILEAD and the Grant Applicant

Once the grant has been expressly accepted, GILEAD will send the grant recipient two signed copies of the Cooperative Agreement used to govern execution of the research project selected. One of the copies of the Cooperative Agreement, duly signed by the legal representative of the grant applicant, must be sent to Gilead within 20 calendar days.

By signing the aforementioned agreement, the grant applicant assumes the following obligations:

a) Execute the project within the terms and deadlines described in the documentation submitted, without prejudice to any modifications imposed with regard to the fundable budget, based on the decision regarding grant award.

b) Notify GILEAD of any specific, duly justified circumstance that would involve changes in the technical or financial conditions taken into account for the grant award and that could require a modification in the approved project. In this case, the changes must be requested before the 24-month deadline for project execution is completed and will only be authorized if the objectives or essential aspects of the project are not lessened. Deadline extensions for the project execution will be authorized only in exceptional cases.

c) Declare that no project funds or funding sources other than those stated on their application have been obtained.

d) Notify GILEAD of the award of any other subsidy, aid or funding source that it could receive for the same project after the agreement has been signed. This fact could lead to a modification in the fundable budget awarded, if the finally funded amount received were to require it under the provisions of Condition Three hereof, it being necessary to refund the excess amount received.

e) Perform regular follow-up of project development to ensure that it meets the work plan proposed in the application. A final report must be prepared by the project's principal investigator to provide a detailed description of the objectives and results achieved in the research and **must be submitted by email to the address Subvenciones.Spain@gilead.com** within 30 calendar days after the end of the project execution deadline. The agreement may also allow such results to be presented at a personal meeting to which they may be called along with other organizations awarded grants hereunder.

f) Include an express reference to GILEAD participation in its funding through the Fellowship Program of the Company in any publication or means in which the research project content is disclosed: in particular, the following text must be included: "*With assistance from the Gilead*

Sciences Fellowship Program". However, the grant applicant is obliged to report to the company, sufficiently in advance, of any public communication event related to the results obtained through the research project subject to grant hereunder. All of the above is understood to be without prejudice to the ownership of any intellectual property rights arising from execution of the project, which will be held by its authors under the terms set forth in the applicable legislation. However, the authors shall provide express consent for GILEAD to cite them under the same condition, both on its website and, where applicable, in any other publication of the Company.

g) Submit a copy demonstrating costs corresponding to the items that comprise the fundable budget approved for execution of the research project, if required by GILEAD. For such purpose, invoices must be submitted to prove all costs and payments made, along with any other documentation that can be used to prove that payment has been made by the grant applicant according to usual business practice.

h) Keep the supporting documentation for both the grant payment from GILEAD and the use of the funds received for a six-year period as of submission, for the purposes of any verification and control activities.

i) Cooperate actively with GILEAD if necessary to certify before the tax authorities any situation regarding the signing and compliance with the Cooperative Agreement, in order to promote the application of the tax system set forth in Article 25 of Law 49/2002, of December 23, with regard to the amount provided by GILEAD to fund the research activities described therein.

j) Return all or part of the grant amount received if the project is not executed, whether in whole or in part, the research project funded or its execution is not demonstrated under the terms described herein.

6. Grant payment

The grant approved by GILEAD will be paid as a lump sum to the grant recipient within 30 calendar days as of date on which the collaboration agreement alluded to in the preceding point is signed.

Payment will be made by bank transfer to the accounts designated by the grant applicant on its application or, where applicable, in the agreement itself.

Follow-up and disclosure of results by GILEAD:

GILEAD reserves the right to perform regular follow-up on the progress of the research projects by the grant applicants. A final report of the research project shall be submitted to GILEAD the month after the date on which it ends.

The results and conclusions reached in this report will be subject to presentation at a public meeting convened for such purpose by GILEAD, which may require the participation of the principal investigators (or, where applicable, of some other member of the research team) responsible for execution of the respective research projects.