



CALL FOR PROPOSALS 2023

NEXT GEN CLINICIAN SCIENTIST GRANT

DEADLINE FOR PRE-SUBMISSION: JUNE 15, 2023

DEADLINE FOR FULL PROPOSAL: NOVEMBER 10, 2023

(BY 17:00 CENTRAL EUROPEAN TIME)

FONDAZIONE AIRC
PER LA RICERCA SUL CANCRO ETS

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AIRC MISSION

AIRC raises funds to support cancer research in Italy. Its mission is to understand, prevent and cure cancer through research and outreach activities. AIRC aims to find solutions to challenges in cancer research, awarding grants to the most deserving projects, as well as supporting training fellowships. **You can read more about our research strategy [here](#).**

Guide to proposal preparation, FEA instructions, templates, Tips for applicants, Eligible costs and Keywords are available at: <https://www.direzionescientifica.airc.it/funding-for-research/individual-grants/>

Foreword

Fondazione AIRC per la ricerca sul cancro ETS (AIRC) is inviting applications for **Next Gen Clinician Scientist (Next Gen CS) Grants** in the area of cancer research. This grant is intended to foster a new generation of talented physician scientists wishing to **optimize clinical practice**. Applications falling within the following cancer research areas are particularly encouraged: academic-driven clinical trials, studies about novel biomarkers and patient stratification, research on innovative diagnostics, and new methods to improve the efficacy of surgery and radiotherapy. The scientific activity must be carried out in a research **organization located in Italy**, organized under public or private law, whose primary goal is to independently conduct biomedical research (university, hospital or other research center).

This grant will start on **July 1, 2024** and will provide support for a period of **5 years** (provided that AIRC has available funds and that the outcome of the mid-term review, to be carried out during the third year of activity, is positive). The grant is **up to a total of € 1.500.000 in 5 years** (with an average of € 300.000/year) and will be awarded once in a lifetime. Grantees are expected to establish an independent line of clinical research and be the leading author of all publications originating from the research carried out with the Next Gen CS grant. Failure to respect this commitment may result in withdrawal of the grant.

1. How to apply

A pre-submission inquiry is mandatory for Next Gen CS Grants. The pre-submission must contain a **3-page Letter of Intent (LOI)** with a description of the proposed work and of the projected achievements, a statement proving the successful history of the Hosting Institution in managing and carrying out clinical research studies, together with a description of the qualifications of the applicant, henceforth defined Principal Investigator (PI). Applicants who meet the eligibility requirements and who present the most competitive pre-submissions will be invited to submit a full proposal. A shortlist of candidates will be invited for a final interview with the reviewers.

2. Eligibility Criteria

Applicants cannot have more than one active AIRC individual grant at the same time. Nevertheless, they can apply to this Call if their active grant is in its final year.

Only one application per applicant can be submitted within the 2023 AIRC Calls. Candidates who have an application under evaluation will not be able to apply for an AIRC Call for individual grants before receiving notification with the results of their current application.

The same research project cannot be presented by more than one applicant within the 2023 AIRC Calls.

2.1 Applicants

Applicants can be of any nationality and are expected to have operated to the highest standards of integrity during their whole career. PIs must be involved in the project for at least 50% of their time.

To submit a proposal, applicants must meet the following eligibility criteria:

- Have obtained a **medical degree (MD)**;
- **Be 45 years old or younger by the time of the pre-submission application's deadline** (born on or after June 15, 1977). Exceptions to the age limit are allowed only in case of research interruptions (see the "Research Interruptions and Justifications" section of the Guide to proposal preparation).
- **Have a strong track record, including at least 5 primary research papers as first/co-first, last/co-last or corresponding/co-corresponding author**, in press or published in the last 5 years in peer-reviewed journals; papers in press must be accepted for publication, not just submitted, by the pre-submission deadline. Reviews, editorials, letters to the editor without data, meeting abstracts (even if they contain original data or are published on journals with Impact Factor) do not count for eligibility.

A significant clinical or laboratory research experience in a competitive institution outside of Italy is not mandatory but is considered a plus.

Applications by candidates who do not meet these requirements will be rejected ("triage").

We are aware that long research interruptions due to maternity leave, illness or personal issues might negatively affect an applicant's productivity: thus, for career breaks longer than 12 months, the track record period of 5 years will be extended. Also, **to help mitigate the impact of COVID-19-related disruptions, a 12-month extension will be granted to applicants whose research activities have been affected by the pandemic** (see the "Research Interruptions and Justifications" section of the Guide to proposal preparation for details).

2.2 Hosting Institution

The research project must be carried out in a Hosting Institution, i.e. a research organization (such as university, hospital or other research center), irrespective of its legal status (organized under public or private law), **located in Italy**, whose primary goal is to independently conduct non-economic biomedical research and to disseminate its results. Possible revenues coming from non-economic research activity must be completely reinvested in the non-economic research activities. Where the Hosting Institution also pursues economic activities, the financing, the costs, and the revenues of those economic activities must be accounted for separately. Shareholders, members, or other individuals that can exert a decisive influence upon the Hosting Institution cannot enjoy a preferential access to the intellectual property of the results generated by the non-economic research activity.

The Hosting Institutions must promote the highest standards of integrity in research, in compliance with the [relevant AIRC policy on this matter](#). AIRC is not responsible, and does not accept any liability, for scientific misconduct of personnel involved in a funded research project.

By signing the application, the Legal Representative of the Hosting Institution declares that the PI will be allowed to carry out the proposed research project for the entire duration of the grant, remaining affiliated with the Hosting institution.

AIRC reserves the right not to fund proposals from PIs who, although jointly affiliated to an Italian institution and an institution abroad, do not meet criteria for substantial presence (at least 70% of their time) in the institution in Italy during the funding period. To make sure this requirement is met, supporting official documentation will be requested from all institutions the PI is affiliated with.

Any change occurring in the relationship between the applicant and the Hosting Institution (e.g., termination, leave of absence, sabbatical etc.) or in the Hosting Institution legal entity or organization (e.g., changes in institution name, merging, Legal Representative turnover, changes in addresses) must be promptly notified to AIRC.

The Hosting Institution will provide the facilities, equipment, and infrastructure necessary to carry out the proposed research. In case the applicant is not yet affiliated to the Hosting Institution at the deadline for submission, the Hosting Institution and the PI **must have already negotiated the terms and conditions of his/her employment contract** and defined the recruitment procedure in case the grant is awarded. This is to ensure that the project can start promptly on July 1, 2024, as indicated in this Call (see Deadlines).

The Hosting Institution must provide a letter that confirms its commitment to support the clinical research project led by the PI and her/his research unit, describing spaces, infrastructure, qualified personnel and resources that will be available to the PI. The Hosting Institution must also guarantee that the PI will be allowed to autonomously manage the resources received to carry out the research project. The letter must include a pledge that **the PI must be listed as leading author** in publications stemming from research carried out with Next Gen CS funds (see “Institutional Commitments” in the Guide to proposal preparation). AIRC reserves the right to verify that these conditions are met. Failure to respect this commitment may result in withdrawal of AIRC support to the investigator.

2.3 Research plan

All proposed research plans must address **outstanding questions to optimize clinical practice** in oncology and be consistent with the AIRC mission. Projects must have a duration of 5 years, with a budget consistent with this time frame.

In particular, AIRC has interest in the following cancer **research areas**:

- Academic-driven clinical trials, especially early phases clinical trials and drug repurposing studies;
- Studies about biomarkers and patient stratification, including diagnostic, predictive and prognostic markers;
- Research on innovative diagnostics, including imaging and novel approaches that may involve collaborations with experts from other fields (i.e., engineering and physical sciences);
- Innovative surgery;
- New methods to improve efficacy of radiotherapy;
- Prospective observational studies of rare tumors.

At the same time, phenomenological, descriptive-at-best, proposals are discouraged.

The following kinds of proposals **will not be funded** and therefore will be **excluded from the peer review**

(triage):

- All phase III and IV clinical trials;
- All phase I and II clinical trials that are company-driven, with the PI or the Hosting Institution excluded from intellectual property rights ownership, with no possibility of publishing the results and of freely exchanging data, reagents and information. This does not exclude collaborative studies with industry;
- Requests for ongoing routine collection of data and materials, such as cancer registries or cell and tissue banks.

All proposals must contain thorough provisions of study design, statistical analysis and sample size (whenever applicable).

For studies involving human subjects, human biological samples or animal experimentation, the approval of the relevant institutional or national authorities is mandatory. AIRC reserves the right to check compliance with this requirement any time, up to ten years after the termination of the grant. AIRC does not accept any liability for harm to participants in AIRC funded trials.

The proposal must be original and **cannot contain copied texts, ideas and figures from other sources unless properly referenced**. At AIRC we are aware that copying may be accidental and that parts of an application (e.g., materials and methods) may include duplicate material originally produced by the PI for other goals than the present application. However, AIRC verifies documents with anti-plagiarism software: proposals that contain blatantly and substantially copied materials originally presented by other PIs will be rejected (for details, please see the form “Declaration on originality of the application” in the appropriate section of the Guide to proposal preparation).

Information about the proposed research (name of the PI, title and abstract), if funded, will be published on AIRC journals and websites; the websites of potential co-funders also contributing to the funding scheme; and other public databases collecting data on national and international funding in cancer research, such as ICRP (International Cancer Research Partnership). Such information may also be shared with donors who wish to support specific research projects with donations or bequests. The sharing will be done in the full respect of the EU General Regulation 2016/679 on data protection.

3. Intellectual property

As indicated in the [AIRC statement on intellectual property](#), for inventions arising from an AIRC funded project, grant money can be used to cover the costs for filing a patent application within the European Union (EU), but not to extend a patent to non-EU countries. Intellectual property and patents resulting from research carried out with AIRC grants will be solely owned and managed by the grantee and the Hosting Institution. All royalties and revenues deriving from the results of an AIRC grant must be reinvested in independent, non-economic oncological research.

Proposals for clinical studies, that are property of companies producing drugs or diagnostic tools and

that receive economic support from such companies, will not be accepted. Drug supply and economic support from companies do not preclude AIRC evaluation, provided that the PIs have the full property of data and results, and that companies have no right to veto the publication of results anytime. A statement must be included in the application, declaring that the management of the study, data acquisition and analysis, and data property are completely independent of any company producing/marketing drugs or diagnostic tools or with any type of economic interest in the study. Such statement must also include the indication on whether the company provides its product(s) to the PI for free or not. Projects will not be funded without such information.

4. Disclosure of Financial Conflicts of Interest

PIs are required to disclose any financial conflict of interest with the proposal, as described in the [relevant AIRC policy on this matter](#). Reviewers will be asked to determine if the conflicts declared may affect the objectivity and integrity of the proposed research plan. Appropriate measures will be taken against applicants who have deliberately or recklessly failed to disclose conflicts of interest, including: the termination of the grant, the obligation to return grant money to AIRC, the ineligibility to apply to future AIRC grants and the exclusion from AIRC review panels and other bodies.

5. Funding

Grants awarded within this Call are for a 5-year period: they will officially start on July 1, 2024 and terminate on June 30, 2029. Funding for the fourth and fifth year will be granted, provided that AIRC has available funds and that the outcome of the mid-term review, to be carried out during the third year, is positive. The grant is **up to a total of € 1.500.000 in 5 years** (with an average of € 300.000/year). If crucial for the development of the project, the PI can allocate different amounts of funding across the 5-year period, providing a clear justification in the budget section of the application.

First year of funding. Once awarded, the grant is assigned to the PI to carry out the project described in the application. Funds will be made available to the Hosting Institution under terms and conditions that AIRC will provide once the application is approved. Funds must be at the grantee's disposal within 30 days from the time the Hosting Institution has access to them.

Each year. The PI must submit a renewal request. Funding for subsequent years will depend on the submission of the renewal requests, which will have to be endorsed by the AIRC Board of Directors (*Consiglio di Amministrazione*), provided that AIRC has available funds. At the end of each funding period (one year + three months), an administrative report must be submitted.

Year 3. During the third year of the project, along with the renewal request, the PI will have to submit a detailed scientific progress report that will be evaluated. A site visit might be scheduled as well. Funding for the last two years will be granted only after a positive assessment, provided that AIRC has available funds.

Year 5. A scientific final report will be required and will strongly impact on the evaluation of future AIRC grant applications.

The PI is fully accountable for the budget allocation in compliance with AIRC grant management guidelines and the Hosting Institution's purchasing procedures.

The Hosting Institution must provide the PI with the necessary infrastructure (access to patients and primary samples, lab/office space, personal computers, furnished labs, major equipment, etc.), personnel, administrative and grant management assistance, and employ him/her for the whole duration of the grant.

Transfer of grant money to other laboratories and/or institutions either in Italy or abroad is not allowed. This does not exclude the possibility to support all units involved in multicentric clinical studies.

AIRC supports 100% of the additional costs generated by a funded project.

The following costs are eligible:

- Direct research costs:
 - a) Consumables and supplies
 - b) Small bench instrumentation
 - c) Equipment: the purchase of large instrumentation will not be looked upon favourably. However, if it is of central importance for the development of the project, it can be requested only if thoroughly justified
 - d) Services
 - e) Maintenance
 - f) Publications
 - g) Meetings and travel
 - h) Personnel: support for up to three units of personnel (only PhD students, early-stage researchers, research nurses, data managers and technicians) at 100% of time on the project. Personnel already holding a permanent position at the Hosting Institution at the time of the grant award cannot be paid with the grant money. The salary for the PI cannot be requested
- Indirect costs
- Overheads

Further information about the terms and conditions of the grant, including renewal requests, scientific and administrative reports, will be provided once the application is approved. Hosting Institutions of grantees might be asked to set up an [agreement with AIRC](#) regulating the terms and condition of the grant.

AIRC reserves the right to site visit the PI's unit and the Hosting Institution anytime while the grant is active.

AIRC reserves the right to audit the administrative management of the project anytime and up to 10 years after the project is concluded.

6. The Review Process

6.1 Eligibility check

All applications are checked for compliance with guidelines and eligibility criteria; those that do not conform will be rejected at this stage.

Eligible applications undergo a peer review process that ensures an expert, fair and independent evaluation of their scientific quality. Only the most scientifically meritorious applications, identified in a rigorous and objective manner through the peer review process described below, will be funded.

6.2 Pre-submission evaluation

For this Call, AIRC has appointed a dedicated Study Section composed of outstanding non-Italian experts with complementary expertise covering various clinical cancer research areas. The Study Section is in charge of the entire review process, including the evaluation of the pre-submission enquiries. The identity of the reviewers will not be disclosed.

In all stages of the review process, reviewer assignments will be made in compliance with conflict of interest and appearance of conflict rules to ensure a review free from inappropriate influence. When accepting to evaluate an application, reviewers agree that they will maintain the confidentiality of the application and associated materials they have received. The [AIRC policy on conflict of interest](#) is available on our website.

Each pre-submission is evaluated by the members of the Study Section, who select the most meritorious applications based on the review criteria listed below, indicating whether the applicant should or should not be invited to submit a full proposal. No detailed feedback will be provided to applicants rejected at this stage.

6.3 Full proposal evaluation

Full proposals are independently reviewed by three members of the Study Section with expertise in the specific area of the research plan. The three reviewers act as *primary reviewer*, *secondary reviewer* or *discussant*. The primary reviewer might also ask to recruit a *reviewer specialist*, should he/she think that the expertise available within the Study Section may not be sufficient for a thorough assessment of the research proposal. The reviewer specialist is recruited from a panel of about 600 well established international investigators working in institutions outside of Italy. Each of the three members of the Study Section provides a score, while the reviewer specialist only expresses a priority for funding.

The review criteria are:

- significance and impact on clinical practice for cancer patients;
- innovation;
- approach, feasibility and scientific rigor of the proposed research;
- PI's international standing in cancer research, leadership and track record adequate to successfully complete the proposed clinical study;
- quality of the Hosting Institution: environment, international standing, resources, facilities, infrastructures and successful history in carrying out clinical studies;

- adequacy of the budget requested.

When all evaluations have been submitted, reviewers are invited to read the critiques by the other reviewers who evaluated the same proposals and, if they deem necessary, to make additional comments.

6.4 Interview

When all reviews are completed, applications are ranked in order of scientific merit (the *preliminary score*, which is used to rank the applications at this stage, is calculated as the mean of the scores received from the three reviewers who evaluated the application). Based on the preliminary ranking, shortlisted candidates will be invited to an **interview in Milan on February 29, 2024**. All applicants are requested to hold this date; all candidates will be notified by the end of January 2024. The interview will include a short presentation followed by Q&A with the members of the committee. Further details will be provided to the shortlisted candidates. The final ranking, which is based on the *final score* of each application, is calculated as the mean of the scores received from all reviewers during the discussion.

The final ranking and the financial availability of AIRC will determine the recommendation for funding, to be endorsed by the AIRC Board of Directors (*Consiglio di Amministrazione*).

All applicants will be notified of the final decision on their application with an official communication from AIRC (the notification date is reported in the “Deadlines” table), and they will have access to the reviewers’ comments. **The decision concerning the funding of an application cannot be appealed.**

7. Revised Applications

Applicants can submit a revision of a previous AIRC project that was not funded in the past five years. If planning to submit a revised application, please consider that:

- revised applications that do not meet all eligibility criteria described in this Call will not be sent out for review;
- PIs must provide a detailed response to the reviewers’ comments through the “Revision” section of the online form available in the full submission.

8. Deadlines

Deadlines are strictly enforced: applications submitted after the deadline will not be accepted.

Deadlines for applications (by 17:00 Central European Time, of the indicated dates).

Pre-submission inquiry (mandatory)	Publication of Call and application form release	May 15, 2023
	Online submission	June 15, 2023
	Online submission with digital signatures of the PI and Legal Representative	June 29, 2023
	Notification of results	October 9, 2023
Full proposal (only if pre-submission is approved)	Full submission form release	October 9, 2023
	Online submission	November 10, 2023
	Online submission with digital signatures of the PI and Legal Representative	November 24, 2023
	Papers in press *	January 2, 2024
	Interview	February 29, 2024
	Notification of results	April 30, 2024
	Start of grants	July 1, 2024

* Requests from applicants that do not meet the eligibility criteria at the time of the submission deadline will not be considered. Communications regarding these papers will be forwarded to all reviewers evaluating the proposal. Please refer to the "Guide to proposal preparation" for details.

The PI and the Legal Representative must digitally sign both the pre-submission and the full proposal: refer to the [FEA instructions](#) ("Firma Elettronica Avanzata") for details. **If the digitally signed applications are not submitted by the indicated deadline, they will not be sent out for review.**

Deadlines for renewal requests, administrative and scientific reports will be communicated in the award letter.