Introduction to Pacira
Pacira BioSciences, Inc. is committed to supporting independent research initiatives that foster the advancement of scientific and clinical information and improve patient care. To that end, Pacira supports investigator-initiated trials (IITs) by parties interested in pursuing research in our therapeutic areas of interest. These research trials provide valued information on the safety, efficacy, pharmacology, and tolerability of the company's marketed products.

Pacira accepts applications for IITs conducted in the United Kingdom and European Union in areas of therapeutic interest for the company, which are:

- Patient selection criteria, protocol, and clinical and economic outcomes in outpatient surgery
- Outcomes of opioid-free perioperative pathways
- Long-term outcomes of enhanced recovery pathways including long-term opioid use, as well as functional and patient-reported outcomes (30+ days)

All applications are reviewed for scientific merit, innovation, clinical impact on patients, and compliance with Pacira policy and requirements. If you are interested in applying for support of an IIT, please review the submission process and apply online by clicking here <https://pacira-iis.icc.solutions.iqvia.com/Pacira-IIS-PROD/DefaultBU1.aspx>. Pacira will review and objectively consider all relevant research proposals but does not have to provide support for any research proposals received.

Investigator-initiated trial (IIT)
An IIT is a research study where the principal investigator or institution designs and implements the research study and acts as the study sponsor. The study sponsor is the individual (or entity) responsible for complying with all applicable regulatory requirements, guidance, and laws related to the research study. This also includes registering the study with applicable governmental agencies and websites like the European Union Drug Regulating Authorities Clinical Trials Database (https://eudract.ema.europa.eu/) and the United States National Library of Medicine clinical trials database (https://clinicaltrials.gov/) and reporting safety data to all relevant regulatory authorities.

Pacira provides research grant support in the form of product or funding in our therapeutic areas of interest based on the scientific merit of the research study. The research must aim to contribute to the greater scientific community and the budget must be reasonable and appropriate for the proposed research study. In considering applications for IITs, Pacira will consider, among other factors, the expertise of the principal investigator and any co-investigators, including their experience in the relevant therapeutic area, demonstrated ability to successfully conduct clinical trials, and available resources.

The study sponsor (ie, principal investigator or institution) will have full and final discretion and responsibility for all aspects of the study design, implementation, data analysis, and data dissemination, including compliance with all laws and regulations applicable to research sponsors.

Please note that IIT funding is not contingent upon the use, purchase, or recommendations of Pacira products.

The IIT process
Pacira maintains a stepwise process for review of IIT proposals. In brief, after registering on the online grant portal, the principal investigator submits a brief concept proposal and if accepted after review by the Pacira Grant Review Committee (PGRC), will be invited to submit a full proposal. Details on brief and full proposal contents are below.

Brief concept proposal:
A brief concept proposal must contain an adequate amount of information in order for the PGRC to determine interest in requesting a full study proposal. When submitting a brief concept proposal, the following information will be requested (if applicable):

- Principal investigator contact information
- Title of the proposed research study
- Brief background and rationale and purpose for the study
- Method of administration of marketed product
- Primary study objectives/endpoints
- Study population including estimated number of subjects and preliminary justification
- Estimated total length of the study
- Estimated study timelines
- Estimated total study budget
- Estimated amount of study drug or device(s)
- Preliminary grant request: funding, drug, device, or a combination thereof
- Experience as sponsor-investigator
- Letter of request on the requesting institution's letterhead
- Curriculum vitae from the principal investigator dated within the last calendar year

The PGRC will review all concept proposals for scientific merit, innovation, clinical importance/potential impact on patients, and compliance with company policy and requirements. The PGRC will extend contingent approval to certain applicants to proceed to the second step of the process, which is submission of a full study proposal. Applicants will be notified of the PGRC's decision via email and the status will also be available on the portal. Please note that an invitation to submit a full study proposal does not guarantee approval of funding.

Full study proposal:
A full study proposal submission must contain enough detail about the research study to enable the PGRC to make an evaluation on support. When submitting a full study proposal, the following information will be requested (if applicable):

- Principal investigator contact information
- Title of the proposed research study
- Study type: non-clinical or clinical
- Study rationale
- Objectives: primary and secondary
- Key inclusion and exclusion criteria
- Study design
- Efficacy variables/measures
- Safety variables/measures

- Adverse event/Serious adverse event reporting
- Decision points/statistical methods/interim analysis
- Study product regimens
- Ethical rationale for the study
- Study deliverables
- Value of the study
- Applicable scientific references
- Publication plan
- Research Setting: single-site or multi-site
- Detailed budget
- Grant request: funding, product, or a combination thereof

Pacira reserves the right to reconsider its support if the research objectives outlined in the final protocol are materially different from the approved full study proposal. Pacira will not compensate for any work performed prior to the execution of a final contract or for impermissible costs, which include:

- Construction funds to build new facilities
- General education and training activities
- Hiring of staff that are not dedicated to the proposed research study
- IIT to involve studying new investigational products or devices
- IITs that are designed to generate business for Pacira
- Purchases of capital equipment unrelated to the study or that would generate revenue
- Requests for support for ongoing or new research without an associated research study protocol
- Start-up funds to establish new clinical or research programs or to expand existing programs
- Support for ongoing clinical programs that are part of an organization's routine operations

Compliance

Pacira requires IIT recipient(s) to comply with all applicable laws, rules, regulations and industry codes related to clinical and/or non-clinical research, including registration of protocols and posting of results on applicable clinical trial registries as well as adverse event reporting systems.

Please note, all clinical trial and ethics committee approvals must be received within four months of Pacira's execution of the IIT Agreement. If this deadline is not met, Pacira reserves the right to rescind approval of the IIT support.

Applicants whose proposal has been approved will be sent an Agreement that will set forth the obligations with respect to the study. Applicants will have four weeks from the date the Agreement is sent/emailed/uploaded to review, sign and return the Agreement. If the Independent Research Agreement is not returned within four weeks, the contingent approval may be withdrawn.

Monthly study status update

Pacira requires at least one study status update per month. Updates should include current enrollment figures (if applicable) and the projected completion date (if different from the

previously reported date). Pacira also requires disclosure of any protocol changes made since the commencement of the research.

Usual adverse event reporting requirements will be included to meet regulatory requirements.

Study closure
The principal investigator (ie, sponsor-investigator) is required to provide Pacira with a written, manuscript quality report of the final study results. Upon study closure, the investigator is required to provide a detailed budget reconciliation demonstrating that IIT funds and/or product were used solely to conduct the study, all safety reporting obligations were met, and unused study drugs/product were destroyed or returned in accordance with the organization's policies.

Publications
Pacira supports the exercise of academic freedom and encourages the publication of study results, whether favorable or not to Pacira and its products. Furthermore, Pacira maintains the right to review each publication and/or presentation (including, but not limited to, full manuscripts, abstracts, poster presentations and oral presentations) of results of the research prior to its submission to anyone not affiliated with Pacira or the principal investigator.

The principal investigator will comply with recognized ethical standards concerning publications, authorship and disclosure of funding, including without limitation the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, www.icmje.org, established by the International Committee of Medical Journal Editors.

The principal investigator will be required to disclose the grant to their employer (who will be the applicant and recipient) and Pacira will publish details of the grant, the applicant and the principal or other investigators as required by applicable laws and/or industry codes. The applicant and its investigators will fully disclose the receipt of the grant in all oral or written presentations of the results of the investigation.

IIT FAQs

What are the principal investigator's responsibilities?

- Meet applicable deadlines as outlined in the executed contract
- Submit periodic study updates as outlined in the executed contract
- Communicate to the Pacira Grant Review Committee (PGRC) key study milestones (failure to communicate or adhere to milestones may result in revocation of support)
- Share prepared manuscripts/abstracts for publication or presentation with the PGRC in the time agreed upon in the signed contract
- Return unused funds (

What are the therapeutic areas of interest?

- Patient selection criteria, protocol, and clinical and economic outcomes in outpatient surgery
- Outcomes of opioid-free perioperative pathways
- Long-term outcomes of enhanced recovery pathways including long-term opioid use, as well as functional and patient-reported outcomes (30+ days)

On what basis does the Pacira Grant Review Committee make its decision?

- Welfare of research study subjects
- Scientific merit of the research
- Overall soundness of study design
- Adherence to Good Clinical Practice
- Alignment with our objectives
- Principal and sub-investigators experience in conducting research
- Compliance with company policy and requirements

How often does the Pacira Grant Review Committee meet?

The grant committee attempts to meet monthly.

How can I contact the Pacira Grant Review Committee?

Email grants@pacira.com

Are there any types of studies Pacira will not fund?

- Construction funds to build new facilities
- General education and training activities
- Hiring of staff that are not dedicated to the proposed research study
- IIT to involve studying new investigational products or devices
- IITs that are designed to generate business for Pacira
- Purchases of capital equipment unrelated to the study or that would generate revenue
- Requests for support for ongoing or new research without an associated research study protocol
- Start-up funds to establish new clinical or research programs or to expand existing programs
- Support for ongoing clinical programs that are part of an organization's routine operations

Who can apply for a Pacira IIT grant?
Any qualified researcher or site wishing to undertake a bona fide scientific or medical research project.

Am I required to apply online?
Yes, you must make your request for support through the Pacira grant portal located here <https://pacira-iis.icc.solutions.iqvia.com/Pacira-IIS-PROD/DefaultBU1.aspx>.

How long does the submission process take?
Every submission is unique but in general, from submitting your study proposal to signing the contract it may take up to 6 months.

What should be included in the study budget?
The budget should include all study-related expenses including all study related drug costs (ie, drugs not supplied by Pacira). Costs should be itemized and in accordance with fair market value.

My Pacira representative told me that my IIT proposal would be approved by the Pacira Grant Review Committee, but I received a denial letter. How did that happen?
No individual Pacira representative can approve IIT proposals. As a requestor, you should not accept any verbal or written promises from any Pacira employee as they are not authorized to make such promises. You will receive notification through the Pacira grant portal on the status of your request.

My proposal was approved, now what?
Upon study approval, Pacira requires an executed contract outlining the responsibilities of the parties with respect to support, conduct of the IIT and any related activities, prior to any transfer of value by Pacira. Pacira will review and consider all relevant research proposals but is not obligated to provide support for any research proposals received.