



Investigator-Initiated Research (IIR) & Requests for Pure Substance (CTP)

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IIR Mission and Purpose

The mission of the Pfizer Investigator-Initiated Research (IIR) Program is to provide support for investigator-initiated research that advances medical and scientific knowledge about Pfizer products and generates promising medical interventions. This global program is open to all researchers who are interested in receiving support for conducting their own research.

Types of Research Eligible for Support

- Clinical studies of approved and unapproved uses, involving approved or unapproved Pfizer drugs
- Observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease
- Other types of independent research on disease states, including novel diagnostic screening tools and surveys where Pfizer has no direct commercial interest
- In vitro or animal studies which include funding*

Pfizer support is typically provided in the manner of funding, and/or drug (either formulated or pure compound) depending upon the type of research.

**Pure compound-only requests that do not require funding should be submitted directly to the Pfizer Global Compound Transfer Group. For more information please click on the following link which will take you to the [Global Compound Transfer Program](#) on the Pfizer website.*

Submitting an Investigator Initiated Research (IIR) Request

Pfizer accepts Concept submissions and Full submissions for Investigator-Initiated Research grant requests. If a Concept submission is of interest, a follow up request for a Full Submission will be issued. A Full submission must be received in order for a request to be considered for approval.

Requests are submitted to Pfizer through a submission website. For more information please click on the following link which will take you to:

[Global Investigator Initiated Research](#).

Prior to submitting a grant request, please contact a Pfizer Field Based Medical colleague, a Pfizer Country Medical Representative, or other Pfizer Medical personnel for more information.

If you do not know who your local Pfizer Medical representative is, please send an email to iir@pfizer.com and you will be provided with the appropriate Pfizer contact to assist you.

Concept Submission

A concept submission must contain an adequate amount of information in order for Pfizer to determine interest in receiving a full proposal. When submitting a Concept proposal, the following information will be requested:

- Principal Investigator contact information
- Study Type: Clinical or Pre-Clinical
- Grant Request: Funding, Drug or both
- Primary Pfizer Drug *(if applicable)*
- Research Setting: Single-site or Multi-site
- Country of Primary Site
- Total Funding Requested *(if applicable)*
- Outside Support *(if applicable)*
- Non-Pfizer drug(s) as part of the study *(if applicable)*
- Preliminary Study Title
- Brief Study Synopsis
- Brief Study Rationale / Objectives

Full Submission

A full proposal submission must contain enough detail about the research study and the grant request to enable Pfizer to make a final evaluation regarding support. When submitting a Full proposal, the following information will be requested:

- Principal Investigator contact information
- Study Type: Clinical or Pre-Clinical
- Grant Request: Funding, Drug or both
- Primary Pfizer Drug *(if applicable)*
 - Drug Type: Commercial, Clinical Image, Pure Substance
 - Formula, Strength, Quantity
- Research Setting: Single-site or Multi-site
- Country of Primary Site
- Total Funding Requested *(if applicable)*
 - Direct Labor Costs subtotal
 - Direct Study Costs subtotal
 - Institution Overhead subtotal
 - Indirect Costs subtotal
- Outside Support *(if applicable)*
- Non-Pfizer drug(s) as part of the study
- Preliminary Study Title
- Brief Study Synopsis
- Brief Study Rationale
- Primary Endpoints
- Statistical Methods
- Inclusion/Exclusion Criteria *(if applicable)*
- Target Enrollment *(if applicable)*
- Treatment Plan or Dosing Regimen *(if applicable)*
- Study Duration
- Target Start and End Dates
- Publication Plans
- Upload current Curriculum Vitae or brief Bio
- Upload itemized Budget *(if applicable)*

Review Process

Pfizer will acknowledge receipt of all grant submissions. The review process is conducted by a Pfizer Grant Review Committee and decisions are made based upon medical and scientific merit as well as available resources and research priorities. A formal notification on the status of your application will be sent once a decision is reached.

Budget and Overhead Costs

Before submitting your budget, please ensure that all study-related expenses have been appropriately itemized and included and are commensurate with fair market value.

Suggested Items to Consider in Calculating the Budget

Direct Study Costs

(including overhead costs) such as:

- Subject-related costs
- Study-related personnel costs
- Diagnostic fees and services
- Data management expenses

Indirect Study Costs

(not including overhead costs) such as:

- Publication costs (e.g., preparation of manuscript, travel, etc.)
- IRB review fees
- Equipment/supply expenses
- Animal-related costs *(if appropriate)*

Pfizer will not compensate for the following:

- Requests for support for ongoing or new research without an associated study protocol or synopsis
- General educational and training activities
- Support for ongoing clinical programs that are part of an organization's routine operations
- Start-up funds to establish new clinical or research programs or to expand existing programs
- Purchases of capital equipment unrelated to the study or that would generate revenue
- Construction funds to build new facilities
- Hiring of staff that are not dedicated to the study

NOTE: For US and Puerto Rico Only: IRS Form W-9

Pfizer requires all research grant proposals within the U.S. and Puerto Rico that include monetary support to submit a completed copy of the payee IRS W-9 Form. The latest version of Form W-9 may be downloaded from the IRS Website: www.irs.gov

Pfizer's Requirements for IIR Collaboration

Upon approval of your full proposal, there are several documents that Pfizer requires before it can initiate support (drug and/or funding). Pfizer requires:

- IRB/Ethics Committee approval
- Regulatory Response Documentation (*IND or CTA documentation if applicable*)
- Fully executed IIR agreement
- Final study protocol*

**NOTE: Please be aware that if the research described in your final protocol is materially different from that in your approved proposal, then Pfizer reserves the right to reconsider its support.*

Study Maintenance

Pfizer requires at least one study status update per year. Updates are expected to include information on enrollment (*if applicable*), projected publications and study completion dates. Pfizer also requires notification of any amendment to the original protocol after the research has begun. Please see note above regarding protocol changes.

Study Closure

An investigator conducting an IIR is contractually required to provide Pfizer with a written report of the final study results. Any planned publications must be sent to Pfizer in advance of submission in accordance with the IIR agreement. Upon study closure, the investigator will be required to certify that the study was conducted and the Pfizer grant funds and/or drug were used solely to conduct or report the study and that all safety reporting obligations were met.

Compound Transfer Program (CTP) (Requests for Pure Substance Only)

Pfizer has an extensive pure powder transfer program that encompasses all of our publicly known compounds. We review each request regarding use of our compounds for content, value, and consistency with Pfizer's direction for the requested compound. We routinely enter Compound Transfer Agreements (CTAs) that provide the compound free of charge to a third party to conduct the agreed upon study. We require a manuscript or report of the conclusions to bring closure to the study. Pfizer reserves the right to deny any request that we feel does not advance our compound(s) or add value to human or animal health.

To request a Pfizer pure substance compound please complete the submission form located on the INSPIIRE portal. You must also include an attachment with a full description of the specific research study proposed with your on-line submission. The on-line form and your attachment will provide Pfizer with the information required to process your request.

Processing time from initial submission to the approved compound(s) shipment to your facility is approximately 12 weeks. You will receive an auto reply email confirming your submission has been completed and you may track the status of your submission on the INSPIIRE portal.

**Studies involving humans or requesting funding support should be submitted through the Investigator Initiated Research program.*

Safety Reporting Requirements

Pfizer has an ethical and legal responsibility to collect and analyze safety information on its products so that the company can fully understand their risk-benefit profile and provide accurate safety information to regulators, prescribing physicians, and consumers. As an independent investigator conducting research involving Pfizer products, you play an important role in partnering with Pfizer to monitor safety.

For all IIR studies using a Pfizer Product and/or Device: Pfizer requires that, within 24 hours of first awareness of the event (or immediately) if the event is fatal or life-threatening), the principal investigator will report to Pfizer by facsimile any Serious Adverse Event (SAE) that occurs during the SAE reporting period in a study subject assigned to receive the Pfizer product. In addition, for studies using a Pfizer device or Pfizer product packaged with a device, reportable events include not only SAEs but also Device Incidents and Device Near-Incidents.

Reporting Forms: The principal investigator will report such SAEs using the Pfizer IIR SAE reporting form or the approved local regulatory form (i.e. FDA MEDWATCH form, CIOMS, etc.) and the Reportable Event Fax Cover Sheet provided by Pfizer. SAEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.

Reporting Period: The Reportable Events that are subject to this provision are those that occur from after the first dose of the Pfizer product through 28 days after discontinuation of the Pfizer product.

Follow-up Information: The institution and/or principal investigator will assist Pfizer in investigating any SAE and will provide any follow-up information reasonably requested by Pfizer.

Regulatory Reporting: Reporting an SAE to Pfizer does not relieve the institution and/or principal investigator of the responsibility for reporting it to the FDA or local regulatory authority, as required.

Sponsor Responsibilities

Regulatory and Ethical Obligations

As the sponsor of the study, the investigator and/or institution must ensure that the study is conducted in accordance with the provisions of the ICH GCP Guidelines and all applicable local and regulatory requirements. The Principal Investigator must assume all regulatory responsibilities including, but not limited to, IRB/IEC approvals, regulatory approvals, and any and all reporting obligations to local Regulatory Authorities.

Publications

Pfizer supports the exercise of academic freedom and encourages Principal Investigators to publish the results of the study, whether or not the results are favorable to the Pfizer product. The Principal Investigator will comply with recognized ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, www.icmje.org, established by the International Committee of Medical Journal Editors.

Registering Your Research on Public Websites

Pfizer recognizes that carefully conducted clinical trials are the fastest and safest way to find treatments to improve health. Pfizer encourages you and your institution to add your study to the FDA's ClinicalTrials.gov database (www.ClinicalTrials.gov) or a trial registry website in your country.

Government Official Identification

Pfizer is committed to full transparency and due diligence around all financial interactions with healthcare professionals, their institutions and related organizations to further ensure and demonstrate the legitimate and invaluable purpose of such interactions. With respect to your request for support, Pfizer is required to make a factual determination of whether you are presently in a position to potentially influence a decision to approve, reimburse or purchase a Pfizer product, or influence an official act that would benefit Pfizer's business. It is for this reason we will ask that you complete a list of questions to the best of your and your organization's knowledge adhering to the spirit and letter of all applicable country and international laws and agreements.

This is critical not only to satisfy applicable legal requirements and restrictions governing such interactions, but also to ensure their integrity and in turn to earn and maintain the trust of the patients, their families and caregivers as well as all other constituencies of the healthcare system that we serve. In doing so, this protects Pfizer as well as you and your organization.

Data Privacy

When you register on this website the personal information you submit will be used for the purpose of evaluating your submission and administering any resultant ongoing relationship with you and may be transferred to Pfizer operations in other countries whose data protection laws may not be equivalent to the data protection laws in your own country. By clicking the "I Agree" button below, you confirm your agreement to this processing by Pfizer of your personal data and to the terms of the Pfizer IIR Submission Policy. For more information please click on the following link which will take you to the [Pfizer Privacy Policy](#) on the Pfizer website.

Financial Disclosure by Pfizer

In the interest of transparency relating to its financial relationships with investigators and study sites, Pfizer may publicly disclose the funding associated with an IIR Agreement. Any such report by Pfizer will clearly differentiate between payments made to institutions and payments made to individuals. For more information please click on the following link which will take you to [Pfizer Responsibility-Grants & Payments](#) on the Pfizer website.

Pfizer Policy on Submission

All materials submitted must be non-confidential and should not contain any markings indicating confidentiality. By submitting your materials to Pfizer for review, you understand that we will not treat the information as confidential or proprietary. It is necessary to refer a submission to a number of different persons in the Company to ascertain whether or not a research proposal is of interest. Thus, while we have no intention of publicizing a submission, we can assume no obligation to keep it confidential. It is our fixed policy to consider investigator-initiated research proposals from persons outside the Company upon the following conditions: 1. That the submission is not made in confidence and is not accompanied by any reservation or condition whatever which imposes upon Pfizer any obligation or restriction with regard to its use. 2. That the submitter's rights shall be only those given under the patent laws and/or under any written contract to which the submitter and Pfizer may mutually agree. 3. That the submitter is the originator of the information and materials or has been authorized by the originator to provide information and materials on their behalf.