Pfizer's Support of Independent Research

Contents

If you have any questions about any information in this document, please contact GMG@pfizer.com.

Introduction

Pfizer supports the global healthcare community's independent initiatives to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

The grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements.

Investigator Sponsored Research

Pfizer supports Investigator Sponsored Research (ISR) projects that advance medical and scientific knowledge about our therapies.

An ISR is a type of grant that supports an independent research study where the investigator or organization is the sponsor of the study and where Pfizer provides financial and/or non-financial support for the development or refinement of specific and defined medical knowledge relating to a Pfizer asset. This global program is open to all researchers who are interested in conducting their own research. This grant type is used as support for pre-clinical and clinical studies (including interventional and non-interventional), that involve a Pfizer asset (e.g., commercial drug, investigational drug, pure compound).

General Research

Pfizer also supports general research projects focused on the development or refinement of specific and defined medical knowledge unrelated to a Pfizer asset.

This grant type is used to support research that does not include the study of a Pfizer asset, including health services research unrelated to a Pfizer asset, registry development and/or queries unrelated to a Pfizer asset, and outcomes research unrelated to a Pfizer asset. This

includes observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease as well as other types of independent research on disease states.

Within the research grant application, you will be asked to identify this project type (Investigator Sponsored Research or General Research). For guidance, please refer to the Project Classification Decision Matrix. If you have any additional questions please email us at GMG@pfizer.com.

Overview of Research Grant Application Questions

The research grant application is divided into sections. The information below provides a view of what is included in each section. Please note this is meant to assist you in preparing your research grant application but in order to submit your request to Pfizer you must answer all questions in the online application through the Grant Medical Grants System available at http://www.cybergrants.com/pfizer/Research.

Section 1: Introduction

Please note that all online application fields (and any uploaded documents associated with the initial application) must be completed in English.

When an application is selected for approval all grants are paid to the requesting organization. Please ensure the person authorized to sign an agreement on behalf of the organization, as well as the primary investigator, are listed as contacts on this application.

Grant Requesters will be asked to agree to the following:

Pfizer Policy on Submission of a Research Proposal: Pfizer refers grant applications to a number of colleagues working for or on behalf of Pfizer to determine if a proposal is of interest and will be supported. While Pfizer will use any information or material submitted only for internal purposes and has no intention of publicly disseminating anything submitted in connection with a grant, Pfizer assumes no obligation to keep any information or material submitted confidential. You agree that any information or material you submit to Pfizer during the grant application stage, or subsequently, is non-confidential and will not contain any markings claiming confidentiality and you acknowledge that Pfizer will not treat such information or material as confidential or assume any obligation of confidentiality.

It is Pfizer policy to consider research proposals from persons outside Pfizer 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.

I acknowledge that I have read the above statement "Pfizer Policy on Submission of a Research proposal", which sets forth Pfizer's policy on the submission of proposals and ideas by persons from outside Pfizer. I agree that I am not submitting any confidential information in making this submission, and I agree to be bound by the terms and conditions set forth in the policy statement. I acknowledge that Pfizer may conduct ongoing or future research identical to my proposal or ideas. In consideration for your examining my proposal and idea, to the fullest extent allowed, I release your company from any and all liability for use of all or any portion thereof, other than infringing uses of my proposal or ideas that are protected by patent.

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 a Research Agreement. Such reports by Pfizer may 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. In addition, Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. All approved proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the GMG website and/or any other Pfizer document or site

Contract Agreement Terms: If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement. Pfizer has recently revised its grant agreement templates based on feedback from both internal and external stakeholders. Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal

department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.

Please provide the name and email address of the individual at your Organization that is authorized to sign the contract if this grant is approved. Pfizer only requires one signature.

Field	Field Type	Description/Notes
Authorized Signatory Name	Text	If approved, name of individual responsible for signing the contract
Authorized Signatory Email	Email Address	If approved, email address of individual responsible for signing the contract
Additional Authorized Signatory Name (Optional)		Optional; If your Organization requires an additional signature please provide that name here.
Additional Authorized Signatory Email (Optional)		Optional; If your Organization requires an additional signature please provide that email address here.

Section 2: Contact Information

Grant Requesters must add at least one main contact for email communications. If not the main contact, the Primary Investigator should also be added as a contact.

Field	Field Type	Description/Notes
Salutation	Text	
First Name	Text	
Last Name	Text	
Title/Position	Text	
E-mail Address	Text	
Telephone	Text	
Fax	Text	Optional

Section 3: Organization Information

In this section Grant Requesters are asked to review the information from their Registration Profile. Please contact GlobalMedicalGrants@pfizer.com if the name of your Organization or your Tax ID information has changed. If approved, the submitting Organization will be the Contracting Organization.

Field	Field Type	Description/Notes
Practice or Private Physician Office	Yes/No	Could your organization be classified as a group practice or an individually owned private physician practice (i.e., an independent group of physicians not affiliated with a hospital, academic institution or professional society)? Please note that Pfizer cannot provide grants to individuals, individually owned private physician practices or informal groups which are not legal entities

Section 4: Project Lead/Principal Investigator

In this section the Grant Requester is asked to enter information regarding the Project Lead/Principal Investigator. Please note that a CV/bio-sketch cannot be uploaded to the research grant application. Any relevant CV/bio-sketch information should be entered in the online fields shown below. If the study involves a co-investigator that information should be entered here as well.

When completing this section, please provide professional contact information provided to you by your institution. All grant requests are made on behalf of the institution, not the individual. The information you provide will be processed by Pfizer for the purpose of evaluating applications. Please do not include any personally identifiable information unrelated to the

grant request such as your personal email, home address, personal phone number, marital status, or a photo.

Please note that the PI must serve as the Primary Safety Contact.

Field	Field Type	Description/Notes
PI First Name	Text	
PI Middle Name	Text	Optional
PI Last Name	Text	
PI Email	Text	
Principal Investigator (PI) is a US-licensed physician	Yes/No	For U.S. federal and state reporting purposes, if the Principal Investigator (PI) is a licensed HCP then the total research grant amount paid by Pfizer to the requesting organization will be reported to federal and state regulatory agencies as an indirect payment to the PI. If the PI is not a US-licensed HCP then the research grant is not subject to U.S. reporting requirements.
PI Address Country	Single Select Dropdown	
PI Address Line 1	Text	
PI Address Line 2	Text	
PI Address City	Text	
PI Address Province/State	Single Select Dropdown	
PI Address Postal Code	Text	
PI Current Position Title	Text	
PI Primary Degree	Single Select Dropdown	
Institution and Location of Primary Degree	Text	
Completion Date of Primary Degree	Date	
Field of Study	Text	
PI Secondary Degree	Single Select Dropdown	Optional
Institution and Location of Secondary Degree	Text	Optional

Completion Date of Secondary Degree	Date	Optional
Field of Study of Secondary Degree	Text	Optional
PI Positions and Honors	Text (Paragraph)	Optional
PI Contributions to Science	Text (Paragraph)	Optional
Additional PI Information	Text (Paragraph)	Optional; Research Support and/or Scholastic Performance

If there is a Co-Investigator, enter his/her information below. If not, you can move to the next section.

Field	Field Type	Description/Notes
Co-PI First Name	Single Select Dropdown	
Co-PI Middle Name	Text	
Co-PI Last Name	Text	
Co-PI Primary Degree	Text	
Co-PI Email	Single Select Dropdown	
PI Certification	Checkbox	Requester must certify the information provided is accurate and complete.

Section 5: Study Details

Project Overview

Field	Field Type	Description/Notes
Project Type	Single Select 1. General Research: Health Services Research (No focus on a Pfizer Drug) 2. General Research: Outcomes Research/Surveillance/Other Non-interventional research (No focus on a Pfizer Drug) 3. General Research: Registry Development (No focus on a Pfizer Drug) 4. General Research: Pre-clinical/Clinical (No focus on a Pfizer Drug) 5. Investigator Sponsored Research: Pre-clinical/Clinical (Includes focus on a Pfizer Drug) 6. Investigator Sponsored Research: Non-interventional (Includes focus on a Pfizer Drug)	Indicate which of the following most accurately represents your project. For guidance, please refer to the Project Classification Decision Matrix.
Grant Request Type	Single Select 1. Funding 2. Funding and Drug 3. Funding and Compound 4. Drug Only	The answer to this question will drive additional questions within the research grant application.

If Project Type = Investigator Sponsored Research, Pfizer Drug of Interest	Single-Select	If your study has a focus on a Pfizer drug, please select the drug or drugs from the list below. If your study does not focus on a Pfizer drug please return to the Project Type question and select a General Research option. If you have any questions email GMG@pfizer.com.
Primary Area of Interest	Single select list	Please select the Pfizer Area of Interest that is most relevant to your research. This will ensure that the appropriate group at Pfizer reviews this request
Secondary Area(s) of Interest	Multi-select list	If your project encompasses any additional Pfizer Areas of Interest you can select them here.
Competitive Grant?	Yes/No	If you are responding to a Request for Proposal (RFP) as part of the Competitive Grant Program select Yes. If not, select No.
*If **yes**, Competitive Grant Program Name*	*Single select list*	*Refer to the "How to Apply" section of the RFP to identify the name of the Competitive Grant Program. Select that name on this list. If you have any questions email GMG@pfizer.com.*
Has your institution submitted this project for consideration to Pfizer previously?	Yes/No	
Study Title	Text	Enter a brief description as this will display on your Welcome page to help you identify your submission(s).
Abstract	Text (paragraph)	Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words. NOTE: This should be the same text that is included in any uploaded proposal.
Protocol/Full Proposal	Upload File	
External Identification Number	Text	Please note any External Identification Number assigned to the study by your institution
Estimated Study Start Date	Date	

Estimated Study End Date	Date	
Project/activity related to Opioids	Yes/No	Please indicate whether or not the project/activity for which you are seeking support from Pfizer is related to or includes discussions about pain or opioids. **NOTE:** To be eligible for funding, project/activity related to opioids must include components: 1) Aimed at increasing awareness of the risks of opioid addiction, abuse, and misuse; and 2) Detecting and preventing abuse, misuse, and diversion of opioids.
If yes, Pain/Opioid Attestation	Certification	Pfizer has agreed not to support outside organizations and individuals that make misleading statements about the risks and benefits of opioids for the treatment of chronic pain. Please review the CDC Guidelines for Prescribing Opioids for Chronic Pain and complete the following certification: On behalf of the Requesting Organization, I certify that the Requesting Organization's external communications about opioids are truthful, accurate, and not misleading, and the Requesting Organization does not make claims that are contrary to the "Recommendations" of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain, issued in March 2016. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. I also certify if the project/activity is related to opioids, the project/activity includes components: 1) Aimed at increasing awareness of the risks of opioid addiction, abuse, and misuse; and 2) Detecting and preventing abuse, misuse, and diversion of opioids.
Will any component of your activity/intervention offer continuing education credit?	Yes/No	If your answer to this question is yes, please contact GlobalMedicalGrants@pfizer.com before submission.

Research Setting	Single Select 1. Single-Site 2. Multi-Site*	Please indicate if your study is a single-site or multi-site study.
Primary Country Site	Single Select	If Multi Site, please specify the Country of Primary Site from the list of countries.
**For Multi-Site studies you will be asked how many sites and to provide in which country/countries those sites are located.*		
Does your study involve genetics or genomics?		
Primary End Points: (i.e., what are you measuring?)		
Total Subject Enrollment		

Investigator Sponsored Research (Clinical/Pre-Clinical)

For Clinical/Pre-Clinical Research you will be asked to answer the following questions.

Field	Field Type	Description/Notes
Study Type	Single Select: Pre-Clinical, Clinical	Please indicate if your study is clinical or pre-clinical. Your answer to this question will impact the questions asked later in the application.
For Clinical Studies:		
Clinical Study Tpe	Single Select: Epidemiology, Interventional, Observational, Retrospective	What type of clinical study?
For Interventional Studies:		
Blinded Study?	Yes/No	Is your study blinded?
For Retrospective Studies:		
Retrospective Design	Single Select: Case-controlled, Co-hort, Other	For Other, Please enter the design in the Text field provided
Age Group of Study Population	Single Select	Indicate the age group(s) of the populations studied

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Ethnicity of Study Population	Multi-Select	Indicate the ethnicity of the populations studied.
Length of Enrollment	Number	Please indicate the anticipated Length of enrollment. Enter number of months.
Study Phases	Single Select: Phase I, Phase I and/or II, Phase II, Phase II and/or III, Phase III and/or IIIb, Phase IV	
Study Design	Single Select: Cross-over, Double Blind, Open Label, Single Blind, Not Applicable	
Is the Study Randomized?	Yes/No	
Total Subject Enrollment	Number	
Number of Arms	Single Select: 1-10	
For Each Arm		
Treatment Plan	Text	
Pfizer Drug	Single Select	
Non-Pfizer Drug	Text	Please enter any non-Pfizer drugs being used in the study arm. Enter 'N/A' if not applicable.
Number of Human Subjects	Number	
For Pre-Clinical Studies:		
Pre-Clinical Type	Single Select: In Vitro, In Vivo, Both In Vitro and InVivo	
For In Vitro:		
Human Tissue Samples	Yes/No	Are human tissue samples being analyzed?
If Yes, Human Tissue Sample Type	Single Select: Blood, Cerebral Spinal Fluid, Tissue, Urine, Other	
For In Vivo:		
Animal Type	Text	
For In Vitro and InVivo:		
Animal Type	Text	
Human Tissue Samples	Yes/No	Are human tissue samples being analyzed?

If Yes, Human Tissue Sample Type	Single Select: Blood, Cerebral Spinal Fluid, Tissue, Urine, Other	

Drug/Compound Questions

If you are requesting Drug from Pfizer the research grant application will include the following:

Drug/Compound Disclosure: Pfizer will strive to provide drug as requested within the grant submission. However, provision of drug for grant requests cannot negatively impact the drug development process or the product needs for ongoing or endorsed internal clinical trials. As such, in some instances, Pfizer may offer to provide alternative drug presentation based on study design.

Field	Field Type	Description/Notes
Number of Pfizer Drugs Requested	Single Select [1-6]	How many Pfizer drugs are you requesting?
Are ALL the Pfizer drugs you are requesting commercially available in the country the study is being conducted?	Yes/No	If you are requesting more than one drug, please only answer yes if **ALL** Pfizer drugs are commercially available in the country the study is being conducted. If even one is not, please answer no.
For each Pfizer Drug Requested:		
Primary Pfizer Drug	Single Select List	
Is this drug commercially available in the country the study is being conducted?	Yes/No	
If Yes, will you be using drug for its labeled indication in this study?	Yes/No	
Strength	Text	Please indicate the dosage strength(s) you plan to use in your study. If you are requesting multiple strengths of the same

		drug, please include all here, separated by a comma (i.e. 10 mg, 20 mg, 30 mg)
Formulation	Text	Please indicate the dosage form(s) you plan to use in your study. If you are requesting multiple formulations of the same drug, please select the number of formulations required as separate drugs under the number of drugs requested dropdown (i.e. Drug A has 2 formulations required for the study, please select "2" from the number of drugs requested dropdown).
Requested Quantity	Text	If you are requesting multiple quantities (due to multiple strengths), please ensure quantities are listed in the same order, separated by a comma, as listed in "strengths" section above (i.e. 200 tablets, 200 tablets, 300 tablets)
Does your study design require a placebo?	Yes/No	Please note Pfizer may not have a developed placebo for the drug you are requesting.
Estimated CTA Submission Date	Date	When do you plan to submit a Clinical Trial Application (CTA) in the primary country?
Vendors Services: Will you be using a vendor for one of these activities?	Single Select List: Yes, No	Pfizer may provide drug in bulk, to be packaged and labeled by the sponsor. In addition, the sponsor may be required to arrange for distribution of the drug to multiple sites, if applicable. Please ensure cost for these activities is included in the study budget

PK/PD Sampling Questions

If the study involves Pharmacokinetic (PK) or Pharmacodynamic (PD) sample analysis the research grant application will include the following:

Pfizer Proprietary Assay: To ensure consistency, accuracy, and precision of PK/PD results across all clinical studies (including ISR trials), PK or PD sample analysis involving Pfizer compounds must be conducted at Pfizer-approved bioanalytical laboratories (CROs) using Pfizer proprietary assays. The Pfizer-approved CROs have developed and validated the assays with oversight by the Pfizer Clinical Assay Group.

Pfizer internal laboratories will not analyze clinical PK samples, and Pfizer will not provide investigator/sponsors (requesters) with Pfizer drug substances for the development of or with the details of any proprietary bioanalytical assays for use at their own facilities.

These requirements do not apply to non-Pfizer compounds (e.g., co-administered drugs, comparator drugs) for which readily available assay methods may exist.

Contracting with the CRO using Pfizer's proprietary assay: The requester will be responsible for contracting the PK/PD sample analysis work with the Pfizer approved contract bioanalytical laboratory and obtaining the data. If Pfizer approves the PK/PD analysis (PK/PD study design and funding) then the Pfizer Clinical Assay Group will issue an authorization letter to the contract bioanalytical laboratory allowing the use of the Pfizer proprietary assay that is study specific. The contract process may then begin between the requester and contract bioanalytical laboratory

Bioanalytical Study Report included: No method details of the proprietary assay will be provided but the contract bioanalytical laboratory will provide a bioanalytical study report containing the concentration data, bioanalytical plan, and assay performance of the batch runs including the statistics of the calibration standards and quality control samples. Please contact Pfizer if any assay information is needed for a publication.

PK/PD Sample Handling Instructions: The Pfizer Clinical Assay Group will provide the sample handling, processing, and storage (e.g., temperature and validated long term stability period) instructions for the PK/PD sample collection to ensure that samples are collected in accordance

with the proprietary assay. If the matrix is plasma then the instructions will include the anticoagulant.

PK/PD Sample Kits/Tube Labels and Shipments: The requester is responsible for ensuring that the appropriate PK/PD sample collection kits (e.g., collection and storage tubes) and tube labels (e.g., Protocol#, Investigator Name, Subject ID, Matrix, Analyte, Nominal Visit/Time Point) are used. In addition, the sample shipment(s) sent to the contract lab is to be scheduled so that the samples are analyzed within the validated stability period for the analyte in matrix. All shipments require that PK/PD samples are shipped on dry ice (unless it is a special case), so for international shipments please use a shipping courier that will monitor the samples and replenish the dry ice.

Field	Field Type	Description/Notes
PK/PD Sampling: Does your study involve Pharmacokinetic (PK) or Pharmacodynamic (PD) sample analysis?	Yes/No	
If Yes,		
PK/PD Agreement	Certification	You must agree to the terms above in order to request PK/PD Analyte Samples.
Number of Analytes	Single Select, number value	How many Analytes are involved?
For Each Analyte:		
PK/PD Analyte (parent, metabolites)	Text	Name of Analyte(s) to analyze in PK/PD samples.
Type of Matrix Collected	Text	Enter type of matrix to be collected for the PK/PD sample analysis. If the matrix is plasma then please use the anticoagulant specified in the validation. *(e.g., human plasma, serum, urine or tissue)*
Number of PK/PD Subjects	Number	Enter the estimated number of subjects participating in PK/PD part of study.

Nominal PK/PD Collection Visits/Time Points	Text	List nominal visits (Cycle1 Day1) and time points (0 H Pre-dose, 24 H Post-dose).
Number of PK/PD Samples to be Analyzed	Text	Enter total number of samples to analyze for the analyte (parent and metabolites).
Co-Administered Drugs	Text	List co-administered drugs, if any. If this is not applicable enter N/A in this field.

Vaccine Specific Questions

If the study is related to vaccines, the research grant application will include the following question:

Field	Field Type	Description/Notes
Does this study collect specimens for shipment to Pfizer Laboratories for assay testing?	Yes/No	
Assay(s) Requested	Multi-select; UAD 1, UAD 2, OPA, IgG	Please note that Pfizer will only consider requests for assay testing with one of the assay tests listed in the drop down.

Planned Results

Field	Field Type	Description/Notes
Target Date to Provide Results to Pfizer	Date	
Publishing Results?	Yes/No	
If Yes,		
Result Type	Multi-Select: Abstract, Final Report, Manuscript, Poster	
Date of First Anticipated Publication	Date	
Planned Results Notes	Text	
If No,		

If you have any questions about any information in this document, please contact GMG@pfizer.com.

Reason for Not Publishing	Text	Provide details as to why the results will not be published.

Section 6: Budget Details

For those studies requesting funding the research grant application requires details regarding the project budget.

Field	Field Type	Description/Notes
Request Amount Currency Code	Single Select list of Currency Codes	Local Currency Code for request amount (Must be completed first before filling in remainder of page)
Capital Expenses	Confirmation: I confirm that my budget does not contain any requests for funds to purchase capital equipment	Pfizer does not provide funding via independent medical grants to purchase capital equipment. Examples of capital equipment include, but are not limited to: Computers, iPhones, tablets, appliances, machinery, camera equipment, sensors etc. Equipment rental is acceptable and may be included in project budget.
Invoices	Confirmation: I Agree	Pfizer does not directly pay invoices for independent medical grants. Please ensure costs for any study related invoices (i.e. IRB/EC fees) which are to be paid by institution, are included in the project budget
In-house Services	Yes/No	Do you plan on using in-house services (in lieu of, or in addition to, third party vendors) to assist in the execution of this project/activity? For example, graphics, marketing materials, audio/visual, etc. If your request is approved and you have answered yes to this question you must provide copies of all internal invoices/charges at the time of completing the reconciliation.

The next section of the Budget Details asks for budget line items related to the amount you are requesting from Pfizer.

Direct Labor Costs

Which role(s) are you requesting funds from Pfizer? (At least 1 role should be selected) If no salary is being requested, please select one role and include $0 for salary.

- Primary Investigator
- Sub PI
- Coordinator
- Study Nurse
- Data Manager/Entry
- Medical Writer
- Statistician
- Pharmacist
- Administrative
- Project Manager
- Lab Technician
- Regulatory
- Post Doc
- Fellow
- Patient/Caregiver Consultant
- Other

For each of the roles selected you will be asked to enter the following information?

Field	Field Type	Description/Notes
Salary per Hour	Number	This number will be used to calculate the estimated annual salary
Primary Investigator - Salary per Year	AUTO CALCULATION	This field is calculated based on the previous field
Percent of Effort per Year (Number Only)	Number	
Total Months on Project	Number	

If you have any questions about any information in this document, please contact GMG@pfizer.com.

Total Salary	AUTO CALCULATION	This field is calculated on the previous fields

Direct Study/Project Costs

Field	Field Type	Description/Notes
Monitoring	Number	
One-time fees	Number	
Participant reimbursement	Number	
Procedures/Test/Assessments/Labs	Number	
Publication Costs	Number	
Statistics/ Biostatistics	Number	
Study Start-up Costs	Number	
Supplies/Consumables	Number	
Travel	Number	
Other Fees	Number	

Other Details

Field	Field Type	Description/Notes
Describe Other Fees	Text (paragraph)	If an amount is entered in the "Other Fees" section above you must enter a description as to how that funding will be utilized.
Institutional Overhead Percentage	Number	*Pfizer maintains a maximum allowed overhead rate of 28% for independent grant projects. Please click here for details.* Enter the % of overhead costs being charged to the grant, if applicable. Enter the number only; do not include the % symbol.
Institutional Overhead Subtotal	AUTO CALCULATION	This is a system calculated field based on values entered.
Total Amount Calculated	AUTO CALCULATION	This is a system calculated field based on values entered. This Total should match the Requested Amount from Pfizer.

If you have any questions about any information in this document, please contact GMG@pfizer.com.

Requested Amount from Pfizer	Number	Enter the amount requested in your local currency. Enter numbers only; do not include currency symbols. This Total should match the Total Amount requested from Pfizer (calculated) above.
Total Budget for the Study/Project	Number	This is your total budget for the entire Study/Project and may be greater than the amount requested from Pfizer.
*Other Sources of Support?	Yes/No	Will support (e.g. funding, drug, lab testing) be requested from sources other than Pfizer?
If yes, Specify Other Sources		*Specify this support and the source.*
Budget Narrative	Text (paragraph)	Please include any applicable information that may help clarify any concerns based on numbers entered.
For Organizations based in the United States, W-9 Form.		Please upload a completed W-9 Form that matches the Organization Name where payment will be made. For example, if you would like the payment to be made to an affiliated Foundation (with a separate Tax ID), the W-9 Form must match the Foundation's organization name, address and Tax ID. A blank W-9 Form can be downloaded from the IRS website. **Please note the W-9 Form MUST be version "Rev. November 2018" or later.**

Section 7: Payee Information

Please select the **EDIT** button on this screen to view/edit the remittance address. If approved, this is where the funding will be mailed if paid via check.

Payments can be made to an AFFILIATED foundation (not-for-profit organization). Under no circumstances will Pfizer make payments to Partners/Collaborators; only to the requesting organization or an affiliated foundation.

Payments will not be sent to P.O. Boxes.

Field	Field Type	Description/Notes
Payment to Affiliated Foundation?	Yes/No	If your request is approved, would you like the payment to be made to an affiliated Foundation (separate entity with a different tax ID)?
*Payee Name1		If you have any issues with the Name listed here please contact GlobalMedicalGrants@pfizer.com. This must remain the name of the Requesting Organization.
*Payee Country		
*Payee Address1	Text	Checks will not be sent to P.O. boxes.
Payee Address2	Text	
*City	Text	
Province	Text	
Zip/Postal Code	Text/Number	

Section 8: Certifications

Requesters will be asked to agree to the following Compliance Certification:

Please read the following certification carefully. You must certify the following before you can submit your request to Pfizer for consideration. Please certify your agreement by clicking "I agree".

You certify that you are an active employee of the requesting organization, with the responsibility and authorization to apply for financial support from Pfizer.

If you have any questions about any information in this document, please contact GMG@pfizer.com.

You certify that you have no knowledge that Pfizer has had involvement in the creation or development of this project.

You certify that, if approved, the source of all support from commercial interests must be disclosed in all publications and presentations. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

You certify that, if approved, you will provide Interim Reports every six months throughout the lifecycle of the project, as well as a Final Report at the conclusion of your project. You also agree to provide monthly patient enrollment reports for clinical studies involving human subjects.

You certify that, if approved, in the performance of all activities related to an independent medical grant, you and all participants must comply with all applicable Global Trade Control Laws. “Global Trade Control Laws” include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

You certify that, if approved, the grant has not been and will not be conditioned on or related, in any way, to: (a) any pre-existing or future business relationship with Pfizer; or (b) any business or other decision made or may be made, relating to Pfizer or its products (including coverage or formulary status decisions).

Further you certify that you are authorized to submit an application and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate and complete. Your certification also represents that neither you nor your organization's directors, trustees, and/or anyone who will be involved in the project(s) that will be funded by this grant are on the OIG debarment list.

Please note, if the request is approved you will be required to sign a contract which includes additional terms and conditions as they relate to the execution of the request.

For all ISR studies using a Pfizer Product and/or Device:

For Investigator Sponsored Research (ISR) studies where the product under study is sourced directly by Pfizer or obtained from supplies on the market and used as per standard of care: the Grant Seeker is required to submit AE/SAEs to Pfizer.

Reporting Timeline: Pfizer requires the Grant Seeker to notify Pfizer within 24 hours of first awareness or secure email exchange any Adverse Event (AE) [serious and non-serious, as applicable] that occurs during the reporting period in a study subject assigned to receive the Pfizer product. In addition, studies

using a Pfizer device or Pfizer product packaged with a device, reportable events include not only AEs but also Device Incidents Malfunctions.

Reporting Forms: Principal investigator will report qualified adverse events using the applicable Pfizer ISR/CRC Adverse Event Report Form or approved local regulatory form (i.e. FDA MEDWATCH, CIOMS, etc.) with the AE/SAE Fax Cover Sheet provided by Pfizer. Grant Seeker may use the institution AE report form provided it is preapproved by Pfizer Safety Leads. SAEs/AEs should be reported as soon as they are determined to meet the definition, even if complete information is not yet available.

Reporting Period: Reportable Events subject to this provision are those that occur from after the first dose of the Pfizer product through at least 28 calendar days after discontinuation of the Pfizer product or longer as specified by the protocol. In addition, any AE/SAEs which occur after active reporting period and are considered related to study drug(s) by investigator should be reported to Pfizer.

Follow-up Information: Institution and/or Grant Seeker will assist Pfizer in investigating any SAE/AE and will provide any follow-up information requested by Pfizer.

Regulatory Reporting: Reporting a SAE/AE 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.

Final protocol: Safety language in the Final Protocol developed by the Grant seeker should always be cross-checked, by the Grant seeker/study team, with the safety language written in contract to make sure these two documents are aligned.

Special consideration for Multiple-site studies: For multi-site studies, lead institutions often use one single point of contact or data coordinating center. This process may be acceptable by Pfizer provided the following terms are met and will be described in the contract with the sponsor:

a. Study must be multi-national.
b. All investigators from each site must report to a single, well established data coordinating center.
c. Pfizer must only receive AE/SAEs from this single and well-established data coordinating center.
d. In such scenario, Pfizer receipt date is the date on which the information is provided to the data coordinating center. Given such, the data coordinating center must document its receipt date on the approved adverse event report form.
e. This single data coordinating center must be responsible for independently initiating and performing all follow-up activities with each individual investigator for missing and/or incomplete medical information for every AE/SAE.
f. Single data coordinating center must agree to accept Pfizer queries/request for additional information about the AE/SAEs and follow up with the investigator until resolution.
g. SAE information provided to Pfizer must not contain any Privacy information.
h. Everything must be exchanged in English.

If you have any questions about any information in this document, please contact GMG@pfizer.com.

Principal Investigator agrees to the Pfizer Policy terms listed above, and downloaded the relevant documents from within the application.