

AGA-Pfizer JAK-IBD Research Grant: Submission Instructions

*To be considered for this grant you must submit your application directly to AGA (www.gastro.org/pfizerJAK) AND to the Pfizer application portal (<https://iirsubmission.pfizer.com>). **Both applications must be completed and submitted no later than 11:59 p.m. on June 6, 2014 (USA Eastern time).** The instructions herein pertain to the Pfizer portal (INSPIIRE) and will facilitate this dual application.*

Complete the AGA-Pfizer Application form (on [AGA's website](#)) first as some of this information can be "cut & pasted" into the INSPIIRE portal. The AGA-Pfizer Application and required documentation (e.g., bio sketch) must be combined into one PDF file, titled by the applicant's last name and first initial and emailed no later than June 6, 2014 to awards@gastro.org.

The following instructions will walk you through the [INSPIIRE portal](#). When you enter the Pfizer portal you will see a great deal of information related to standard Investigator Initiated Research (IIR) Submissions, some of which will not be applicable to this grant. The application form you submit to AGA is the most critical piece of information and will be used to evaluate your proposal. Data fields completed on the INSPIIRE portal may use a "best fit" approach; cutting & pasting from the AGA-Pfizer Application Form to INSPIIRE is acceptable.

Note: In completing this application, it is anticipated that most proposed studies will meet the definition of "preclinical studies."

If you have issues using Explorer with the INSPIIRE site, please try a different browser (Firefox or Chrome).

Disregard the statement concerning "Contact a Pfizer Medical Representative prior to Submission."

GETTING STARTED

Create Account with all relevant details. Once created, click **CREATE NEW PROPOSAL**.

Under New Users, click Create Account.

Select "I Agree" on the Privacy Statement page.

Create a New Account.

INITIATE SUBMISSION

Review and accept Pfizer's Policy on Submission of an Investigator Initiated Research proposal and Financial Disclosure.

Select Request Type: Investigator Initiated Research (IIR) program.

Click **Initiate Submission**.

GENERAL INFORMATION

Are you applying to a Competitive Grant Program? YES

Please select from the active programs in the dropdown: 2014 AGA-Pfizer JAK-IBD Research Grant

External Identification Number (optional): Add any institutional assigned number.

Study title: [insert]

Primary Pfizer Therapeutic Area: Select *Inflammation* from the drop down menu.

Secondary Pfizer Therapeutic Area: only if applicable.

Study Type: **Clinical**: includes retrospective, outcomes research, epidemiology. **NOTE**: interventional studies with Pfizer products are out of scope for this program. **Pre-Clinical**: e.g., animal studies, in vivo, in vitro, anything described as non-clinical.

Grant Request Type: Funding (Drug trial proposals are not in scope for this program)

Research Setting: Single-site or Multi-site

Additional fields will appear based on your selection, e.g., number of sites, other countries and the Coordinating Organization Type.

Country of Primary Site: Enter from drop down list

Click SAVE and CONTINUE on BOTTOM RIGHT

FUNDING REQUEST SECTION

Funding Local Currency: enter USD

Breakdown of study costs:

Total direct, indirect and overhead costs cannot exceed \$200,000.

Direct Labor Costs Subtotal: PI salary, other staff salary

Direct Study Costs Subtotal: supplies, animal costs, software, etc.

Note: capital equipment purchase cannot be funded by this grant.

Institutional Overhead Subtotal: the % rate your institution requires to be added to grants

Institutional Overhead %: Will be automatically calculated based on costs entered above.

Indirect Costs Subtotal (e.g., IRB fee, travel, publication, misc. pass through costs):

Total study costs: Will be automatically calculated based on costs entered above.

Upload budget document:

Note: Because Pfizer will pay your institution directly, the budget section has been eliminated from the AGA application form. You will need to develop your own budget document to upload. If you require supplemental funding above and beyond this grant, that will need to be obtained from other sources.

Requesting support from any other source? Enter Yes or No

Using any non-Pfizer drug in the study? Enter Yes or No

SAVE and CONTINUE

STUDY INFORMATION

Note: Below is a list of potential fields in this section. Only applicable fields will be visible based on entries in the General Section. This is a dynamic form and additional fields may appear as applicable based on previous answers in this section. You may cut and paste information from your AGA PDF application file.

General Information

Study Synopsis (from AGA app form sec. 3):

Study Rationale (from AGA app form sec 3):

Type of Clinical/pre-clinical: Select clinical or preclinical from dropdown

Are human tissue samples used: select Yes or No

Is Pfizer drug used in the study: Yes or No (This should generally be No.)

Primary Endpoints (from AGA app form section 7):

PK: Yes or No

Target Enrollment:

Optional: Gender, Age, Ethnicity

UPLOAD PROPOSAL: (Upload the AGA PDF application file)

SAVE and CONTINUE

RESEARCH TIMING AND DELIVERABLES

Target study start date: enter October 2014

Study duration: 24 months (2 yrs)

Study completion date: (this is automatically calculated based on entries above)

Target dates to provide 1-year and final scientific progress reports to AGA and Pfizer. (Estimated timelines are acceptable.)

Plan to publish: Yes (Submission to *Gastroenterology* is strongly encouraged.)

Upload any supporting documents (letter of recommendation, collaborator CV, as applicable.)

Note: Applicants may disregard this request. Any required supporting documents should be included in the AGA PDF application file.

SAVE and CONTINUE

LEGAL, REGULATORY, SAFETY INFORMATION

Answer as appropriate

SAVE and CONTINUE

PI/SITE INFORMATION

Some items will auto-populate based on information provided during your account set-up. All other fields can be populated with "TBD" for ease of submission. All fields are required, even if not marked with a red *. All fields accept "TBD" except where an email is requested; you can enter *tbd@tbd.com* in that field.

Enter Primary Investigator Information

Primary Investigator Mailing Address

Primary Investigator's Organization

Primary Investigator's Contact for Safety Reports:

This is usually the PI or a study coordinator.

Primary Site Contracting Organization: The office to where the check will be sent.

Contracting Organization Contact: Contact in your institution's grants office.

SAVE and CONTINUE

Summary page will appear which you can save for your records.

Once you are ready, be sure to click **SUBMIT** (not save). You will immediately receive a system generated email confirming success. If you do not receive this email, your submission is likely still in draft. Log back in and click SUBMIT. This application must be submitted by June 6, 2014.

Questions about the INSPIRE portal should be directed to: IIR@Pfizer.com