Online Collaborator Solicitation for BrIDGs Program

From PCDEMO site, 4-17-2012

Title Page

Form Approved
OMB NO. 0925-XXXX
Exp. Date XX/XX/2015

BrIDGs **proposalCENTRAL**

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Pilon, Andre

Proposal To: NIH - BrIDGs *NIH - BrIDGS Program*
Title (Applicant): ***Test application to BrIDGs program (AMP)*** **(Pilon, Andre)**

Deadline: **5/30/2012 5:00:00 PM (U.S. Eastern Time)**

Proposal Sections
Click name below to go to that section.

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5) Institution & Contacts
6) Key Personnel
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8) Abstract
9) Proposal Narrative and Other Attachments
10) Validate
11) Print for Personal Use - No signatures required
12) Submit

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Proposal Identifiers
Proposal ID: 66752

Title Page

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Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

This is not a grant application rather this is an opportunity to collaborate with the BrIDGS Program. Instructions

Enter a title for your application, then press Save.
Press Next to save any changes and go to the next proposal section.

* **Project Title**	Test application to BrIDGs program (AMP)
* **Affiliation**	Government Agency
* **Is this a resubmission**	No
* **Application Type**	Biologic
* **How did you hear about BrIDGs?**	Other
If you selected Conference or Other, please describe	Colleague is a current BrIDGs collaborator
* **Mechanism of Action**	N/A
* **Therapeutic Area**	Other

Download Templates and Instructions

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Download	Template Type	Description	File Type	File Size
Download	Proposal	Proposal	.DOCX	53276
Download	Instructions for Required Documents	Instructions for Required Documents	.DOC	72192

Many of the grantmakers in proposalCENTRAL request or require that applicants submit their attachments as portable document format (.pdf). Using PDFs allows you to preserve the formatting of your document. In order to save your documents as PDFs, you will need to use PDF generator software. The National Endowment for Humanities website (neh.gov) provides a sampling of PDF generators, available for both PCs and Macs, along with websites that will do the conversion for you. Many are free or very low-cost. Click here for a list of PDF generators.

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Hints & Tips for Access Permissions: Click to Show/Hide

This screen allows you to give other users access to your grant application. When you give a person access to your grant application, you can give them one of three levels of permissions. These include:

- View (View only. Cannot change any details.)
- Edit (Can view and change information in the grant application. Cannot Submit or view this Access Permission screen)
- Administrator (Can view, edit and submit the application. Can give access rights to others.)

Steps to Give Another Person Access to Your Grant Application:

1. Make sure each person is registered. To grant access to another person, that person must be registered as a "user" in the proposalCENTRAL system. If they are not registered, direct them to register the same way that you did. They do not need to completely fill out their Professional Profile - only the required fields of first and last name.
2. Enter the "userid" of the person you wish to give access to in the "User ID/E-Mail" field of the "Proposal Access User Selector" section at the bottom of the screen then click the "Find User" button. The person will now be added to the list at the top of the page of users who have access to your application. The default access permission is "View."
3. Finally, select the permissions level for the person you have just added - View, Edit, or Administrator - then click the "Accept Changes" button.

Note: This process only gives access to your application, access to your Professional Profile must be done separately from within the Professional Profile.

Note: The check boxes for **"Approval Section"** and **"References"** in the **Proposal Access Rights** section below have **no effect** on the permissions granted to other users at this time.

Auto Notify: To enable your co-investigators, department or grants administrators to receive system notifications, add them with at least "View" access below and check the box "Auto Notify".

Proposal Access Rights

Del	Auto Notify	Role	Name	E-Mail	Permissions
			Pilon, Andre	pilona@mail.nih.gov	Administrator

Accept Changes

Proposal Access User Selector

User Selector **User ID/E-Mail** Enter the E-Mail address or User ID of the User and press the button to select.

Find User

Applicant/PI

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Applicant/PI

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Person who initially creates the proposal is pre-loaded as the PI. Contact information from PI's profile is shown below. To update profile, click Edit Profile. To change PI, select from list and click button to confirm selection. Instructions

Principal Investigator Pilon, Andre - National Institutes of Health

Edit Professional Profile

Name: **Prefix** ____ * **First** Andre **Middle** ____ * **Last** Pilon

* **Institution** National Institutes of Health

Address: **MailStop**

* **Street** 9000 Rockville Pike

* **City** Bethesda **State/Province** MD * **Zip/Postal Code** 20892

* **E-Mail** pilona@mail.nih.gov * **Country** United States

Phone: * **Work:** 301-827-2746 **Fax:** ____

Applicant/PI

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Institution and Contacts

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Institution & Contacts

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PI's institution is pre-loaded as Lead Institution. To change, select from list below or Search all registered institutions. Instructions
Press button to confirm selection. Click Edit Profile button to change institution information.

Lead Institution
No Institution Available

Click this button to Change the Lead Institution: Change Institution

Note: Changing institution will delete currently displayed contacts.

Address

* **Street**	6707 Democracy Blvd Suite 104
* **City**	Bethesda
State/Province	MD
* **Zip/Postal Code**	20817
* **Country**	United States

If required institution information is missing or appears to be incorrect, please contact the following Administrator(s) of this Profile. The Administrator will make the necessary updates to the Profile.

Administrator	Email	Phone
Miller, Brad	bradmiller123@example.com	703-964-5863

* **Organization Type** Please select:

Key Personnel

BrIDGs **proposalCENTRAL**

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Key Personnel

Print <<Previous Next>> Cancel Exit

Provide contact information for key personnel, other than the applicant, in the table below.

Role	Name	Title	Institution	Email	Phone	Effort	Action
No Personnel Currently Identified							

INSTRUCTIONS:
To add a new contact to the table above, enter the e-mail address of the person you wish to add. Click 'Add'. Complete the contact form. (Note: If the person is already registered in proposalCENTRAL, some information will be pre-loaded into the contact form). To edit the person's contact information, click, 'Edit' (in the far right Action column). To delete a person from the table, click 'Del'. (Note: Changes that you make to the person's contact information will be for this proposal only. Permanent changes must be made in the person's Professional Profile).

Enter email address	David.Coinvestigator@mail.nih.go
Confirm email address	David.Coinvestigator@mail.nih.go

Add

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Project Information

BrIDGs

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Biology/Efficacy:

* **Select the button that describes the stage of your project:**

- ○ Identified target(s), likely pharmacological endpoints & functional assays;defined mechanism of action (MOA) of lead compunds;projected the human efficiacy dosage and dosing regimen;developed PK/PD relationship
- ◉ Demonstrated in-vivo pharmaocology in a key animal model (not necessarily by the route of administration)
- ○ Not yet demonstrated in-vivo pharmacology OR in vivo model not yet available or validated
- ○ Not Sure

Medicinal Chemistry:

* **Select the button that describes your project stage:**

- ○ SAR trends exemplified;no significant physiochemical property concerns
- ◉ SAR trends have been identified. Modest challenges still exist,including pharmacologic potency-SAR trends are developing
- ○ SAR trends are unclear OR chemistry comlexity interferes with the teams's ability to advance the SAR OR multiple active platforms remain to be prioritized
- ○ Not Sure

Drug Metabolism and Pharmacokinetics (DMPK) Characterization:

In vivo pharmacokinetic studies and/or in vitro ADME assays (e.g.,solubility, permeability, metabolic stability) of lead compounds in thie proposal show they have the following DMPK characteristics (select one):

* **Select the button that describes your project:**

- ◉ High quality DMPK characteristics, thus leads need minimal structure modification

Project Information (cont'd)

Unassigned

CLint < 0.5 HBF, 1 h < PK t1/2 < 8 h, or 50% < %F < 80%)

- ○ Poor DMPK characteristics, thus leads need major structure modification (e.g., solubility < 10 µg/mL, CLint > 0.5 hepatic blood flow (HBF), PK t1/2 < 1 h, or %F < 20%)
- ○ Unknown DMPK characteristics,because few studies have been performed

Toxicology

*** Select the button that describes your project:**

- ○ Chronic toxicology in two species completed successfully; finished safety pharmacology, mutagenecity, and sub-chronic tox studies
- ○ Conducted acute toxicological studies in rodents; no data generated to date to cause concern
- ○ Literature or experience with this platform indicate that toxicology may be an issue (for peptides, immunogenicity issues have been identified with the lead molecule) OR for pre-lead efforts - in silico & appropriate Tox due diligence not yet complete
- ○ Not Sure

Chemistry, Manufacturing and Controls (CMC)

Select the button that describes the stage of your project most accurately:

- ○ API scale up – no purification issues, all reactions are scalable; Formulation – identified formulation of lead compounds for animal testing and FIH testing; Bioanalytical methods – developed and validated bioanalytical methods
- ○ Have preliminary characterization of API, purity, stability, solvents, for NBE's: chemical composition, glycosylation patterns, payload/protein scaffold ratio, etc.
- ○ Have preliminary formulation and bioanalytical methods for animal studies
- ○ Have not initiated any work on CMC for the lead compounds

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Abstract

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Abstract

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Please provide a general audience summary below. 4,000 characters max, including spaces. Instructions
Text only. No special characters or formatting. See instructions for details.

* General abstract and description of the project should be entered here.

Select the BrIDGs resources that apply. You must select at least 1. If resources required are not listed, please list them in the BrIDGs Proposal document. Instructions

***BrIDGS Resources**

Development of analytical methods
Development of suitable formulations
Pharmacokinetic/ADME studies including bioanalytical method development
Product development planning and advice in IND preparation
Range-finding intial toxicology
Synthesis

>> Add

Selected Categories

Del IND-directed toxicology
Del Manufacture of clinical trial supplies
Del Scale-up production

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Download all templates and instructions files located at the bottom portion of this page. Once you have completed each template, click the Browse button in the section directly below, and select the file to attach.

Please note that BrIDGS does not require signatures OR a signature page for submission, this option is for your own optional use only.

Describe Attachment: AMP Proposal (Please provide a meaningful description no longer than 250 characters)

* **Select Appropriate Attachment Type:** Proposal

Allowable File Type: .PDF

* **Select File From Your Computer to attach:** Browse...

Upload Attachment

Current list of uploaded attachments are listed in the table below:
(Files with a red highlight cannot be assembled for printing)

Att. Type	Desc.	Ext.	Size	Date	Del	Show
No attachments currently uploaded.						

Required attachments that have not been uploaded are listed in the table below. Optional attachments that have not been uploaded are not shown.

Allowable File Types	Att. Type	Max.File Size in KB
.PDF	Application	10000

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Validate Proposal

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Click the 'Validate' button below to check for any missing REQUIRED information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the next step.

Validate

Print – (not required for BrIDGs)

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After you complete all the proposal sections, click one of the Print buttons below to open and print the cover/signature pages and application files. ***Before printing, please use the "Validate" option (in the gray navigation menu to the left) to verify that you have entered all the required information.***

Print Signature Pages

Click this button to print just the signature pages. Clicking the print button will open the cover/signature pages in PDF format. Data that you entered in the other sections of the proposal are automatically included in the cover/signature pages. If information is missing in the cover/signature pages, it could be because you have not entered the information in one of the proposal sections OR the information is not required for this grant program.

Print Signature Pages and Attached PDF Files

Click this button to print the signature pages plus attached PDF files. (Excludes non-PDF files). Follow the program guidelines for any additional requirements for printing and submitting any other proposal information in the hard-copy submission.

You must have the FREE Adobe Acrobat Reader installed to view either of the above options.
Attention Apple/Mac users: The default Apple PDF viewer will not work properly.
Download the latest version of the Acrobat Reader from Adobe at http://www.adobe.com/products/acrobat/readermain.html

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Submit

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Login and click the 'Submitted' tab under 'Manage Proposals'. Your application should be listed with the status of 'Submitted' along with the date and time of the submission.