

COVER SHEET NOTICE

The following screen shots of the “Online Collaborator Solicitation” are specific to the TRND program data collection through the Proposal CENTRAL system, hosted by Altum, Inc.

After approval of the TRND program forms, NCTT will develop a very similar Proposal CENTRAL data collection form for the BrIDGs program.

This BrIDGs collection form has not yet been developed, but will be very similar in length and information content to the forms contained in the following TRND program screen shots.

Online Collaborator Solicitation

From PCDEMO site, 2-14-2012

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Pilon, Andre

Proposal To: NIH - Therapeutics for Rare and Neglected Diseases *NIH - Therapeutics for Rare and Neglected Diseases***Proposal Sections**Click name below to
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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 TRND 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

* Affiliation

* Is this a
resubmission

* Application
Type

* Phase

* Disease indications Select Rare or Neglected from the drop-down list. If both,
select "Rare and Neglected".

* How did you hear about TRND?

If you selected Conference or Other, please describe

* Mechanism of Action

Download Templates and Instructions



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Frosst, Phyllis

Proposal To: NIH - Therapeutics for Rare and Neglected Diseases *NIH - Therapeutics for Rare and Neglected Diseases*
Title (Applicant): **TESTING NEW VERSION (Hemmig, Randy)**

Deadline: **5/30/2011 5:00:00 PM (U.S. Eastern Time)**

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Download	Instructions for Required Documents	Instructions for Required Documents	.DOC	72192
Download	Proposal	Proposal	.DOCX	53276

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
Del	☐		Hemmig, Randy	grantcreator@yahoo.com	Administrator ▼
Del	☐		Yang, Nora	na.yang@nih.gov	Administrator ▼
Del	☐		Frosst, Phyllis	frosstp@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

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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

You are not permitted to edit this profile.

Name: Prefix Mr * First Randy Middle ____ * Last Hemmig

* Institution RAMS Research Company

Address: MailStop 230A

* Street 20410 Century Boulevard

* City Germantown

State/Province MD * Zip/Postal Code 20874

* E-Mail grantcreator@yahoo.com

* Country United States

Phone: * Work: 301 555 1212 Fax: 301 555 1214

Applicant/PI

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Institution and 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. **Press button to confirm selection.** Click Edit Profile button to change institution information.

Instructions

Lead Institution

RAMS Research Company

Click this button to Change the Lead Institution:

Note: Changing institution will delete currently displayed contacts.

Address

* **Street** 20410 Century Boulevard
Suite 230A
* **City** Germantown
* **State/Province** MD
* **Zip/Postal Code** 20874
* **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
Kelly, Nathaniel	nathaniel.kelly@altum.com	1234

* **Organization Type**

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Key Personnel



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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). NCI WILL PROVIDE MORE TEXT

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Frosst, Phyllis

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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 compounds; projected the human efficacy dosage and dosing regimen; developed PK/PD relationship
- ☐ Demonstrated in-vivo pharmacology 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 complexity interferes with the team'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 this 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 (e.g., solubility > 60 µg/mL, CL_{int} < 0.25 HBF, PK t_{1/2} > 8 h or %F > 80%)
- ☐ Moderate DMPK characteristics, thus leads need some structure modification (e.g., 10 µg/mL < solubility < 60 µg/mL, 0.25 HBF < CL_{int} < 0.5 HBF, 1 h < PK t_{1/2} < 8 h, or 50% < %F < 80%)
- ☐ Poor DMPK characteristics, thus leads need major structure modification (e.g., solubility < 10 µg/mL, CL_{int} > 0.5 hepatic blood flow (HBF), PK t_{1/2} < 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

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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 this 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
(e.g., solubility > 60 µg/mL, CL_{int} < 0.25 HBF, PK t_{1/2} > 8 h or %F > 80%)
- ☐ Moderate DMPK characteristics, thus leads need some structure modification
(e.g., 10 µg/mL < solubility < 60 µg/mL, 0.25 HBF < CL_{int} < 0.5 HBF, 1 h < PK t_{1/2} < 8 h, or 50% < %F < 80%)
- ☐ Poor DMPK characteristics, thus leads need major structure modification
(e.g., solubility < 10 µg/mL, CL_{int} > 0.5 hepatic blood flow (HBF), PK t_{1/2} < 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, mutagenicity, 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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Frost, Phyllis

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

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*

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

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*TRND Resources

- 01 For small molecules: secondary assay development
- 02 For small molecules: Medicinal chemistry/SAR
- 03 For small molecules: Compound synthesis/ lab scale
- 04 For biologics: Produce biologic/lab scale
- 05 Compound/biologic profiling (ADMET/potency/ selectivity/ PK/PD & stability)
- 06 Evaluate mechanism of action
- 07 Evaluate imaging in vitro
- 08 Evaluate functional activity in vitro
- 09 In vivo efficacy or imaging studies
- 10 Develop/validate biomarker assays
- 11 Evaluate synthesis & formulation
- 12 Evaluate safety issues

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Proposal Narrative and other Attachments



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

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

* Select Appropriate Attachment Type:

Allowable File Type:

* Select File From Your Computer to attach: [Browse...](#)

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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.

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