Online Collaborator Solicitation - TRND

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Title Page

Form Approved
OMB NO. 0925-0658
Exp. Date 06/30/2015

TRND **proposalCENTRAL**

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Pilon, Andre

Proposal To: NIH - Therapeutics for Rare and Neglected Diseases *NIH - Therapeutics for Rare and Neglected Diseases*
Title (Applicant): ***AMP-086 for the treatment of Pompe Disease (TEST SUBMISSION)*** **(Pilon, Andre)**

Deadline: 9/30/2013 5:00:00 PM (U.S. Eastern Time)

Proposal Sections
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5) Institution & Contacts
6) Key Personnel
7) Project Information Category
8) Abstract
9) Proposal Narrative and Other Attachments
10) Validate
11) Print- NO SIGNATURE PAGES REQUIRED FOR TRND

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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. The current OMB number is 0925-0658. The expiration date is: 06/30/2015. 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 (0925-0658). 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**	AMP-086 for the treatment of Pompe Disease (TEST SUBMISSION)
* **Affiliation**	Government Agency
* **Is this a resubmission**	No
* **Application Type**	Please select
* **Phase**	Please select
* **Disease indications**	Please select — Select Rare or Neglected from the drop-down list. If both, select "Rare and Neglected".
* **How did you hear about TRND?**	Please select
If you selected Conference or Other, please describe	
* **Mechanism of Action**	AMP-086 inhibits enzyme X

Download Templates and Instructions

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Download	Template Type	Description	File Type	File Size
Download	Instructions for Required Documents	Instructions for Required Documents	.PDF	244283
Download	Proposal	Proposal	.DOCX	62979

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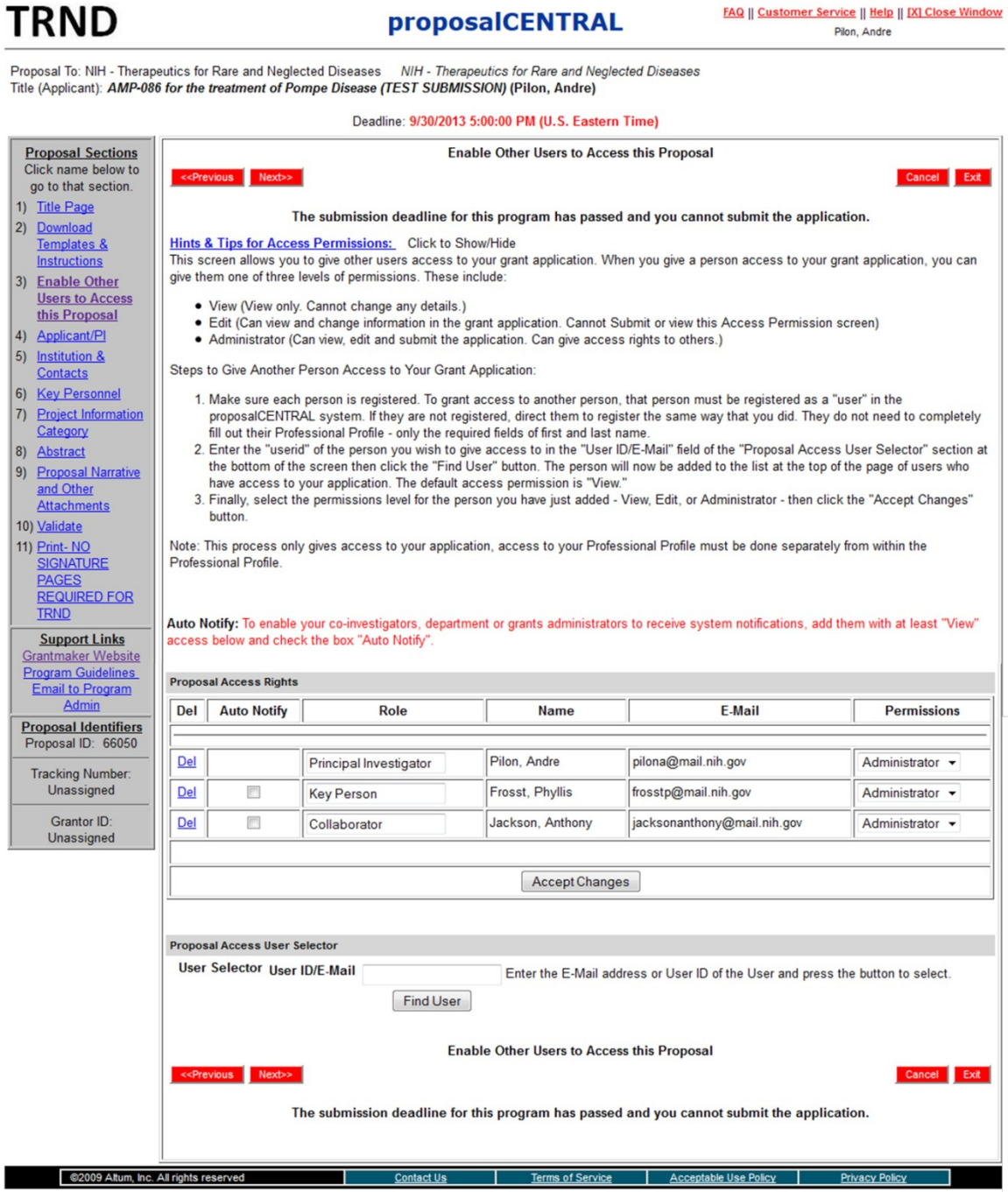

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Proposal Identifiers
Proposal ID: 66050

Tracking Number: Unassigned

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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.

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		Principal Investigator	Pilon, Andre	pilona@mail.nih.gov	Administrator
Del	☐	Key Person	Frosst, Phyllis	frosstp@mail.nih.gov	Administrator
Del	☐	Collaborator	Jackson, Anthony	jacksonanthony@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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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:** 301-827-2534

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. Press button to confirm selection. Click Edit Profile button to change institution information. Instructions

Lead Institution
National Institutes of Health

Click this button to Change the Lead Institution: Change Institution

Note: Changing institution will delete currently displayed contacts.

Address

* **Street**	9000 Rockville Pike
* **City**	Bethesda
State/Province	MD
* **Zip/Postal Code**	20892
* **Country**	United States

If required institution information is missing or appears to be incorrect, please contact the following individual(s). They have access to the institution profile and can make the necessary updates.

Contact	Email	Phone
Piringer, Patricia	ppiringer@nih.gov	301-402-2435

---

* **Organization Type** Please select

Institution & Contacts

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Key Personnel

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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
Key Person	Frosst, Phyllis	Director of Awesomeness	National Institutes of Health	frosstp@mail.nih.gov	301-555-1212		Edit Del
Key Person	Mockname, James	Vice-President of Research	Pfenix Pharmaceuticals	mockname@domain.com	301-555-6869		Edit Del

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

Enter email address	
Confirm email address	

Add

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Project Information – 1

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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:

Project Information – 2(cont.)

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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 (e.g., solubility > 60 µg/mL, CLint < 0.25 HBF, PK t1/2 > 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 < 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:**

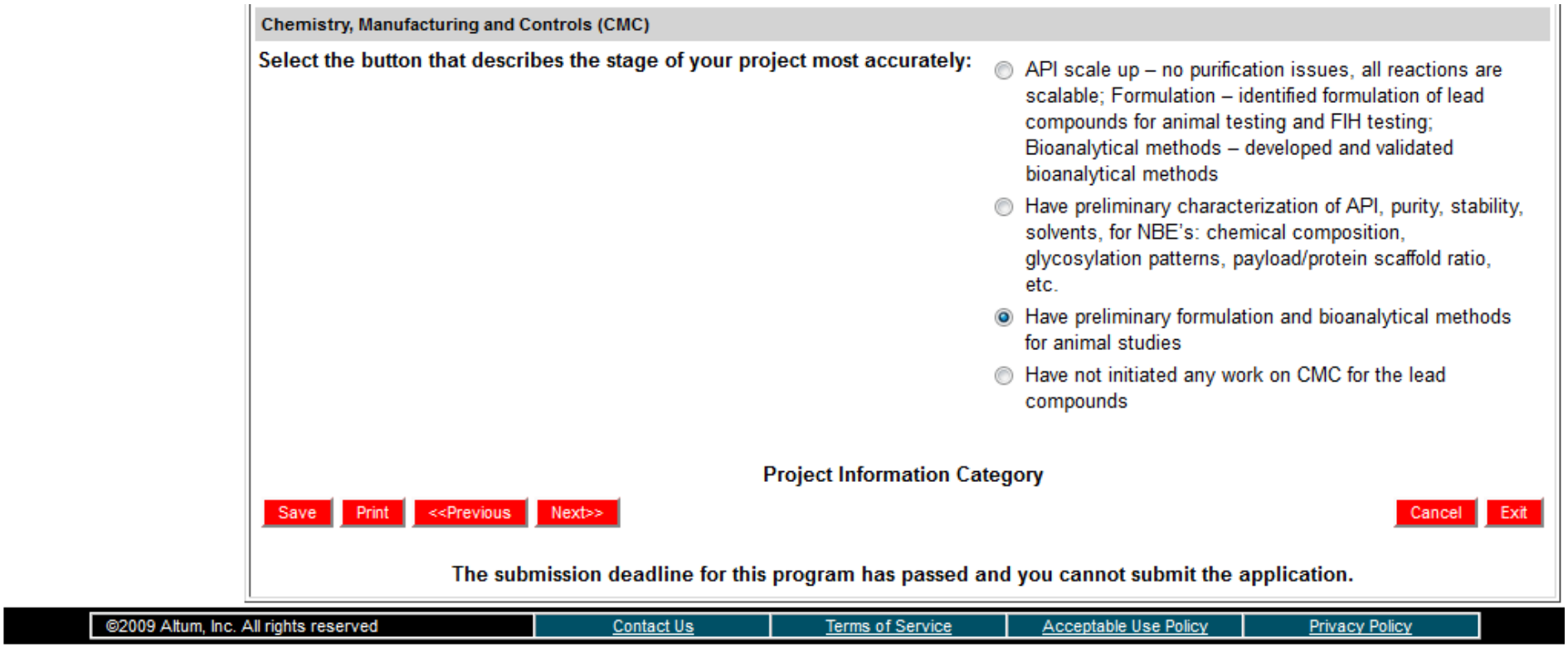
- ○ Chronic toxicology in two species completed successfully; finished safety pharmacology, mutagenecity, and sub-chronic tox studies
- ◉ Conducted acute toxicological studies in rodents; no data generated to date to cause concern
- ○ Literature or experience with this platform indicate that toxicology 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

Project Information – 3(cont.)



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.

* Kryptonian Syndrome (or Krypto) affects an estimated 5000 patients worldwide. Symptoms become apparent during infancy, with affected children first demonstrating exceptional strength, speed, and agility. Symptoms progress to include an ability to see through walls and levitate above the surface of the Earth. Preliminary evidence suggests that Krypto arises due to the absorption of radiation from the Earth's yellow sun. There are no approved therapies for the treatment of Krypto, other than supportive care. Recently, we have developed a series of compounds that ameliorate the severity of Krypto symptoms in animal models of the disease when administered by slow IV infusion. It is a very effective agent, with good efficacy and toxicity data, but the infusion-related side effects (eg, chills, rigor, fever) have limited the utility of these compounds for chronic administration. We seek support for reformulation of our compounds for oral administration, as well as the appropriate etc. etc. etc. etc.

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. Instructions

***TRND Resources**

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
13 Assess potency against efficacy
14 Evaluate biopharmaceutical properties (bioavailability/ biodistribution/clearance)
15 For radiopharmaceutical/ animal dosimetry studies
16 Manufacture GMP-grade bulk drug
17 Conduct IND-directed toxicology studies
18 Prepare and review clinical protocol

>> Add

Selected Categories

Del 01 For small molecules: secondary assay development
Del 02 For small molecules: Medicinal chemistry/SAR
Del 03 For small molecules: Compound synthesis/ lab scale
Del 04 For biologics: Produce biologic/lab scale
Del 05 Compound/biologic profiling (ADMET/potency/ selectivity/ PK/PD & stability)
Del 06 Evaluate mechanism of action

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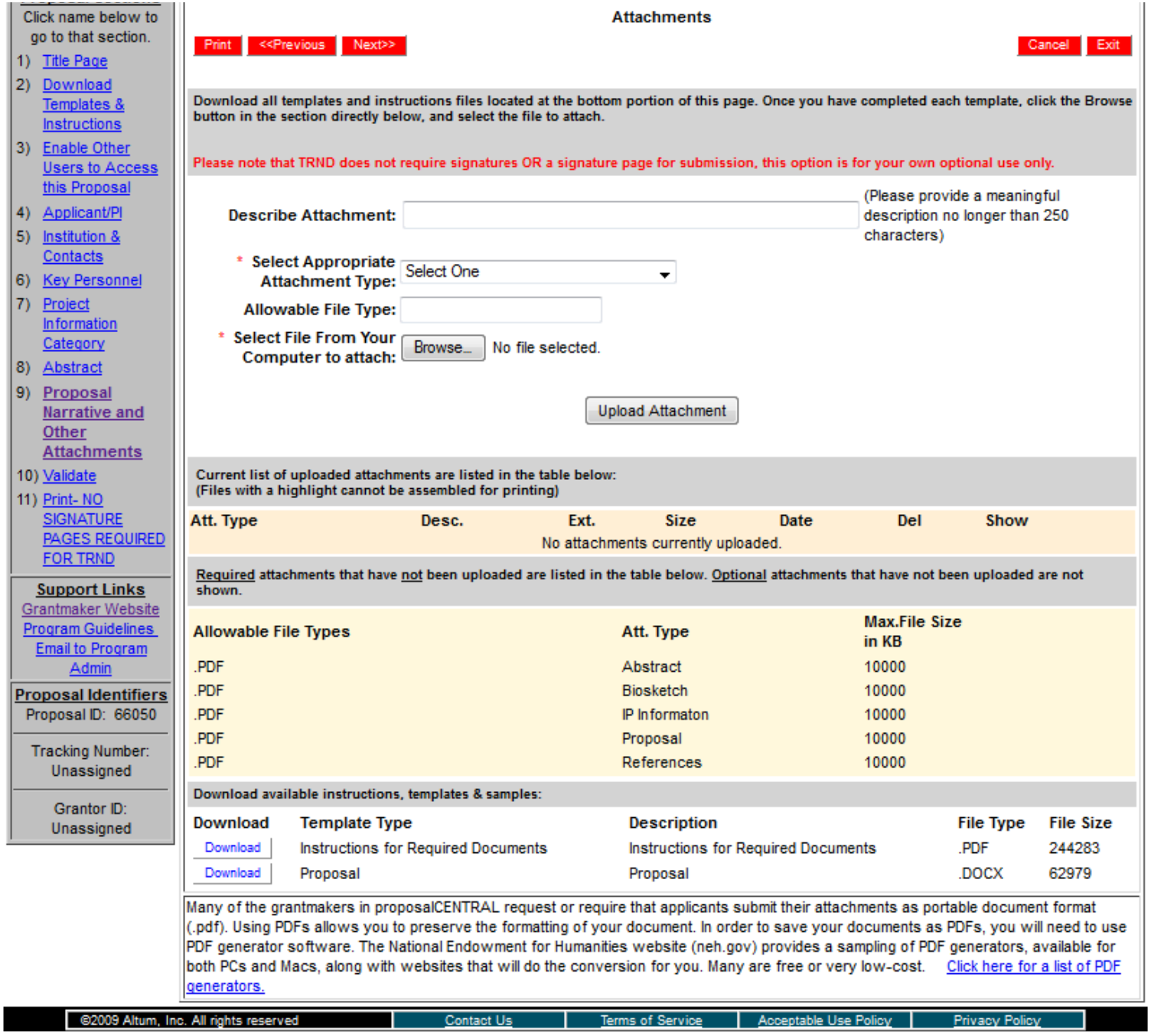
Proposal Narrative and other Attachments



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Attachments

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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 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:** Select One

Allowable File Type:

* **Select File From Your Computer to attach:** Browse... No file selected.

Upload Attachment

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(Files with a 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.

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.PDF	Biosketch	10000
.PDF	IP Informaton	10000
.PDF	Proposal	10000
.PDF	References	10000

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Validate

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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.

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