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

Title Page

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

THERAPEUTICS FOR RARE & NEGLECTED DISEASES

proposalCENTRAL

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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 go to that section.

1) Title Page
2) Download Templates & Instructions
3) Applicant/PI
4) Institution & Contacts
5) Key Personnel
6) Project Information Category
7) Abstract
8) Proposal Narrative and Other Attachments
9) Validate
10) Print- NO SIGNATURE PAGES REQUIRED FOR TRND

Support Links
Grantmaker Website
Program Guidelines
Email to Program Admin

Proposal Identifiers
Unassigned

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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** Enter a title here, then press Save.

* **Affiliation** Please select:

* **Is this a resubmission** No

* **Application Type** Please select:

* **Phase** Please select:

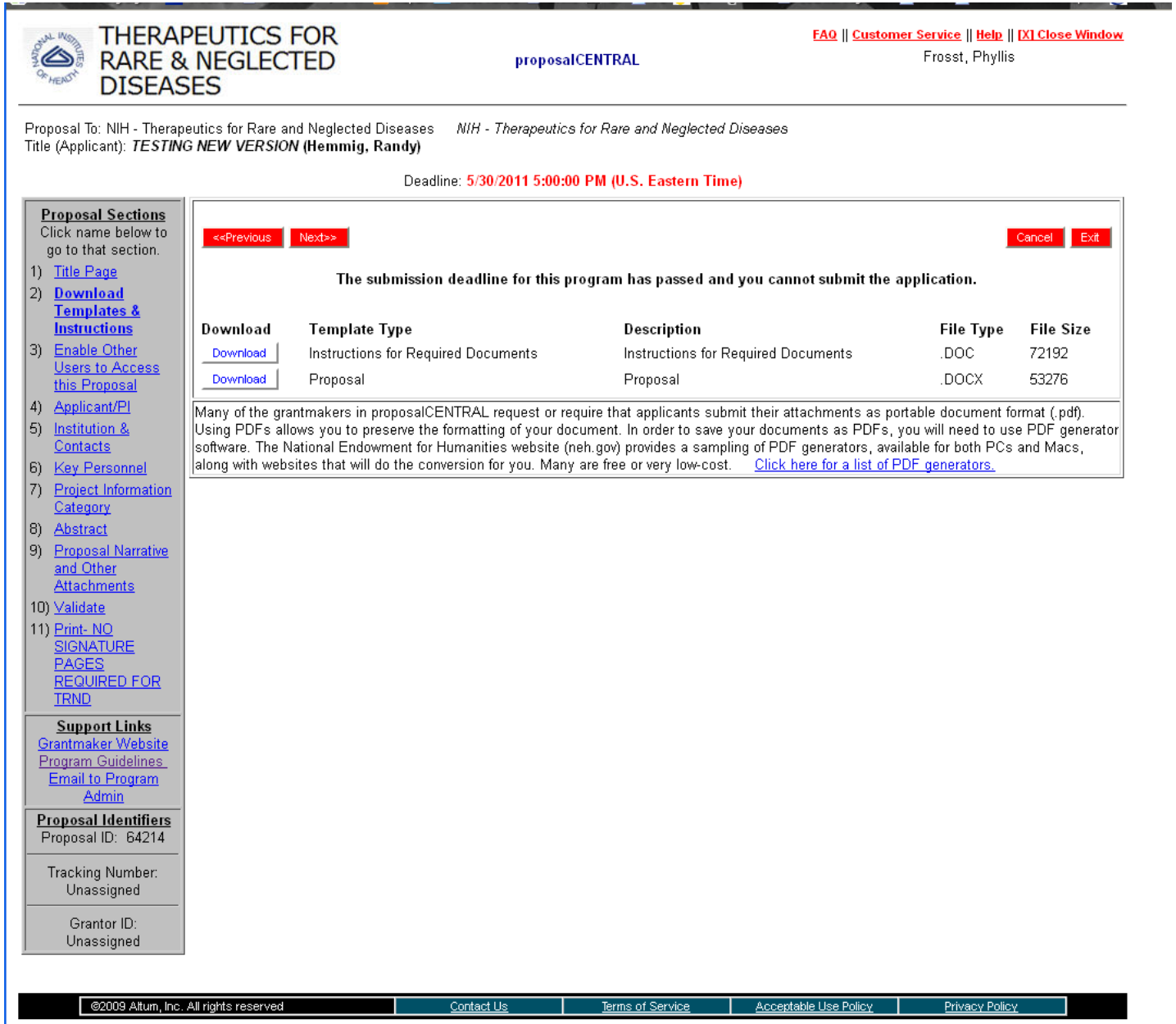
* **Disease indications** Please select: Select Rare or Neglected from the drop-down list. If both, select "Rare and Neglected".

* **How did you hear about TRND?** Please select:

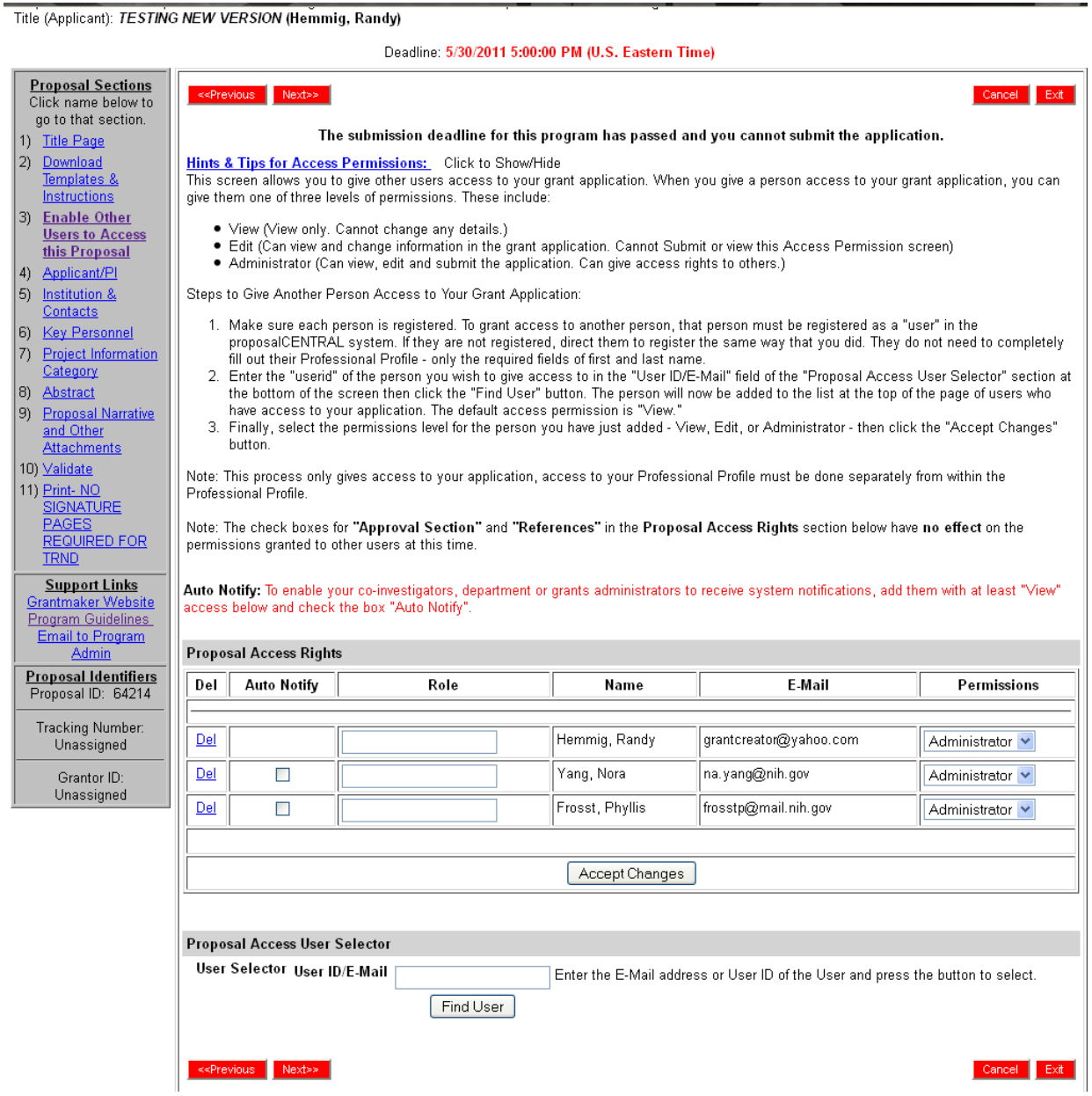
If you selected Conference or Other, please describe

* **Mechanism of Action**

Download Templates and Instructions



Enable other users to access this proposal



Applicant/PI

THERAPEUTICS FOR RARE & NEGLECTED DISEASES

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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)**

Proposal Sections
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1) Title Page
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Proposal Identifiers
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Grantor ID: Unassigned

Applicant/PI

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The submission deadline for this program has passed and you cannot submit the application.

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 Hemmig, Randy - RAMS Research Company

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

Save | Print | <<Previous | Next>> | Cancel | Exit

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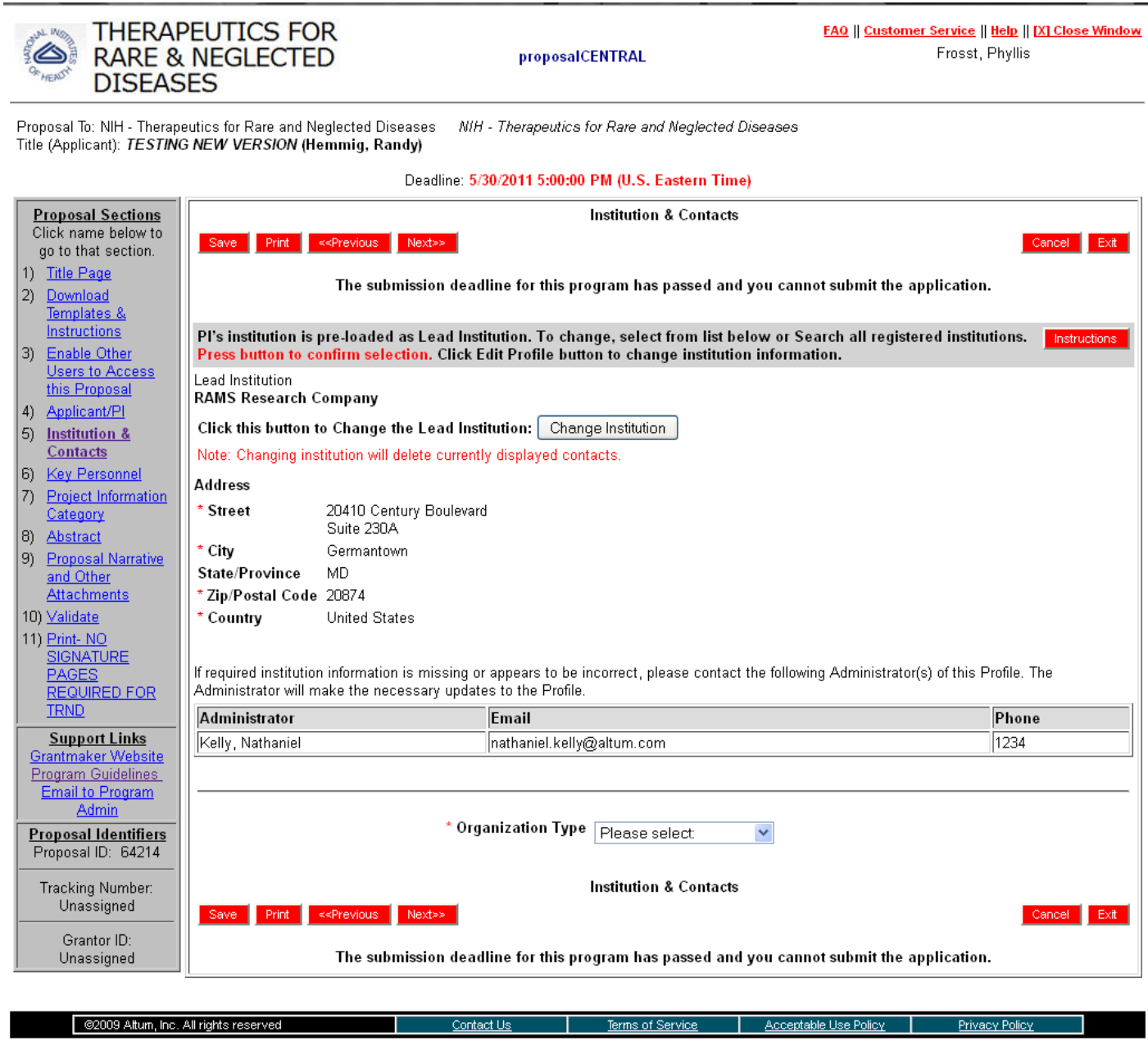
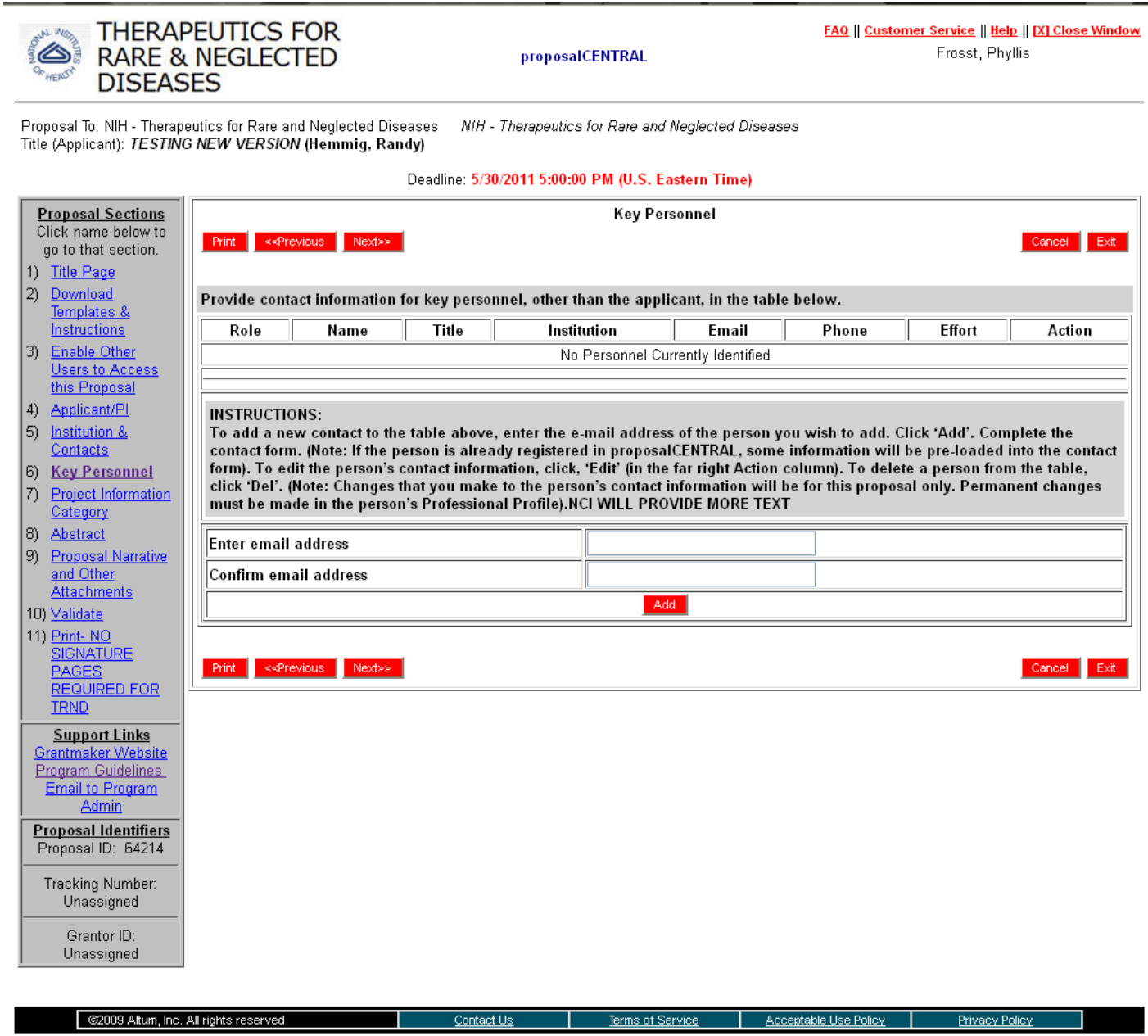
Institution and Contacts



Key Personnel



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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

Enter email address	
Confirm email address	

Add

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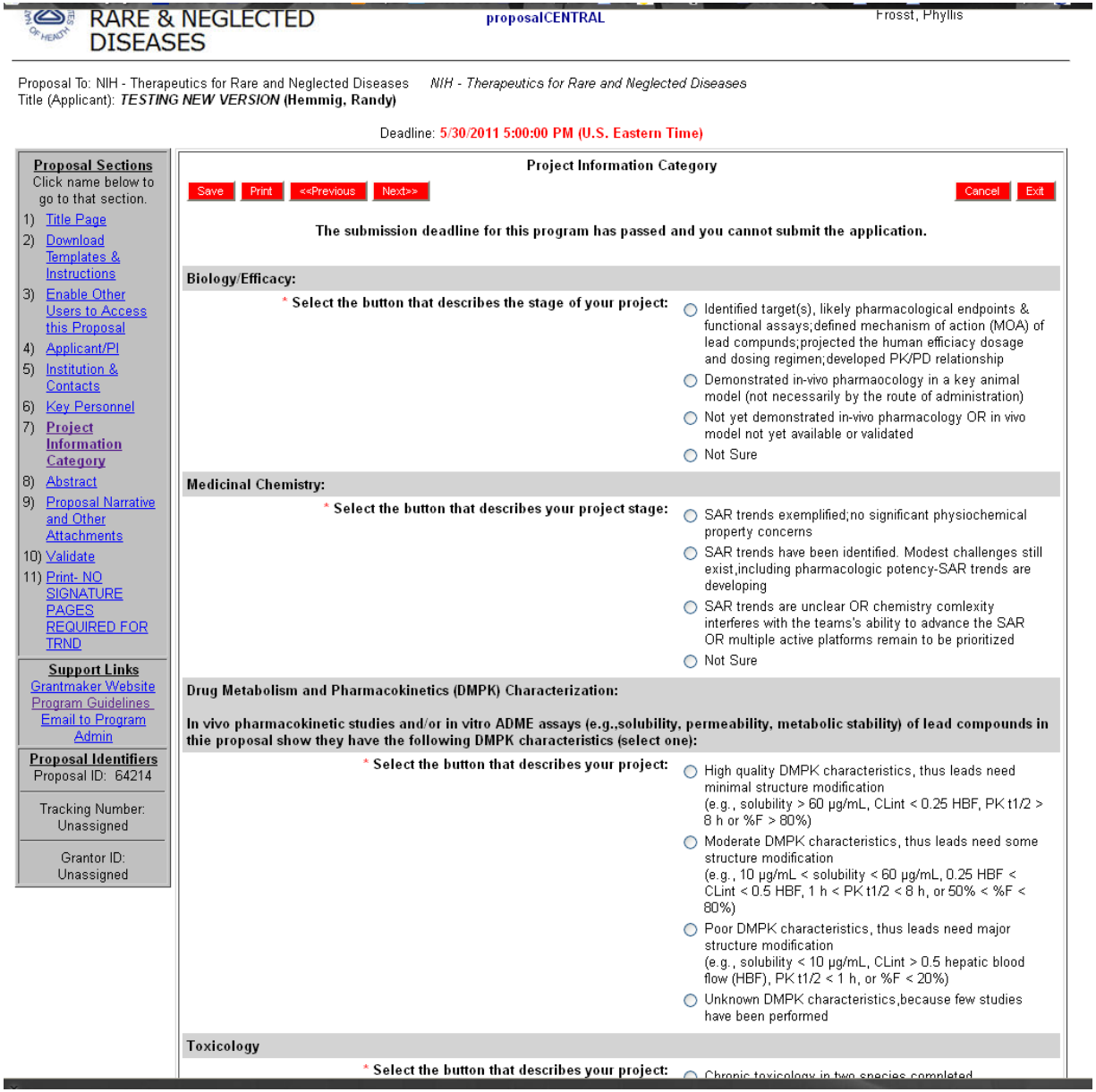
Project Information – 1



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Project Information Category

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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:**

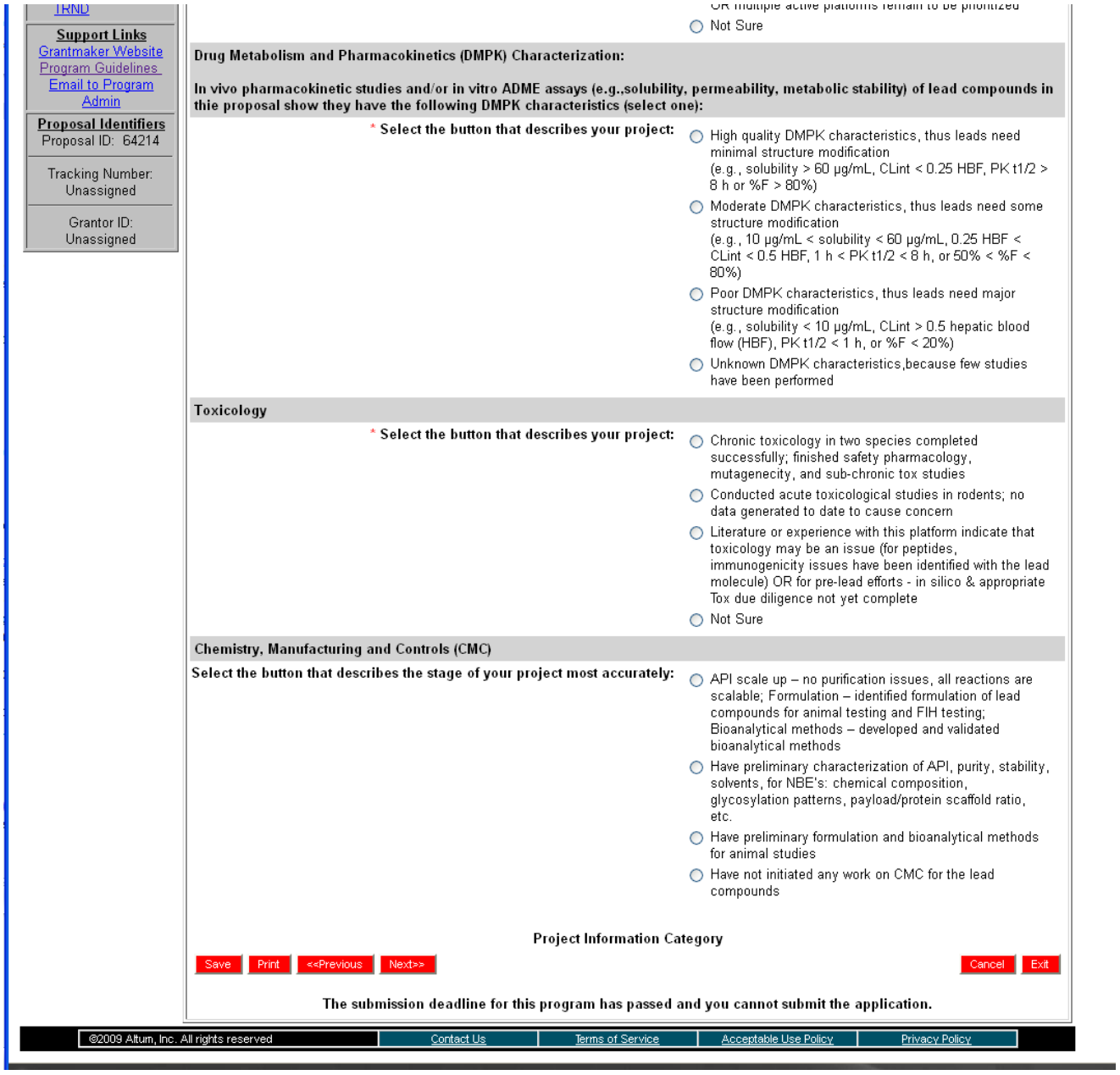
- ○ High quality DMPK characteristics, thus leads need minimal structure modification (e.g., solubility > 60 µg/mL, CLint < 0.25 HBF, PK t1/2 > 8 h or %F > 80%)
- ○ Moderate DMPK characteristics, thus leads need some structure modification (e.g., 10 µg/mL < solubility < 60 µg/mL, 0.25 HBF < CLint < 0.5 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

Project Information – 2(cont.)



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- 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

Project Information Category

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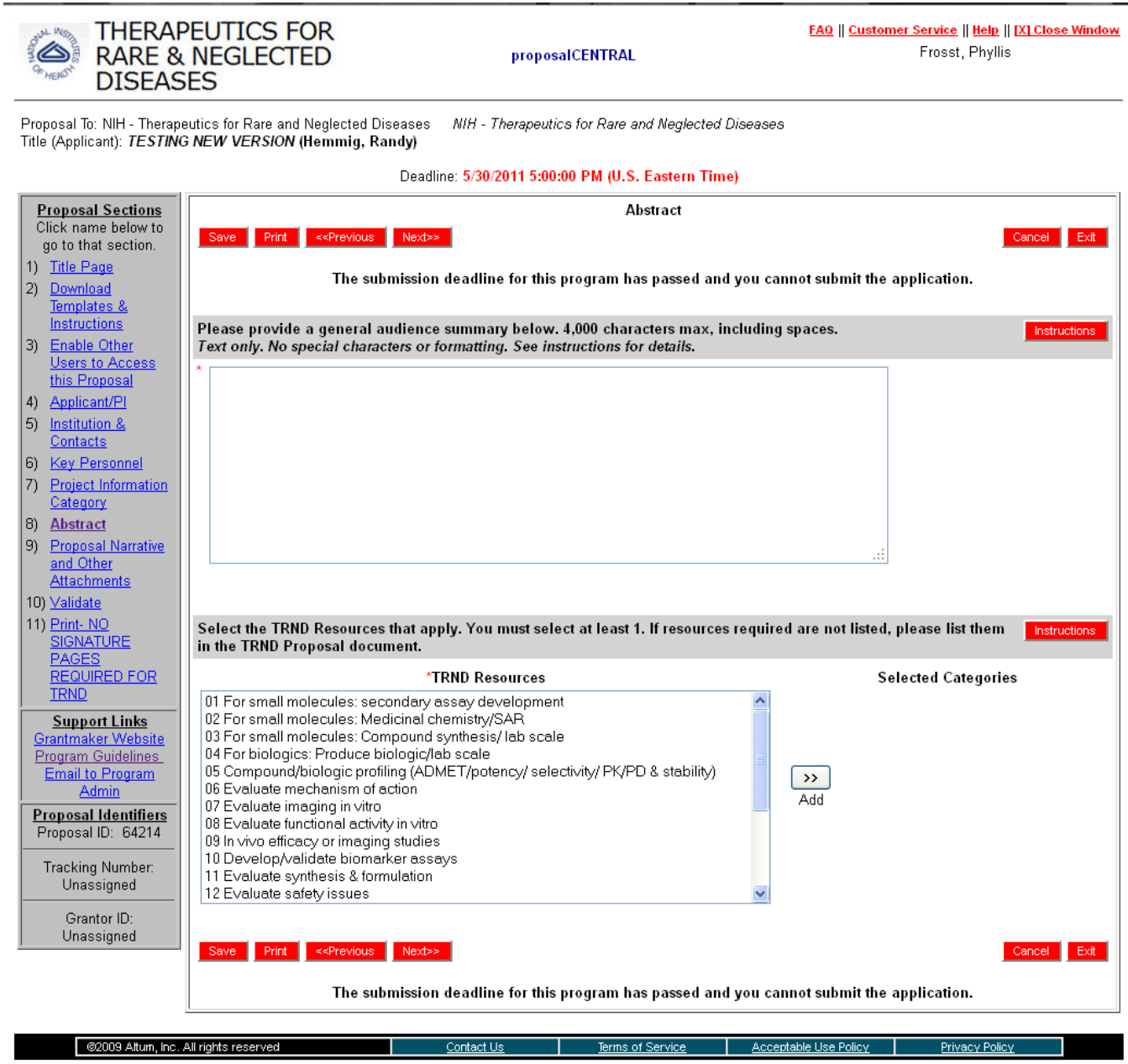
Abstract


THERAPEUTICS FOR RARE & NEGLECTED DISEASES
proposalCENTRAL
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Abstract
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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.
Instructions
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
Selected Categories
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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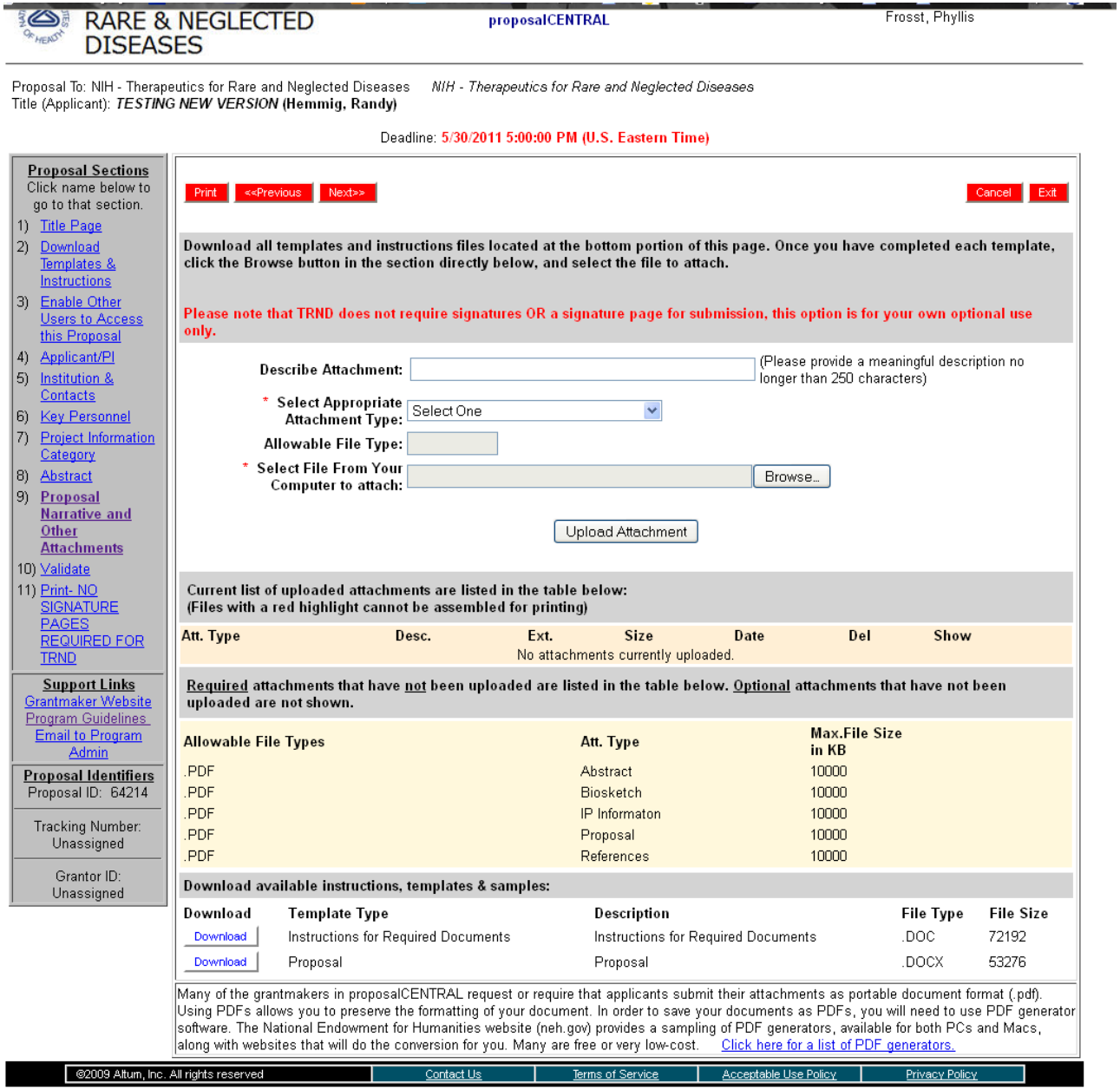
Proposal Narrative and other Attachments



RARE & NEGLECTED DISEASES

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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...

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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.						

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Allowable File Types	Att. Type	Max.File Size in KB
.PDF	Abstract	10000
.PDF	Biosketch	10000
.PDF	IP Informaton	10000
.PDF	Proposal	10000
.PDF	References	10000

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Download	Proposal	Proposal	.DOCX	53276

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Validate

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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 TRND)

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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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