

- 1. Go to: <u>https://ncrms.niaid.nih.gov/NCRMS/Main/Login.aspx</u>. Enter your user name and password and click Login. Select Protocol Registration.
- 2. From the Home Page, click Submission on the main navigation bar and then click New Submission from the drop-down menu, which takes you to the New Submission page.
- **3.** Enter the Submission Details: Enter the appropriate information under the Site & Protocol details heading. Click the LOV i icon to select the Site, IoR and Protocol No. Click the list of values to select the version/LOA.
- 4. Select Sub-Studies (if applicable): This list of values displays all sub-studies associated with the study. Select a sub-study displayed to submit materials for the sub-study along with the study. The packet will be created when the main study is submitted.

Submission       Search Submissions       Reports         Packet Number: Packet Number will be generated upon saving this submission       Site & Protocol details         To initiate a submissions, select as the and protocol       *Site: 11601 - NARI Pune CRS       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site & Site as a submission checkbox below       Image: Site &	Protocol Registr DIVISION OF A	New New	Submission	
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5. Submissions: Select the appropriate checkboxes under the Submissions heading.

**Note:** The system selects the same submission type for the sub-study as on the main study.

6. Next: Click Next. If the save is successful, the Upload Documents heading appears in the lower half of the screen.

Required: Ether upload a document or enter notes for a document type.					
Document Type	File-Date Uploaded			Notes	
<ul> <li>IRB/EC/RA Documentation More</li> </ul>		٠	7	× 1	
* FDA 1572 More		٠		20 27	
* Updated IoR Form for existing IoR More		٠		2	
- IoR CV More		٠		2 2	
Informed Consent Forms More	1	٠		20	

7. Upload Documents: Click the upload 🔶 icon to upload the appropriate documents. Enter notes to provide additional clarification. Click **Save**.



8. Confirm Submission Details: When finished, click Submit. At the pop-up confirmation window, confirm the Site, IoR Name and Protocol No. Select the version and again click Submit.

Packet Number: 2011-01-7535					
To confirm a submission, select same a site and protocol for the submission					
*Site:	E				
*Protocol No.:	Select Version 💌				
Bads         Discard					

9. The system confirms whether the submission was successful.

**Optional:** The system will provide option to submit sub-study packets that have not yet been submitted by selecting a packet number at the top of the Notification screen. If you have created a sub-study packet, you must submit independently.

10. To complete the sub-study submissions or view the sub-study packet, select a packet number at the top of the screen to view any other associated packets for this study. The Sub-Study screen appears similar to the main submission except the Protocol Number is changed to the sub-study number. The submission type remains the same.

**Note:** You can use this feature to toggle between the sub-study packets. You also can copy person information to sub-study packets.

Protocol Registr DIVISION OF A	ation DS		New Submission	
Submission	Search Submissions	Reports		
		P	acket Number: 2011-01-6375	
Associated Packets Select the packet num	ber to view any other ass	ociated pac	kets created for the Main Study/ Embedded Sub-Study(ies): 9	
Select a Packet	1		•	
Select a Packet A5150 - 11601 - [2011	01-6374]			
To initiate a submission, se	lect a site and protocol			
*Site:	11601 - NARI Pune CRS		<b>u</b>	Eq.
*Protocol No:	A5153s		Version 1.0	
			To view LOA Versions, click the LOA Registration checkbox below	IND: N/A
Select the Investigator of R	ecord (IoR) below for the above	rprotocol and	l site.	
*Select IoR:	Raman Raghunathrao Gar	ngakhedkar	[32084]	

## Still Have Questions?

- Submit a Help Ticket Online: Point to Help on the top right menu bar and Click CRMS Support.
- Contact NIAID CRMS Support:
  - Phone: 1-240-778-2517
  - Email: <u>CRMSSupport@niaid.nih.gov</u>

More information on the DPRS and how to request a User name and Password is available at <a href="http://ncrms.niaid.nih.gov">http://ncrms.niaid.nih.gov</a>.

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Allergy and	Support	of AIDS (DAIDS), NIAID, NIH, DHHS, u	Inder contract No. HHSN272201000013C, for
Infectious Diseases	Center	the NIAID DAIDS Regulatory Support C	enter (RSC)