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Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff	
Covered Topics	 How to create a new reportable information How to edit a reportable information 	
	6 now to call a reportable mornation	



- 1. Please consult the Investigator's Manual for the list of Reportable New Information categories. If no categories apply, the information may be reportable at time of continuing review.
- 2. Create a Reportable New Information (RNI)
 - In the study workspace, click on the **Reportable New Information** button



• Item 1 displays a list of studies associated with the same PI. Select all studies to which this reportable information applies. Fill out the required information and then click **Continue** in the top or bottom right-hand side of the screen.

Rep	ortable New Information		
1.	* RNI Nickname:		
2.	Select Protocol(s) that are affected: Protocol ID Protocol 4 H00006054 H00006056	Study Nickname MDI R01	Status Approved Approved
з.	Person completing this form:		
4.	* Description of new information (Corrective action plan	ı is required)	
5.	Has the Prinicipal Investigator reviewed this information	17 Öyes Öno Clear	
6.	Does the Principal Investigator agree with this assessme	ent? O'Yes O'No Clear	
7.	* Date the Principal Investigator became aware of this	information	

• Identify the appropriate categories for the reportable new information. If no categories apply, the information may be reportable at time of continuing review. If



you pick a category that is not an exact match to your information, be sure to explain how the information is different and why you are submitting.

ortable I	New Information	Categories	
Identify CATEC	which specific category(s) DRY TYPE	that this new information falls under (i.e. 1. 6) 🥥 DESCRIPTION	
E 1	RISK	Information that indicates a new or increased risk, or a safety issue.	
2	HARM	Any harm experienced by a subject or other individual, which in the opinion of the Investigator are unexpected and at least probably related to the research procedures.	
		a. A harm is "unexpected" when its specificity of severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.	
		b. A harm is "probably related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not (>50%) caused the harm.	
□ 3	NON-COMPLIANCE	Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non- compliance.	
0.4	AUDIT	Audit, inspection, or inquiry by a federal apency.	
1 5	STAFF-ERROR	Failure to follow the protocol due to the action or inaction of the investigator or research staff.	
D 6	BREACH	Breach of confidentiality.	
D 7	UNAUTHORIZED CHANGE	Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.	
8	INCARCERATION	Incarceration of a subject in a study not approved by the IRB to involve prisoners.	
9	SUBJECT- COMPLAINT	Complaint of a subject that cannot be resolved by the research team.	
10	TERMINATION	Premature suspension or termination of the research by the sponsor or the investigator.	
D 11	ADVERSE-DEVICE- EFFECT	Usantiopased adverse device effect (any series adverse effect on the health or rafety or any life-threasening problem or death cased by, or associated with a device. If that effect, problem, or death was net provisional identified in name, searchy, or degree of excludes of the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)	
12	INVESTIGATOR	Revised Investigator brochure.	

• Answer the three specific questions regarding the reportable event. If you answer yes to questions 2 or 3, you **must** submit a separate Modification request in addition to submitting the Reportable New Information.

<< 8a	K Save Exit Hide/Show Errors Print Jump To: New Information General •	Finish
Rep	ortable New Information - Continued	
1.	Does this information indicate a new or increased risk, or a safety issue? Ves ONo Clear	
2.	Does this information require a modification to the study? Yes O No Clear	
3.	Does this information require a modification to the consent document(s)? Yes No Clear	
4.	If YES for Question 2 or 3, submit a request for modification,	
5.	Attachingss Add Sector Anne Name There are no kems to display	

• To attach supporting documentation for the Reportable New Information, select the **Add** button under attachments.

			Submit a Document	. Pre
5.	Attachments		Tible:	If not provided, the name of the file will be used
		Name	* File:	Broose
	Upload Revision	Request of Mod	Show Advanced Options	
			* Required	OK OK and Add Another Cancel

• Click the **Finish** button in the top or bottom right-hand side of the screen to close.

3. Edit RNI

- Use the **Save** and **Exit** buttons at the top of the screen to prepare a submission that is not yet ready for the IRB.
- Select **Edit Reportable Event** to re-open the submission and to complete as required.



- 4. Submitting the RNI
 - For Study Staff:
 - After clicking 'Finish' in the RNI submission, select **Ready for PI Review** under **My Current Actions** in the submission workspace. **The PI is the only member of the study team that may submit the RNI to the IRB office.**



• For the PI:

After clicking 'Finish' in the RNI submission, select **Submit** under **My Current Actions** in the submission workspace.

My	Current Actions
T	Submit
0	Cancel RNI
0	Ready for PI Review

!Note: You will know that the RNI has been submitted successfully when the submission's 'state' has changed from **Pre-Submission** to **Reportable New Information Review.**



TIPS

• *If you are reporting a protocol deviation,* explain why the deviation did or did not put the subject at increased <u>risk</u> of harm. It is not sufficient to confirm that no harm occurred.