eHIRB User Guide: *How to Submit a Reportable Event*

Last Update	February 7, 2014
Intended Audience	Principal Investigator/Researcher
Purpose	To provide the user with step-by-step instructions on how to submit a reportable event.

\Rightarrow Refer to the <u>eHIRB Getting Starting Guide</u> before getting started.

Important Reportable Event Facts:

- 1. PIs are required to submit reportable events to the IRB as soon they become aware of the event.
- 2. The possible categories of reportable events that must be reported to the IRB include, but are not limited to: protocol deviation, participant complaint, unanticipated problem, adverse event.
- 3. The eHIRB reportable event form may be used to notify the IRB of a single type of reportable event which occurred in one or more participants.
- 4. Only the PI can submit a reportable event, but anyone on the study team can complete the SmartForm.

Follow the steps below to submit a reportable event:

- **STEP 1. Close** all open web browsers.
- STEP 2. Open a new browser and go to: https://hirb.jhu.edu
- **STEP 3.** Login using your JHEDID and password,
 - > The **My eHIRB Studies** workspace should appear, if not, select it from left side.
- **STEP 4. Select** the "**Approved**" tab, and then select the approved New Application for which you need to submit a reportable event.

eHIRB	Electronic Homewood Ins	titutional Review	w Board		PI2 Test HIRB My Home Proje	ects Logoff
All eHIRB Studies Help Desk						
Page for HIRB P2 Testaccount					Layout	Properties
My HIRB Studies	My eHIRB Studies	archer Prep In P	rocess Approved 4	ll My eHIRB Studies		
Our sta New Availantian						
Create New Application	New Applications					
	Filter by ID	~	60	Clear Advanced		
	ID	Name	Current State	Last State Change	PI Last Name	
	HIRB00000297	test	Approved	3/29/2012 3:16 PM	Test HIRB	
			10 A	1 to 1 of 1 ▷ ▷		10 / page
	Amendments					
	Filter by ID	~	Go	Clear Advanced		
			No	data to display.		

Figure 1

eHIRB User Guide Reportable Event

Questions? Contact the HIRB Office at hirb@jhu.edu.

STEP 5. Select the "Create Future Study Action" button.

eHIRB ⊧	lectronic Homewood Ins	titutional Review Board	PI2 Test HIRB My Home Projects Logoff	
All eHIRB Studies Help Desk				
All eHIRB Studies > test				
Current Status Approved View Form Print Friendly View	New Applicati	on Workspace 800000297 : PI2 Test HIRB		
view Differences	Study Team:			
View Form Progress	Last Name There are no items to	display	First Name	Role
Contact IRB	Review Type: Full Boa	rd		
Log Comment	Study Expiration: 4/1	9/2013		
	Original Approval: 3/	29/2012		
Create Further Study Action				
	Review Items:			
	Review Date	Review Type	Outcome	Letter Sent
	3/29/2012	Full Board	Approved/Acknowledged	View Letter



STEP 6. Select the "**Reportable Event**" check box.



Figure 3

- **STEP 7. Select "Continue**" to save the application and proceed to the next section.
 - The system will save the reportable event and generate a HIRB ID number which will appear in the right corner of the form.

	eHIRB Electronic Homewood In	nstitutional Review Board	Edit: IRB Project - HIRB00000296
<< Back	Save Exit Hide/Show Errors Print	Jump To: 3 - Research Personnel 🔻	Continue >>
-			



- **STEP 8. Complete Section 1 Reportable Event**, by providing answers to all the required questions.
 - \succ Required fields are indicated with a red asterisk (*).

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Questions? Contact the HIRB Office at hirb@jhu.edu.

	eHIRB Electronic Homewood Institutional Review Board	Edit: IRB Project - RE00000302
<< Back	Save Exit Hide/Show Errors Print Jump To: 1 - Reportable Event +	Continue >>
		Reportable Event
1 - Rep	ortable Event	
This form ma	ay be used to notify the IRB of a single type of Reportable Event which occurred in one or mo	ore participants.
1.0	* Select the event type.	
	Protocol Deviation	
2.0	* Briefly summarize the protocol event. You will be prompted on the following page to des occurred, specific to each participant (if applicable).	cribe how the event
	· · · · · · · · · · · · · · · · · · ·	
3.0	* Describe any corrective action(s) taken by the study team to date and their outcome. Ind that were taken without prior approval by HIRB and explain why they were taken (e.g., to immediate hazard).	dicate any actions eliminate an

Figure 5

STEP 9. Select "Continue" to proceed to **Section 2 – Participant Information**.

e⊦	IRB Elect	ronic Homewoo	od Institutional I	Review Board	Edit: IRB Project - RE00000302
	Save Exit	Hide/Show Errors	Print Jump To:	2 - Participant Information \star	Continue >>
icipant	Informati	on			Reportable Event
* Click `A	\dd' to enter info	mation for a new	Reportable Event(s), or `Update' to revise an	existing one.
Add					
	Participant ID	Date of Event	Date Event Disco	vered Site Which Ever	nt Occurred
Update	12345	3/30/2012	3/5/2012	test site	Delete
	Save Exit	Hide/Show Errors	Print Jump To:	2 - Participant Information -	Continue >>
	Click 'A	eHIRB Elect Save Exit	Click 'Add' to enter information for a new Add Participant ID Date of Event Update 12345 3/30/2012	Click 'Add' to enter information for a new Reportable Event (Add Participant ID Date of Event Date Event Discor Update 12345 3/30/2012 3/5/2012	eHIRB Electronic Homewood Institutional Review Board Save Exit Hide/Show Errors Print Jump To: 2 - Participant Information Click 'Add' to enter information for a new Reportable Event(s), or 'Update' to revise an Add Participant ID Date of Event Date Event Discovered Site Which Event Update 12345 3/30/2012 3/5/2012 test site Save Exit Hide/Show Errors Print Jump To: 2 - Participant Information

STEP 10. Select "Add" to enter details about the reportable for each participant that was involved.

At least one participant information record must be added.

STEP 11. Complete the "**Participant View**" form, and then select **OK** to save the answers and return to the SmartForm.

Edit RE	Event Reported
Parti	cipant View
Please	answer the items on this page in relevance to the individual participant identified below.
1.0	* Participant ID
	12345
2.0	* Date of event
	3/30/2012
3.0	* Date the event was discovered
	3/5/2012
4.0	* Site at which event occurred
	test site
5.0	* Describe the circumstances leading up to the event specific to this participant.
	test describe.
	M
9.0	* Explain how the event barmed participant(s) and/or involved risk to participants or
5.0	others
	test
* Requ	ired OK OK and Add Another Cancel
	~



- **STEP 12.** Select "Continue" to complete the remaining sections using the blue navigation bar (Figure 4, above).
 - The navigation bar can be found at the bottom and top of the form.
 - You can select "**Continue** to proceed through each page of the application SmartForm.
 - When "**Continue**" is selected the system automatically saves the form.
 - You can select "Save" at any time and "Exit" the form. If needed, you can come back later and finish the form.
 - Select "Exit" to close the SmartForm. The system will confirm that the form will be saved.
 - You can skip to a specific section of the form by choosing a page name from the "Jump To" drop-down menu located on the blue navigation bar.
 - NOTE: If the "Back" button is selected the system will not automatically save the information entered on that page of the form. Be sure to select "Save" before the "Back" button is selected.

- **STEP 13.** Make sure required questions are answered. The system will not allow the reportable event to be submitted to the IRB until all required items are completed on the reportable event SmartForm.
 - To assess completeness of the form, you can **Turn on** the **Hide/Show Errors** feature, from the blue navigation bar, to provide a list of validation errors that the system finds along the way.
 - As required questions are answered in each section, the error/warning messages will disappear from the list.
 - The hide/show errors feature is optional and can be turned on/off at anytime from the blue navigation bar.

	eHIRB	Electronic Homewood I	nstitutional Rev	iew Board	Edit: IRB Project - RE00000302
< e Back	Sa	ve Exit Hide/Show Errors	Print Jump To:	1 - Reportable Event 👻	Continue >>
					Reportable Event
1 - Repo	rtable Event				
This form may	be used to notify the	e IRB of a single type of Rep	oortable Event whi	ich occurred in one or	more participants.
1.0	* Select the event t	vne.			
	Protocol Deviation	×			
2.0	* Briefly summarize occurred, specific to	the protocol event. You wi each participant (if applica	ll be prompted on ible).	the following page to a	lescribe how the event
				~	
<					>
Error/Warning	j Messages				Refresh
Message				Field Name	Jump To
😑 This is a re	quired field; therefor	e, you must provide the requ	ired information.	Summary of Event	1 - Reportable Event
😑 This is a re	quired field; therefon	e, you must provide the requ	ired information.	Explain Corrective	Action 1 - Reportable Event



- **STEP 14. Once you have completed the form, Select** the **"Finish**" button on the last section of the SmartForm entitled **"Finalize Application**".
 - The SmartForm will close and you will be taken to the application workspace where you will be able to finally "Submit" the application to the IRB.
 - The application is NOT sent to the IRB until the "Submit" activity on the workspace is run. NOTE: THE PI MUST SUBMIT THE REPORTABLE EVENT.



Figure 8

- **STEP 15.** From the application workspace, select the "Submit" activity, located on the left side of the workspace.
 - If additional changes are need on the SmartForm before the reportable event is submitted, select the "View/Edit Form" activity to open up the form and resume completing it.
 - WARNING: The PI cannot edit the form after submission, unless the IRB sends it back with questions.

	tronic Homewood Institutional Revi	ew Board	PI2 Test HIRB My Home Projects Logoff
All eHIRB Studies Help Desk			
All eHIRB Studies > test > Reportable B	Event: RE00000302 For: HIRB00000297		Layout
Current Status Researcher Prep View/Edit Form Print Friendly View View Differences View Form Progress Submit	Reportable Event Works Title: Reportable Event: RE00000302 For: HIRE Protocol Number: RE00000302 Principal Investigator: P12 Test HIRB Study Team: Last Name There are no items to display Review Type:	pace 00000297 First Name	Role
Withdraw Contact IRB Log Comment	Review Items: Review Date Review There are no items to display	/ Type Outcome	Letter Sent
	Special Populations: Children Students Prisoners Non-English Speakers	Consent/Assent: Written Assent Oral Assent Oral Assent Oral Consent Written parental permission Waiver written consent	Special Categories: Deception Classified Drugs Devices
History Log Reviewer Notes			

Figure 9

▶ If the system finds error/warning messages they will be displayed.

STEP 16. To correct error/warning message, select the errors in the list and the system will take you directly to the page where the answer can be corrected, repeat this until all error messages have disappeared from the list.

Er	ror/Warning Messages		Refresh
	Message	Field Name	Jump To
	This is a required field; therefore, you must provide the required information.	Student Research	3 - Research Personnel
	This is a required field; therefore, you must provide the required information.	Non Hopkins Entity	5 - Research Sites

Figure 10

- **STEP 17.** After all error/warning messages are resolved, **select** the "**Submit**" activity again, the PI certification appears.
- **STEP 18.** Read the PI Certification text, and then select "OK".

Submit	
New Application	n
Submit	
DI Certification	
By submitting this application, the PI is taking responsibility for his or her own research project, or is acting as a supervisor for a student project, for the individual student's research project. PIs overseeing a student research project are expected to work closely with the student in preparing the application for Homewood IRB (HIRB) review, overseeing the conduct of the research, and ensuring that the study is appropriately closed upon completion.	
PI responsibilities include, but are not limited to, the following:	
(a) Reviewing thoroughly the submission materials to ensure that a complete and accurate application is	
(b) Ensuring that the research team members complete the required training in human participant research and have the appropriate knowledge and skills to carry out the research in a manner that protects all participants. (c) Monitoring the conduct of the research project to ensure that all research team member fulfills the following responsibilities:	
 Obtaining and documenting the informed consent of each participant or each participant's legally authorized representative (LAR), unless HIRB has waived these requirements. This includes ensuring that each potential participant understands the nature of the research and, unless HIRB specifically waives this requirement, each participant or the participant's LAR receives a copy of the HIRB-approved informed consent document(s) at the time of consent. Informing HIRB of any new personnel to be added to the research team. Ensuring that all members of the research team have completed the required training in the protection and ethical treatment of human research participants and have been appropriately trained for their role in the study. Ensuring that all members of the research team report any potential conflicts of interest regarding the research. Reporting on the progress of approved research to HIRB as often as and in the manner prescribed by HIRB. This includes complying with all requirements for continuing review. Ensuring that HIRB is notified when the research project is complete so that the study may be appropriately closed. Retaining all signed consent documents for at least three years after the completion of the study according to institutional policy. Promptly reporting proposed changes to the research protocol or consent documents to HIRB. The proposed changes may not be initiated without HIRB review and approval, except where necessary to eliminate apparent immediate hazards to participants. Promptly reporting to HIRB any serious or continuing noncompliance with Federal regulations or HIRB policies and procedures. 	1 r
Click OK below to complete this activity.	
Cancel)

Figure 11

STEP 19. After submission, **select "My Home**" located on the top left corner to return to your Inbox.

- The system will send an email notification confirming the submission of the reportable event.
- > The IRB office will receive the submission and begin reviewing the application.
- > The reportable event can no longer be edited at this time, unless the IRB office sends it back for clarification and/or changes.
- **STEP 20.** To view the reportable event that was just submitted, **select** the "**In Process**" tab located on the **My HIRB Studies** workspace.

Site Administration All eHIRB St	udies Reports He	elp Desk Comm	ittee Meetings								
Page for Sue Tindall									3	Layout Pro	operties
Site Managers Help Desk IRB Staff	My eHIRB S	itudies	Prep In Process	Approved	All My (HIRB Studies					
My HIRB Studies	New Applicati	ions									
in no nemero	Filter by	ID	•	Go	Clear	Advanced					
	@ 1D	Name						Current State	Last State Change	e PILas Name	R
Create New Application	HIRB00000254	ALPHA TEST: RES turned sixty, and	POND TO REVIEWER that's the law.	NOTES. My pare	ints didn	't want to move to Florida, b	ut they	Waiting Review	3/15/201 8:26 AM	2 Stein	
	HIRB00000263	ALPHA TEST: RES there's no better	POND TO REVIEWER place to dance than	NOTES. Do you a slick surface r	really water	ant music in the shower? I g glass door.	uess	IRB Pre Review	3/15/201 8:18 AM	2 Feiger	nson
	HIRB00000275	DO NOT DELETE	Sue's Test Study					IRB Pre Review	3/14/201 5:59 PM	2 Tindall	1
				14 -	1 t	o3 of 3 ♀ ♀				10 /	page
	Amendments										3
	Filter by	ID	-	Go	Clear	Advanced					
	ID AM00000267 U00000267	Name Amendment:	AM00000267 For: HI	RB00000265		Current State Waiting Review	Last 5	tate Change 012 11:01 /	r MM	PI Last Name Testaccount	¢
	AM00000278	Amendment:)	AMUUUUU278 FOR: HI	KB00000246	1 t	o 2 of 2 ^D	3/9/20)12 9:12 AM		10 /	page
	Continuing Re	view									
	Filter by	ID	•	Go	Clear	Advanced			_		
	@ 1D	Name				Current State	La	st State Cha	ange	PI Last Nam	le .
	CR00000273	Continuing Rev	riew: CR00000273 F	or: HIRB000002!	57] 1 t	Waiting Review	3/	20/2012 4:1	9 PM	Feigenson 10 /	/ page



- For questions about the status of an application, contact the IRB by selecting the "Contact IRB" activity on the application workspace. This sends the IRB Office an email notification containing your question through the eHIRB system.
- **STEP 21.** To close out of eHIRB, Select "Logoff", located on the top left corner.



Figure 13