

# Reportable Events: How to Report in myIRB

## When the IRB of Record is NOT the WU IRB or the NCI CIRB

When the WU IRB and the NCI CIRB are not the IRB of record, you must follow the policies of the IRB that is overseeing your research. In addition to their reporting requirements you must notify the WU IRB of the following events.

Event Type	Reporting Timeframes		How to Report
	1 working day	10 working days	
Any unexpected events that are at least possibly related to the research that result in the death of one of your participants	✓		Unanticipated Problem Reportable Event Form (REF) submitted in myIRB
Any unexpected events that are at least possibly related to the research that result any other harm or injury to one of your participants*		✓	Unanticipated Problem Reportable Event Form (REF) submitted in myIRB
Noncompliance that results in the death of one for your participants	✓		Noncompliance Reportable Event Form (REF) submitted in myIRB
Noncompliance that results in the any other harm or injury to one of your participants *		✓	Noncompliance Reportable Event Form (REF) submitted in myIRB
Notice of <b>FDA</b> Audit – Initial Notice of Upcoming Audit	✓		<a href="#">Email</a> both the HRPO Associate Director for Education & Compliance and the Executive Director
Arrival of <b>FDA</b> Inspector	✓		<a href="#">Email</a> a copy of the FDA Inspection Notice (482) to both the HRPO Associate Director for Education & Compliance and the Executive Director

During conduct of <b>FDA</b> Audit – Close Out Visit	✓		<a href="#">Email</a> both the HRPO Associate Director for Education & compliance and the HRPO Executive Director the Date and Time of Close Out so that HRPO may attend
<b>FDA</b> Audit - Follow-up Information (e.g., form 483, Warning Letter, Establishment Inspection Report).		✓	<a href="#">Email</a> both the HRPO Associate Director for Education & Compliance and the Executive Director
Notice of any <b>For-Cause</b> audits, inspections, or inquiries	✓		<a href="#">Email</a> both the HRPO Associate Director for Education & Compliance and the Executive Director
<b>For-Cause</b> audit report or follow-up information	✓		<a href="#">Email</a> both the HRPO Associate Director for Education & Compliance and the Executive Director

\* **Note:** Harm may include physical harm, informational harm, social harm, emotional/psychological harm, or financial harm.