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 and possibly related event that results in the death of one of your participants	✓		Unanticipated Problem Reportable Event Form (REF) submitted in myIRB
Any unexpected and possibly related event that may result in permanent or long-term disability to one of your participants		✓	Unanticipated Problem Reportable Event Form (REF) submitted in myIRB
Notice of **FDA** Audit	✓		Email both the HRPO Associate Director for Education & Compliance and the Executive Director
Arrival of *any* **FDA** Inspector	✓		Email a copy of the FDA Inspection Notice (482) to both the HRPO Associate Director for Education & Compliance and the Executive Director
During conduct of **FDA** Audit	✓		Email 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
FDA 483		✓	Noncompliance Reportable Event Form (REF) submitted in myIRB
Notice of any **For-Cause** audits, inspections, or inquiries	✓		Email both the HRPO Associate Director for Education & Compliance and the Executive Director
For-Cause audit report or follow-up information (report and/or findings)	✓		Email both the HRPO Associate Director for Education & Compliance and the Executive Director