Reportable Events: How to Report in myIRB
When the IRB of Record is the WU IRB or the NCI CIRB

Event Type	Reporting Timeframes				How to report
	1 working day	**10 working days**	**Continuing review**	**Other**	
An event that meets the definition of an unanticipated problem involving risk to participants or others and results in the death of one of your participants	X				Reportable Event Form (REF)- Unanticipated Problem
An event that meets the definition of an unanticipated problem involving risk to participants or others and does NOT result in the death of one of your participants.		X			Reportable Event Form (REF)- Unanticipated Problem
Adverse Events and Serious Adverse Events that do not also meet the definition of an unanticipated problem involving risks to participants or others			X		In the description of the study's progress, provide a summary of these events.
Unexpected Adverse Drug Event that results in the death of one of your participants	X				Reportable Event Form (REF)- Unanticipated Problem

Event Type	Reporting Timeframes				How to report in myIRB
	1 working day	**10 working days**	**Continuing review**	**Other**	
Unexpected Adverse Drug Event that does not result in the death of one of your participants		X			Reportable Event Form (REF)- Unanticipated Problem
Unanticipated Adverse Device Experiences that result in the death of one of your participants	X				Reportable Event Form (REF)- Unanticipated Problem
Unanticipated Adverse Device Experiences that does not results in the death of one of your participants		X			Reportable Event Form (REF)- Unanticipated Problem
Protocol exception - a planned change in the conduct of the research for one participant.				IRB approval must be obtained prior to implementation.	Protocol Exception Form
Changes initiated without IRB approval to alleviate an immediate hazard.				10 working days from the date the change was implemented or 1 working day if the change resulted from a participant death.	If the change was initiated due to an unanticipated problem: report as a REF- Unanticipated Problem If the change was initiated due to noncompliance: report as a REF-

Event Type	Reporting Timeframes				How to report in myIRB
	1 working day	**10 working days**	**Continuing review**	**Other**	
A Major Deviation that results in the death of one of your participants.	X				REF-Noncompliance Or REF – Unanticipated Problem (if deviation was instigated by an Unanticipated Problem)
A Major Deviation that does not result in the death of one of your participants.		X			REF-Noncompliance Or REF – Unanticipated Problem (if deviation was instigated by an Unanticipated Problem)
Minor Deviations			X		In the description of the study's progress, provide a summary of these events.
A Series of Minor Deviations that represent a systemic issue with the conduct of the study.		X			REF-Noncompliance
Complaints from participants that result from an Unanticipated Problem or Noncompliance		X			Reportable Event Form (REF)- Unanticipated Problem OR Noncompliance
Complaints that cannot be resolved by the study team without assistance, but do not involve an Unanticipated Problem or Noncompliance				X	Email both the HRPO Associate Director for Education & Compliance and the Executive Director
All complaints			X		Information about complaints is requested as part of the myIRB continuing review application

Event Type	Reporting Timeframes				How to report in myIRB
	1 working day	**10 working days**	**Continuing review**	**Other**	
Breach of confidentiality (When the actions of the study team do not cause the breach)		X			REF- Unanticipated Problem
Breach of confidentiality (When actions of the study team lead to the breach)		X			REF - Noncompliance
Incarceration of a participant in a protocol not approved to enroll prisoners and the withdrawal of the participant poses a safety issue.		X			REF-Unanticipated Problem
Incarceration of a participant in a protocol not approved to enroll prisoners where the withdrawal of the participant will not represent a safety issue.			X		In the description of the study's progress, provide a description of this event.
Incarceration of a participant in a protocol not approved to enroll prisoners where the participant will not be withdrawn.				IRB approval is required before any further research procedures take place.	A modification to add prisoners as a population must be approved for research with this participant to continue. If halting research procedures in the interim represents a safety issue, contact the HRPO Executive

Event Type	Reporting Timeframes				How to report in myIRB
	1 working day	**10 working days**	**Continuing review**	**Other**	
New Information: An interim analysis or safety monitoring report that indicates the frequency or magnitude of harms or benefits may be different than initially presented to the IRB		X			Modification Form
New Information: A paper published from another study that shows the risks or potential benefits of the research may be different than initially presented to the IRB		X			Modification Form
New Information: Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol – black box warning		X			Modification Form
New Information: Data Safety Monitoring Board/Data Monitoring Committee reports that identify a safety issue		X			Modification Form NOTE: If no problems are identified and the study can continue with no change provide this information at the time of continuing review.

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	1 working day	**10 working days**	**Continuing review**	**Other**	
For cause audit from any agency – Initial notice	X				Email both the HRPO Associate Director for Education & Compliance and the Executive Director
For cause audit from any agency – Follow up when the audit revealed no reportable findings	X				Email both the HRPO Associate Director for Education & Compliance and the Executive Director
For cause audit from any agency – Follow up when the audit revealed reportable findings		X			REF - Noncompliance
FDA audit – Initial notice	X				Email both the HRPO Associate Director for Education & Compliance and the Executive Director
FDA audit – Notification of Closeout meeting	X				Email both the HRPO Associate Director for Education & Compliance and the Executive Director
FDA audit – 483 observations		X			REF - Noncompliance
Routine Audits, Inspections or Inquiries – where there are reportable findings		X			REF-noncompliance
Routine Audits, Inspections or Inquiries – where there are no reportable findings			X		Information about audits, inspections and inquiries is requested as part of the myIRB continuing review application