

**HRPP Document:** GUI325

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**Subject:** Summary of Reporting Requirements for Investigators to the IRB

Investigators have the following reporting requirements as part of the Human Research Protection Program described in the table below. Please refer to the in-depth policy and/or procedure referenced.

**UAB IRB**

<b>Investigator Must Report</b>	<b>Time Frame</b>	<b>Policy and/or Procedure #</b>
Adverse events and unanticipated problems	According to the requirements for the event	<a href="#">POL006</a> , <a href="#">PRO106</a>
Amendments/Revisions to previously approved research	Prior to enacting changes, except when it is to eliminate apparent immediate hazard	<a href="#">PRO148</a> , <a href="#">PRO124</a> , <a href="#">PRO152</a>
Compliance issues	ASAP, but no later than 10 working days	<a href="#">POL028</a> , <a href="#">PRO128</a>
Changes in PI	Prior to enacting change	<a href="#">PRO148</a>
Conflict of interest	At the time of initial review and at any time during the conduct of the study	<a href="#">PRO123</a>
Continuing review	At least 30 days prior to the expiration date to avoid lapse in approval	<a href="#">PRO147</a> , <a href="#">PRO150</a>
Data safety monitoring reports	Within 10 working days of receipt	<a href="#">PRO116</a>
Emergency use of a drug or device in a life-threatening situation	Within 5 days	<a href="#">PRO151</a>
Participant becomes incarcerated during the course of the research	Immediately upon discovery or notification	<a href="#">POL033</a> , <a href="#">PRO133</a>
Study suspension/termination	ASAP, but no later than 10 working days from notification	<a href="#">PRO140</a>

**Western IRB**

<b>Investigator Must Report</b>	<b>Time Frame</b>	<b>Western Institutional Review Board “A Guide to Researchers” Ver. 1.5</b>
Adverse Events and Unanticipated Problems	Within 10 working days of becoming aware of the event	Section 11
Changes to previously approved research	Prior to enacting changes, except when it is to eliminate apparent immediate hazard	Section 9
Compliance Issues	ASAP, but no later than 10 working days	Section 11
Changes in PI	Prior to enacting change	Section 9
Conflict of Interest	At the time of initial review	Section 4
Continuing Review	Quarterly reporting with full board review annually	Section 12
Study Suspension/Termination	Up to 30 days before the expiration date	Section 12