



Processing Prompt Reports

Go to Privacy Website and complete a Privacy Pro Report Wrongful Use or Disclosure

PI summarizes the event at the time of continuing review using Event Report Summary Sheet

Send acknowledgement letter to PI - event does not meet reporting requirements.

The submission is assigned to ORC for review.

ORC investigates. If applicable a RIC review is scheduled

RIC Reviews and provides recommendations

ORC completes iRIS Reviewer Sheet, updates outcome tab, and sends outcome and recommendations to the PI

Did the event occur at a site where Geisinger is the IRB of record?

PI Completes the Prompt Reporting within the iRIS electronic IRB system

IRB Analyst or Specialist confirms that the event meets the reporting requirements

Are additional areas of the system involved in the report?

The report is assigned to an IRB Member Reviewer

The report is scheduled for Convened IRB Review

Convened IRB determines if report is UP or serious and/or continuing non-compliance

If UP or serious and/or continuing noncompliance, the IRB reports to the IO/OHRP/FDA/Funding Agency as applicable

ORC sends acknowledgement letter to PI

IRB notifies the PI of IRB review outcome

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Report to IRB of Record (external IRB)

PI attaches external IRB report to iRIS Prompt Report Form

IRB Staff Triage and Assign to ORC for Review

ORC reviews, enters into tracking report. Is RIC review necessary?

IRB completes outcomes tab and sends outcome to PI

No

Yes

ORC forwards to RIC

RIC Reviews

ORC completes iRIS Reviewer Sheet and reassigns to IRB Staff

ORC reports to quarterly Research Compliance Committee

ORC sends report to IO as needed

PI summarizes the event at the time of continuing review using Event Report Summary Sheet

PI reports the UP or serious and/or continuing non-compliance to the sponsor or other entity as applicable