IND SAFETY REPORTING:

What Sites Need to Submit

WCG IRB — Site Guidance

BACKGROUND

On December 16, 2025, the FDA published final guidance entitled "Investigator Responsibilities—Safety Reporting for Investigational Drugs and Devices" (Docket No. FDA-2021-D-0368). This guidance replaces the 2009 FDA guidance that had significantly reduced the number of IND safety reports requiring submission to the IRB. Under the new guidance, any event that warrants an IND safety report is now considered an unanticipated risk to subjects and must be submitted to the IRB for review. The WCG IRB Compliance team and IRB Executive Committee have interpreted this guidance and confirmed the interpretation with independent experts across regulatory bodies, major institutions, pharmaceutical, and CRO partners.



WCG'S POSITION

- All IND safety reports go to the IRB — not all SUSARs. FDA considers safety information meeting the 21 CFR 312.32(c) criteria to be an unanticipated problem involving risk to participants or others. Some sponsors submit a broader range of AEs on the FDA Medwatch form even if it does not meet IND safety reporting requirements. This may drive over-reporting.
- Submit within 5 calendar days, calculated from the date the submitter becomes aware the event meets reporting criteria — regardless of whether the event occurred at your site or another site on a multicenter study.
- The sponsor determines whether a SUSAR requires reporting as an IND safety report. If the submitter indicates a report is serving as an IND safety report, WCG will treat it as one.
- Policy references: WCG Guide for Researchers, updated 4/1/2026 (safety reporting, p. 62); IRB.POL.HRP.071, updated 4/26/2026 and revised 5/6/2026; PRI submission forms updated 4/17/2026.
- Services: an acknowledgement applies on receipt of every safety report; a review applies only when SME or Board review is conducted.

TRIAGE TOOL — SHOULD THIS SAFETY REPORT BE SUBMITTED TO WCG IRB?

Use this as a quick decision guide for adverse events, Suspected Unexpected Serious Adverse Reactions (SUSARs), Council for International Organizations of Medical Sciences (CIOMS) forms, line listings, and other safety information. Work through the questions in order and stop at the first clear answer.

#	Decision Question	If Yes	If No
1	Has the sponsor, CRO, or submitting party identified this as an IND safety report?	Submit to WCG within 5 calendar days.	Go to Question 2.
2	Even if it is labeled as a SUSAR, CIOMS report, or line listing, does the information appear to meet the FDA IND safety reporting criteria under 21 CFR 312.32(c)?	Submit to WCG within 5 calendar days.	Go to Question 3.
3	Does the event or safety information require a change to the protocol, consent form, investigator brochure, study procedures, or participant-facing materials?	Submit to WCG within 5 calendar days.	Go to Question 4.
4	Is this a SUSAR, CIOMS form, aggregate summary, or line listing with no IND safety report designation and no required document or procedure change?	No submission required. Retain according to your institution's or sponsor's process.	Go to Question 5.
5	Has the sponsor already submitted the same report to WCG IRB on behalf of the site or study?	No separate site submission is needed. Avoid duplicate submissions when confirmed.	Escalate if unsure. Contact WCG or follow your sponsor's instructions before submitting.

QUICK REFERENCE

Submit to WCG IRB	Generally Do Not Submit
Reports identified by the sponsor, CRO, or submitter as IND safety reports	SUSARs, CIOMS forms, or line listings that are not designated as IND safety reports and do not require changes
Safety information that appears to meet 21 CFR 312.32(c) criteria	Aggregate safety summaries with no new risk determination and no required protocol, consent, or procedure change
Any event or safety information requiring a change to the protocol, consent, investigator brochure, study procedures, or participant-facing materials	Reports already submitted to WCG IRB by the sponsor on behalf of the site or study
Reports from other sites when they are identified as IND safety reports	Duplicate copies of the same report when sponsor submission has been confirmed

WHEN IN DOUBT

If the sponsor's designation is unclear, or if the site cannot determine whether the information meets IND safety reporting criteria, follow the sponsor's instructions or contact WCG for triage guidance before submitting duplicate or non-required reports.

WHAT HAPPENS AFTER YOU SUBMIT

WCG acknowledges receipt and reviews the information submitted to determine what, if any, additional action is required to maintain IRB approval. IND safety reports reflecting an FDA UPIRSO determination that do not require further action will be acknowledged and will only be reported by WCG to FDA if the submission indicates FDA has not been notified of the event. Safety events requiring protocol or consent changes that are determined by the IRB to be UPIRSO will continue to follow applicable reporting requirements under 21 CFR 56.108.