My protocol is approved for **Reliance on Another IRB**.

Q. If there is a Reportable Event that occurred at BCH, which IRB do I need to inform?

A. **Both!** You must report the reportable event to **both** the sIRB and the BCH IRB.

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**How do I submit a Reportable Event to ...**

**sIRB?**

- You must follow the IRB reporting policy for the sIRB.
- Contact the Lead PI and/or sIRB to understand how to formally submit the reportable event.

**BCH IRB?**

- Events that meet the reporting criteria as outlined in BCH IRB Policy: [Reportable Events: Unanticipated Problems and Adverse Events Involving Risks to Research Subjects and Others](#).

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**Submit a Reportable Event to BCH IRB**

1. Create a Reportable Event in CHeRP.
2. Complete (Edit) the Reportable Event SmartForm and be sure to adequately summarize the event, who has been notified (i.e. sIRB, Lead PI, sponsor, FDA, etc.) and the proposed corrective action.
3. Upload any relevant documents using the “+ADD” function.
4. Save and submit Reportable Event.
5. Inform the Lead PI/sIRB that you have submitted a reportable event to BCH.

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**BCH IRB review and determination**

1. Once received, the IRB will review the Reportable Event and trigger any applicable ancillary reviews.
2. If the IRB has any questions or concerns, the submission will be returned with Sticky Notes. The PI/research team should promptly respond to each Sticky Note and resubmit.
3. The BCH IRB will administratively accept the reportable event or assign the reportable event to an IRB meeting for review. You will be provided with a letter documenting the IRB’s determination.
4. Provide the letter to the Lead PI/sIRB.