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**G-006 – Guidance on Reporting Unanticipated Problem Involving Risks to Participants or Others**

The following flowchart describes the process for determining whether an event qualifies as an “Unanticipated Problem”, which requires reporting to the IRB. Please see the Unanticipated Problems Involving Risks to Subjects or Others policy on the HRPP website for further information.

No

**Is the event serious?**

* Includes adverse events, subject complaints, other problems
* May involve physical, psychological, legal, economic, or social harms

**Flowchart for Reporting Unanticipated Problems to the IRB**

Yes

Yes

No

**Is the event related to the research?**

* Reasonable possibility event was caused by research procedures
* Include events that are definitely, probably, or possibly related

Yes

No

Do not report event unless subjects’ willingness to continue the study may be affected

**Is the event unexpected?**

* Unexpected given the nature of the research and subject population
* Not described in the protocol or informed consent document

Report in summary at the time of continuing review (or provide DSMB report for external events)

Report using Unanticipated Problem Reporting Form

<http://www.pbrc.edu/hrpp/forms/>