

Unanticipated Problems/Violations

If a researcher encounters *unanticipated problems regarding risks* to human participants or others *in HSRB-approved research*, the researcher should *promptly* report these problems to the chair of the HSRB. “Unanticipated problems involving risks” is defined as information that people are at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. “Promptly” means report such information within 48 hours. Provide a detailed description of the problem, your response, your project’s title, and all funding sources related to the research. The chair will then convene the HSRB to determine what steps should be taken, including possible suspension or termination of the research. Serious harm that occurs to research participants will be reported to the Provost, along with the recommendation of the HSRB.

If the HSRB deems that the event is NOT an unanticipated problem, no further action will be taken.

Because Hope College participates in the federal-wide assurance program of the Office for Human Research Protections (OHRP) with the federal government, federal regulations require three serious problems (incidents) in research to be reported the OHRP. **We suggest that researchers take extra precautions to prevent these three serious problems.** They include:

- a) any unanticipated problems involving risks to subjects or others
- b) any serious or continuing noncompliance with Federal Regulations or the requirements of Hope College’s HSRB
- c) any suspension or termination of HSRB approval

The HSRB will follow the federal guidelines in determining which incidents should be reported to the OHRP. See the decision chart at http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html.

If the HSRB agrees that any of these three problems have occurred, the HSRB chair will notify the Provost. The HSRB chair will indicate the researcher and project title, indicate any funding associated with the project, and provide a detailed description of the problem, noncompliance, or reason for termination. The HSRB chair will also summarize the HSRB’s recommended actions to be taken (and actions already taken) to address the problem. The Provost will then send this information on to OHRP within four weeks of learning about the event, if the event matches the criteria for doing so.