

Protocol Deviation Guidance

A protocol **deviation** is **any departure** from the IRB approved protocol procedures, forms, and other attachments.

A **deviation** must be reported within **10 days of deviation occurrence or identification**. For information about Deviation Reporting and Non-compliance see **HRP Policy Number 98.104**.

Serious adverse events must be reported within **24 hours** of the **researcher becoming aware of the event**. **All other adverse events** must be reported within 5 days of the researcher becoming aware of the event. For more information on Unanticipated Problems and Adverse Events, see **HRP Policy Number 98.105**.

PLEASE NOTE: any unapproved change resulting in a deviation must be halted immediately *unless* it is necessary to eliminate apparent immediate hazards to the human subjects. Please contact the Office of Research Compliance (ORC) for more information.

A Principal Investigator should include the following information when reporting a deviation. Please submit your report to the Office of Research Compliance, 560 N 16th street, room 102 or submit via email to elizabeth.mcdonough@marquette.edu. Please note that additional information may be requested as the deviation undergoes review.

1. Date of report
2. Protocol number: HR-####
3. Principal investigator
4. Department
5. Phone
6. Project title
7. Project advisor (if PI is a student)
8. Date of initial deviation
9. Date deviation was discovered
10. Date deviation was reported to the ORC/IRB
11. Describe the deviation
12. Why did the deviation occur?
13. Did the deviation increase the level of risk to subjects? Why or why not?
14. How will deviations be avoided in the future?
15. If the deviation included the addition of researchers, please list those researchers and a copy of their NIH training certificate(s), if available.

For more information, please contact the Marquette University Office of Research Compliance at 414-288-7570.