



REPORTING THE CHANGES THAT WERE MADE TO ELIMINATE AN IMMEDIATE HAZARD TO SUBJECTS

Federal regulations (HHS [45 CFR 46.108\(a\)\(3\)\(iii\)](#) and FDA [21 CFR 56.108\(a\)\(4\)](#)) and IRBMED Standard Operating Procedures permit researchers to immediately implement a protocol change without IRB approval ONLY when the change is intended to eliminate an apparent immediate hazard to subjects.

Note that these types of circumstances are generally expected to be rare.

Investigators should use their best judgment in determining to proceed without IRB approval. As applicable and feasible, permission/advice of sponsors may be necessary for evaluating modifications for investigational agents. IRBMED also can be contacted for consultation (email IRBMED at IRBMED@umich.edu during normal business hours or contact the IRBMED chair-on-call through the Michigan Medicine paging operator).

If a study team determines it is necessary to make a protocol modification to eliminate apparent immediate hazards to subjects and there is no adequate time to obtain IRB approval, these modifications can be made without prior IRBMED approval but must be reported to the IRBMED **within 5 calendar days** via the ORIO reporting mechanism.

Reporting to IRBMED
<p>When submitting the ORIO, please follow the below instructions:</p> <ul style="list-style-type: none">➤ In the ORIO title, indicate “Protocol change Implemented without IRB approval” along with any other indicators related to change➤ Select “Protocol Deviation” sub-type➤ In 6.1, select “Deliberate protocol departure for subject’s safety”➤ In 6.3, describe the protocol change(s) that were made. Also, indicate if any changes to the study documents (protocol, informed consent, etc.) are required. Provide enough information for IRBMED to acknowledge that the changes were intended to eliminate an apparent immediate hazard to subjects.➤ Upload any supporting documentation (such as sponsor’s approval or other similar documentation)
<p>NOTE(s):</p> <ol style="list-style-type: none">1. If the modification is a permanent change to the research study, an Amendment must also be submitted in eResearch.2. Additional reports to FDA may be needed if the U-M PI is also IND/IDE holder. Contact MICH MIAP for assistance.

Please review IRBMED AE/ORIO guidance (available on the IRBMED website) for information related to reporting AE/ORIOs.

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