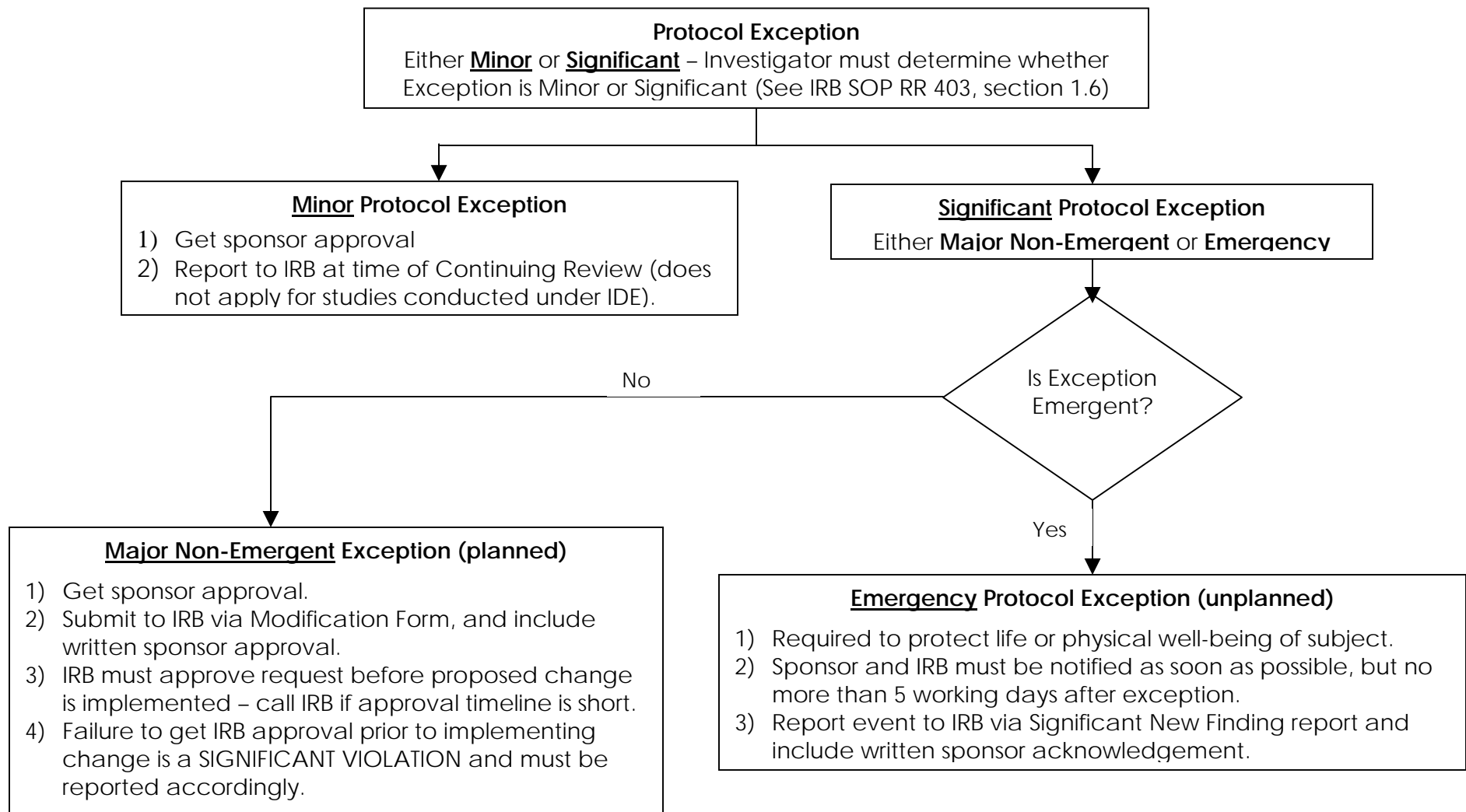


# PROTOCOL EXCEPTIONS

Federal regulations require IRBs to have written procedures to ensure “changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.” For Aurora IRB purposes, a Protocol Exception (change) is a one-time, intentional, time-sensitive action or process that departs (deviates) from the IRB-approved study. All sponsor approved eligibility exceptions require IRB review and approval before enrolling a subject who does not meet the approved eligibility criteria.



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## PROTOCOL EXCEPTIONS FOR INVESTIGATIONAL DEVICE EXEMPTION (IDE) STUDIES

FDA regulations state, “prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB in accordance with 812.35(a) also is required.” Planned exceptions of an IDE study must be submitted and approved by the IRB PRIOR to implementation of any such planned exceptions from the IRB approved protocol.

Following Significant Protocol Exception process outlined above, submit all planned exceptions to IRB via a Modification Form, and include written approval/acknowledgement from the sponsor.  
Call IRB office if timeline is short

## PROTOCOL EXCEPTIONS FOR INVESTIGATOR-INITIATED STUDIES

In the case of Investigator-Initiated research, the investigator serves as the sponsor of the research. ALL requests for Protocol Exceptions must be submitted to the IRB PRIOR to implementation.

- 1) Submit request to IRB by completing a Modification Form, except for those that are required to protect the life or physical well-being of the subject (emergent).
- 2) For emergency exceptions, IRB must be notified as soon as possible, but no later than 5 working days after exception.
- 3) A second request for the same Protocol Exception in an Investigator-Initiated research protocol will necessitate that the Investigator modify the protocol. A modified protocol must be submitted to the Aurora IRB for approval.