

Protocol Deviations

A Single Subject Protocol deviation is a change in an IRB-approved protocol which is permitted for an individual subject when it is in the best interest of that subject and/or is necessary for research purposes (e.g., data completion). Protocol deviations are classified as either “minor” or “more than minor.” Once the form is received, the deviation will be reviewed and processed by the IRB.

Deviations may be approved in one of two ways:

1. Deviations that are **minor** are eligible for expedited review under the provisions of HHS regulations at 45 CFR 46.110(b)(2) and FDA regulations at 21 CFR 56.110(b)(2), as applicable.
2. Deviations that are **more than minor** do not qualify for expedited review and therefore must be reviewed by the full IRB.

Once the deviation is approved, an approval letter for the Single Subject Protocol Deviation will be attached to the electronic IRB application. The PI and Lead Coordinator will be notified via email when this occurs.

To obtain Single Subject Protocol Deviation approval, a Single Subject Protocol Deviation Request must be submitted PRIOR to the implementation of the deviation. The instructions for submission are below:

RSS Studies & Existing Paper Format Studies

The Single Subject Deviation form can be created by pulling up the protocol in RSS. The 'Forms' section will be found in the left-side menu. When clicking on 'Forms' a list will appear allowing you to choose the 'single subject protocol deviation request'. Please follow the instructions provided to complete the form and once completed the PI will electronically sign and click 'SUBMIT'.

If you have any questions regarding this submission process, please contact the IRB Office at irbora@unmc.edu.

Revision #4

Created 12 July 2024 18:55:55 by Robert A Lewis

Updated 31 July 2024 16:59:39 by Robert A Lewis