

PROTOCOL CHANGES

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CONDITION FULFILLMENT

If the IRB places a conditional approval on your protocol, you will not receive official approval until the IRB Chair reviews and approves the required modifications. You must submit a new ORSP/IRB Cover Sheet (with the "Condition Fulfillment" box checked) to Research and Sponsored Programs. Please attach to the ORSP/IRB Cover Sheet a copy of the modified protocol, highlighting the areas that you have changed. If the required modifications are minor (i.e., title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review and approve the changes (policy applies to EXEMPT, EXPEDITED, and FULL protocols). If major modifications are required for a protocol reviewed under the FULL BOARD process, the condition fulfillment must also be included on the next IRB agenda for FULL BOARD review UNLESS the Board specifically vests the Chair (during initial review) with the authority to review and approve the required condition fulfillment modifications.

MODIFICATIONS

If you make any changes to your protocol, you must submit a new ORSP/IRB Cover Sheet (with the "Modifications" box checked) to Research and Sponsored Programs. Please attach to the ORSP/IRB Cover Sheet a copy of the modified protocol, highlighting the areas that you have changed. If the modifications are minor (i.e., title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review and approve the changes (policy applies to EXEMPT, EXPEDITED, and FULL protocols). If major modifications are made to a protocol originally requiring FULL BOARD review, the modified protocol will be included on the next IRB agenda for another FULL BOARD review.