

<b>IRB Policy #:</b>	<b>270</b>
<b>Policy Title:</b>	<b><i>Amendments to Protocols</i></b>
<b>Date Approved:</b>	
<b>Date Reviewed:</b>	

**Purpose:** To define the process for requesting amendment to an existing protocol.

**Policy:**

As required by 45 CFR 46.103(b)(4), all amendments to currently approved research must be reviewed and approved by the IRB before implementation. Changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved research projects that are more than minimal risk and do not qualify for expedited review must be forwarded to the full IRB for review and, if appropriate, to those participating in the study by way of a revised informed consent.

The PI shall incorporate each approved revision to a research protocol or consent document into the approved protocol to ensure that there is only one complete protocol.