

Submit this form in OnCore ONLY if scientific elements are modified.

If no scientific elements in the protocol are modified, then no submission is required to the SRC.

If this is an industry or NCTN trial, no submission is required to the SRC.

RG#:	PI:	Date:
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The modification impacts the following scientific elements (*Check all that apply*):

Design	Adding a new protocol arm; Changing objectives or primary endpoints; Changing statistical analysis
Eligibility	Change in overall patient population (Does not include administrative clarifications to eligibility)
Therapy	Deleting or adding investigational drugs that were not in original trial design; Scientifically significant change any protocol drug (may include dose, administration, route pre-medications, dose modification, preparation)
Risk/Benefit Ratio	Change to the risk/benefit ratio that significantly affects the scientific value (more effective treatment option available)

Provide a list or summary of changes noted above:

Provide a brief rationale for scientific changes noted above or indicate where the SRC can review the rationale in other documents provided.

Version Number	Current Effective Date	Original Effective Date
10	06/13/2022	04/23/2013