

Summary of protocol changes following the start of enrollment [Version 05 (published protocol) to Version 07]

Summary of Key Changes from Version 05 to Version 06:

Affected Section(s)	Summary of Revisions Made (05 to 06)	Rationale
Waiver of Consent section	To last paragraph in section: <ul style="list-style-type: none"> Added option to post handout materials. 	Additional flexibility for sites.

Summary of Key Changes from Version 06 to Version 07:

Affected Section(s)	Summary of Revisions Made (06 to 07)	Rationale
Training and Implementation subsection	<ul style="list-style-type: none"> Deleted “review of instructional manual” Deleted “co-assess cases with the “gold-star raters” and added reference to Training & Implementation Manual, instead of MOP Replaced protocol study team with site research team Added the number of gold-star raters (3) that will be assessed each period to ensure fidelity. Added “training milestones” to the criteria to assess for before moving to the ESC intervention period. Renamed webinars to coaching calls and deleted “biweekly.” 	Protocol clarifications and internal consistency; study procedure changes
Page 24, line 523	<ul style="list-style-type: none"> Changed section title to ESC Intervention Periods 	Consistency with other study periods
Page 24 Intervention subsection; lines 577-587	<ul style="list-style-type: none"> Replaced protocol study team with site research team Deleted “study” and added “ESC intervention” Deleted “assessing 10 individuals” Added “NOWS infant, written cases” Deleted “through a centralized training platform” for utilizing just-in-time training 	Protocol correction and clarification; add flexibility
Intervention subsection; lines 588-596	<ul style="list-style-type: none"> Deleted “the protocol study team will develop an electronic platform that will allow...” Deleted “The electronic platform will contain items from the ESC IRR tool (see MOP)” Added “keep completed ESC Implementation Process Evaluation Forms with other study documentation” Deleted sentence that stated sites will enter implementation process evaluation data into the electronic application and will send it directly to a central repository 	Clarify and correct process

