## Communication Escalation

Initial Request • The Trial Team PM communicates response request to Site Team (Site PI + Site PSC)

Escalation Step 1  If Site Team is unresponsive after follow-up, Trial Team PM may ask Trial PI to communicate response request to Site Team (Site PI + Site PSC)

Escalation Step 2

- If Site Team is still unresponsive after follow up, Trial Team PM to communicate response request to Site Team including Site PI + Site PSC + RCC PI + RCC Manager + Trial PI.
- The RCC Team will be asked by Trial Team to intervene with unresponsive Site Team.
- Possible corrective and preventive action (CAPA) report may be issued by Trial Team to ensure future timely responsiveness.

Escalation Step 3  If Site Team is still unresponsive after follow up, Trial Team may evaluate Site for probation / enrollment suspension at the <u>trial level</u>. This may be warranted for not responding to queries regarding participant safety, non-compliance or other serious matters.

Escalation Step 4

- The Trial Team will communicate Site probation to NINDS + NCC + NDMC Leadership to review if this is a
  pattern across trials.
- If pattern exists, NINDS +NCC + NDMC Leadership + RCC Team to intervene with StrokeNet level CAPA.

