Clinical Research Support Office ("CRSO")
STANDARD OPERATING PROCEDURE

SOP NUMBER	**TITLE**
CTG-6001	**CT.GOV Escalation Process**
EFFECTIVE DATE	**WRITTEN BY**
09/23/2025	**Ashley Walton-Robbins**

APPROVAL

Jessica Heskel — **9/23/2025**

SIGNATURE — **DATE**

1. POLICY STATEMENT

   To ensure the total quality management of data within the University of Kentucky Clinicaltrials.gov system (PRS), including record registration, record maintenance, and results reporting for trials that require results, a communication plan is necessary. If communication with study teams does not resolve the data entry issues (problems and errors) in a timely manner, escalation may be necessary.

2. PURPOSE

   This SOP outlines the escalation plan if data entry within the PRS is not completed per existing regulations and policies.

3. SCOPE

   This SOP is applicable to all Responsible Parties (RP)/Principal Investigators (PI) with records in the University of Kentucky Clinicaltrials.gov PRS system.

4. PROCEDURE

   - The Institution's PRS Administrator will work closely with the RP/PI and study teams to proactively address problems before non-compliances are escalated.
   - If the RP/PI is non-responsive after three attempts (minimum 1 week between each attempt), the RP/PI will be given an additional 5 business days to respond to the PRS administrator before escalating to the applicable party.
   - If no response is received after the lapse of the additional 5 business days an

escalation email will be sent copying the applicable department chair, division chief, research dean, or other institutional official of the RP/PI as well as the Executive Director of the CRSO.

- If the RP/PI or the applicable party named above is not responsive within a week of sending the escalation email, an escalation phone call with the department chair, division chief, research dean, or other institutional official may be necessary.

5. REFERENCES
   University of Kentucky Clinicaltrials.gov Policy