

# CLINICAL TRIALS: NO COST TIME EXTENSION & EARLY CLOSURE

*Revised September 28, 2023*

## OVERVIEW OF NO-COST TIME EXTENSION (NCTE)

- **Description:** Extends the project period end date up to current IRB expiration.
- **Due (*minimum*):** 2 weeks prior to project period end date. Recommended to initiate NCTE request a month in advance.
- **Mechanism:** Email to CTC&SR Team at [ClinicalTrials-NCTE@mednet.ucla.edu](mailto:ClinicalTrials-NCTE@mednet.ucla.edu)
  - 1) Current IRB Approval Notice
  - 2) [NCTE Request Form](#)
- **Processing Time:** 3-5 business days processing by CTC&SR, followed by updated NCTE award documents (including Snapshot) processed by Office of Research Data Management (ORDM)
- **Notes:**
  - A NCTE can be processed without having to amend the contract if:
    - 1) there is no hard End Date written into the contract and
    - 2) there are no changes to the protocol, IRB, budget, or PI
  - If a Contract Amendment is under review when NCTE request is received, the NCTE will be processed with the amendment once Amendment Minimum Documents have been received.

## HOW TO REQUEST A NCTE

1. Obtain current IRB approval notice from Study Team
2. Complete [NCTE Request Form](#)
3. Submit the following NCTE Request Minimum Documents to [CTC&SR](#) Team via email:
  - a. **To:** [ClinicalTrials-NCTE@mednet.ucla.edu](mailto:ClinicalTrials-NCTE@mednet.ucla.edu)
  - b. **Subject:** Request for NCTE - Fund #, Sponsor, Protocol #, IRB #
  - c. **Attachments:**
    - 1) [NCTE Request Form](#)
    - 2) Current IRB Approval Notice
  - d. **Body:** Requested date of contract extension (up to current IRB expiration)

## OVERVIEW OF EARLY CLOSURE

- **Description:** The project period end date is speed up to current IRB closure.
- **Due (*minimum*):** After receipt of IRB Closure Notice. Recommended to initiate Early Closure if contract end date is projected further than the IRB Closure Notice date.
- **Mechanism:** Email to CTC&SR Team at [ClinicalTrials-NCTE@mednet.ucla.edu](mailto:ClinicalTrials-NCTE@mednet.ucla.edu)
  - 1) Current IRB Closure Notice
  - 2) [Early Closure Request Form](#)
- **Processing Time:** 3-5 business days processing by CTC&SR, followed by updated end date award documents (including Snapshot) processed by Office of Research Data Management (ORDM).
- **Notes:**
  - A Early Closure can be processed without having to amend the contract if:
    - 1) there is no hard End Date written into the contract and
    - 2) there are no changes to the protocol, IRB, budget, or PI
  - No Contract Amendments should be under review when an Early Closure request is received.

## HOW TO REQUEST AN EARLY CLOSURE

1. Obtain current IRB Closure notice from Study Team
2. Complete [Early Closure Request Form](#)
3. Submit the following Early Closure Request Form to [CTC&SR](#) Team via email:
  - a. **To:** [ClinicalTrials-NCTE@mednet.ucla.edu](mailto:ClinicalTrials-NCTE@mednet.ucla.edu)
  - b. **Subject:** Request for Early Closure - Fund #, Sponsor, Protocol #, IRB #
  - c. **Attachments:**
    - 1) [Early Closure Request Form](#)
    - i. 2) Current IRB Closure Notice
  - d. **Body:** Requesting early close out date for internal contract new end date to (Today). Currently the snapshot indicates (Start and End Date). Confirming final payment received and study is closed.

## CONTACTS & RESOURCES

- CTC&SR NCTE Team: [ClinicalTrials-NCTE@mednet.ucla.edu](mailto:ClinicalTrials-NCTE@mednet.ucla.edu)
- CTC&SR Intake Team: [ClinicalTrials@mednet.ucla.edu](mailto:ClinicalTrials@mednet.ucla.edu)
- CTC&SR: [Submission / Preparation of Minimum Documents](#)