Responding to Theradex Clarifications

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Purpose: To identify the procedure for responding to research data clarifications for CTEP sponsored, CTMS monitored (Theradex) clinical trials at the CCR.

STEP 1: Receipt and review of clarification(s)

Theradex clarifications are electronically received in the Office of the Clinical Director (OCD).

- Clarifications are received at the beginning of the week (usually Monday afternoon).

The clarifications are processed by the Program Assistant to the Clinical Director (Pat Klevins).

- The email is forwarded to a point of contact in all affected branches, the Data Management contract Quality Assurance team, and Project Manager.
    - Contact Pat Klevins for your Branch's point of contact.
- Clarifications will be entered into centralized database by the Data Management contract Quality Assurance team.

STEP 2: Team processing of responses

Each Team will respond to each clarification within 3 days.

- The research nurse or data manager will investigate the clarification, correct or respond to the query.
- The research nurse must review the response and sign the query form .

STEP 3: Review by Data Management Quality Assurance (QA) team

Clarification responses are faxed (301-480-0196) or emailed to the Data Management QA team (barretta@mail.nih.gov) for review.

The QA team will review the responses and contact the research team within 24 hours if there are any issues to clarify.

If no issues are discovered, the QA team will fax or forward the responses to Caryn Steakley at 301-496-9020 or steaklec@mail.nih.gov who will then submit to Theradex.

If there are issues, the QA team will work with the research nurse or data manager until resolved. If needed, OCD can be contacted to assist in resolution.

STEP 4: Finalized clarification responses are posted

Finalized Theradex Clarification responses are posted on the OCD shared folder at: L:\CCR_QA Team\QA Team\CLARIFICATIONS .