



Monday Morning Practice Pearls #37

You learn that one of your study patients, who is not an inpatient at NIH, has died.

First, the PI will need to assess if the death is possibly, probably or definitely related to the research. If so, then report the death to the IRB within 24 hours (see M2P2 #8).

Second, inform the CCR Clinical Director via email if the death is not progressive disease which occurred within the protocol reporting timeframe. Please include in the email to NCI CCR QA (in global) if you also informed the IRB.

Third, inform the CC of the death. When a patient dies outside of the NIH, the CC refers to this as an “Outpatient Expiration”. Whether the patient is currently on your study or not, there are 2 things that you will need to do.

Step 1: Enter an Outpatient Expiration Service Request in CRIS



- Click on the ‘Enter Order’ icon.
- Click on the + next to ‘Medical Record Services’
- Find the “Outpatient Administrative Expiration” from the list of services and double click

The screenshot shows the CRIS system interface. At the top, it displays 'CC-CADRE' and 'Unreviewed Allergies' for 'Herion, David W'. Below this, there are fields for 'Requested By' (Me/Other), 'Date', 'Time', and 'Session'. A search bar is visible with the text 'Start Of Browse' and 'Contents of "/>

- Enter in the date the patient expired (required) and the place of expiration (if known).

The screenshot shows the 'MR Out Pt Admin Expiration - NIHCCTEST, ONEPOIS T' form. At the top, it displays 'NIHCCTEST, ONEPOIS T' and '46-79-37-4 / 111005250363' with '52y (05/18/1959)'. Below this, there are fields for 'Requested By' (Kehler, Amanda) and 'Template Name'. A message box contains the text: 'Solely used to enter information about an outpatient who has expired in a location outside the Clinical Center. Not to be used to record the expiration of an inpatient or an inpatient on pass. Call Medical Records with questions (301-496-2271)'. The 'Date Patient Expired' and 'Place of Expiration (City/State)' fields are highlighted with a red box.

Step 2: Document the death

Using a structured progress note, document the death in CRIS. Since the first step is an order, source documentation about the death is still necessary, especially if the patient is still on-study. Include:

- how you found out about the death (this may even be from a death notice)
- date of death, if know
- cause of death, if known

REMEMBER: if the patient is still on-study, you may need to submit an expedited adverse event report to the sponsor, especially if still on active treatment, so check your protocol.