

## More CRO Fun

Last year, coming off the heels of an editorial by Mikkael Sekeres in *ASH Clinical News*, I wrote a piece for this column called “Take Back the Research” (August 2017). I was jumping on the bandwagon that Mikkael and a group of European investigators had started, pushing back on contract research organizations (CROs) and all the non-value-added work they have injected into clinical research. For your amusement, I provide below an exchange that I had with a monitor this past week (names have been changed to protect the guilty).

Dear Dr Kahl,

I need to request additional updates to the site DOA (delegation of authority):

- The site DOA does not list staff delegated to process CT/MRI scans obtained per protocol requirements. Please update the site DOA to list staff delegated to complete this task and file their training documentation in the site electronic regulatory file for the CRA (clinical research administrator) to obtain a copy for the TMF (trial master file).
- The site DOA does not list staff delegated to complete IP infusions required by the protocol. Please update the DOA to list staff delegated to complete this task and file their protocol training documentation in the site electronic regulatory file for the CRA to obtain a copy for the TMF.
- The site DOA does not list staff delegated to complete protocol-required radiology scans (CT/MRI). Please update the site DOA to list staff delegated to complete this task and file their protocol training documentation in the site electronic regulatory file for the CRA to obtain a copy for the TMF.
- The DOA does not list staff delegated to complete required tumor measurements per protocol. Please update the site DOA to list staff delegated to complete this task and file their protocol training documentation in the site electronic regulatory file for the CRA to obtain a copy for the TMF.
- The site DOA does not list staff delegated to complete bone marrow biopsy per protocol requirements. Please update the site DOA to list staff delegated to complete this task and file their protocol training documentation in the site electronic regulatory

file for the CRA to obtain a copy for the TMF.

- The site DOA does not list staff delegated to complete EKGs per protocol requirements. Please update the site DOA to list staff delegated to complete this task and file their protocol training documentation in the site electronic regulatory file for the CRA to obtain a copy for the TMF.



Kind regards,  
Your CRO Torture Chamber

My column from last year clearly has had zero impact to date. The CRO is demanding that anyone at our center who touches a study patient be added to the DOA, and that such people undergo protocol training. According to that logic, if anyone stops for gas on the way to a protocol-required visit, should the gas station attendant be added to the DOA and undergo protocol training? For those of you who do not know, keeping DOAs perfectly up-to-date is an enormous task, and many monitors appear to thoroughly enjoy findings errors in DOA logs.

We replied, respectfully but firmly, as follows:

Dear Torture Chamber,

None of the staff you mention in the six bullets is ever listed in our DOA log. We have never done this before for any other study. We will not be adding the below staff to our DOA. Attached is our DOA log policy for reference. Please let us know if you have further questions.

Thanks,  
The Voice of Reason

Our policy basically states that nurses, fellows, laboratory personnel, and other ancillary staff are not listed on the DOAs. Nor should they be. They are not conducting study-specific functions, but rather are performing routine care functions involving study patients. I am currently waiting for the reply from the monitor. I anticipate another letter concluding with “Kind regards.”

Until next month ...

Brad S. Kahl, MD