From: Toth-Allen, Jean
Sent: Friday, August 11, 2006 12:20 PM
To: [purged]

Dear Mr. [purged]:

Your inquiry was forwarded to us for response.

If total cholesterol values are a variable that the protocol requires to be and/or remain within a certain range for subject eligibility in a clinical study, then the clinical investigator cannot simply notate values outside the prescribed range as NCR. The sponsor would need to be informed if this occurs during the study after treatment with the investigational product. If these results occur during screening for the study, the individual with values outside the prescribed range should not be included in the study. Sponsors will sometimes grant exceptions for subject who are not too far out of the range prescribed by the protocol, but this is not advised, as consistency among study subjects is essential for poolable data.

If the measurement is not vital to the study - i.e., a prescribed range for total cholesterol is not among the study's inclusion/exclusion criteria - and the clinical investigator just notes a value that is technically out of range for what is generally expected for total cholesterol, then such a notation could be appropriate. However, this should appear somewhere on study paperwork that is sent to the sponsor. If such out-of-range values occur with any frequency for study subjects when reviewed across all investigational study sites it might prove to be related to the investigational treatment and something the sponsor needs to follow-up on.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Wednesday, August 09, 2006 6:38 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: With respect to pathology results in clinical trials certain items may be out of range e.g. Total cholesterol. It s generally considered best practice for the investigator to review the data and annotate the pathology results, if appropriate, with NCR (not clinically relevant)and initial and date the entry. Could you please tell me if FDA expect this approach and what rule they apply to ensure compliance.

Sincerely

[purged]