From:	OC GCP Questions
To:	▓▓▓▓▓▓
Subject:	Access revoke to clinical database
Date:	Monday, June 29, 2015 11:36:56 AM

Good morning –

This office cannot specifically answer your questions. We recommend that you consult FDA's regulatory project manager (RPM) for your IND. This person can give you direction on locking your database.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, 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.

From: ▓▓▓▓▓▓
Sent: Monday, June 29, 2015 12:25 AM
To: OC GCP Questions
Subject: Access revoke to clinical database

Dear All,

Please let me know if it is fine to revoke access to Oracle Clinical Database once we have done with the database lock. Our process may take a maximum of 5 working days to revoke all users access to Oracle Clinical Database. I could not find any requirement in the "Guideline for Good Clinical Practice E6".

1. Is there a requirement that we need to have all users access to be revoked before database lock?
2. Is it fine to have read-only access post DBL?

Best Regards,

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