



OPRS NEWS

The following news update from OPRS highlights an OPRS Submit Enhancement and Amendment Submission Clarifications

OPRS NEWS
July 26, 2007

I. OPRS Submit Enhancement for CTEP Amendments

II. Amendment Submission Clarifications

- 1. PLEASE SUBMIT RESEARCH TEAM UPDATES SEPARATELY FROM OTHER AMENDMENTS**
- 2. TRACKED CHANGE DOCUMENTS REQUIRED.**

I. OPRS Submit Enhancement for CTEP Amendments:

OPRS Submit has been enhanced to now allow study teams to identify CTEP Amendments (including NCI / Cooperative Group / NABTT / NABTC sponsored trials) requiring 90 day IRB review and approval. To submit such an amendment, please select "Amendments - CTEP: NCI/Cooperative Groups/NABTT/NABTC" from the "Document Type" pull down list. Please continue to use the amendment form including the sponsor amendment number/version date and attaching all sponsor correspondence/documentation regarding the amendment. For example, the IRB must have for review a copy of any NCI supporting documentation.

II. Amendment Submission Clarifications:

1. PLEASE SUBMIT RESEARCH TEAM UPDATES SEPARATELY FROM OTHER AMENDMENTS.

Please do not bundle any Research Team Update Forms / Site Addition Forms / PI - Site PI Changes with Amendments via OPRS Submit. Research Team Update Forms / Site Addition Forms / PI - Site PI Changes should be submitted by appropriate submission type listed in OPRS submit under the "Document Type" pull down. While each of these submissions are all considered amendments to the protocol, they are triaged and reviewed differently. A study team update may take only a few days for it to be reviewed, but if it is submitted with an amendment that requires both SRC and IRB review - the study team update will take significantly longer to review and approve than if it was submitted separately.

2. TRACKED CHANGE DOCUMENTS REQUIRED.

Please note with all amendments clean and tracked change versions are required for all revised study documents. If the study sponsor does not provide a tracked change version of a protocol document then the study team is responsible for identifying by hand the changes to the document. Submissions not including required clean and tracked change versions may be returned to the study team.

Thank you!

For further information, contact:
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