



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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## Operations Office

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Date: September 25, 2009

To: NCCTG Primary Clinical Research Associates

From: Tracee L. Shevlin, Research Protocol Specialist

Re: N08C1, Paclitaxel-Associated Acute Pain Syndrome Natural History Study

It has come to our attention that there is some confusion with regards to the definition of 'new' pain/aches in the patient completed questionnaires.

The first question is asked daily on the 6 days following each dose of therapy (days 2-7): "Please rate any aches/pains that are new since your last dose of paclitaxel, and that you think might be related to your chemotherapy treatment by circling **ONE** number that best describes your aches and pains at its **WORST in the last 24 hours.**"

Another question is asked on day 8 following each dose of therapy: "Over the previous week, have you developed any new aches/pains that you did not have prior to your last dose of chemotherapy and that you think is from this chemotherapy?"

This seems fairly self explanatory for the very first cycle of treatment. However, subsequent cycles can be confusing. In this setting, there are three situations.

1. The aches and pains experienced with the previous cycle of therapy have completely resolved by the time the next cycle of therapy begins, but the same aches and pain are experienced again. **In this situation, we would consider these to be new since the aches and pain went away with the last dose and now are new again.**
2. The aches and pains that occurred in the previous cycle of therapy have not completely resolved by the time the next cycle of therapy begins, but the aches and pain are the same after the new therapy started. **In this situation, we would not consider these to be new pains since the aches and pains did not get worse.**
3. The aches and pains that occurred in the previous cycle of therapy have not completely resolved by the time the next cycle of therapy begins, but the aches and pain are worse after the new therapy is started. **In this situation, we would consider these to be new pains since the aches and pain are new in intensity.**

Please let me know if you have any questions regarding this. I can be reached at 507-538-6647.