After review of our NCI audit findings I wanted to use the opportunity to remind and alert staff to the areas where special attention is needed.

1. **Re-consenting** is required in response to NCI Action Letters about potential new risks. When a subject is re-consented, document the process in the medical record.

2. You must always use the most **current version** of the consent form which is posted on ONCPRO. Whenever possible, the consent should be printed on the day the subject is signing consent to avoid the wrong version of the consent being used. If the consent is printed in advance, you should check ONCPRO to verify that an updated consent has not been posted in the interim.

3. The protocol describes the **dose modification** process. It is essential that the study team and anyone involved in treating the subject be aware of and carry out the dose modifications required by the protocol.

4. Study **medication diaries** or notes in the medical record are required when a research subject is taking at home study medications. Document attempts to retrieve unused study medications and the completed study medication diaries.

5. Reminder to treating clinical staff to **recalculate doses** when the subject has had substantial weight loss. Refer to the protocol and your institution's clinical policy regarding the % weight change which would require a dose recalculation.

6. Document **best clinical response** in the Medical Record. Make arrangements to have the response confirmed by someone not associated with the protocol and document that result. Follow the response criteria identified in the protocol. Use the same imaging method of tumor measurement for baseline and restaging. Additional information and training will be forthcoming.

7. **Adverse Events** for NCI trials must be reported through AdEERS as per the sections of the protocol containing the CAEPR [which includes the Expected Adverse Events List (ASAEL)] and the AdEERs reporting requirements table. This reporting is required and may differ with what is required by DFCI IRB.

8. **Pencil** is not to be used for source documentation or the recording of research data.

9. **White Out** (correction fluid or correction tape) must never be used to revise any source document. You must cross out with a single line and date/initial the entry change so that the original entry and the revised entry are legible.

10. **Missing labs** and evaluation notes are problematic. Always follow the protocol requirements paying particular attention to both the text and the required data tables, if applicable.

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