

North Central Cancer Treatment Group

N0543: A Phase II Trial of Pharmacogenetic-Based Dosing of Irinotecan, Oxaliplatin, and Capecitabine as First-Line Therapy for Advanced Small Bowel Adenocarcinoma

Addendum 9 – March 26, 2010

**Summary**

- The study statistician has been revised
- NCCTG Research Base Nurse has been revised.
- Update protocol for specimen submission from ~~MML~~ to **BAP**
- Editorial/administrative changes.

**Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.**

**Title page** The study statistician has been revised as follows:  
~~Bruce W. Morlan~~ **Michelle Mahoney, M.S.**  
~~507/284-8803~~ **266-4456**

Title page has been revised to include Addendum 9 and a new NCI version date.

**Protocol Resources**

Page 2: Contact information has been updated for the “NCCTG Research Base Nurse” as follows:

~~Dianne M. Herrera~~ **Jerri Spohn, R.N.**  
NCCTG Research Base Nurse  
Phone: (507) 284-2459  
Email: ~~herrera.dianne@mayo.edu~~ [lee.jeraldine@mayo.edu](mailto:lee.jeraldine@mayo.edu)

**Schema**

Page 4: An editorial error has been corrected. The reference to Footnote 2 has been added to all three arms of the study and has been annotated in the diagram.

**Section 14.0 Translational/Pharmacologic Studies**

Pages 39-40: Sections 14.212, 14.213, 14.251, 14.254, 14.255, 14.256 and 14.257 have been modified to revise the current area that is receiving the specimens and to provide additional instructions. The affected sections are revised as follows:

- 14.212 Participating institutions may obtain **blood** kits by completing and faxing the Supply Order Form (found in the Forms Packet) to **Biospecimen Accessioning Processing (BAP)**. Fill out the site address to where the kits will be shipped. Because we are now being charged for all outgoing kits, a small, but sufficient, supply of the specimen collection kits should be ordered prior to patient entry. Do not send unused kits back to ~~MML~~ **BAP Receiving or the BAP Shared Resource**.
- 14.213 Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Allow at least two weeks to receive the kits. **Kits will arrive inside the shipping boxes.**
- 14.251 Verify ALL sections of the Blood Specimen Submission Form (see Forms Packet), ~~MML~~ **BAP** Requisition Form (provided in kit), and specimen collection labels are completed and filled in correctly.
- 14.254 Ship specimens overnight to ~~Mayo Medical Laboratories (MML)~~ **BAP Receiving according to kit instructions. Do not send samples on weekends or holidays.**
- 14.255 **The BAP kits will include a smart shipper label (3x5 white barcoded label) affixed to the shipping boxes. The smart shipper label is a pre-addressed return label, which replaces the need for an airbill. Shipping costs will be covered by NCCTG if the shipping box provided with the BAP kit is used for shipping specimens to BAP Receiving. The white barcoded FedEx mailing labels are affixed to the shipping boxes for shipment to MML.**
- 14.256 ~~MML~~ **BAP Receiving** will receive the samples and immediately forward specimens to the NCCTG Research Base ~~Biospecimens Accessioning and Processing (BAP)~~ **Shared Resource** laboratory, Stabile 13-10A, Attention: BAP Supervisor
- 14.257 **The BAP Shared Resource** will record receipt of specimens and process specimens according to Appendix V instructions.

**Section 17.0 Pathology Considerations for Quality Control**

Page 66: Sections 17.12 and 17.13 have been modified to revise the current area that is receiving the specimens and to provide additional instructions. The affected sections are revised as follows:

17.12 For UGT1A1 testing, a blood sample will be collected and shipped to ~~MML~~ **BAP Receiving** (see Section 14.2).

With every sample, in addition to the ~~MML~~ **BAP** Requisition Form...

17.13 ~~MML~~ **BAP Receiving** will forward the specimens to the Biospecimen...