June 1, 2011

FORMS PACKET

Title: N0147, A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for KRAS Wild-Type Patients with Stage III Colon Cancer

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✓designates revised/new forms

N0147
Protocol Paper or Electronic Forms Instructions
Updated June 1, 2011

STARTING on <u>Wednesday, June 1st 2011</u>, all Case Reports Forms, Reports and related documentation [including all outstanding CTSU generated Data Clarification Forms] are to be <u>mailed</u> directly to NCCTG. Beginning September 1, 2011, NCCTG sites will begin using NCCTG Remote Data Entry Systems (all other sites will continue to mail data to NCCTG).

CTSU website will still be maintained for NCCTG purposes. Access to this website will be available for the remainder of the study.

General Information	• All forms are protocol specific and contain only the data that is pertinent to the protocol's analysis. • Complete form header information on multi-page forms EXACTLY the same on all pages. • Forms and reports sent to the NCCTG must include an NCCTG Data Submission Cover Sheet. • It is important to comply with the protocol's test schedule (Section 4.0). Not all protocol test schedule requirements will be captured/recorded on the forms; however, the tests/procedures are required for patient management. • All data items on the forms must be completed unless there are specific instructions on the form indicating that only one choice must be marked. • Initials on all Case Report Forms should be the same as they are collected on the registration form: **<u>Last, First, Middle</u>**. • Place an "x" over the appropriate AE value on the toxicity forms; it is difficult to discern when boxes are blackened. • Access the "MedDRA 6.0 Coding For Adverse Events (AEs)" dated 10-04-07 accessible under the N0147 protocol (under Documents) of the CTSU members' web site at <u>https://members.ctsu.org/.</u> • Sites will be queried if any required fields are not completed.

	• The header on all forms requires **Patient Study ID** which will be the 90_ _ _ _ _ number that the patient received at random. • The **Patient Medical Record Number** is your local internal patient number. • **All patients enrolled on or after the date of February 1, 2009; must submit the NCI Cooperative Group Colorectal Cancer – Treatment Form –Subset <u>and</u> the NCI Cooperative Group Colorectal Cancer-Toxicity Form Subset. The protocol is re-implementing these forms which were disconnected with Addendum 7; for all treatment cycles for Patients randomized to Arms A & D.** • **All applicable forms are required to be submitted, even if a patient is deemed ineligible, a cancellation, or in major treatment violation. In such cases, patients are still considered part of the study and proceed to other phases of the trial (per Section 13.0) as this study will be using an "intent to treat" analysis for the primary endpoint.** • **All enrolled patients are used for the primary endpoint, regardless of receiving study treatment or eligibility status.**
Pre-Randomization Form **"New Process regarding KRAS results** ***Addendum 9, dated August 18, 2008 – the trial will be restricted to patients with wild-type KRAS"***	• Refer to Appendix XII. • **NOTE: The purpose of the pre-randomization requirement is to obtain a 9-million NCCTG number for the patient.** • Initials on all Case Report Forms should be the same as they are collected on the registration form: **<u>Last, First, Middle</u>**. NOTE: Following pre-randomization, the two site contacts listed on the Pathology Submission Form will be notified by NCCTG (via e-mail) of the patient's KRAS results (i.e., wild type or mutant) for patient assignment within ≤10 business days from receipt of all required pathology materials. The site will then need to call CTSU to complete patient registration/randomization. o Patients with wild type KRAS will then be registered to the trial and will be randomized to either FOLFOX (arm A) or FOLFOX and cetuximab (arm D) and receive therapy as currently occurs in the trial. o Patients with mutated or not evaluable KRAS will be registered to the trial and assigned to a data

	collection arm (Arm G). Treatment will be determined by the treating physician and minimal follow-up information will be collected by the trial.
Pre-Registration Screening Failure Form	• Complete only if patient is not registered/randomized after pre-randomization completed. See Section 18.0 • NOTE: If the patient is not proceeding to Registration/Randomization, the site must FAX this form (as noted on the form) to the NCCTG, Attention: N0147 QAS using FAX number 507-284-1902.
Registration Form	• Refer to Appendix XII. • Initials on all Case Report Forms should be the same as they are collected on the registration form: **Last, First, Middle**.
On-Study Form	• Refer to Section 18.0 for submission of the On-Study Form. • Primary staging is based on only one advanced primary tumor. • At least one lymph node must be examined. • At least one lymph node must be positive.
Patient completed QOL Forms	**NOTE: questionnaires are not required for patients that were enrolled after the implementation of Addendum 9 (August 18, 2008). Patients enrolled prior to Addendum 9 are to continue with the submission of original questionnaires that were in place at the time of their randomization (which includes submission even if the patient DID NOT complete the questionnaire.)** • All questionnaires must be submitted prior to January 30, 2009. • Refer to Appendix V and XII for submission instructions.
Treatment Form-Subset (As of Addendum 10 – we are returning to full/subset data collection starting with enrollments on Feb. 1, 2009)	• **This form was required for patients enrolled prior to Addendum 7 (January 4, 2008) and is required for all patients (Arms A & D only) enrolled on or after February 1, 2009.** • **If data was submitted for patients enrolled between 1/08/2008 and 1/31/2009 this data will be reviewed but not used in analysis** • **This form is NOT for patients registered to Arm G.**

- NCCTG defines a cycle as the time treatment starts until patient returns for re-evaluation by the physician (i.e., every 2 weeks).
- Data will be collected for 2 cycles on one form. It is very important that both cycles are recorded on the same form.
- In June 2005, patients receiving CPT-11 were required to cross over to a different treatment arm. The current treatment arm is to be entered onto the Case Report Forms and will change during the course of treatment for those patients who crossed over. For this reason, "Current Treatment Arm" is reflected on the forms for this trial as of Addendum 6.
- Reporting period start date is the first date of treatment. Reporting period end date is the date of physician evaluation prior to initiation of the next cycle of treatment.

Arms A & D patients only

- Refer to the memo on the CTSU website dated October 4, 2007 – Part 2

Clarification of the relationship between "Reporting Period Start Date" (Treatment Form-Subset of Patients) to "Assessment Date" (Toxicity Form – Subset of Patients)

The Assessment Date (Toxicity Form – Subset of Patients) for a given cycle is the date the patient was evaluated for adverse events occurring during the current cycle. The Assessment Date for one cycle is the latest date on which adverse events were assessed prior to starting the next cycle of treatment. Therefore, the Assessment Date for one cycle will be earlier, or the same as, the Reporting Period Start Date (Treatment Form- Subset of Patients), for the next subsequent cycle.

Example of the same Assessment Date and Reporting Period Start Date:

- *Patient receives Cycle 2 therapy on 1/1/2006.* ***Cycle 2 is the current cycle.***
- *Patient returns on 1/17/2006 to be evaluated by the physician prior to Cycle 3. The patient starts Cycle 3 treatment on 1/**17**/2006.*
- *For this patient, the Assessment Date (Date Patient Evaluated for Adverse Events This Cycle) 1/17/2006* ***should be reported on the Cycle 2 form for the current cycle.***
- *The Reporting Period Start Date 1/**17**/2006* ***should be reported on Cycle 3 form for the next cycle.***

	• Cumulative dose is **total** dose of agent for this cycle. Round to the nearest whole mg. **Cetuximab (C225)** may be given without the other agent(s) for Day 1 of a new cycle, if the criteria for administering the other agent(s) are not satisfied (i.e. held or delayed). However, this dose will be included on the total for the previous cycle. That is, the cycle start date and Day 1 will always coincide with the administration of non-C225 agent(s). Once the criteria are satisfied for the non-C225 agent(s) for the new cycle, administer Day 1 and Day 8 of treatment (multiple agents) in accord with the treatment schedule. It is recognized that the total dose for C225 will be higher for the previous cycle (i.e., 3 administrations vs 2). • For example, a patient is to be administered day 1 of FOLFOX for cycle 4 on 4/14/08, but due to adverse events FOLFOX was held. However, the adverse events were acceptable for C225 to be administered. The patient then returns on 4/21/08 and the adverse events have resolved, therefore FOLFOX is given to the patient as well as C225. The start date for cycle 4 is 4/21/08 (i.e., date FOLFOX is given for a "new" cycle) and the total dose for C225 must be updated for cycle 3 to include the dose given to the patient on 4/14/08/ **Given that C225 may be administered even though non-C225 agents are not, a maximum Cetuximab dose for any given cycle cannot be defined; except in cases when the FOLFOX regimen is held after 4 weeks due to adverse events, the patient must be taken off study, per protocol.**
Capecitabine Use In Replace of 5-FU (See Dear Doctor Letter dated 11/22/05)	**Updated information:** • The 5-FU shortage from November 2005 has been resolved and patients who were treated using the Capecitabine in place of 5-FU were required to return to using the 5-FU. **Information for use during 5-FU shortage (November 22, 2005):** • Patients currently receiving active treatment, but are unable to obtain 5-FU have the following options: 1) Remain on-study, and start their next treatment cycle receiving the alternative treatment (Oxaliplatin/Capecitabine) as outlined in the dear doctor letter Or 2) Discontinue active treatment on N0147, opting to use

	appropriate alternative treatment off-study as determined by the treating physician. • If you choose to continue on-study and receive the alternative treatment (Oxaliplatin/Capecitabine), you are required to complete page 6 of 6 of the dear doctor letter. After completion of the form, the form should be faxed to NCCTG (507-284-1902) to the attention of "N0147 QCS". **Note:** Treatment with this regimen should be repeated every 2 weeks until 5-FU is again available.
Leucovorin Administration Form	**NOTE: Refer to Dear Doctor Letter Updated December 5, 2008; for the Leucovorin Shortage information.** The following guidelines apply to both <u>patients currently receiving N0147 protocol-directed therapy and for new patients</u> enrolled on or after August 18, 2008. 1) For patients on protocol-directed therapy on N0147 and for new patients, a lower dose of leucovorin may be used instead of 400 mg/m2 if a limited supply of the drug is available. Giving the lower dose is likely to be of benefit compared to giving no leucovorin at all. 2) For patients on protocol-directed therapy and for new patients, alternative forms of leucovorin may be used. The protocol currently uses leucovorin 400 mg/m2 of the racemic mixture of leucovorin. Because of this high dose of leucovorin the only practical alternative is the use of levo-leucovorin, levo-leucovorin (Fusilev) o Fusilev 200 mg/m2 IV - It is important to recognize that the dose of Fusilev <u>is 50% of the dose of the leucovorin (racemic mixture).</u> 3) For patients currently receiving protocol-directed therapy on N0147, if the current racemix mix of leucovorin is not available and other forms of leucovorin can not be obtained, it is permissible to continue therapy with 5-fluorouracil and oxaliplatin alone. Therapy should **not** be changed to capecitabine and oxaliplatin. NOTE: While oral leucovorin exists, the bioavailability of oral

	leucovorin at higher doses is uncertain and a large number of tablets would need to be taken. As such this option is not recommended. **Please refer to the Leucovorin administration form required found in the forms packet. After completion of this form, the form should be faxed to NCCTG (as noted on the form) (507)284-1902 to attention of "N0147 QAS".**
Treatment Summary Form	This form is submitted only **once** at end of treatment. **There are two forms: <u>1) patients randomized to arms A and D</u> and <u>2) patients registered to Arm G.</u>** This form is required for all patients, regardless of the patient receiving treatment and should be completed as soon as possible. For a patient that did not receive any treatment, record 0 in the Total Number of Cycles Given. o First Date Protocol Therapy was given and the Last Date Protocol Therapy was given, will be left blank. • First date protocol therapy given is the first date of cycle one. • Last date of protocol therapy is the last date any protocol therapy is given. • Give only **one** reason treatment ended. • Refer to Section 18.0 to see if more forms are required. To be completed as soon as possible once the decision has been made to discontinue treatment, if the patient never received any treatment following randomization/registration, at the time AE's are assessed following the last cycle of treatment, upon disease recurrence, or if the patient died. A Follow Up Form is additionally required at this time point when patients have either had disease recurrence or died, using "0" for the Visit number for this situation. • For planned dose modifications, refer to Section 8.0 in the protocol. • Unplanned dose modifications are those not specified in Section 8.0 of the protocol. (Example: Dosing error or day missed due to scheduling.) • If other reason for modification, please specify. Assessment date for response status at this assessment must be provided. • Physical examinations are to be performed every 2 weeks

	during treatment, per footnote 1, of the Test Schedule in Section 4.0 of the protocol. All examinations are to include patient weight, ECOG Performance Status and medical history, and must include a MD, DO, PA, NP or RN assessment. (This includes the physician evaluation in the two weeks following completion of Cycle 12.) Height must be recorded at the baseline visit only. • Although a disease assessment is not required at the end of active treatment, there is an area to collect this information if the patient was assessed for disease status at this time (e.g. discontinuing treatment due to recurrence). This is a mandatory question in the database and must be answered or a query will be generated. **<u>Arm G patients only</u>** **KRAS mutant or not evaluable patients, non study treatment - New Adjuvant Disease Summary Form (Arm G Only)** • Required at the time Arm G patients discontinue their off-study therapy. Submitted only once, per patient.
Toxicity Form-Subset (As of Addendum 10 – we are returning to full/subset data collection starting with enrollments on Feb. 1, 2009)	• **This form was required for patients enrolled prior to Addendum 7 (January 4, 2008) and is required for all patients (Arms A & D only) enrolled after the implementation of Addendum 10, February 1, 2009. Note: Continue to submit subset forms if started at Cycle 1 for a patient enrolled in Addendum 7.** • **If data was submitted for patients enrolled between 1/08/2008 and 1/31/2009 this data will be reviewed but not used in analysis.** • **This form is NOT for patients registered to Arm G.** • In June 2005, patients receiving CPT-11 were required to cross over to a different treatment arm. The current treatment arm is to be entered onto the Case Report Forms and will change during the course of treatment for those patients who crossed over. For this reason, "Current Treatment Arm" is reflected on the forms for this trial as of Addendum 6. • The Assessment Date (Date Patient Evaluated for Adverse Events This Cycle) for a given cycle is the date the patient was evaluated for adverse events occurring during the current cycle. The Assessment Date (Date Patient Evaluated for Adverse Events This Cycle) for one cycle is the latest date on

which adverse events were assessed prior to starting the next cycle of treatment. Therefore, the Assessment Date (Date Patient Evaluated for Adverse Events This Cycle) for one cycle will be earlier, or the same as, the Reporting Period Start Date, for the next subsequent cycle.

Example of the same Assessment Date and Reporting Period Start Date:

- *Patient receives Cycle 2 therapy on 1/1/2006.* ***Cycle 2 is the current cycle.***
- *Patient returns on 1/17/2006 to be evaluated by the physician prior to Cycle 3. The patient starts Cycle 3 treatment on 1/**17**/2006.*
- *For this patient, the Assessment Date (Date Patient Evaluated for Adverse Events This Cycle) 1/17/2006* ***should be reported on the Cycle 2 form for the current cycle.***
- *The Reporting Period Start Date 1/**17**/2006* ***should be reported on Cycle 3 form for the next cycle.***

- Data will be collected for 2 cycles on one form. It is very important that both cycles are recorded on the same form.

- Physical examinations are to be performed every 2 weeks during treatment, per footnote 1, of the Test Schedule in Section 4.0 of the protocol. All examinations are to include patient weight, ECOG Performance Status and medical history, and must include a MD, DO, PA, NP or RN assessment. [This includes the physician evaluation in the two weeks following completion of Cycle 12 (or their final cycle).) Height must be recorded at the baseline visit only.

- Only report the grades that are reflected on the form.

- **Routine AEs in Section 10.0:** It is expected that all grade 3+ events, regardless of attribution, and outside of those required by other expedited reporting forms (e.g., AdEERS, MedWatch, NonAER form) are submitted via Case Report Forms for this trial.

- **Long Term Toxicity:** A long term toxicity is defined as an adverse event occurring >30 days from the last treatment. This is an adverse event that has not been reported previously on the toxicity subset or toxicity summary forms.

	• All adverse events reported through AdEERS must also be reported on this form. • This study utilizes the CTCAE version 3.0 for toxicity and Adverse Event (AE) reporting. MedDRA 6.0 Coding For Adverse Events (AEs)" dated 10-04-07 is accessible under the N0147 protocol (under Documents) of the CTSU members web site at https://members.ctsu.org/.
Toxicity Summary Form (This form is required only for patients enrolled AFTER the effective date of Addendum 7, January 4, 2008 to February 1, 2009)	• **This form is required only for patients between January 4, 2008 and February 1, 2009.** • This form is NOT required for patients registered to Arm G. Refer to Section 18.0; footnote 10: To be completed as soon as possible once the decision has been made to discontinue treatment (if treatment ends early) or at the time AE's are assessed following the last cycle of treatment. • **Long Term Toxicity:** A long term toxicity is defined as an adverse event occurring >30 days from the last treatment. This is an adverse event that has not been reported previously on the toxicity subset or toxicity summary forms. • **CTCAE v3.0 and MedDRA 6.0 must be used.** o **This study utilizes the CTCAE version 3.0 for toxicity and Adverse Event (AE) reporting. "MedDRA 6.0 Coding For Adverse Events (AEs)" dated 10-04-07 is accessible under the N0147 protocol (under Documents) of the CTSU members web site at https://members.ctsu.org/.** • Any event reported through AdEERS and also occurring as the maximum severity for a patient must also be reported on this form.
Follow Up Form	**There are two Follow Up Forms** **1. Not for Arm G Patients (patients randomized to arms A and D), and** **2. Arm G Patients Only** **Note: Updated instructions on the Follow-Up Form applicable to Arm G (KRAS mutant or not evaluable patients only) with the new follow up form for Arm G patient's only.**

	Arm G Patients – Follow Up Form • Refer to section 13.21 of the protocol. Patient will go directly to the event-monitoring phase of the study, which includes annual follow-up per section 18.0. On-Study material is to be submitted, which includes tissue and blood specimens. • Event monitoring data is required on these patients. Whenever treatment ends, follow up is due 1 year from the end of active treatment date, then annually up to 8 years from registration (or death, whichever occurs first). • Although this form is required on an annual basis for Event Monitoring for arm G patients, the same considerations and guidelines apply in terms of the forms submission, visit windows, and missing visits, as described below. • The first visit is scheduled to occur 1 year after ending treatment. Here, FUP form submitted is recorded as Visit • If a patient dies or has recurrent disease during their adjuvant treatment, the FUP form is submitted to report the death or recurrent disease and is recorded as Visit 0. **Not for Arm G Patients – Follow Up Form** • This form is to be submitted during the Observation and Event Monitoring phases of the study. See Sections 4.0, 13.0, and 18.0 of the protocol for further information regarding the frequency of tests and submission of this form during these phases. • By consenting to participate in this study, patients have agreed to participate in all phases of the study (i.e., Active Treatment, Observation, and Event Monitoring). Given that 5-year disease-free survival is the primary endpoint of this study, patients are to begin the Observation Phase of the study after completion (or early discontinuation) of active treatment, and in accord with Sections 4.0 and 13.0. NOTE: This is true, even if the patient begins alternative treatments for their disease, or is deemed ineligible or in major treatment violation (see Section 13.0). Patients cancelling treatment, prior to ever receiving study treatment, will begin the Event Monitoring Phase (see Section 13.0).

Addendum 12	• In rare instances, a patient may refuse to participate in the Observation Phase. They are then to begin the Event Monitoring Phase. If the patient additionally refuses to participate in Event Monitoring, they will be removed from the study entirely. • Since each situation may require specific instruction, please contact the NCCTG NO147 QAS if either of these cases happen and for further direction as to how to complete the Adjuvant Disease Treatment Summary and Follow-Up forms. • Answer YES, to the question "Were you able to obtain any information about the patient since the last report?" if this is the first report submitted for a patient. This is true even if this form is reporting a death or a patient having had a recurrence as described below. (There may be rare cases in which the NCCTG N0147 QCS will direct you to answer NO, for the first follow-up form submitted for a patient.) **Frequency of Form Submission:** • There are two phases of the study that use the Follow-Up form: 1=Observation, 2=Event Monitoring. • In Observation, Patients are followed for tests, according to the Test Schedule in protocol Section 4.0; under the Observation column; also refer to footnote #12. - footnote #23 has been added; CT scans may be performed annually rather than every 6 months. • During the Observation Phase (see the Test Schedule, protocol Section 4.0) – submit the Follow Up form every 6 months starting from the date of ending active treatment (ie, Last Date of Protocol Therapy Given), regardless of the reason for ending active treatment, and until disease recurrence or a total of 5 years from randomization (whichever is earlier), thereafter the patient begins Event Monitoring. • During the Event Monitoring Phase – (see the Data Submission Table, Section 18.0) the patient is monitored for disease recurrence and survival. It begins at the end of the Observation phase noted or if a patient refuses to participate in the observation phase. The timing of the forms starts with the date the patient had disease recurrence or ended the observation phase (ie, having reached 5 years post-

	randomization). Submit the form annually, until death or 8 years from randomization (whichever is earlier). • After the first follow up form (using the end of active treatment date); the next follow up forms are based off the last form received; for example in the observation phase where follow up forms are due every 6 months, earlier forms are accepted but then the 6 months would start from the visit date on last follow up form received. So if we received a follow up form with a visit date at 3 months (earlier than the 6 months required), the next follow up form that would be due during the observation phase would be 6 months from the visit date on the last follow up form submitted. • If a scheduled appointment for a Visit was missed, continue to submit a Follow-Up form for that planned Visit. "Were you able to obtain any information…" is unknown as it's a MISSED Visit, then it's answered as NO and then follow the instructions on the form. Here, the visit number is reported as if the patient status was known. In essence, the visit number represents the number of reports submitted in accord with the Observation/Event Monitoring schedules, not the actual number of times the patient is physically seen or contacted. **How to complete "Visit" field on this form:** • Visit numbering starts with the very first time this form is submitted and should coincide with the first visit following the end of active treatment. • If a patient discontinues treatment and refuses any further study participation, without having had a Follow-Up Form submitted, please submit this form with a Visit number of 1 and the date last known alive as the date of last contact associated with the end of active treatment. • Visit (Other) 0 is only used at off treatment when the reason on the Adjuvant Disease Treatment Summary CRF is death or progressive disease, relapse during active treatment. Visit "0" is viewed in analysis as "Not applicable, occurred during treatment". "Were you able to obtain any information about the patient since the last report?" should be answered YES but no dates should be recorded in this section. Answer all other questions. **Missed Visits** • If the Vital Status of the patient can be confirmed as ALIVE

(verbally or sighting) even if the patient was not assessed, then 'Were you able to obtain any information about the patient since the last report?' should be YES and the post-treatment follow-up visit date should be the date this vital status was confirmed. Other questions (except resection) must be answered on the CRF. This information pertains to documentation from the last follow up form submitted. If a YES response cannot be confirmed NO must be checked.

- If scheduled visit is missed, circle the visit that was missed, 'Were you able to obtain any information about the patient since the last report?' should be NO and the date should be the last date the site attempted to reach the patient to schedule the visit (which should be close to the date that the visit was expected on the patient's schedule). Cross off the rest of the form.

➢ *<u>Example</u>: Patient came in for 1st follow up visit at Month 6, and missed (or wasn't able to be contacted for) the 2nd visit at Month 12. For the missed Month 6 visit choose visit # 2 and enter the date it should have occurred. Cross off rest of form.*

- For patients having ended active treatment and started Observation or Event Monitoring: If the patient dies (or has a recurrence), prior to their next Visit and in a period of time that is shorter than the length of time required between reports (i.e., see protocol sections 13.0 and 18.0), the Visit number will be the next consecutive Visit number and the Visit Date will be the patient's date of death (or recurrence date, whichever is applicable). In the case of a recurrence, the next expected Visit will be one year from the date of the report submitted for the recurrence.

<u>Example 1</u>:
- *A patient is seen by their physician for Visit 4 on January 15, 2006, and shows no evidence of a recurrence.*
- *The patient is expected to be seen in 6 months, as they have not met the criteria for 1-year follow-up reports yet. That is,*
- *Visit 5 is expected some time around June 15, 2006.*
- *The patient dies on March 4, 2006.*
- *This form would be completed for Visit 5, using the patient's death date of March 4, 2006, as the Visit Date.*

<u>Example 2:</u>
- *A patient is seen by their physician for Visit 7, on May 15,*

2006, with no evidence of recurrence. Visit 8 is expected to occur around November 15, 2006.

- *In late July, the patient experiences symptoms indicative of recurrence. On August 1, 2006, a CT scan was performed and the patient had pulmonary metastases.*
- *Visit 8 would be completed, to report the recurrence, with a Visit Date of August 1, 2006.*
- *The patient would end the Observation Phase, to begin the Event Monitoring phase. The next report (Visit 9) would be due August 1, 2007.*

- If attempted contacts with a patient fail for at least a year, please contact the NCCTG N0147 QCS for further direction.

Here is another table to illustrate the expectations of Visit numbering and due dates for FUP forms and contact:

Last Date of TX = 06-01-2006 Randomization Date = 04/15/2006	Reason: Discontinued treatment at cycle 4, due to toxicity and without progression. Submit the Adjuvant Disease Treatment Summary Form . Start Observation Phase with reporting q 6 mos. Continues until 5 yrs, post-randomization (ie, 04/15/2011) unless prog or death.
Follow Up Visit 1 expected 12/01/2006, based on date of last TX.	Actual Visit 1 = 12/15/2006. No prog.
Follow Up Visit 2 expected 6/15/2007, based on date of Visit 1. No prog.	Actual Visit 2 = 05/30/2007. No prog.
Follow Up Visit 3 expected 11/30/2007, based on date of Visit 2.	Actual Visit 3 = Appointment for scheduled Visit on 12/01/2007 was missed, but patient known alive per phone call on that date. Counts as contact with patient, although prog status is unknown. Submit Follow Up Form Visit # 3 for the missed visit.
Follow Up Visit 4 expected 06/01/2008, based on the date of the missed Visit 3 (but confirmed contact with patient) on 12/1/2007.	Actual Visit 4 = 04/04/2008, patient had a progression. Start Event Monitoring phase. Continues annually, until 8 yrs post-randomization (ie, 4/15/2014) unless death.
Follow Up Visit 5 now expected in 1 year (ie, 4/04/2009)	Actual Visit 5 = 3/28/2009
Follow Up Visit 6 expected 3/28/2010,	Actual Visit 6 = 3/15/2010

based on last actual visit.	
Follow Up Visit 7 expected 3/15/2011, based on last actual visit.	Actual Visit 7 = 4/03/2011
Follow Up Visit 8 expected 4/03/2012, based on last actual visit.	Actual Visit 8 = 4/20/2012
Follow Up Visit 9 expected on 4/20/2013	Actual Visit 9 = 5/1/2013
Follow Up Visit 10 expected 4/15/2014 (not 5/1/2014), because the 8 yr criteria ends 4/15/2014.	Patient scheduled for visit on 5/1/2014. However, patient died on 11/25/2013. Submit one last FUP form to report the death. This is considered Visit 10.

Other considerations:

- Send documentation of recurrence, per Section 11.22.
    - If response to question "If the patient had developed a first progression (or recurrence), was a secondary resection performed THAT HAS NOT BEEN PREVIOUSLY REPORTED?" is YES, then the "Secondary Resection Follow Up" form must be completed and submitted. If response to question "If the patient had developed a first progression (or recurrence), was a secondary resection performed THAT HAS NOT BEEN PREVIOUSLY REPORTED?" is UNKNOWN then a specific comment is needed for this response. (E.g., "Patient moved, no further details can be obtained")
- Provide the date and outcome of colonoscopy assessments after treatment has completed and during the Observation and Event Monitoring phases of the study.
- If a patient has had a recurrence, complete the applicable sections of this form for the first report. Thereafter, (i.e., for subsequent recurrences) you can answer the question "*Has the patient developed a first progression (or recurrence) that HAS NOT BEEN PREVIOUSLY REPORTED?*" as NO and skip to the next section of the form.

Long Term Toxicity:

- A long term toxicity is defined as an adverse event occurring >30 days from the last treatment. This is an adverse event that has not been reported previously on the toxicity subset or toxicity summary forms. Use CTCAE v3.0 and MedDRA 6.0.
- Use the same non-MedDRA codes provided on the Toxicity

	Form-Summary and Toxicity Form-Subset forms, for the Oxaliplatin induced, non-CTCAEs of Laryngopharyngeal-Dysesthesia (code 8000002) and Paresthesia-Dysesthesia (code 8000001).
Secondary Resection Follow Up Form	• This form is not required for patients registered to Arm G. • Send documentation of secondary resection, per Section 11.221. • Submit this CRF only if the patient has developed a first progression (or recurrence) and a secondary resection was performed but not previously reported. Do not complete this form if the secondary resection was reported on Follow up Form - Not for Arm G Patients.
Recurrent Research Tissue Submission Form (Effective with Addendum 12)	• Submit this form ≤30 days following surgical resection following disease progression or ≤30 days following activation of Addendum 12 (dependent on IRB approval) if patient has already had disease recurrence and surgical resection to: NCCTG Operations Office Attention: PC Office (Study N0147) RO_FF_03_ 24-CC/NW Clinic 200 First Street SW Rochester, MN 55905 • In the event of serial or sequential resections following the first evidence of recurrent disease, submit this form only for the first secondary resection of the recurrent disease. • Submit Operative and Pathology reports with this CRF. An Operative or Pathology Cover Sheet CRF is required when submitting all operative and pathology clinical reports.

Specimen Submission Form (Blood) (Effective with Addendum 12)

- Refer to Section 14.0 in the protocol.
- Form to be filled out by all sites and sent to NCCTG.
- **All sites - send BAP Requisition Form (which is different from the Specimen Submission-Blood Form) and the blood specimen to Biospecimen Accessioning and Processing (BAP) Receiving (See Section 14.23). Be sure to include NCCTG patient identification number on the forms.**
- Translational blood specimens for Section 14.2 must be

collected **following pre-randomization/randomization and at the first Observation visit, or next Observation visit for patients already in the Observation phase.**

- **Pay close attention to Section** 14.23, Appendix XII, and Appendix XIII – Submission Logistics.

IHC Request Letter

- **See Appendix XV – Request Letter for Immunohistochemistry (IHC) Test Results. The NCCTG ID number must be on the request forms. Both pages must be completed (including contact information on page 2) and submitted to the address stated in the letter for processing.**
- **If the patient has died, or moved, as well as the physician being relocated, it is up to each treating institution to see that the LMD gets in contact with the patient or the patients family to relay the results.**

Pathology Submission Form	• Refer to Section 14.0 and 17.0 of the protocol. • Form to be filled out by all sites. • Form accompanies the tissue and is sent to the NCCTG Pathology Coordinator, per Section 17.0. **Please note that this form will not be removed from the delinquency report until all of the required pathology materials have been received per protocol.**
Specimen Submission Form (Fresh Frozen Tissue)	• Refer to Section 14.0 of the protocol. • This form is **required** to be completed by **MAYO SITES ONLY** (MCR, MCS, MCJ) regardless of whether or not the tissue has been submitted. • Fax copy of this form to NCCTG, per Section 14.3. Submit form and fresh frozen tissue as specified in Section 14.3. **As of Addendum 9, August 11, 2008… The optional fresh frozen tissue component has been removed because it is not longer required and protocol adjusted accordingly.**

Notification Form Grade 4 or 5 Non-AER Reportable Events/Hospitalization (NCCTG sites only)	This form has been DROPPED from data collection as part of Amendment 6. Refer to Forms Instructions (Addendum 9) for historical instructions
Transfer Patients	The institution name and treating physician where the patient is receiving treatment must be on all forms. This identifying information will change if the patient is transferred to a different location to receive treatment. The new information must be on all future forms. Patient transfer procedures can be found on the CTSU web site. Click on **EDUCATION & RESOURCES** and go under **CTSU Generic Forms and click on CTSU Transfer Form and Checklist.** The CTSU transfer form is available at this site and will continue to be submitted and processed through the CTSU..
Report Submission Form: Colonoscopy, Operative, and Pathology	• Refer to Section 18.0 of the protocol • Form must accompany the applicable report • Effective immediately, all NCCTG sites (until August 31, 2011) and all non-NCCTG sites all data and forms are to be mailed directly to: NCCTG Operations Office Attention: Quality Assurance Office (Study N0147) RO FF 03 24-CC/NW Clinic 200 First Street SW Rochester MN 55905 • Beginning September 1, 2011, all NCCTG sites will submit all forms via the NCCTG Remote Data Entry System.
Regulatory & Monitoring	The Study Audit procedures can be found on the CTSU web site. Click on **EDUCATION & RESOURCES** go under **Audit Resources.** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) can be found on the CTSU web site at https://www.ctsu.org/HIPAA/. The Clinical Data Update System (CDUS) Monitoring can be found on the CTSU web site. Click on **EDUCATION & RESOURCES** go under **Researcher Resources** and click on **Clinical Data Update System (CDUS).**

NORTH CENTRAL CANCER TREATMENT GROUP

PREREGISTRATION SCREENING FAILURE FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

NOTE: If the patient is not proceeding to Registration/Randomization, the site must FAX this form to the NCCTG Operations Office, Attention: N0147 Quality Control Specialist (507-284-1902).

DO NOT FAX OR SEND THIS FORM TO CTSU

Date aware of preregistration screening failure: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Primary reason screening failed: *(check one)*

5 ☐ Not evaluable for KRAS
1 ☐ Investigator decision
2 ☐ Patient decision
3 ☐ Did not meet *(other)* eligibility criteria
4 ☐ Other, Specify_____

NCI COOPERATIVE GROUP

REGISTRATION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Institution Code (CTEP assigned number) ☐☐☐☐☐☐☐

Physician of Record _____

Visit: Pre-Treatment (prior to randomization)

Protocol Administration

Projected Start Date of Treatment ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Person Completing Form, Last Name_____

Person Completing Form, First Name_____

Date of Randomization ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Person Completing Form, Phone (_____)_____

Person Completing Form, FAX (_____)_____

Patient Demographics / Pre-Treatment Characteristics

Patient Initials (L, F, M) ☐☐☐

Patient Height (cm) ☐☐☐ Patient Weight (kg) ☐☐☐.☐ Body Surface Area (m^2) ☐.☐☐

Performance Status (check one)

☐ *0 = Fully active, able to carry on all pre-disease performance without restriction (Karnofsky 90-100)*

☐ *1 = Restricted in physically strenuous activity but ambulatory (K 70 - 80)*

☐ *2 = Ambulatory and capable of all selfcare but unable to carry out any work activities (K 50 - 60)*

NCI COOPERATIVE GROUP
PRE-RANDOMIZATION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG
Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer
Patient Study ID _____ Patient Medical Record Number _____
Participating Group Code (Cooperative Group where credit will be applied) _____
Institution Name (treating location/performance site) _____
Institution Code (CTEP assigned number) _____ _____ _____ _____ _____
Physician of Record _____

NOTE: The N0147 Pre-Randomization Eligibility Checklist must be sent to CTSU along with the NCI Cooperative Group Registration Form.

Visit: Pre-Treatment (prior to registration/randomization)

Protocol Administration

IRB/REB Approval Date:
(mm/dd/yyyy) __ __/__ __/__ __ __ __
Date Informed Consent Signed:
*(mm/dd/yyyy)*__ __/__ __/__ __ __ __
Date of Prerandomization:
*(mm/dd/yyyy)*__ __/__ __/__ __ __ __

Person Completing Form, Last Name _____
Person Completing Form, First Name _____
Person Completing Form, Phone (_____)_____
Person Completing Form, Fax (____)_____
Person Completing Form, Email _____

Patient Demographics/Pre-Treatment Characteristics

Patient Initials (*L, F, M*) _____ _____ _____

Patient Birth Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ Patient Gender: ____ Male ____ Female

Patient Race
(***check all that apply***)
(U.S. and Canada only)

___ *White*
___ *Native Hawaiian or other Pacific Islander*
___ *Asian*
___ *Black or African American*
___ *American Indian or Alaska Native*
___ *Unknown: Patient is unsure of race*
___ *Not Reported: Patient refused or data not available*

Patient Ethnicity
(***check one***)

___ *Hispanic or Latino* ___ *Non-hispanic* ___ *Unknown: Patient is unsure of ethnicity*
___ *Not Reported: Patient refused or data not available*

Patient's ZIP Code *(USA)* ___ ___ ___ ___ ___-___ ___ ___ ___ Country of Residence *(if not USA)* _____

Method of Payment (**check one**) (U.S. only)

__ Private Insurance
__ Medicare
__ Medicare & Private Insurance
__ Medicaid
__ Medicaid & Medicare
__ Military or Veterans Sponsored NOS
__ Military Sponsored (including CHAMPUS & TRICARE)
__ Veterans Sponsored
__ Self pay (no insurance)
__ No means of payment (no insurance)
__ Other
__ Unknown

Is patient age 70 and over?
____ Yes (IRB approval required before pre-registering patients)
Addendum 10 dated May 8, 2009 IRB approved?
____ Yes. If Yes, Addendum 10 approval date (mm/dd/yyyy) __ __/__ __/__ __ __ __
____ No. If No, End form, Addendum 10 IRB approval required.
____ No (IRB approval not required before pre-registering patients)

REMINDER OF DRUG SUPPLY CHANGE FOR OXALIPLATIN: Patients enrolled after IRB approval of Addendum 10 must use commercially supplied Oxaliplatin. See the CTSU members website and protocol for further details. Plan cycle 1 of treatment accordingly, if the patient is determined to be KRAS status of Wild-Type and subsequently randomized to arms A or D.

KRAS Results Contacts

Contact Person (for KRAS results) **(Print clearly)**
Last Name: _____
First Name: _____
Phone: _____
Fax: _____
Email: _____

Contact Person *(alternate)* (for KRAS results) **(Print clearly)**
Last Name: _____
First Name: _____
Phone: _____
Fax: _____
Email: _____

Note: Following pre-randomization, the two site contacts listed above will be notified by NCCTG (via e-mail) of the patient's KRAS results (wild-type, mutant or not evaluable) for patient assignment. This notification will be sent **≤10 business days from receipt of ALL required pathology materials. ("ALL pathology materials" includes the H&E slides that are required to be submitted. If H&E slides are not submitted, NCCTG will prepare an H&E slide for the KRAS testing, but this will delay the process of reporting KRAS back to the site.)** The site will then need to call CTSU to complete patient registration/randomization.

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Required Characteristics

Yes No

____ ____ Histologically documented adenocarcinoma of the colon. The gross inferior (caudad) margin of the primary tumor must be ≥12 cm from the anal verge by rigid proctoscopy (i.e., patients with rectal cancer are not eligible). A rigid proctoscopy will be performed in only those settings where it is important to establish if the tumor is a rectal tumor or a colon tumor. Stage III tumor must have been completely resected. Resected Stage IV patients are not eligible. In patients with tumor adherence to adjacent structures en bloc resection must be documented in the operative report. Patients with tumor-related obstruction or colonic perforation are eligible for enrollment.

Note: Evidence of Epidermal Growth Factor Receptor (EGFR) in the resected tumor is **NOT** required.

Note: Patients with ≥one synchronous primary colon cancer are eligible. For the purposes of this protocol, staging classifications will be based on the stage of the more advanced primary tumor.

Note: Patients with positive radial (serosal, circumferential) margins are eligible as long as there is no evidence that the surgeon cut through the tumor; no evidence the tumor invaded adjacent tissues; and the entire specimen was resected by en bloc.

____ ____ At least one pathologically confirmed positive lymph node identified.

____ ____ There must be no evidence of residual involved lymph node disease. At least one lymph node must be found in the pathologic specimen. To help ensure optimal stratification, the recommended number of identified nodes is four or more.

____ ____ ECOG performance status (PS) 0, 1, or 2 (Appendix II).

____ ____ Age ≥18 years. Age = _____

____ ____ Must be willing to provide blood and tissue samples for eligibility and research purposes, as described in Sections 14.0 and 17.0. NOTE: tumor tissue must be submitted immediately after pre-randomization and ≤42 days following surgery to allow time for central KRAS testing prior to registration/randomization.

____ ____ Tumor tissue will be made available to NCCTG for centralized KRAS testing prior to registration/randomization.

____ ____ A pre-randomization pathology review (i.e. KRAS analysis) is required. The site has reviewed and understands the process listed in Section 17.0 and must account for sufficient time to complete pre-randomization and registration/randomization steps.

All responses in above section must be "Yes."

Contraindications

____ ____ Any of the following:

- Pregnant women
- Nursing women
- Men or women of childbearing potential who are unwilling to employ adequate contraception

This study involves agents (cetuximab, oxaliplatin, and 5-fluorouracil) whose teratogenic effects on the developing fetus and newborn are unknown.

____ ____ Evidence of residual involved lymph node diseases. ≥1 lymph node must be found in the pathologic specimen. To help ensure optimal stratification the recommended number of identified nodes is ≥4.

____ ____ Distant metastatic disease at the time of registration/randomization.

____ ____ Prior chemotherapy or radiation therapy for treatment of this malignancy.

____ ____ Prior therapy with agent(s) directed against EGFR.

____ ____ Prior allergic reaction (known sensitivity) to chimerized or murine monoclonal antibody therapy or documented presence of human anti-mouse antibodies (HAMA).

____ ____ Previous or concurrent malignancy. Exceptions: Treated basal cell or squamous cell skin cancer, in situ cervical cancer, or lobular carcinoma in situ in one breast; or other cancer for which the patient has been disease-free ≥5 years.

Eligibility Check – *(Contraindications continued)*

Yes No

____ ____ Any of the following conditions:
- Uncontrolled high blood pressure
- Unstable angina
- Symptomatic congestive heart failure
- Myocardial infarction ≤6 months prior to randomization
- New York Heart Association classification III or IV (Appendix III)
- Symptomatic pulmonary fibrosis or interstitial pneumonitis
- Active uncontrolled bacterial, viral (including HIV or clinically defined AIDS)
- Systemic fungal infection

____ ____ Other medical condition which, in the opinion of the treating physician, would make this protocol unreasonably hazardous for the patient.

____ ____ Clinically significant peripheral neuropathy at the time of randomization (defined in the NCI Common Terminology Criteria for Adverse Events [CTCAE] v3.0 as ≥grade 2 neurosensory or neuromotor toxicity).

____ ____ Concurrent use of other anti-cancer therapy including chemotherapy agents, targeted agents, or biological agents.

____ ____ Known allergy to other platinum compounds.

____ ____ History of gastrointestinal bleeding that has not been appropriately addressed based on the assessment of the enrolling physician.

All responses in above section must be "No."

Pre-Randomization Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

____ ____ Request Letter for Immunohistochemistry (IHC) Test Results (Appendix XV) has been given to the patient.

____ ____ Consent form signed and dated.

Is this a USA institution? (This question may be answered yes or no.)

____ Yes → Complete next question.

____ No → Check "not applicable **(Non-USA institution only)**" and skip to the next question.

____ ____ Authorization for use and disclosure of protected health information signed and dated.

Date of authorization _____-_____-_____ vs. not applicable **(Non-USA institution only)** ____.

____ ____ Patient has agreed by signature of consent form to allow tissue and blood samples to be used for correlative science studies associated with this study.

____ ____ Patients will automatically be registered to the mandatory translational research component of this study at the time of pre-randomization.

____ ____ Blood draw kit availability checked.

All responses in above section must be "Yes."

The following will also be recorded:

____ ____ Patient has given permission to store blood and paraffin-embedded tissue for future research of colorectal cancer.

____ ____ Patient has given permission to store blood and paraffin-embedded tissue for future research to learn, prevent, or treat other health problems.

____ ____ Patient has given NCCTG permission to give their blood and paraffin-embedded tissue to outside researchers.

Responses in above section may be "Yes" or "No."

Assigned Treatment

_____ Pre-Randomization

Person *(Site personnel)* pre-randomizing _____ CTSU Random. specialist _____

Signature initials

Investigator Signature _____ Date of Investigator Signature _____-_____-_____

M D Y

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG
Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer
Patient Study ID _____ Patient Medical Record Number _____
Patient Initials (last, first middle) _____
Participating Group Code (Cooperative Group where credit will be applied) _____
Institution Name (treating location/performance site) _____

Institution Code (CTEP assigned number) _____ _____ _____ _____ _____ Physician of Record _____

NOTE: The N0147 Registration/Randomization Eligibility Checklist must be sent to CTSU along with the NCI Cooperative Group Registration Form.

Patient to be Registered/Randomized to: *(check one)*

____ Arm A or D - Wild Type KRAS *[Go to Required Characteristics – Randomization (to Arm A or D) section below]*
____ Arm G – Mutated KRAS or Not Evaluable KRAS *[Go to Required Characteristics – Registration (to Arm G) section below]*

Required Characteristics – Randomization (to Arm A or D)

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Required Characteristics

Yes No

____ ____ Randomization must occur ≤56 days post surgery.
____ ____ KRAS wild-type status determined by central testing.
____ ____ Laboratory values obtained ≤28 days prior to randomization. Earliest laboratory test date _____-_____-_____; latest laboratory test date _____-_____-_____. NOTE: These dates pertain to the following labs only:
____ ____ • Hgb ≥9 g/dL. Hgb = _____.
____ ____ • Absolute neutrophil count ≥LNL (e.g. 1500/mm^3). Absolute neutrophil count = _____; LNL = _____.
____ ____ • Platelet count ≥100,000/μL. Platelet count = _____.
____ ____ • Creatinine ≤1.5 x UNL. Creatinine = _____; UNL = _____.
____ ____ • Total bilirubin ≤1.5 x UNL. Total bilirubin = _____; UNL = _____.

Is this patient a woman of childbearing potential? (This question may be answered yes or no.)
____ Yes → Complete question "Negative serum pregnancy test …"
____ No → Skip question "Negative serum pregnancy test …"

____ ____ Negative serum pregnancy test done ≤7 days prior to randomization, for women of childbearing potential only. Negative serum pregnancy test date _____-_____-_____.

Required Characteristics – Registration (to Arm G)

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Required Characteristics

Yes No

____ ____ KRAS mutant status determined by central testing, or KRAS status not evaluable.

All responses in above section must be "Yes."

Registration/Randomization Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes	No	
____	____	Must collect translational research blood sample for Section 14.2 following pre-randomization, but prior to registration/randomization.
____	____	Study drug availability checked.
		The following criteria are for Arms A & D only: *(Arm G patients go to Stratification Factors section)*
____	____	Treatment on this protocol must commence at the accruing membership under the supervision of a CTSU member physician (Arms A & D only).
____	____	Treatment cannot begin prior to randomization and must begin ≤14 days after randomization (Arms A & D only).
____	____	Pretreatment tests must be completed within the guidelines specified on the test schedule (see Section 4.0) (Arms A & D only).
____	____	All required baseline symptoms must be documented and graded in the patient's medical record (Arms A & D only).
____	____	Patient Instructions for Preventing and Treating Diarrhea (Appendix IV) and Patient and Physician Fact Sheet (Appendix X) have been given to the patient; treating physician has discussed their contents with the patient (Arms A & D only).

All responses in above section must be "Yes."

Stratification Factors at the Time of Randomization (for KRAS wild-type patients only)

NOTE: The following are required to be collected for all patients at the time of registration/randomization to Arms A, D, or G. These factors are used for stratification for randomization to Arms A or D.

Positive lymph node involvement
_____ 1-3
_____ ≥4

Histology
_____ High (poorly differentiated or undifferentiated)
_____ Low (well or moderately differentiated)

Clinical T Stage
____ (T1 or T2)
____ T3
____ T4

Descriptive Factors at the Time of Registration/Randomization

Tumor Characteristics:

Perforation	Obstruction	Adherence
____ Yes	____ Yes	____ Yes
____ No	____ No	____ No

Baseline number of stools reported *(for KRAS wild-type patients only)*:
____ Yes → Baseline number of stools per day: _____
____ No, patient has a colostomy/ileostomy

Assigned Treatment

_____ A) Oxaliplatin + Fluorouracil/Leucovorin Regimen (FOLFOX)
_____ D) Oxaliplatin + Fluorouracil/Leucovorin Regimen (FOLFOX) + C225
_____ G) Locally-Directed Therapy

Person *(Site personnel)* registering _____ CTSU Random. specialist _____
Signature initials

Investigator Signature _____ Date of Investigator Signature _____-_____-_____
M D Y

NCI COOPERATIVE GROUP

COLORECTAL CANCER - ADJUVANT ON-STUDY FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit: Pre-Treatment (prior to randomization)

Disease Characteristics

Primary Site(s)
- ☐ *Cecum*
- ☐ *Ascending colon*
- ☐ *Hepatic flexure*
- ☐ *Transverse colon*
- ☐ *Splenic flexure*
- ☐ *Descending colon*
- ☐ *Sigmoid colon*

Was there bowel obstruction? ☐ *Yes* ☐ *No*

Was there bowel perforation? ☐ *Yes* ☐ *No*

Disease Extent
- ☐ *Tumor invades submucosa (T1)*
- ☐ *Tumor invades muscularis propria (T2)*
- ☐ *Tumor invades through the muscularis propria into the subserosa, or into nonperitonealized pericolic or perirectal tissue (T3)*
- ☐ *Tumor directly invades or is adherent to other organs or structures and/or involves the visceral peritoneum (T4)*
- ☐ *Primary tumor cannot be assessed (TX)*

Number of Lymph Nodes Examined ☐☐ Number of Positive Lymph Nodes ☐☐

Surgical Information

Surgery Date *(date primary tumor removed; ≤ 56 days prior to randomization)* ☐☐ ☐☐ ☐☐☐☐
MM DD YYYY

Type of Procedure:
- ☐ Open
- ☐ Laparoscopic

Comments

Comments _____

_____

NCI COOPERATIVE GROUP

COLORECTAL CANCER - TREATMENT FORM - SUBSET OF PATIENTS

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Colorectal: Treatment Reporting Interval - Every two cycles during treatment for patients enrolled pre-January 4, 2008 or post-February 1, 2009.

Visit: Reporting Period *(Please indicate which cycles this CRF includes from time of registration):*
Circle one:

Cycles 1 & 2 ***Cycles 3 & 4*** ***Cycles 5 & 6*** ***Cycles 7 & 8*** ***Cycles 9 & 10*** ***Cycles 11 & 12***

Reporting Period Start Date* ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY) Cycle Number: ☐☐ Current Treatment Arm: ☐

Reporting Period End Date** ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY) Body Surface Area (M^2) for this cycle: ☐.☐☐☐

Dosing Information

Agent Name	Agent Total Cumulative Dose, for this Cycle	
OXAL	☐☐☐☐	mg *(units)*
5-FU Push	☐☐☐☐	mg *(units)*
5-FU Infusion	☐☐☐☐	mg *(units)*
C225	☐☐☐☐	mg *(units)*

* First date of treatment this cycle.

** Date of physician evaluation prior to the start of next cycle of treatment.

Reporting Period Start Date* ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY) Cycle Number: ☐☐ Current Treatment Arm: ☐

Reporting Period End Date** ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY) Body Surface Area (M^2) for this cycle: ☐.☐☐☐

Dosing Information

Agent Name	Agent Total Cumulative Dose, for this Cycle	
OXAL	☐☐☐☐	mg *(units)*
5-FU Push	☐☐☐☐	mg *(units)*
5-FU Infusion	☐☐☐☐	mg *(units)*
C225	☐☐☐☐	mg *(units)*

* First date of treatment this cycle.

** Date of physician evaluation prior to the start of next cycle of treatment.

Comments _____

_____

NCI COOPERATIVE GROUP

NOT FOR ARM G PATIENTS

COLORECTAL CANCER - ADJUVANT DISEASE TREATMENT SUMMARY FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit: Off Treatment

Treatment Summary Interval - End of Treatment ALL Patients Except Arm G

First Date Protocol Therapy was Given ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Last Date Protocol Therapy was Given ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Reason Treatment Ended (check one)

- ☐ *Treatment completed per protocol criteria*
- ☐ *Disease progression, relapse during active treatment*
- ☐ *Adverse Event/Side Effects/Complications*
- ☐ *Patient withdrawal/refusal after beginning protocol therapy*
- ☐ *Patient withdrawal/refusal prior to beginning protocol therapy*
- ☐ *Alternative therapy*
- ☐ *Patient off-treatment for other complicating disease*
- ☐ *Disease Progression before active treatment*
- ☐ *Cytogenetic Resistance*
- ☐ *Death on study*
- ☐ *Other (specify in comments on next page)*

Colorectal: Treatment Schedule - Systemic Therapy

****NOTE: Additions to protocol treatment are not permitted per N0147 protocol guidelines. ****

Total Number of Cycles Given ☐☐

Were there any dose modifications *(decreases/increases)* or additions/ omissions to protocol treatment?

- ☐ No *modification (decrease/increase) or omission (go to Disease Evaluation on next page)*
- ☐ Yes, planned *(i.e., the treatment was changed according to protocol guidelines)*
- ☐ Yes, unplanned *(i.e., the treatment change was not part of protocol guidelines)*

Check the reason(s) each agent was modified as listed below each agent name.

Agent Name: Oxaliplatin *[OXAL]*

Was agent modified (decreased/increased) or omitted? ☐ Yes ☐ No (*Go to "Agent Name: 5-Fluorouracil" below)*

If Yes, Reason(s) *[OXAL]* modified *(decreased/increased/omitted)*

[Reason(s) modified are based on Dose Modification Table in Protocol section 8.0]

- ☐ Infection
- ☐ Febrile Neutropenia
- ☐ Hematologic
- ☐ GI
- ☐ Neurologic
- ☐ Pulmonary
- ☐ HUS
- ☐ Other *(specify below)*

Other Reason agent *[OXAL]* modified *(decreased/increased/omitted)* _____

5-FU and C225 on NEXT PAGE

NCI COOPERATIVE GROUP

NOT FOR ARM G PATIENTS

COLORECTAL CANCER - ADJUVANT DISEASE TREATMENT SUMMARY FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Agent Name: 5-Fluorouracil *[5-FU]*

Was agent modified (decreased/increased) or omitted? ☐ Yes ☐ No (*Go to "Agent Name: C225" below)*

If yes, Reason(s) *[5-FU]* modified *(decreased/increased/omitted)*
[Reason(s) modified are based on Dose Modification Table in Protocol section 8.0]

- ☐ Infection
- ☐ Febrile Neutropenia
- ☐ Hematologic
- ☐ GI
- ☐ Pulmonary
- ☐ HUS
- ☐ Other, non hematologic, *(specify below)*
- ☐ Other *(specify below)*

Other, non hematologic Reason agent *[5-FU]* modified *(decreased/increased/omitted)* _____
Other Reason agent *[5-FU]* modified *(decreased/increased/omitted)*_____

Agent Name: C225 *[cetuximab]*

Was agent modified (decreased/increased) or omitted? ☐ Yes ☐ No (*Go to "Disease Evaluation" section below)*

If yes, Reason(s) *[C225]* modified *(decreased/increased/omitted)*
[Reason(s) modified are based on Dose Modification Table in Protocol Section 8.0]

- ☐ Allergic reaction
- ☐ Rash/Desquamation
- ☐ Nail changes
- ☐ GI (specific to patients ≥70 years)
- ☐ Other, non hematologic *(specify below)*
- ☐ Other *(specify below)*

Other, non hematologic Reason agent *[C225]* modified *(decreased/increased/omitted)* _____
Other Reason agent *[C225*] modified *(decreased/increased/omitted)*_____

Disease Evaluation

Response status at this assessment: ☐ *NED* ☐ *Recurrence* ☐ *Not Evaluated*

Assessment Date: ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Comments

Comments _____

NCI COOPERATIVE GROUP

ARM G PATIENTS ONLY

COLORECTAL CANCER - ADJUVANT DISEASE TREATMENT SUMMARY FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit: Off Treatment

Treatment Summary Interval - End of Adjuvant Treatment ALL Arm G Patients

First Date Adjuvant Therapy was Given ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Last Date Adjuvant Therapy was Given ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Colorectal: Treatment Schedule - Adjuvant Therapy

Adjuvant Chemotherapy for Colorectal Cancer: (check one)

- ☐ 5-FU, Oxaliplatin, Leucovorin (e.g. FOLFOX, FLOX)
- ☐ Capecitabine, Oxaliplatin (e.g. XELOX, CAPOX)
- ☐ 5-FU and Leucovorin
- ☐ Capecitabine alone
- ☐ Other, specify _____

Was bevacizumab used as a component of adjuvant therapy? ☐ Yes ☐ No

Did the patient complete the planned adjuvant therapy? ☐ Yes ☐ No

Comments

Comments _____

_____

_____

NCI COOPERATIVE GROUP

COLORECTAL CANCER - TOXICITY FORM - SUBSET OF PATIENTS

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

All Grade 3+ adverse events, regardless of attribution, and including those reported via expedited reporting systems (e.g. AdEERS, MedWATCH) MUST be additionally recorded onto this form.

Treatment Reporting Interval - Every two cycles during treatment for patients enrolled pre-January 4, 2008 or post-February 1, 2009.

Visit: Reporting Period *(Please indicate which cycles this CRF includes from time of registration)*: **Circle one:**

Cycles 1 & 2 ***Cycles 3 & 4*** ***Cycles 5 & 6*** ***Cycles 7 & 8*** ***Cycles 9 & 10*** ***Cycles 11 & 12***

* Last Date Patient Evaluated for Adverse Events on current cycle prior to start of next cycle of treatment.

Current Treatment Arm: ☐

Cycle Number: ☐☐

Assessment Date:*

☐☐ ☐☐ ☐☐☐☐
MM DD YYYY

Are all Adverse Event grades less than those required for reporting as listed below?

☐ Y(es) ☐ N(o)

If Y(es), skip rest of form.

CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.*

Current Treatment Arm: ☐

Cycle Number: ☐☐

Assessment Date:*

☐☐ ☐☐ ☐☐☐☐
MM DD YYYY

Are all Adverse Event grades less than those required for reporting as listed below?

☐ Y(es) ☐ N(o)

If Y(es), skip rest of form.

CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.*

CTC Adverse Event Term	MedDRA Code *(v.6.0)***	(Only report Grades listed below)	(Only report Grades listed below)
Neutrophils/granulocytes (ANC/AGC)	*[10029363]*	4 5	4 5
Platelets	*[10035528]*	4 5	4 5
Cough	*[10011224]*	3 ■ ■	3 ■ ■
Diarrhea	*[10012745]*	3 4 5	3 4 5
Dyspnea (shortness of breath)	*[10013968]*	3 4 5	3 4 5
Febrile Neutropenia	*[10016288]*	3 4 5	3 4 5
Hypoxia	*[10021143]*	3 4 5	3 4 5
Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils -			
Skin (cellulitis)	*[90030270]*	3 4 5	3 4 5
Abdomen NOS	*[90030154]*	3 4 5	3 4 5
Colon	*[90030180]*	3 4 5	3 4 5
Catheter-related	*[90030174]*	3 4 5	3 4 5
Wound	*[90030304]*	3 4 5	3 4 5
Biliary tree	*[90030162]*	3 4 5	3 4 5

**For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents ⟶ All.

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

CTC Adverse Event Term	MedDRA Code *(v.6.0)***	Cycle number: ☐☐ CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)	Cycle number: ☐☐ CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)
Lung (pneumonia)	*[90030220]*	3 4 5	3 4 5
Pleura (empyema)	*[90030258]*	3 4 5	3 4 5
Upper aerodigestive NOS	*[90030286]*	3 4 5	3 4 5
Upper airway NOS	*[90030288]*	3 4 5	3 4 5
Bladder (urinary)	*[90030164]*	3 4 5	3 4 5
Kidney	*[90030210]*	3 4 5	3 4 5
Urinary tract NOS	*[90030294]*	3 4 5	3 4 5
Pelvis NOS	*[90030248]*	3 4 5	3 4 5
Magnesium, serum-low (hypomagnesemia)	*[10021027]*	3 4 5	3 4 5
Laryngopharyngeal Dysesthesias (non-CTC)	*[8000002 (non-MedDRA)]**	3 ■ ■	3 ■ ■
Nausea	*[10028813]*	3 4 5	3 4 5
Paresthesias/dysesthesias (non-CTC)	*[8000001 (non-MedDRA)]**	3 4 ■	3 4 ■
Pneumonitis/pulmonary infiltrates	*[10035755]*	3 4 5	3 4 5
Mucositis/stomatitis - oral cavity (clinical exam)	*[90030045]*	3 4 5	3 4 5
Mucositis/stomatitis - pharynx (clinical exam)	*[90030046]*	3 4 5	3 4 5
Mucositis/stomatitis - oral cavity (functional/symptomatic)	*[10042128]*	3 4 5	3 4 5
Mucositis/stomatitis - pharynx (functional/symptomatic)	*[90030064]*	3 4 5	3 4 5

* Grade per Section 8.11 of the protocol.

**For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents ⟶ All.

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

CTC Adverse Event Term	MedDRA Code *(v.6.0)***	Cycle number: ☐☐ CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)	Cycle number: ☐☐ CTC Adverse Event Grade: Report the highest grade by *placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)
Thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura or hemolytic uremic syndrome)	*[10043646]*	3 4 5	3 4 5
Vomiting	*[10047706]*	3 4 5	3 4 5
Cardiac ischemia/infarction	*[10028600]*	3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5
Other, _____		3 4 5	3 4 5

Comments

Comments _____

_____

* Grade per Section 8.11 of the protocol.

**For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents ⟶ All.

NCI COOPERATIVE GROUP

COLORECTAL CANCER - TOXICITY FORM - SUMMARY

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit: Off Treatment

Adverse Events - At the end of treatment for patients enrolled during the reduced data collection period (i.e., enrolled between January 4, 2008 and February 1, 2009).

All Grade 3+ adverse events, regardless of attribution, and including those reported via expedited reporting systems (e.g. AdEERS, MedWATCH) MUST be additionally recorded onto this form.

Date last protocol therapy was given: ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Are all Adverse Event grades less than those required for reporting as listed below?

☐ Y(es) → If Y(es), skip rest of form ☐ N(o).

CTC Adverse Event Term	MedDRA Code *(v.6.0)***	CTC Adverse Event Grade: Report the highest grade *by placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)
Neutrophils/granulocytes (ANC/AGC)	*[10029363]*	4 5
Platelets	*[10035528]*	4 5
Cough	*[10011224]*	3
Diarrhea	*[10012745]*	3 4 5
Dyspnea (shortness of breath)	*[10013968]*	3 4 5
Febrile Neutropenia	*[10016288]*	3 4 5
Hypoxia	*[10021143]*	3 4 5
Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils -		
Skin (cellulitis)	*[90030270]*	3 4 5
Abdomen NOS	*[90030154]*	3 4 5
Colon	*[90030180]*	3 4 5
Catheter-related	*[90030174]*	3 4 5
Wound	*[90030304]*	3 4 5
Biliary tree	*[90030162]*	3 4 5
Lung (pneumonia)	*[90030220]*	3 4 5
Pleura (empyema)	*[90030258]*	3 4 5
Upper aerodigestive NOS	*[90030286]*	3 4 5
Upper airway NOS	*[90030288]*	3 4 5
Bladder (urinary)	*[90030164]*	3 4 5

**For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents ⟶ All.

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

CTC Adverse Event Term	MedDRA Code *(v.6.0)***	CTC Adverse Event Grade: Report the highest grade *by placing an "X" over the appropriate box; do **not** blacken the box.* (Only report Grades listed below)
Kidney	*[90030210]*	3 4 5
Urinary tract NOS	*[90030294]*	3 4 5
Pelvis NOS	*[90030248]*	3 4 5
Magnesium, serum-low (hypomagnesemia)	*[10021027]*	3 4 5
Laryngopharyngeal Dysesthesias (non-CTC)	*[8000002 (non-MedDRA)]**	3
Nausea	*[10028813]*	3 4 5
Paresthesias/dysesthesias (non-CTC)	*[8000001 (non-MedDRA)]**	3 4
Pneumonitis/pulmonary infiltrates	*[10035755]*	3 4 5
Mucositis/stomatitis - oral cavity (clinical exam)	*[90030045]*	3 4 5
Mucositis/stomatitis - pharynx (clinical exam)	*[90030046]*	3 4 5
Mucositis/stomatitis - oral cavity (functional/symptomatic)	*[10042128]*	3 4 5
Mucositis/stomatitis - pharynx (functional/symptomatic)	*[90030064]*	3 4 5
Thrombotic microangiopathy (e.g. thrombotic thrombocytopenic purpura or hemolytic uremic syndrome)	*[10043646]*	3 4 5
Vomiting	*[10047706]*	3 4 5
Cardiac ischemia/infarction	*[10028600]*	3 4 5
Other, _____		3 4 5
Other, _____		3 4 5
Other, _____		3 4 5
Other, _____		3 4 5
Other, _____		3 4 5
Other, _____		3 4 5

Comments

Comments _____

_____

* Grade per Section 8.11 of the protocol.

**For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents ⟶ All.

NCI COOPERATIVE GROUP

NOT FOR ARM G PATIENTS

COLORECTAL CANCER - FOLLOW UP FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

PLEASE SEE FORMS INSTRUCTIONS

Visit: (Please indicate which follow-up visit number from end of treatment.)

Circle one: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 Other: _____

Were you able to obtain any information about the patient since the last report?

1 ☐ Yes. If Yes, post-treatment follow-up visit date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ Continue to next section.

2 ☐ No. If No, date of last attempt to contact patient: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ Stop here, cross off the remainder of the form, and return form to NCCTG.

Vital Status

Patient's Vital Status ☐ *Alive* ☐ *Dead*

Death Date/Last Contact Date ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY

Disease Follow-Up Status

Has the patient had a documented clinical assessment for this cancer *since submission of the previous follow-up form*?

☐ *Yes* ☐ *No*

Date of Last Clinical Assessment ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY

(only provide date if assessment since submission of previous follow-up form)

Has the patient had a colonoscopy assessment for this cancer *since submission of the previous follow-up form*?

☐ *Yes* ☐ *No*

Date of Last Colonoscopy ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY

(only provide date if assessment since submission of previous follow-up form)

Notice of Recurrence

Has the patient developed a first progression (*or recurrence*) that HAS NOT BEEN PREVIOUSLY REPORTED? ☐ *Yes* ☐ *No*

Date of First Recurrence or Progression ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY

Site(s) of Progression ☐ Local ☐ Regional ☐ Liver ☐ Lung ☐ Other specify _____
(check all that apply)

Continued on next page

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Notice of Secondary Resection

If the patient has developed a first progression (*or recurrence*), was a secondary resection performed THAT HAS NOT BEEN PREVIOUSLY REPORTED? ☐ *Yes* ☐ *No* ☐ *Unknown, explain unknown* _____

If Yes, submit the "Secondary Resection Follow Up Form"and the "Recurrent Research Tissue Submission Form" for only the first surgery following recurrence. Use the "Comments" section for subsequent surgeries (see Section 17.13).

Notice of New Primary

Has a new primary cancer or MDS *(myelodysplastic syndrome)* been diagnosed that has not been previously reported? ☐ *Yes* ☐ *No*

Date of Diagnosis ☐☐ ☐☐ ☐☐☐☐ MM DD YYYY

Site(s) of New Primary _____

(If new primary site is AML/MDS, please submit NCI AML/MDS form.)

Notice of Long Term Toxicity

Has the patient experienced any grade 3 or greater, long-term toxicity since the submission of the last follow-up form? ☐ *Yes* ☐ *No* ☐ *Unknown*

NOTE: Use the same non-MedDRA codes provided on the Toxicity Form-Summary and Toxicity Form-Subset forms for the Oxaliplatin induced non-CTCAEs of Laryngopharyngeal Dysesthesias (code 8000002) and Paresthesias/ Dysesthesias (code 8000001).

MedDRA Code version 6 for Adverse Event*

CTC Adverse Event Term _____ ☐☐☐☐☐☐☐☐

CTC Adverse Event Term _____ ☐☐☐☐☐☐☐☐

CTC Adverse Event Term _____ ☐☐☐☐☐☐☐☐

Comments

Comments _____

_____

_____

*For MedDRA v.6.0 use: "https://members.ctsu.org/" under Documents → All.

NCI COOPERATIVE GROUP

ARM G PATIENTS ONLY

COLORECTAL CANCER - FOLLOW UP FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

PLEASE SEE FORMS INSTRUCTIONS

Visit: (Please indicate which follow-up visit number from Registration.)

Circle one: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 Other: _____

Were you able to obtain any information about the patient since the last report?

1 ☐ Yes. If Yes, post-treatment follow-up visit date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ Continue to next section.

2 ☐ No. If No, date of last attempt to contact patient: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __ Stop here, cross off the remainder of the form, and return form to NCCTG.

Vital Status

Patient's Vital Status ☐ *Alive* ☐ *Dead*

Death Date/Last Contact Date ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Disease Follow-Up Status

Has the patient had a documented clinical assessment for this cancer *since submission of the previous follow-up form*?

☐ *Yes* ☐ *No*

Date of Last Clinical Assessment ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

(only provide date if assessment since submission of previous follow-up form)

Has the patient had a colonoscopy assessment for this cancer *since submission of the previous follow-up form*?

☐ *Yes* ☐ *No*

Date of Last Colonoscopy ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

(only provide date if assessment since submission of previous follow-up form)

Notice of Recurrence

Has the patient developed a first progression (*or recurrence*) that HAS NOT BEEN PREVIOUSLY REPORTED? ☐ *Yes* ☐ *No*

Date of First Recurrence or Progression ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

Site(s) of Progression ☐ Local ☐ Regional ☐ Liver ☐ Lung ☐ Other specify _____
(check all that apply)

Biospecimen Accessioning Processing

Fax Supply Order Form – No Cover Sheet Necessary

Fax to Research Kit Building @ 507-538-4103

NOTE: Form must be either typed or printed legibly and filled out completely.

Study ID: _N0147_____

Investigator: _____

Order Placed By: _____ Phone #: ( ) _____

Email: _____ Fax #: ( ) _____

Complete Address (kits sent to):

_____

_____

_____

_____

ALLOW AT LEAST TWO WEEKS TO RECEIVE THE KITS.

NOTE: Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. **The study will not cover the cost for rush delivery of kits.**

Date Needed: _____
(Please be specific)

Fed Ex account number (Rush deliveries only) _____

Type of Kits	**# of Kits Needed**
N0147 Research Kit	_____
_____	_____
Total Kits	**_____**

Questions? Contact the Biospecimen Resource Manager listed on the Protocol Resource page of the protocol.

NCI COOPERATIVE GROUP

COLORECTAL CANCER - SPECIMEN SUBMISSION FORM (BLOOD)

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit: ☐ **Pre-Treatment (prior to randomization) OR indicate which follow-up visit number from end of treatment *(Arms A & D only)***

Circle one :

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 Other: ___

RESEARCH BLOOD SPECIMEN

INSTRUCTIONS

- Complete this form for all patients and submit to NCCTG..
- Complete this form for Arms A & D patients only in the Observation phase.
- Complete the Requisition Form in addition to this form.
- Include **only** the Requisition Form with the blood sample shipment to Biospecimen Accessioning and Processing (BAP) Receiving.
- See Section 14.2 & Appendix XIII - Blood Specimen Logistics.

1. Was a research blood specimen collected?

   1 ☐ Yes ⟶ Specimen Collection Date: ☐☐ / ☐☐ / ☐☐☐☐ (m m / d d / y y y y)

   2 ☐ No

   ↓

2. Reason research blood specimen was not collected: _____

   _____

   _____

NORTH CENTRAL CANCER TREATMENT GROUP

ARMS A & D ONLY
RECURRENT RESEARCH TISSUE SUBMISSION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Visit (circle one):
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 Other: _____

INSTRUCTIONS:

- Required for all Arm A and D patients having had a surgical resection for recurrent disease per Addendum 12.
- Submit this form ≤30 days following surgical resection following disease progression or ≤30 days following activation of Addendum 12 *(dependent on IRB approval)* if patient has already had disease recurrence and surgical resection to:

  NCCTG Operations Office
  Attn: PC Office (Study N0147)
  RO_FF_03_24-CC/NW Clinic
  200 First Street SW
  Rochester, MN 55905

- See Section 17.13 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission *(See Section 17)*.

Patient's re-consent *(per Addendum 12)* given for recurrent tissue specimen use for research on the patient's cancer? *(check one)*

1 ☐ Yes. If Yes, complete rest of form
2 ☐ No. If No, end form

Was sample obtained? *(check one)*

1 ☐ Yes. If Yes: Date of collection: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date Specimen Shipped: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: *(check one)*
3 ☐ Facility will not release block
4 ☐ Block depleted/insufficient tissue
5 ☐ Other reason, specify _____

Number of slides sent: _____

Accession number(s) (on the slides sent):

_____ _____
_____ _____
_____ _____
_____ _____

Number of blocks sent: _____

Accession number(s) (on the blocks sent):

_____ _____
_____ _____
_____ _____
_____ _____

Institution Contact Information: (Please print)

Contact Person at Institution *(CRA/Nurse)*:

_____

Institution Name: _____

Street Address: _____

_____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

NORTH CENTRAL TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

INSTRUCTIONS

This form must accompany pathology materials (blocks and slides) listed in Section 17 of the protocol.

Date materials sent to central laboratory: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Number of slides sent: __ __ __

Accession number(s):

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Number of blocks sent: __ __ __

Accession number(s):

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

COMMENTS:

_____

_____

_____

_____

_____

Institution Contact Information: (Please Print)

Contact Person at Institution (*CRA/Nurse*):

_____

Institution Name: _____

Street Address: _____

_____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

NCCTG Study N0147

COLONOSCOPY REPORT SUBMISSION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Instructions: Attach each report to a separate Submission Form. Always submit with an NCCTG Data Submission Cover Sheet.

REPORTING PERIOD: ☐ PRE-TREATMENT ☐ POST-TREATMENT

Procedure Date: ☐☐ / ☐☐ / ☐☐☐☐
m m d d y y y y

Submission Form Completed by (print name): _____

*****Use for Colonoscopy Reports only. Use the "N0147 Operative Report Submission Form" for all other surgical procedures.*****

NCCTG Study N0147

PATHOLOGY REPORT SUBMISSION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Instructions: Attach each report to a separate Submission Form. Always submit with an NCCTG Data Submission Cover Sheet.

REPORTING PERIOD: ☐ PRE-TREATMENT ☐ POST-TREATMENT (submitted as part of materials to document a first resection post-recurrence)

Procedure Date: ☐☐ / ☐☐ / ☐☐☐☐
m m d d y y y y

Specimen Type: _____

Submission Form Completed by (print name): _____

NCCTG Study N0147

OPERATIVE REPORT SUBMISSION FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Instructions: Attach each report to a separate Submission Form. Always submit with an NCCTG Data Submission Cover Sheet.

REPORTING PERIOD: ☐ PRE-TREATMENT ☐ POST-TREATMENT (submitted as part of materials to document a first resection post-recurrence)

Procedure Date: ☐☐ / ☐☐ / ☐☐☐☐
m m d d y y y y

Procedure Type: _____

Submission Form Completed by (print name): _____

*****Do not use for Colonoscopy Reports. Use the "N0147 Colonoscopy Report Submission Form."*****

NORTH CENTRAL CANCER TREATMENT GROUP

NOT FOR ARM G PATIENTS

COLORECTAL CANCER - LEUCOVORIN ADMINISTRATION FORM

For Use at NCCTG Only

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

This form is required for all patients randomized after August 18, 2008 to Arms A or D, and captures information regarding the administration of Leucovorin associated with Addendum 10 of the protocol.

Do not use this form for Arm G patients.

Fax this form within 30 days from the last day of treatment (per 18.0) to the NCCTG Operations Office - Attention: N0147 Quality Control Specialist (507-284-1902). **NOTE: Do not fax or send this form to the CTSU.**

***** All Cycles of study treatment and date fields must be reported on this form *****

Cycle Number	Reporting Period Start Date: (mm/dd/yyyy)	Drug Administration
1	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
2	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
3	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
4	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____

NOT FOR ARM G PATIENTS
COLORECTAL CANCER - LEUCOVORIN ADMINISTRATION FORM

For Use at NCCTG Only

Coordinating Group Protocol Number N0147 Patient Study ID _____

Cycle Number	Reporting Period Start Date: (mm/dd/yyyy)	Drug Administration
5	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
6	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
7	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
8	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
9	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
10	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____

NORTH CENTRAL CANCER TREATMENT GROUP

NOT FOR ARM G PATIENTS
COLORECTAL CANCER - LEUCOVORIN ADMINISTRATION FORM

For Use at NCCTG Only

Coordinating Group Protocol Number N0147 Patient Study ID _____

Cycle Number	Reporting Period Start Date: (mm/dd/yyyy)	Drug Administration
11	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____
12	__ __/__ __/__ __ __ __	Was agent *(Leucovorin)* administered? *(check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____ Was agent *(l-Leucovorin)* administered *(in place of Leucovorin)? (check one)* 1☐ Yes 2☐ No If No, reason: *(check one)* 1☐ Toxicity 2☐ Drug Supply 3☐ Other, specify _____

NCI COOPERATIVE GROUP

NOT FOR ARM G PATIENTS

COLORECTAL CANCER - SECONDARY RESECTION FOLLOW UP FORM

Coordinating Group Protocol Number N0147 Coordinating Group Code NCCTG

Protocol Title A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Patient Study ID _____ Patient Medical Record Number _____

Patient Initials (L, FM)_____

Participating Group Code (Cooperative Group where credit will be applied) _____

Institution Name (treating location/performance site) _____

Instructions

- *Submit this CRF only if the patient has developed a first recurrence and a secondary resection was performed but not previously reported.* ***Submit this form once, per patient.***
- *DO NOT complete this form if the secondary resection was reported on the Addendum #10 "Not For Arm G Patients Follow-Up Form"*
- *Submit operative and pathology reports with this CRF.*
- *In the event of serial or sequential resections following the first evidence of recurrent disease, submit this form for the first secondary resection of the recurrent disease. The answers to the questions below are relevant to the intent and outcome of* ***only*** *the first attempted resection following recurrent disease.*

Date of secondary resection: ☐☐ ☐☐ ☐☐☐☐ (MM DD YYYY)

(submit operative and pathology reports)

Intent of resection: *(check one)*

- ☐ Curative intent and successful R0 resection *(complete resection)*
- ☐ Curative intent but less than R0 resection
- ☐ Palliative intent

Site(s) of *(secondary)* resection ☐ Local ☐ Regional ☐ Liver ☐ Lung ☐ Other specify _____ *(check all that apply)*

Comments

Comments _____

_____

NCCTG
NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Operations Office
Attention: Quality Assurance Office (Study N0147)
RO FF-3-24-CC/NW Clinic
200 First Street SW
Rochester, MN 55905

NCCTG DATA SUBMISSION COVER SHEET

Submit data by mail to the address above

NCCTG Protocol number: N0147 **NCCTG Patient ID:** _____

Data Type: *(NOTE: If more than one data type, submit separate submission cover sheets for each data type)*
(check one) ☐ **Original data** ☐ **Amended data** ☐ **Response to query (attach query)**

Date data submitted: _____ **Number of pages:** _____
(Including this sheet)

Contact information:

Completed by: _____

Phone number: _____

Fax number: _____

E-mail address: _____

Site name: _____

Site mailing address: _____

_____

_____

_____