

## FORMS PACKET

N04C2, An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR® Depot) for Symptomatic Ascites in Cancer Patients

- Eligibility checklist (7/13/07)
- Cancer Control Specific Forms Instructions (12/18/07)
- \* Forms completion instructions
  - On-study form (1/16/2006)
  - Baseline adverse events/symptoms (5/11/05)
  - Concurrent treatment log (2/11/05)
  - Evaluation/treatment form (2/11/05)
  - Adverse event log (5/11/05)
  - Paracentesis data collection form (1/16/06)
  - End of active treatment form (1/22/07)
  - Event monitoring form (2/11/05)
  - Blood specimen submission form (1/22/07)
  - Baseline VEGF specimen submission form (2/11/05)
  - VEGF specimen submission form (12/18/06)
  - Grade 4 or 5 non-AER reportable events/hospitalization form (2/11/05)
  - Booklet order form (8/22/05)
- ➔ MML Fax Supply Order Form
  - Patient questionnaire booklet compliance form 1/22/07)
  - Booklet (*via surface mail*)

➔ designates revised/new forms

\* Forms completion instructions are available on the NCCTG web site under “Remote Data Entry Screen Instructions (Forms Completion).”

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

7/13/2007  
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**N04C2: An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR® Depot) for Symptomatic Ascites in Cancer Patients**

To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Randomization Center between 8 a.m. and 4:30 p.m. central time Monday through Friday.

Has the patient ever been on a prior study entered through the Mayo/NCCTG Random. Center?  Yes  No

If yes: Last protocol number \_\_\_\_\_

Study reg. number \_\_\_\_\_

Registration date \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
M D Y

Patient's initials (*For Mayo-Roch Pt's: include first four letters of last name*) \_\_\_\_\_  
Last, First Middle

Membership \_\_\_\_\_

Gender (check one)

- Male  
 Female  
 Unknown

Treating institution \_\_\_\_\_

Physician \_\_\_\_\_

Race code(s) (enter all applicable codes):

\_\_\_\_ / \_\_\_\_ / \_\_\_\_ / \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Inst. pt. number (local subject #) \_\_\_\_\_

Ethnicity code (check one)

- Hispanic or Latino (1)  
 Non-Hispanic (2)  
 Not Reported: Pt. refused or data not available (8)  
 Unknown: Pt. is unsure of their ethnicity (9)

Date of birth \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
M D Y

Zip code \_\_\_\_\_ - \_\_\_\_\_

IRB approval date \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
M D Y

Country \_\_\_\_\_

Method of payment \_\_\_\_\_

Addendum 2 (*dated July 13, 2007*) IRB approved?

Yes. If Yes, Addendum 2 approval date (*mm/dd/yyyy*) \_\_\_\_/\_\_\_\_/\_\_\_\_

No. If No, End form, Addendum 2 IRB approval required.

NCCTG Eligibility Checklist N04C2

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Study reg. number \_\_\_\_\_

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

Yes No

**Inclusion Criteria**

- \_\_\_\_   ≥18 years of age. Age = \_\_\_\_\_
- \_\_\_\_   Current or previous histologic or cytologic proof of malignancy (except lymphoma).
- \_\_\_\_   Treating oncologist thinks that ascites is caused by cancer (positive cytology is not necessary).
- \_\_\_\_   Therapeutic paracentesis planned ≤3 days after randomization or completed in the preceding 2 days prior to randomization.
- \_\_\_\_   Patient views ascites as a problem (documentation not necessary).
- \_\_\_\_   Must be willing to give ascites fluid sample for research.
- \_\_\_\_   Ovarian cancer patients at Mayo Rochester must be willing to give a blood sample for research.

All responses in above section must be "Yes."

**Exclusion Criteria**

- \_\_\_\_   History of cholecystitis with no cholecystectomy.
- \_\_\_\_   Known allergy to subcutaneous octreotide (Sandostatin®) or depot octreotide (Sandostatin LAR® Depot).
- \_\_\_\_   Known latex allergy.
- \_\_\_\_   Patients with known history of chronic renal failure (defined by serum creatinine ≥2 x UNL). It is not necessary to obtain a serum creatinine in patients who do not have a history of renal disease.
- \_\_\_\_   Any medical condition that may interfere with ability to receive protocol treatment.
- \_\_\_\_   Life expectancy <4 weeks.
- \_\_\_\_   Lymphomatous ascites.
- \_\_\_\_   Any of the following:
  - Pregnant women
  - Nursing women
  - Men or women of childbearing potential who are unwilling to employ adequate contraception
- \_\_\_\_   Currently receiving octreotide or depot octreotide (Sandostatin LAR® Depot).
- \_\_\_\_   Patient is receiving intraperitoneal chemotherapy.
- \_\_\_\_   On coumadin or warfarin or at high risk for bleeding from a procedure. (Prophylactic warfarin 1 mg/day is permitted.)
- \_\_\_\_   Currently or about to receive first-line chemotherapy for any cancer other than pancreatic cancer. (Second-line chemotherapy or later-line chemotherapy is allowed.)
- \_\_\_\_   Currently receiving bevacizumab.
- \_\_\_\_   Known cirrhosis or portal hypertension.
- \_\_\_\_   Uncontrolled diabetes mellitus.

All responses in above section must be "No."

\_\_\_\_   Patient eligible.

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

Yes No

- \_\_\_\_   Consent form signed and dated. Date of consent \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_.
- \_\_\_\_   **Is this an USA institution?** (This question may be answered yes or no.)
  - \_\_\_\_  Yes → Complete authorization question below.
  - \_\_\_\_  No → Check "not applicable (Non-USA institution only)" and go to next question.
- \_\_\_\_   Authorization for use and disclosure of protected health information signed and dated.
- \_\_\_\_   Date of authorization \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ vs. not applicable (Non-USA institution only) \_\_\_\_\_.
- \_\_\_\_   Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.

NCCTG Eligibility Checklist N04C2

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Study reg. number \_\_\_\_\_

Registration Check – (continued)

Yes No

- \_\_\_\_ Treatment cannot begin prior to registration and must begin ≤48 hours after paracentesis.
- \_\_\_\_ Pretreatment tests/procedures must be completed within the guidelines specified on the test schedule(see Section 4.0).
- \_\_\_\_ All required baseline symptoms must be documented and graded.
- \_\_\_\_ Study drug availability checked.

- \_\_\_\_ Randomization Center will register patients separately to the translational research component of this study (see Section 14.0)
- \_\_\_\_ Patient has given permission to give ascites sample for research testing.

**Is this a Mayo Rochester patient with ovarian cancer?**

- \_\_\_\_ Yes → Complete next question
- \_\_\_\_ No → Skip the next question
- \_\_\_\_ Patient has given permission to give blood sample for research testing **(required for Mayo Rochester patients with ovarian cancer.)**

**All responses in above section must be “Yes.”**

- \_\_\_\_ Randomization/registration allowed.

Stratification Factors

- Ongoing chemotherapy anticipated
- \_\_\_\_ Yes
  - \_\_\_\_ No

- Frequency of paracentesis prior to enrollment
- \_\_\_\_ Never
  - \_\_\_\_ Other

- At registration, patient has received chemotherapy
- \_\_\_\_ Never
  - \_\_\_\_ Only first-line chemotherapy
  - \_\_\_\_ Second-line chemotherapy
  - \_\_\_\_ Other

Descriptive Factors

- Cancer type
- \_\_\_\_ Ovarian cancer
  - \_\_\_\_ Primary peritoneal cancer
  - \_\_\_\_ Gastrointestinal cancer
  - \_\_\_\_ Other

- Ongoing diuretic therapy anticipated
- \_\_\_\_ Yes
  - \_\_\_\_ No

- Liver metastases in >25% of the liver
- \_\_\_\_ Yes
  - \_\_\_\_ No

NCCTG Eligibility Checklist N04C2

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Study reg. number \_\_\_\_\_

Assigned Treatment

Contact person (data manager/nurse/pharmacist) name: \_\_\_\_\_

Contact person may not be involved in assessing adverse events or any other outcome measure.  
(See Section 6.31.)

Contact person (data manager/nurse/pharmacist) phone number: \_\_\_\_\_

\_\_\_\_\_ Depot Octreotide (Sandostatin LAR Depot) vs. Placebo

Treatment assignment number: \_\_\_\_\_

Person registering \_\_\_\_\_ Random. specialist \_\_\_\_\_

Signature

initials

Physician \_\_\_\_\_

Signature

M

D

Y

## **N04C2: Cancer Control Specific Forms Instructions**

Not all required forms may be covered in the following instructions. Please refer to Sections 4.0 and 18.0 for completion and submissions timelines. ALL FORMS ARE FORWARDED TO THE RESEARCH BASE FOR THIS STUDY.

<b><i>General Information</i></b>	<ul style="list-style-type: none"><li>• Refer to the <b><i>Remote Data Entry Screen Instructions (Forms Completion)</i></b> on the NCCTG website for additional, non-specific forms instructions. Even though this is <b><u>NOT</u></b> a remote data entry study, you can still utilize these instructions.</li><li>• <b>The study is cycled as followed. Please note that a cycle begins on the injection date (located on Evaluation/Treatment Form) and ends prior to the next injection (cycle of treatment).</b><ul style="list-style-type: none"><li>➤ Cycle 1 = 1<sup>st</sup> treatment and month following 1<sup>st</sup> treatment (Month 1)</li><li>➤ Cycle 2 = 2<sup>nd</sup> treatment and month following 2<sup>nd</sup> treatment (Month 2)</li><li>➤ Cycle 3 = 3<sup>rd</sup> treatment and month following 3<sup>rd</sup> treatment (Month 3)</li><li>➤ Etc...</li></ul></li></ul>
<b><i>Baseline Blood Specimen Submission Form</i></b>	<ul style="list-style-type: none"><li>• This form is completed <b>ONLY</b> for Mayo patients.</li></ul>
<b><i>Evaluation/Treatment Form</i></b>	<ul style="list-style-type: none"><li>• The following form is used for Cycle 1 ONLY:<ul style="list-style-type: none"><li>➤ Evaluation/Treatment Form Cycle 1</li></ul></li><li>• The following form is used for all remaining cycles:<ul style="list-style-type: none"><li>➤ Evaluation/Treatment Form Cycle <math>\geq 2</math></li></ul></li><li>• When answering the question, “Did the patient have paracentesis this cycle?” please note that “this cycle” refers to the month following the injection date.</li><li>• The weight completed should be what was recorded on the date of the injection (day 1 of cycle).</li></ul>

<p><b><i>Concurrent Treatment Log</i></b></p>	<ul style="list-style-type: none"> <li>• There are two separate concurrent treatment logs, one for baseline and one for active monitoring. Please make sure you are submitting the appropriate form. (Do not use the baseline form for the active monitoring cycles or vice versus).</li> <li>• The active monitoring phase form is completed at the end of each cycle (same as the adverse event log). Only <b>one</b> concurrent treatment log should be completed for each cycle.</li> </ul>
<p><b><i>Adverse Event Log</i></b></p>	<ul style="list-style-type: none"> <li>• There are two separate adverse event logs, one for baseline and one for active monitoring. Please make sure you are submitting the appropriate form. (Do not use the baseline form for the active monitoring cycles or vice versus).</li> <li>• The pt should be evaluated for adverse events at the <b>end</b> of each cycle (same as concurrent treatment log). Only <b>one</b> adverse event log should be completed for each cycle.</li> </ul>
<p><b><i>Paracentesis Data Collection Form</i></b></p>	<ul style="list-style-type: none"> <li>• Please use whole numbers (do not use decimals) when completing the section for “<b>Abdominal circumference at the umbilicus prior to paracentesis.</b>” Round up to the next whole number for <math>\geq .5</math> and round down for <math>\leq .4</math>.</li> <li>• This form is <b>ONLY</b> completed when a paracentesis is done. If no paracentesis was performed during a cycle, do not complete this form.</li> </ul>
<p><b><i>VEGF Specimen Submission Form</i></b></p>	<ul style="list-style-type: none"> <li>• There are two separate VEGF Specimen Submission Forms, one for baseline and one for active monitoring. Please make sure you are submitting the appropriate form. (Do not use the baseline form for the active monitoring cycles or vice versus).</li> <li>• This form is <b>ONLY</b> completed when a paracentesis is done. If no paracentesis was performed during a cycle, do not complete this form. If multiple paracentesis are done for a cycle, submit this form for each paracentesis.</li> </ul>

<b><i>Patient Questionnaires</i></b>	<ul style="list-style-type: none"> <li>• There is one questionnaire/booklet in this study that is to be completed and cycled as followed: <ul style="list-style-type: none"> <li>➤ Cycle 0 = Baseline</li> <li>➤ Cycle 1 = Two Weeks After Starting Study Medication <b>AND</b> Month 1 (1 month after 1<sup>st</sup> treatment)</li> <li>➤ Cycle 2 = Month 2 (1 month after 2<sup>nd</sup> treatment)</li> <li>➤ Cycle 3 = Month 3 (1 month after 3<sup>rd</sup> treatment)</li> <li>➤ ETC...</li> </ul> </li> </ul>
<b><i>Patient Questionnaire Booklet Compliance Form</i></b>	<ul style="list-style-type: none"> <li>• Only enter this form if the <b>entire</b> Patient Questionnaire booklet was not completed. If a portion of the booklet was completed, then this form <b>does not</b> need to be completed.</li> <li>• The “Date this form completed” is the date <b>you</b> complete the form (not when the patient should have completed).</li> </ul>
<b><i>Event Monitoring Form</i></b>	<ul style="list-style-type: none"> <li>• Event monitoring begins after completion of active monitoring and is done every 6 months for 2 years from on-study.</li> <li>• Patients who are on octreotide/placebo for the full two years do not go on to event monitoring.</li> </ul>

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
CANCER CONTROL  
ON-STUDY FORM**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials:     

Local ID # \_\_\_\_\_ Institution     L    F    M    

**DESCRIPTION OF PRIMARY DISEASE**

MedDRA code for primary tumor site: [ 10029000 ]

**CURRENT SYMPTOMS AND DISEASES**

Current Symptom/Disease		
Abdominal pain? (check one)	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No
Abdominal distension? (check one)	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No
Shortness of breath? (check one)	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No

**HEIGHT** (cm):     .

**WEIGHT** (kg):     .

PLACE LABEL HERE

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CANCER CONTROL**

**BASELINE**

**ADVERSE EVENTS/SYMPTOMS FORM**

**BASELINE ADVERSE EVENTS/SYMPTOMS**

Baseline # of Stools Per Day:

**Required Baseline Adverse Events from Section 10.0 of Protocol**

Adverse Event/Symptom	MedDRA Code v. 6.0	Grade (CTCAE v. 3.0)
<b>Constipation</b>	1 0 0 1 0 7 7 4	0 1 2 3 4
<b>Proctitis</b>	1 0 0 3 6 7 8 2	0 1 2 3 4
<b>Cholecystitis</b>	1 0 0 0 8 6 1 9	0 1 2 3 4
<b>Pain - Abdominal NOS</b>	1 0 0 0 0 0 8 5	0 1 2 3 4

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT LOG  
(BASELINE)**

**ALL ITEMS MUST BE COMPLETED**

Amended Data:  if yes, check box and **highlight** amended areas

Evaluation Date:   /   /      
                          m m           d d           y y           y y

Concomitant Treatment	Reason for Use (check one)
Diuretics? 2 <input type="checkbox"/> No      1 <input type="checkbox"/> Yes -->	1 <input type="checkbox"/> Ascites 2 <input type="checkbox"/> Other 3 <input type="checkbox"/> Both
Chemotherapy? 2 <input type="checkbox"/> No      1 <input type="checkbox"/> Yes	

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT LOG  
(ACTIVE MONITORING PHASE)  
ALL ITEMS MUST BE COMPLETED**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Amended Data:  if yes, check box and **highlight** amended areas

Cycle :

Evaluation Date:   /   /      
m m d d y y y y

Concomitant Treatment	Reason for Use (check one)
Diuretics? 2 <input type="checkbox"/> No      1 <input type="checkbox"/> Yes -->	1 <input type="checkbox"/> Ascites 2 <input type="checkbox"/> Other 3 <input type="checkbox"/> Both
Chemotherapy? 2 <input type="checkbox"/> No      1 <input type="checkbox"/> Yes	

NORTH CENTRAL CANCER TREATMENT GROUP

CANCER CONTROL  
EVALUATION/TREATMENT FORM  
CYCLE 1

ALL ITEMS MUST BE COMPLETED

Amended Data:  if yes, check box and **highlight** amended areas

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Use one form per cycle, one column per agent.

Cycle:

Actual Weight (kg):    .   
(used for this cycle, round to the nearest tenth)

Day	Cycle 1, Day 1		Cycle 1, Day 2		Did the patient have paracentesis this cycle? 1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No → End Form. ↓ How many paracenteses were performed? <input type="checkbox"/> <input type="checkbox"/> Fill out Paracentesis Data Collection Form.
Agent	Sancostatin (SOM)/ Placebo		Sandostatin LAR Depot (SOMLAR)/ Placebo		
Injection date (mm/dd/yyyy)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Did patient receive agent this day this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No ↓ Specify reason: _____ _____ _____ _____	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No ↓ Specify reason: _____ _____ _____ _____			

NORTH CENTRAL CANCER TREATMENT GROUP

CANCER CONTROL  
EVALUATION/TREATMENT FORM  
CYCLE ≥2

ALL ITEMS MUST BE COMPLETED

Amended Data:  if yes, check box and highlight amended areas

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Use one form per cycle, one column per agent.

Cycle:

Actual Weight (kg):    .   
(used for this cycle, round to the nearest tenth)

Agent	Sandostatin LAR Depot (SOMLAR)/Placebo	Did the patient have paracentesis this cycle?
Injection date (mm/dd/yyyy)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/> Yes                      2 <input type="checkbox"/> No → End Form.
Did patient receive agent this cycle?	1 <input type="checkbox"/> Yes                      2 <input type="checkbox"/> No ↓ Specify reason: _____ _____ _____ _____	How many paracenteses were performed? <input type="checkbox"/> <input type="checkbox"/> Fill out Paracentesis Data Collection Form.

**NORTH CENTRAL CANCER TREATMENT GROUP  
CANCER CONTROL  
ADVERSE EVENT LOG**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED** pg 1 of 2

Amended Data:  if yes, check box and **highlight** amended areas

Adverse Events associated with treatment cycle:

Evaluation Date:   /   /      
m n1 d d y y y y

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle)	Relationship to Study Medication If Grade > 0	AER*
1 <input type="checkbox"/> Yes GRADE ALL ADVERSE EVENTS BELOW ↓	2 <input type="checkbox"/> No Adverse Event; (stop here)	INCLUDE GRADE 0's	1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Check if sub- mitted

**Required Adverse Events from Section 10.0 of Protocol**

<b>Constipation</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Diarrhea</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Proctitis</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Cholecystitis</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Pain - Abdominal NOS</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Injection site reaction/ extravasation changes</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>

**Adverse Events\*\* beyond those required in Section 10.0 of the protocol.  
Record grade 2 with attribution of possible, probable or definite and all grade  
3, 4 and 5 regardless of attribution.**

<b>Other:</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Other:</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>
<b>Other:</b>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>

\* See Section 10.0 of the protocol.

\*\* Both hematologic and non hematologic Adverse Events must be graded on this form as applicable.

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CANCER CONTROL**

**ADVERSE EVENT LOG (continuation)**

**ALL ITEMS MUST BE COMPLETED**

Amended Data:  if yes, check box and **highlight** amended areas

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Adverse Events associated with treatment cycle :

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle)	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER*  Check if sub- mitted
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
Other:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>

\* See Section 10.0 of the protocol.



Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

**NORTH CENTRAL CANCER TREATMENT GROUP  
CANCER CONTROL**

**END OF ACTIVE TREATMENT FORM**

**Submit Once Per Patient**

Amended Data:  if yes, check box and **highlight** amended areas

Date of last treatment dose on this study :   /   /      
m m d d y y y y

Date decision was made to end active treatment :   /   /      
m m d d y y y y

This patient will now go to :  
(See Schema and Section 13.0 of  
the protocol)

2  Event monitoring (Complete Event Monitoring Form)  
**NOTE:** If patient receives 2 full years of treatment no  
Event Monitoring is required.

PRIMARY REASON (check one)	COMMENTS
1 <input type="checkbox"/> Completed Treatment Per Protocol	
2 <input type="checkbox"/> Refused Further Treatment	Specify:
3 <input type="checkbox"/> Adverse Event	Specify:
4 <input type="checkbox"/> Disease Progression	
5 <input type="checkbox"/> Alternative Treatment	Specify:
6 <input type="checkbox"/> Other Medical Problems	Specify:
7 <input type="checkbox"/> Died On Study	
8 <input type="checkbox"/> Other	Specify:

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
CANCER CONTROL**

**EVENT MONITORING FORM**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

Amended Data:  if yes, check box and **highlight** amended areas

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

1 Yes  2 No → Date of last attempt to contact patient:  /  /  → Return form to Operations Office  
m m d d y y y y

**VITAL STATUS**

Vital Status: 1  Alive 2  Dead

Date last known alive or death:  /  /   
m m d d y y y y

Comments:

**LATE ADVERSE EVENT (post completion of active monitoring)**

Has the patient developed any of the following **not previously reported**:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment not due to disease progression.
- Death any time at least possibly treatment related.

2  No 3  Unknown/  
Not evaluated 1  Yes

↓  
Submit Event Monitoring Continuation Form for Late Adverse Event Reporting

**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVENT MONITORING CONTINUATION FORM**

**(LATE ADVERSE EVENT REPORTING)**

**ALL ITEMS MUST BE COMPLETED**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**Amended Data:**  if yes, check box and **highlight** amended areas

**LATE ADVERSE EVENTS**

The CTCAE Version 3.0 will be used to evaluate the following signs/symptoms:

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Highest Grade	Relationship to Study Medication 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Start Date (mm/dd/yyyy)
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □
<b>Other:</b>	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	□ □ / □ □ / □ □ □ □

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**BASELINE**

**BLOOD SPECIMEN SUBMISSION FORM**

**MAYO ROCHESTER PATIENTS WITH  
OVARIAN CANCER ONLY**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**INSTRUCTIONS**

Complete this form for all Mayo patients with ovarian cancer and submit within 14 days of study entry. See Section 14 of the protocol for specimen requirements and shipment.

Did this patient consent to provide blood specimen(s) for research?

1  Yes → Complete rest of form.

2  No → End form.

Was a research blood specimen collected?

1  Yes Date of collection:   /   /      
m m d d y y y y

2  No Reason: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**BASELINE**

**VEGF SPECIMEN SUBMISSION FORM**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**INSTRUCTIONS**

Complete this form **for all patients** and submit directly to the Operations Office within 14 days of study entry. See Section 14 of the protocol for specimen requirements and shipment.

Did this patient consent to provide VEGF specimen(s) for research?

1  Yes → Complete rest of form.

2  No → End form.

Was a research VEGF specimen obtained?

1  Yes Date of biopsy:   /   /      
m m d d y y y y

2  No Reason: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ACTIVE MONITORING**

**VEGF SPECIMEN SUBMISSION FORM**

Protocol # N04C2

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Cycle:

**INSTRUCTIONS**

Complete this form for all patients if a paracentesis is done, and submit directly to the Operations Office within 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment.

Was a research VEGF specimen obtained?

1  Yes Date of biopsy:  /  /   
m m d d y y y y

2  No Reason: \_\_\_\_\_

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N04C2

NOTIFICATION FORM

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Grade 4 or 5 Non-AER Reportable Events/Hospitalization

Instructions:

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- If AER has been submitted for this event do not submit this form.
- Fill out all information known.
- Fax to the North Central Cancer Treatment Group Operations Office within 5 working days of notification (507-284-1902).
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s):

Person Completing/Submitting Form:

□□ / □□ / □□□□  
m m d d y y y y

Name: \_\_\_\_\_

Phone #: ( ) - \_\_\_\_\_

Cycle #: □□ Arm: □

Event ≥ Grade 4

2 □ No 1 □ Yes

Date of First Occurrence	Event Type (only one event per line)	Grade	Relationship to study medication. In your opinion, is this related to the study medication? <sup>1</sup>
□□ / □□ / □□□□		4 5	1 □ Yes 2 □ No 3 □ Unknown
□□ / □□ / □□□□		4 5	1 □ Yes 2 □ No 3 □ Unknown
□□ / □□ / □□□□		4 5	1 □ Yes 2 □ No 3 □ Unknown
□□ / □□ / □□□□		4 5	1 □ Yes 2 □ No 3 □ Unknown
□□ / □□ / □□□□		4 5	1 □ Yes 2 □ No 3 □ Unknown

1. Answer YES if attribution is unlikely, possible, probable or definite.

Answer NO if unrelated, answer UNKNOWN if you are not sure.

Hospitalization

2 □ No 1 □ Yes → Date of Admission: □□ / □□ / □□□□  
m m d d y y y y

Reason(s) for Hospitalization:

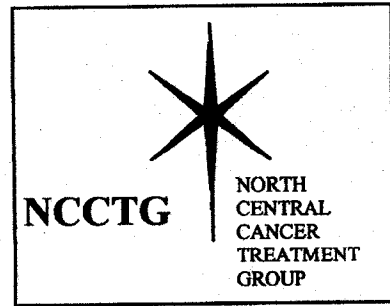
1 □ Adverse Event, specify type and grade \_\_\_\_\_

2 □ Prophylactic, specify \_\_\_\_\_

3 □ Other, specify \_\_\_\_\_

**Operations Office:**

Telephone (507) 234-3005



August 22, 2005

**Order Form**

**Quality-of-Life Booklets**

**N04C2, An Exploratory, Randomized, Placebo-Controlled Trial of Depot Octreotide (Sandostatin LAR<sup>®</sup> Depot) for Symptomatic Ascites in Cancer Patients**

Number of booklets needed: \_\_\_\_\_

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: \_\_\_\_\_ Phone: \_\_\_\_\_

Affiliate/Member ship: \_\_\_\_\_ / \_\_\_\_\_

Shipping address: \_\_\_\_\_

\_\_\_\_\_

Date: \_\_\_\_\_

*Revised 2/23/05*

**Mayo Medical Laboratories**  
**Fax Supply Order Form – No Cover Sheet Necessary**  
Fax to Kit Building @ 507-538-4103

**Study ID:**     N04C2    

Investigator: \_\_\_\_\_

Order Placed By: \_\_\_\_\_ Phone #: (    ) \_\_\_\_\_

Email: \_\_\_\_\_ Fax #: (    ) \_\_\_\_\_

<b><u>Name of Kit</u></b>	<b><u># of Kits Needed</u></b>
---------------------------	--------------------------------

N04C2 Ascites Fluid Research	_____
------------------------------	-------

**Total Kits** \_\_\_\_\_

**Date Needed:** \_\_\_\_\_  
**(Please be specific)**

**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.**

**Fed Ex account number (Rush deliveries only)** \_\_\_\_\_

Address (kits sent to):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N04C2

**PATIENT QUESTIONNAIRE BOOKLET COMPLIANCE FORM**

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED**

Are data amended? (check one)  Yes  No  
(if data are amended, please circle in red when using paper form)

**Complete this form only if the entire Patient Questionnaire booklet contains absolutely NO patient provided assessment information.**

Baseline: \_\_\_\_\_ or Current Cycle Number: \_\_\_\_\_

Date this form completed: (mm/dd/yyyy) \_\_\_\_/\_\_\_\_/\_\_\_\_

**Reason Patient Questionnaire booklet was not completed. (check one)**

- 1  Patient refusal
- 2  Unable to accommodate disability or language needs
- 3  Staff unavailable
- 4  Patient not given form by staff
- 5  Patient did not like content of questions
- 6  Site did not like content of questions
- 7  Other reason, specify \_\_\_\_\_