



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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**Date:** April 17, 2009

**To:** Primary Clinical Research Associates

**From:** Linda S. Long  
Research Protocol Specialist

**Re:** PATIENT SAFETY ISSUE: N064B, Randomized Phase II Trial of  
Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine in  
Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

Starting IMMEDIATELY the attached version of Appendix II (Patient Erlotinib Medication Diary) should be used instead of the version that is in the current protocol. A correction has been made in item 3 to indicate that the patient should take **one (1)** pill by mouth once a day.

An official amendment will be issued in the near future. If you have any questions, please feel free to contact me at 507-266-3853.

**Patient Erlotinib Medication Diary**

**Protocol Number:** \_\_\_\_\_ **Institution Number:** \_\_\_\_\_

**Patient ID Number:** \_\_\_\_\_ **Patient Initials (LFM)** \_\_\_\_\_

**INSTRUCTIONS TO PATIENT:**

1. Complete one form for each cycle (28 days).
2. Please record the date and time you take your erlotinib pills for this study.
3. You should take one (1) pill by mouth once a day. It is best to take the pill in the morning one hour before or two hours after food. Take the erlotinib with up to 8 ounces of water
4. Bring this medication diary, the pill bottles (even if empty or unopened), and any unused pills with you to the last visit at the end of each cycle. Make sure that you get a new medication diary at that time.

<b>Day</b>	<b>Date</b>	<b>Time pill taken</b>	<b>Day</b>	<b>Date</b>	<b>Time pill taken</b>
1			15		
2			16		
3			17		
4			18		
5			19		
6			20		
7			21		
8			22		
9			23		
10			24		
11			25		
12			26		
13			27		
14			28		

\_\_\_\_\_  
**Patient signature**

\_\_\_\_\_  
**Date**

**Physician's office will complete this section:**

1. Date patient started protocol treatment: \_\_\_\_\_
2. Total number of pills taken this cycle: \_\_\_\_\_

Physician/Nurse/Data Manager's signature \_\_\_\_\_

Date \_\_\_\_\_