

**Cancer And Leukemia Group B
Memorandum**

To: Clinical Research Associates

From: Debbie Sawyer, Director of Data Operations
Kathy Karas, Senior Protocol Editor

Subject: New Malignancy and Long-Term Follow-up Reporting

Date: October 15, 2004

Submission of new malignancies including new primaries (tumors not likely resulting from therapy for a previous cancer) and secondary malignancies (tumors resulting from treatment for a previous cancer including AML/MDS) should be reported on the CALGB: New Malignancy Form (C-1001v2, attached) and submitted to the Statistical Center. This form replaces the CALGB: Secondary AML/MDS form C-215. In addition to this form, continue to report:

- any diagnosis of AML/MDS following treatment for cancer on NCI-sponsored trials with investigational agents to the CALGB Central Office using the NCI/CTEP Secondary AML/MDS Report Form.
- all other secondary malignancies using the routine adverse event reporting mechanism outlined in the protocol.

Report long-term follow-up data on the updated CALGB Long-Term Follow-up Form (C-400v4, attached).

All open studies that use these forms (with the exception of 90104 and 90202) have been updated to reflect this change, which is effective October 15, 2004. The C-215 form has been retired.



15075

CALGB: NEW MALIGNANCY FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy use black ink. **Mark an X** in the appropriate box for fields with a choice. **Print text in capital letters.** Avoid contact with the edges of the boxes. If data are amended, circle amended items and check the "Yes" box. If submitting by mail, retain a copy for your records. If submitting by fax, use an original form for maximum clarity in transmission and fax to 919-416-4990. If submitting electronically, click the Send button when you have completed the form.

CALGB Form		C-1001
CALGB Study No.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
CALGB Patient ID	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Diagnosis date of new malignancy	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	<small>M M / D D / Y Y Y Y</small>	
Are data amended?	<input type="checkbox"/> Yes	

Patient Initials <input type="text"/> , <input type="text"/> <input type="text"/> <small>Last, First Middle</small>	Participating Group _____
Patient Hospital No. _____	Participating Group Study No. _____
Institution/Affiliate _____	Participating Group Patient ID _____

INSTRUCTIONS: Report any malignancy that is:

- A new histologic type
- A previous histologic type which is judged to be a new primary
- A secondary malignancy related to cancer treatment, including AML/MDS

Submit pathology and/or cytogenetic report(s) documenting the new primary or new secondary malignancy along with this form.

DO NOT REPORT RECURRENCES ON THIS FORM.

Record new malignancy type, site and histology below.

New malignancy type <i>(Mark one with an X.)</i>		Specify site:	Specify histologic type:
New primary malignancy	New secondary malignancy*		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>

* Secondary AML/MDS malignancies must also be reported to NCI/CTEP on NCI/CTEP Secondary AML/MDS Report Form.

* Report non AML/MDS secondary malignancies on adverse event or follow-up form per protocol submission requirements.

Completed by: _____ <small>(Last name, First name)</small>	Date form completed <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>M M / D D / Y Y Y Y</small>
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