CANCER AND LEUKEMIA GROUP B

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MEMORANDUM

TO:

CALGB Participants

FROM:

Sherry Breaux, Director of CALGB Quality Assurance

DATE:

December 15, 2007

SUBJECT:

New Lost to Follow-up Policy

In June 2007, the CALGB Board of Directors approved a policy that provides institutions with a procedure for removing lost patients from delinquency lists and calculations. This policy will become effective December 15, 2007, and will be phased in during a 6-month transition period. Under the new policy, after the institution has tried unsuccessfully for 2 years to contact a patient, the institution may submit to the CALGB Statistical Center the new C-1742 form (CALGB: Confirmation of Lost to Follow-up), which asks for limited details about the follow-up procedures that were used by the institution. The C-1742 will be used on CALGB studies still in follow-up. The new policy is described in section 8.1.2.6 of the CALGB *Policies and Procedures* manual: http://www.calgb.org/Private/COOP_Groups/CALGB/policies/manual/pdfs/08_Data_management.pdf

On November 7, 2007, the CALGB Statistical Center held a webinar to train main and atlarge member institutions on the new policy and procedures. An open access training module from the webinar is posted on the CALGB Web site in two formats at the following URLs:

- PowerPoint Presentation: <u>http://www.calgb.org/Private/COOP_Groups/CALGB/training/policies/LTFU_policy_11072007.pps</u>
- PDF Version (Handouts):

 http://www.calgb.org/Private/COOP_Groups/CALGB/training/policies/LTFU_policy_11072007.pdf

Please review the module for more information about the transition period and other details of the new procedures.

The C-1742 form will be available immediately on the CALGB Web site on the Forms by Number page:

http://www.calgb.org/Private/COOP_Groups/CALGB/studies/forms/by_number/1700_1799_forms.php .

It will also be available in the Common Forms section. This section displays in the lower right side of all study- and forms-related pages:

http://www.calgb.org/Private/COOP_Groups/CALGB/studies.php

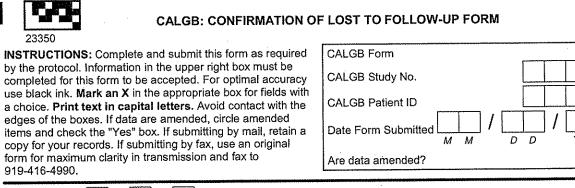
Eventually, the C-1742 form will also appear in the forms lists on pages for Study Specific Forms for Active and Closed Studies.

- Initially, the "all forms" document for existing studies will not be updated to include the C-1742.
- In the future, the C-1742 will be included in the "all forms" document for any study receiving a forms update.
- The C-1742 will be included in the "all forms" document for all new activating studies.

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| 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. | CALGB Study No. CALGB Patient ID Date Form Submitted M M M D D D Y Y Y Y Y Are data amended? Participating Group |
|--|--|
| Last, First Middle | Double alter Common Ofrich No. |
| Patient Hospital No. | Participating Group Study No. Participating Group Patient ID |
| Institution/Affiliate | |
| this natient (NOTE: Submit the entire form even if page 2 | cal Center, the patient will not be included in delinquency |
| AMENDING THIS FORM: If data are now available to cha follow-up" status), check the "amended" box on the top of | ange this patient's survival or clinical status (from "lost to this form and complete page 2. |
| CRITERIA FOR LOST TO FOLLOW-UP STATUS | |
| 1. Has it been at least 2 years since you were last able to | contact the patient? No Yes |
| NOTE: If the answer is No, your patient is not eligib | le to be confirmed as lost. Please do not submit. |
| Date of last contact prior to this confirmation M M | |
| NOTE: This date should correspond to the patient s date is more recent, send any required data | survival date on the last delinquent data report. If this a factor of the interim period. |
| Please indicate when steps were taken to contact the Certified/Registered Letter methods must be attempted patient can be declared lost. | patient. Both Social Security Death Index and ed without success after 2 years without contact before a |
| Researched Social Security Death Index and for information for this patient; specify most recent of | und no late: M M M D D Y Y Y Y |
| Sent certified or registered international letter to address; specify most recent date sent: (Mark or | last known ne with an X.) |
| Letter returned unclaimed or marked add | iressee unknown |
| ☐ No response 1 month after confirmed rec | eipt of letter |
| I verify that the above information is correct and that all a | attempts to contact this patient have failed. Date / / / / / / / / / / / / / / / / / / / |
| (Signature of Principal Investigator) | M M D D Y Y Y Y |
| Form completed by: | Email |
| (Last Name, First Name) | |

C-1742



| | MATION OF LOST TO FOLLOW | V-UP FORM | |
|--|---|-------------------------------|-------------|
| 23350 | CALGB Form | | C-1742 |
| | CALGB Study No. | | |
| | CALGB Patient ID | | |
| Patient Initials Last, First Middle | Date Form Submitted | M M D D Y | YYY |
| PATIENT NO LONGER LOST TO FOLLOW- | -UP | | |
| If data are now available to change this patier "amended" box on the top of page 1 and com | nt's survival or clinical status (from plete the following: | n "lost to follow-up status") | , check the |
| New information for this patient is now ava | | · | |
| | | | |
| ☐ Clinical and survival status. This pat (Send new clinical data to the CALC) | | | |
| Survival status based on new data (Mark o | one with an X.) | | |
| ☐ Dead (If patient is dead, also submit collects death informaton.) | t C-113 Notification of Death Forr | n or study specific form tha | ıt |
| Date patient was last known alive, | or date of death M M D | D / Y Y Y Y | |
| NOTE: For data submission instructions for Chapter 8. | patients no longer lost to follow-u | p see CALGB Policies and | Procedures |
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| CALGB STATISTICAL CENTER USE ONLY | | | |
| Patient accepted as Confirmed Lost to Follow | -Up? ☐ No ☐ Yes | | |
| If No enocify reason: | | | |

D D

Page 2 of 2

Review date

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Data Coordinator's name