


Public reporting burden for this collection of information is estimated at 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

## Filling out PDF Forms

This PDF form contains “**roll-over** or **double-click**” help functionality.

This form allows you to enter data directly onto the screen. After completing the form, you are able to print the document so that you can fax/mail the document.

To fill out a form:

1. Select the hand tool. 
2. Position the pointer inside a field, and click to type text.
3. After entering text or selecting a check box, do one of the following:
  - Press tab to accept the form field change and go to the next form field.
  - Press Shift+Tab to accept the form field change and go to the previous form field.
  - Press Enter (Windows) or Return (Mac OS) to accept the form field change and deselect the current form field.
4. Once completed, print the form.

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| <h2 style="margin: 0;">Cancer Trials Support Unit</h2> <h3 style="margin: 0;">INSTITUTIONAL REVIEW BOARD</h3> <h3 style="margin: 0;">CERTIFICATION</h3>  |  | <p><b>Email, Mail or Fax to:</b><br/>                 Cancer Trials Support Unit (CTSU)<br/>                 ATTN: Coalition of Cancer Cooperative Groups (CCCG)<br/>                 Suite1100<br/>                 1818 Market Street<br/>                 Philadelphia, PA 19103<br/>                 FAX: 1-215-569-0206<br/> <a href="mailto:CTSURegulatory@ctsu.coccg.org">CTSURegulatory@ctsu.coccg.org</a></p> |  |
| 1) Protocol #:   |  | 2) Protocol Version Date (Required for Amendments):<br>____/____/____<br>mm dd y y y y   |  |
| 3) Protocol Title:   |  |  |  |
| 4) Institution Name (List all institutions covered by IRB approval that will conduct this study. Attach complete list if necessary.)<br>Indicate # sites on supplemental sheet if applicable: ____<br><i>Ex: University of State</i>   |  | 5) NCI Institution Code<br><i>ALXXX</i>  | 6 & 6a) OHRP Federalwide Assurance Number<br>FWA FWA Expiration Date (mm/dd/yyyy)<br><i>FWA00000123 03/01/2006</i> |
| 7) Principal Investigator:   |  | 8) NCI Investigator #:   |  |
| This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations or subparts:  |  |  |  |
| 9) Approval Type:<br>Original <input type="checkbox"/> Amendment <input type="checkbox"/> Renewal <input type="checkbox"/>   |  | 10) Review Type:<br>Full Board <input type="checkbox"/> Expedited* <input type="checkbox"/> Facilitated <input type="checkbox"/><br>*Provide number from applicable category in box 11) ____   |  |
| 11) Expedited Review Categories (Pick only one for box #10):<br>(45CFR46.110.8a-c: Continuing review of research previously approved by a convened IRB)<br><b>8.a</b> Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects<br><b>8.b</b> Where no subjects have been enrolled and no additional risks have been identified<br><b>8.c</b> Where the remaining research activities are limited to data analysis<br>11a) Expedited Review (Other) If any other expeditable review category is utilized as the review type, please provide an explanation below:<br>_____ |  |  |  |
| 12) Date of IRB Meeting:<br>____/____/____<br>m m d d y y y y  |  | 13) Approval Period:<br>Effective: ____/____/____ Expiration: ____/____/____<br>m m d d y y y y m m d d y y y y  |  |
| 14) Was the protocol approved with contingencies? YES NO<br>Date all contingencies were met: ____/____/____<br>mm dd yyyy  |  | 15) NCI CIRB Review <input type="checkbox"/> (check if NCI CIRB review)<br>Give date if this is an initial facilitated review ____/____/____<br>m m d d yyyy   |  |
| 16) OHRP IRB Registration Number:<br>IRB   |  | 17) Comments:  |  |
| <p><b>The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed &amp; certification will be provided. Questions #1 through #20 must be completed for this form to be accepted.</b> <input type="checkbox"/></p> <p><i>Check here if the person signing this form is an IRB signatory as documented on the institutional assurance with OHRP.</i></p>   |  |  |  |
| 18) Name of IRB Signatory:   |  | 19) Name of approving IRB:   |  |
| 20) Title of IRB Signatory:  |  | 21) Phone<br>(____)  ____  -  ____   |  |
| 22) Signature:   |  | 23) Date:<br>____/____/____<br>m m d d y y y y   |  |

**Cancer Trials Support Unit**  
**INSTITUTIONAL REVIEW**  
**BOARD**  
**CERTIFICATION**  
**Supplemental Page**

Optional page for listing additional sites approved by the local IRB. Please indicate on certification form the number of sites listed on the supplemental form.

**Email, Mail or Fax to:**  
Cancer Trials Support Unit (CTSU)  
ATTN: Coalition of Cancer Cooperative Groups (CCCG)  
Suite 1100  
1818 Market Street  
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[CTSURegulatory@ctsu.coccg.org](mailto:CTSURegulatory@ctsu.coccg.org)

In Reference to Protocol #:

| Additional Institution Names <i>(List all additional institutions covered by IRB approval that will conduct this study.)</i> | NCI Institution Code | OHRP Federal Wide Assurance Number and Expiration Date (mm/dd/yyyy) |            |
|--|----------------------|---|------------|
| <i>Ex. University of Texas</i>   | TX002                | FWA00000123   | 09/02/2007 |
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