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.

Cancer Trials Support Unit
INSTITUTIONAL REVIEW BOARD CERTIFICATION

Email, Mail or Fax to:
Cancer Trials Support Unit (CTSU)
ATTN: Coalition of Cancer Cooperative Groups (CCCG)
Suite1100 , 1818 Market Street
Philadelphia, PA 19103
FAX: 1-215-569-0206
CTSURegulatory@ctsu.coccg.org

1) Protocol #: *(Lead Group #)*

2) Protocol Version Date (Required for Amendments):
_____/_____/_____
m m d d 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.)* Indicate # sites on supplemental sheet if applicable: ____	5) NCI Institution Code	6 & 6a) OHRP Federalwide Assurance Number FWA	FWA Expiration Date (mm/dd/yyyy)
Ex: University of State	*ALXXX*	*FWA00000123*	*03/01/2006*

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:

Original ☐ Amendment ☐ Renewal ☐

10) Review Type:

Full Board ☐ Expedited* ☐ Facilitated ☐

**Provide number from applicable category in box 11)* _

11) Expedited Review Categories ***(Pick only one for box #10):***
(45CFR46.110.8a-c: Continuing review of research previously approved by a convened IRB)

8.a 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

8.b Where no subjects have been enrolled and no additional risks have been identified

8.c Where the remaining research activities are limited to data analysis

11a) Expedited Review (Other) If any other expeditable review category is utilized as the review type, please provide an explanation below:

_____

12) Date of IRB or Designee Review from box 10:
/ /
m m d d y y y y

13) Approval Period:
Effective: | | Expiration: / /
m m d d y y yy m m d d y y y

14) Was the protocol approved with contingencies? ☐ YES ☐ NO
Provide date all contingencies were approved by the IRB or Designee:
/ /
mm dd yyyy

15) NCI CIRB Review ☐ (check if NCI CIRB review)
Give date of the initial facilitated review by the local IRB or Designee:
/ /
mm dd yyyy

16) OHRP IRB Registration Number (8 digits long):
IRB

17) Comments:

The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed & certification will be provided. Questions #1 through #20 must be completed for this form to be accepted. ☐
Check here if the person signing this form is an IRB signatory as documented on the institutional assurance with OHRP.

18) Name of IRB Signatory:

19) Name of approving IRB:

20) Title of IRB Signatory:

21) Phone
(_____) |_____| - |_____|

22) Signature:

23) Date:
_____/_____/_____
m m d d y y y y