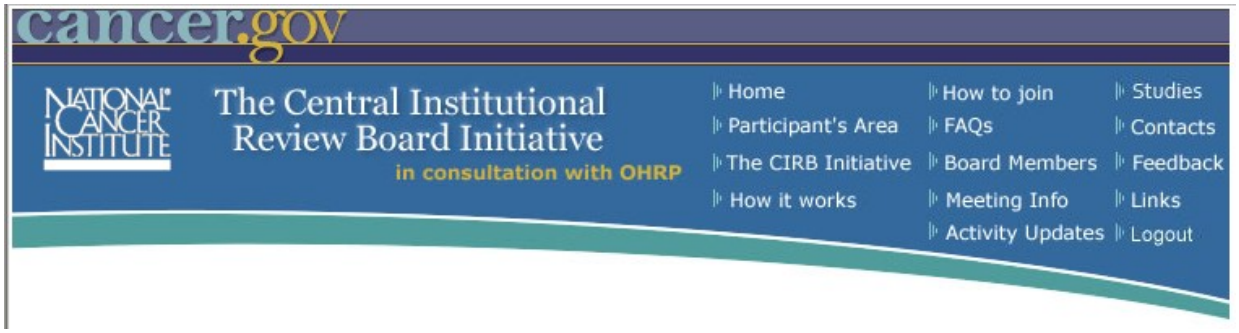
One-Time Study Roll-Over Interface



One-Time Study Roll-Over Worksheet

OMB#: 0925 – 0625
Expiry Date: 01/31/2014

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 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 (0925-0625). Do not return the completed form to this address.

Fields marked with * are required.

*Study Number:	Select from the List
Study Title: (populates with Study Number)	
*Name of Local IRB:	Select from the List
Institution's FWA Number:	FWA00003095
Local IRB Registration Number: (populates with Name of Local IRB)	
*Select Principal Investigator for this study:	Select from the List

NOTE: If the Principal Investigator for this study is not listed in the drop-down list above, you must contact the NCI CIRB Helpdesk to resolve. Select a new Study Number from the list above to continue.

Did your IRB make any changes to the following based on review of local context considerations?

*Protocol ☐ Yes ☐ No

If yes, Describe changes

*Informed Consent Document (excluding boilerplate language and letterhead changes described in Annual Institution Worksheet)

☐ Yes ☐ No

If yes, Describe changes

*Were any study-specific material(s) developed and approved locally? ☐ Yes ☐ No

If yes, attach document(s) and approval letter(s):	

Click Confirm to save information and continue.

If you wish to return to the Facilitated Review Submission Report, and loose the information entered, click here.

NOTE: All Research Staff, including sub-Investigators, named on the Annual PI Worksheet will be associated with this study.