

Attachment 9B:

Survey to Determine IRB Policy Regarding NCI Action Letters

OMB No. 0925-0046-09
Expiry Date:

Public reporting burden for this collection of information is estimated to average 5 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 (0925-0046-09). Do not return the completed form to this address.

1. Does your IRB review Action Letters for NCI Cooperative Group Phase 2 or 3 treatment trials? Yes ___ No ___

2. Please identify your role:
____ IRB Administrator/Director
____ IRB Chair

3. Does your IRB allow expedited review for Action Letters?
___ Always ___ Sometimes ___ Never

4. If your IRB does not allow Action Letters to receive expedited review, why not? (answer all that apply)
____ Was not aware OHRP allows it
____ OHRP written statement confusing
____ IRB office wants to process all Action Letters the same way regardless of level of risk
____ Individuals who conduct expedited review do not have sufficient oncology expertise
____ Other, explain: _____

5. To the best of your knowledge, are patients at your institution not enrolled on trials due Action Letters resulting in temporary suspension? ___ Yes ___ No