Attachment 6K: CIRB SAE Reviewer Worksheet

OMB#: 0925 – xxxx Expiry Date: xx/xx/xxxx

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. While your participation is completely voluntary, to participate in the NCI CIRB, completion of this form is required. Data collected as part of the NCI CIRB review is private and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be kept private under the Privacy Act and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 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.

CIRB SAE Reviewer Worksheet

1 No Changes to informed consent document and/or protocol
2 Informed consent document requires clarification of existing risk
5 CTEP Action Letter-awaiting Group's amendment
12 New Risk identified not currently in informed consent document: request more information
13 New Risk identified not currently in protocol: request more information
14 New Risk identified not currently in protocol and informed consent document: request more information
15 Need more information-AE Report contains preliminary information and a determination cannot be made

AENumber	Study	Study Status	IND Holder	Agent	Report Date	PrimaryEvent	Previous Rcmnd And Comments	OHRP Expiration Date	Subcommittee Reviewer	DateReceivedFromGroup	DateSentToSubcommittee	Recommendation	Rationale	DateOfSubcommitteeReview
1034535 FU1	CALGB 40502	Newly received from CTEP	CTEP	bevacizumab	05/15/2009	Dehydration	Initial report in review	02/22/2010		05/18/2009				
1277486	CALGB 40502	Newly received from CTEP	CTEP	Bevacizumab and Lenalidomide	04/07/2009	Gr. 3 pneumonitis/pulmonary infiltrates, atrial fibrillation	Initial report	02/22/2010		05/18/2009				
1314985	CALGB 40502	Newly received from CTEP	CTEP	Bevacizumab	04/17/2009	Sudden death	Initial report	02/22/2010		05/18/2009				
1433885 FU1	CALGB 40502	Newly received from CTEP	CTEP	bevacizumab	04/15/2009	Pneumonitis/piulmonary infiltrates, pericardial effusion	1-fever and infections noted	02/22/2010		04/22/2009				