**IRB Protocol Review Sheet for Convened Event Report**

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| Protocol Number: | 2014C1234 | **PI:** | Miller |
|  |  |  |  |
| Description of Event: | 76 year old female with grade 2 stroke; internal event | | |

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| **DETERMINATIONS** | | | | | |  | **NONCOMPLIANCE (check all that apply)** | |
|  | |  | | | |  |  |  |
| Unanticipated problem involving risks to subjects or others | | | | | |  | x | N/A |
|  | |  | | | |  |  |  |
|  | |  | Yes |  | No |  |  | Unsubstantiated |
|  | |  | | | |  |  |  |
| Further information or action required | | | | | |  |  | Minor (not serious, not continuing) |
|  | |  | | | |  |  |  |
|  | | x | Yes |  | No |  |  | Serious |
|  | |  | | | |  | |  |
| Additional information or action needed | | | | | |  |  | Continuing |
|  | | | | | |  |  |  |
| (check all that apply) | | | | | |  |  | Refer to IRB Investigative Committee |
|  | |  | | | |  | |  |
|  | |  | Amendment required to revise protocol/procedures | | |  |  | Refer to another university review process |
|  | | | | | |  |  |  |
|  | |  | Amendment required to revise consent process/form | | |  |  | Determination pending/ Further information required |
|  | | | | | |  |  |  |
|  |  | | Re-consent required for current participants | | |  |  | Corrective actions(s) required - \*provide comments |
|  | | |  | | |  |  |  |
|  |  | | Additional follow-up required for current participants | | |  |  |  |
|  | | | | | |  |  | |
|  | |  | Information should be provided to past participants | | |  |  | |
|  | | | | | |  |  | |
|  | |  | Additional follow-up required for past participants | | |  |  | |
|  | | |  | | |  |  | |
|  |  | | Continuing review schedule should be modified | | |  |  | |
|  | | |  | | |  |  | |
|  |  | | Suspension of some or all research activities | | |  |  | |
|  | | | | | |  |  | |
|  | |  | Termination of research activities | | |  |  | |
|  | | |  | | |  |  | |
|  | | x | Other – \*provide comments | | |  |  | |

**\*COMMENTS/MODIFICATIONS:**

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| SUMMARY:   * Study purpose: * Funding course (funded/unfunded/sponsor name): * Description of event (including internal/external): * UPIRSO determination * [describe any additional findings]   COMMENTS:  [Reviewer describes any concerns or further actions required]  **EXAMPLE:**  SUMMARY:  This phase I/II, NCI-funded clinical trial will test the combination of an experimental drug, ixazomib, with two approved drugs, pomalidomide and dexamethasone, in patients with multiple myeloma, that has become resistant to commonly accepted treatments. The investigator reported an internal event where a 76 year old subject was admitted to an outside hospital with grade 2 stroke which is unexpected and possibly related to the study drug. The investigator did not include information about the other potential risk factors for stroke that the subject may have. It is not possible to confirm whether this is a UPIRSO without further information.  COMMENTS:   * Provide more detail on the other potential risk factors that the subject had for stroke (if any). * Provide follow-up on the subject’s hospital admission and if he was discharged, etc. |

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|  | Jane Doe |  | 6/1/2016 |  |
|  | IRB Reviewer |  | Date |  |