**IRB Protocol Review Sheet for Convened Amendment**

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| Protocol #: | 2015H1111 | **Amendment #:** | 02 | **PI:** | Smith |

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| **DETERMINATIONS** |  |  |
|  |  |  |
|  | Approved |  |  |
|  |  |  |  |
| x | Requires Modifications (specify below) |  |  |
|  |  |  |  |
|  | Deferred (provide comments) |  |  |
|  |  |  |  |
|  | Disapproved (provide comments) |  |  |
|  |  |  |
| **POPULATIONS (check *only* those changing with this amendment)** |  | **CONSENT/HIPAA (check *only* those changing with this amendment)** |
|  |  |  |  |  |
|  | Approval for Pregnant Women/Fetuses |  |  | Waiver of Consent |
|  |  |  |
|  | Approval for Children |  |  | Alteration of Consent  |
|  |  |  |  |
|  | Approval for Prisoners |  |  | Waiver of Consent Documentation |
|  |  |  |  |  |
|  | Approval for Adults with Decisional Impairment |  |  | Waiver of Parental Permission |
|  |  |  |  |  |
|  | Approval for Non-English Speaking Subjects |  |  | Alteration of Parental Permission |
|  |  |  |  |  |
|  | Approval for Non-Viable Neonates |  |  | Waiver of Parental Permission Documentation |
|  |  |  |  |  |
|  | Approval for Neonates of Uncertain Viability |  |  | Waiver of Assent |
|  |  |  |  |  |
|  |  |  |  | Consent by Legally Authorized Representative |
|  |  |  |  |  |
| **NONCOMPLIANCE (check all that apply)** |  |  | Waiver of HIPAA Research Authorization  |
|  |  |  |  |  |
| x | N/A |  |  | Partial Waiver of HIPAA Research Authorization  |
|  |  |  |  |  |
|  | Unsubstantiated |  |  | Alteration of HIPAA Research Authorization |
|  |  |  |  |
|  | Minor (not serious, not continuing) |  |  |
|  |  |  |  |
|  | Serious |  |  |
|  |  |  |  |
|  | Continuing |  |  |
|  |  |  |  |
|  | Refer to IRB Investigative Committee |  |  |
|  |  |  |  |
|  | Refer to another university review process |  |  |
|  |  |  |  |
|  | Determination pending/ further information required |  |  |
|  |  |  |  |
|  | Corrective actions(s) required – \*provide comments |  |  |

**COMMENTS/MODIFICATIONS:**

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| --- |
| SUMMARY:* Study purpose:
* Funding source (funded/unfunded/sponsor name):
* Changes requested:
* Overall risk assessment with amendment:
* [describe any additional findings]

COMMENTS:[Reviewer describes any necessary modifications or concerns]**EXAMPLE:**SUMMARY:The purpose of this study is to determine the safety of ranolazine treatment in a small number of patients with myotonia congenita and to evaluate the usefulness and feasibility of clinical assessment tools and outcome measures for this population. The investigators are seeking approval to include subjects with paramyotonia congenita in response to a recent study that has shown benefits of using ranolazine in this population. The investigators are requesting an increase in the number of subjects to 150 overall to accommodate the additional subjects and study documents have been revised accordingly. The investigators have also received additional funding through Gilead Sciences. Since funding is now available, the investigators are seeking approval to provide $50 in compensation to study subjects and to provide DNA testing to study subjects at no cost. The amendment also includes a change to the study title and change in the PI. The overall risk is not changing with this amendment.COMMENTS:Buck-IRB:* Study summary: Revise the study summary page in Buck-IRB to include the new population being added to the research.

Informed consent:* Section 11/page 7: This section was not changed to reflect the $50 compensation to subjects.
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|  | Jane Doe |  | 6/1/2016 |  |
|   | IRB Reviewer |  | Date |  |