**IRB Protocol Review Sheet for Convened Continuing Review**

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| --- | --- | --- | --- |
| Protocol Number: | 2015H1234 | **PI:** | Jones |

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| --- | --- | --- | --- | --- | --- |
| **DETERMINATIONS** | | |  | **CONSENT/HIPAA (check all that apply)** | |
|  |  | |  |  |  |
| x | Approved | |  |  | No Waivers, Alterations, or LAR Consent |
|  |  | |  |  |  |
|  | Requires Modifications – \*provide comments | |  |  | Waiver of Consent |
|  |  | |  |  |  |
|  | Deferred – \*provide comments | |  |  | Alteration of Consent |
|  |  | |  |  |  |
|  | Disapproved – \*provide comments | |  |  | Waiver of Consent Documentation |
|  | | |  |  |  |
|  | | |  |  | Waiver of Parental Permission |
|  | | |  |  |  |
| **POPULATIONS (check all that apply)** | | |  |  | Alteration of Parental Permission |
|  |  | |  |  |  |
| x | No Special Populations | |  |  | Waiver of Parental Permission Documentation |
|  |  | |  |  |  |
|  | Approval for Pregnant Women/Fetuses | |  |  | Waiver of Assent |
|  |  | |  |  |  |
|  | Approval for Children | |  |  | Consent by Legally Authorized Representative |
|  |  | |  |  |  |
|  | Approval for Prisoners | |  |  | Waiver of HIPAA Research Authorization |
|  |  | |  |  |  |
|  | Approval for Adults with Decisional Impairment | |  | **x** | Partial Waiver of HIPAA Research Authorization |
|  |  | |  |  |  |
|  | Approval for Non-English Speaking Subjects | |  |  | Alteration of HIPAA Research Authorization |
|  |  | |  |  | |
|  | Approval for Non-Viable Neonates | |  |  | |
|  |  | |  |  | |
|  | Approval for Neonates of Uncertain Viability | |  | **NONCOMPLIANCE (check all that apply)** | |
|  | | |  |  |  |
|  | | |  | **x** | N/A |
|  | | |  |  |  |
| **LEVEL OF RISK** | | |  |  | Unsubstantiated |
|  | |  |  |  |  |
|  | Minimal risk | |  |  | Minor (not serious, not continuing) |
|  |  | |  |  |  |
| **x** | Greater than minimal risk | |  |  | Serious |
|  | | |  |  |  |
|  | | |  |  | Continuing |
|  | | |  |  |  |
| **NEXT REVIEW DATE** | | |  |  | Refer to IRB Investigative Committee |
|  |  | |  |  |  |
| x | One year | |  |  | Refer to another university review process |
|  |  | |  |  |  |
|  | Other – specify: | |  |  | 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): * Summary of special populations and waivers (if any): * Study status (open/closed to enrollment): * Subject enrollment: * Research progress (amendments, withdrawals, complaints): * Adverse events: * DSMB report (if applicable): * Any changes requested with continuing review (personnel and/or numbers): * [describe any additional findings]   COMMENTS:  [Reviewer describes any necessary modifications or concerns]  **EXAMPLE:**  SUMMARY:  The purpose of this funded study is to compare metformin to placebo in subjects with early breast cancer who have completed standard adjuvant therapy. The study is approved for a partial waiver of HIPAA authorization for recruitment. 62 subjects have enrolled onto the study; 22 are off treatment. The study is closed to accrual but not all subjects have completed interventions. There were two amendments since the last continuing review to update the protocol and to discontinue a particular study arm (described below). There were no unanticipated issues, complaints, or withdrawals since the last review.  The DSMC met and reviewed the results of a planned analysis. The outcome of the DSMC review was that criteria for futility had been met in the hormone receptor negative group but that follow-up was inadequate for an assessment of either efficacy or futility in the hormone receptor positive group. Therapy will be discontinued in the subjects with ER and PgR negative breast cancer. Therapy will continue for the ER and PgR positive group. These subjects will stop study drug no later than 4/14/16. The amendment for these notifications was approved on 4/1/2016.  The investigator is requesting to remove three key personnel with this submission.  COMMENTS:  No issues; recommend approval for another year. |

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|  | Jane Doe |  | 7/1/2016 |  |
|  | IRB Reviewer |  | Date |  |