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| Big Ten Cancer Research Consortium Letter of Intent |
| Study Title |  |
| Study Phase |  |
| LOI Submission Date |  |

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| SPONSOR INVESTIGATOR |
| **Name:** |  |
| **Lead Institution:** |  |
| **Address:** |  |
| **Phone:** |  |
| **Fax:** |  |
| **Email:** |  |
| OTHER CONTACTS |
| **Name:** | Jessica Roy |
| **Phone:** | 317-634-5842 x 19 |
| **Email:** | jroy@hoosiercancer.org |

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| STUDY DRUG(S) AND FUNDING SOURCE |
| **Name of Study Drug(s)** |  |
| **Study Drug Supplier** |  |
| **Placebo?** | [ ]  Yes [ ]  No |
| **Name of Commercial Drug(s)** |  |
| **Trial Funding Source(s)**  |  |

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| STUDY DESIGN INFORMATION |
| **Rationale:** |  |
| **Objectives:**Primary |  |
| Secondary |  |
| **Key inclusion/exclusion criteria** |  |
| **Treatment Plan:** *State the dose, method of administration, and schedule of each drug, and, if phase 1, provide the dose escalation scheme, and definitions of DLTs.*  |  |
| **Study Assessments** *Specify all non-routine care assessments and their specific time points using objective practice guidelines (e.g. NCCN).* |  |
| **Follow-up durations** |  |
| **Sample Size** |  |
| **Estimated Accrual/Mo:** |  |
| **Estimated Total Study Duration:** |  |
| **Statistical Methods:** |  |
| **Publication Plan:** |  |
| **Do you plan to submit an Investigational New Drug (IND) application or Investigational Device Exemption (IDE)?** | [ ]  Yes [ *specify* ][ ]  No  |
| **Additional Comments: e.g. key challenges and dependencies** |  |

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| CORRELATIVE STUDIES (PHARMCOKINETICS / PHARMACOGENOMICS) |
| **Correlative studies to be performed. Please specify which sample collections are optional vs. mandatory for study participation.** |  |
| **Funding source for correlative studies** |  |

**References:**