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| **Protocol Information** | | |
| **IRB #:**  **Title:** | | |
| **Pharmacy Reviewer:** | | |
| **Initial Review** | **Protocol Modification** | **Investigator’s Brochure/Package Insert Update** |
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| **Summary of Pharmacy Observations for the Proposed Research:** |
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| **Directions:** When completing the sections below, if all suggested considerations are acceptable, check YES. Otherwise, indicate the items that are problematic. Describe the issue(s) in a comment box or in Requested Modifications at the end. | |
| **Review Criteria 45 CFR 46.111(a) or 21 CFR 50.111(a)** | |
| Yes | **Risks to subjects are minimized** |
|  | The objectives and hypotheses are not clearly stated |
|  | Pharmacokinetic/pharmacodynamic aspects of study design are not appropriate |
|  | Dose selection is not adequately justified based on Investigator’s Brochure and cited literature |
|  | Inclusion/exclusion criteria are not appropriate (including dosage form-specific criteria such as swallowing tablets whole, drug contraindications and FDA’s Special Alerts/Black Box Warnings) |
|  | All known important interactions are not addressed (e.g., drug-drug, drug-herb, drug-dietary supplement) |
|  | Laboratory monitoring plan is not adequate |
|  | Dose modifications for organ dysfunction are not included |
|  | Supportive care therapy is not adequately delineated or is not appropriate (e.g. pre-medications, hematopoietic growth factor support, infection prophylaxis). |
|  | Research will not contribute to Generalizable Knowledge and is not worth exposing subjects to risk. Include the following considerations: is the research feasible? |
|  | Alteration of study design, research procedures or subject population would reduce the likelihood of harm. |
| Yes | **Informed Consent Document is appropriate** |
|  | FDA investigational or approval status is not clear |
|  | All common (>5%) and serious/life-threatening known risks are not included in the document |
|  | Risks of all pre-medications or other required supportive medications are not included if not standard of care |
|  | Prohibited concomitant medications (prescription and over-the-counter medications, herbal and dietary supplements, and food restrictions) are not adequately described |
|  | Risks language is too technical (not lay language) |
|  | Cost to the subject, if any, are not adequately explained |

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| **FDA Regulated Drugs or Biologics Articles** | | |
| N/A | **Experimental Drugs and Biologics** (including approved drugs used outside their labeled indication) | |
| Yes  No | | Is an IND required for the use of an experimental drug or biologic? |
| Yes  No | | If “yes” has an IND application been submitted? **IND Number**: |
| Yes | **Investigational Drug/Biologic Information is sufficient and appropriate** | |
|  | Adequate information regarding drug preparation, storage, and stability is not provided | |
|  | Adequate information regarding special handling procedures is not provided | |
|  | Adequate information for drug requisition and disposal is not provided | |
| Yes | **Non-Investigational Drug/Biologic Information is sufficient and appropriate** | |
|  | Insufficient information was provided regarding the non-investigational drugs/biologics, including placebos to be administered during the research.  Considerations should include: whether the drug is on Formulary and if not, the reputation of the source, quality, purity and stability of the drug. | |
|  | Compounding is required with non-USP source materials | |
|  | Inadequate information provided for compounding procedures. | |
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| **Additional Information** | | |

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| **Recommendations** |

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| **Pharmacy Recommendations** | |
| No Major issues  Minor modifications/Clarifications required that do not impact approval  Major modifications/clarifications required that impact one or more criteria for approval | |
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| **Pharmacy Reviewer Name/Signature:** | **Date:** |

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| **Required Modifications** (if any) | **Addressed (Y/N)** |

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| **eIRB Application** | Yes  No  N/A |

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| **Protocol:** | Yes  No  N/A |

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| **Consent Form:** | Yes  No  N/A |

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| **Other:** | Yes  No  N/A |

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| **Recommendations after Review of Modifications** | | |
| All requested modifications/clarifications addressed  Additional modifications/clarifications required | **Stipulations to be reviewed by:**  Review by Chair or Designee  Full Board Review | |
| **Pharmacy Reviewer Signature:** | | **Date:** |