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| --- | --- | --- | --- | --- |
| **Study Title:** | | | | |
| **HSR or UVA Study Tracking #** | | | | **Pharmacist Reviewer:** |
| **IRB Meeting Date:** | | | |  |
| **Principal Investigator:** | | | | **Study Coordinator/Study Team:** |
| **Investigational Intervention:** | | | | |
| **Modification:**  Minor changes/minimal risk significant changes/ Greater than minimal risk  *Description:* | | | | |
| **Considerations** | | | | |
| **Drug dosing significantly changed and reflected in consent appropriately** | Yes No N/A | | *Comments:* | |
| **Toxicity/side effect significantly changed and reflected in consent appropriately** | Yes No N/A | | *Comments:* | |
| **Concomitant medications and potential drug interactions are addressed via this mod and are reflected in consent appropriately** | Yes No N/A | | *Comments:* | |
| Risks (new or increased) of study medications are represented clearly and don’t change the risk-benefit ratio significantly | Yes No N/A | | *Comments:* | |
| **Forms** | | **Comments/Issues** | | |
| Protocol | |  | | |
| IB | |  | | |
| Consent Form/Lay Language | |  | | |

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| --- | --- | --- |
| 1. Risks to participants are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose participants to risk AND   whenever appropriate, that are already being performed for diagnostic or treatment procedures. | **Protocol**  **YES**  **NO**  **Consent**  **YES**  **NO** |  |
| *If NO, list conditions that must be met to meet this criterion:*   * + **Required Conditions** | | |