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| **IRB Log No.:** |  | | | |
| **Study Title:** |  | | | |
| **Category of Review:** | | Exempt | Expedited | Full |
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| **Executive summary of the objectives and methodology** | | | | |
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| **Review of Documents1** | | | | |
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| **Ethics Review2** | | | | |
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| **Overall Assessment** | | | | |
| Approve as is | | | | |
| Reject | | | | |
| Approve after the following modifications: | | | | |
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| Ask the investigator(s) to make the following clarifications: | | | | |
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**1** *The review should cover the following:**(a)* ***The cover sheet:*** *complete and adequate? (b)* ***PI submission checklist:*** *complete?**PI signature? HOD signature? (c)* ***CRF*** *adequate? (d)* ***IDS****: submitted / approved? (e) P****rotocol****: simple and logical? eligibility and exclusion criteria? objective and easy to assess outcome measures? Subject selection procedures adequate? simple intervention not likely to be mistaken? adequate sample size and power to detect a difference? Risk of missing important data by too short a follow up? overall reliability of the trial results? (f)* ***ICF****: complete information? (g)* ***IB*** *– adequate? (h)* ***Investigators****: is PI and Co-PI qualified by education, training, experience, knowledge of Investigational product? investigators’ knowledge of GCP guidelines? Investigators’ time availability? investigators have qualified staff?*

**2** *The review should cover the following: (a) Are* ***risks*** *are minimal and are reasonable in relation to the anticipated benefits (b) Is* ***consent*** *informed and is properly documented (c) Is* ***privacy and confidentiality*** *assured? (d)* ***Are safety monitoring measures adequate? (e) Is subject selection*** *equitable? (f) Protection of* ***vulnerable subjects*** *if relevant (g) Any COI and funding issues?*