Chickasaw Nation Department of Health

Research Investigator Statement

* I agree to conduct the study in accordance with the Chickasaw Nation guidelines as set forth in Chickasaw Nation Department of Health policies ADM 1400, “CNDH Participation in Research”, ADM 1401, “ Patient Rights Pertaining to Research”, ADM 1410, “CNDH Institutional Review Board” and ADM 1411, “Release and Dissemination of Research Results and Findings”.
* I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the CNDH Institutional Review Board (CNDH IRB).
* I agree to personally conduct or supervise the described investigation.
* I agree to inform any patients or any persons used as controls, of any drugs that are being used for investigational purposes (if applicable) and I will ensure that the requirements relating to obtaining informed consent and institutional review and approval are met.
* I have read and understand the information in the investigator’s brochure including the potential risks and side effects of the drug (if applicable).
* I agree to report to the CNDH IRB within 48 hours any adverse experiences that occur in the course of the investigation.
* I agree to maintain adequate and accurate records and to make those records available for inspection upon request.
* I will ensure that an Institutional Review Board (IRB) will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the CNDH IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
* I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements as determined by the Chickasaw Nation.
* I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

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Principal Investigator Signature Date

CNHS 3/27/03; 7/19/07

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