WRITTEN INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

Subject's name (printed) _____

Karen T. Snider, D.O, Michael Lockwood, D.O. and Erica Waddington, D.O. of the AT Still University- Kirksville College of Osteopathic Medicine (ATSU-KCOM) have requested the participation of my newborn in a research project entitled, "**The Incidence of Somatic Dysfunction in the Newborn**". The major purpose of this project is to investigate whether the birth process may have resulted in changes to the muscles and joints on my baby's spine and head. These changes in the muscles and joints are known as somatic dysfunction.

Approximately 100 newborns between the ages of 6 to 72 hours old, who were born at Northeast Regional Medical Center (NRMC), will be participating in this study during 2011-2012. The participation of my newborn will include the following:

1. Review of my newborn's medical record.
2. Review of his/her mother's medical record.
3. A physical exam of my newborn's head and back.

The physical exam will be performed by physicians who are trained in the osteopathic physical exam of the newborn. The total time of the physical exam will be about 15 minutes and carries no significant foreseeable risk other than that normally incurred from a newborn physical exam.

The results of this research may be published; however, neither my child's name or his/her parents' names nor identity will be revealed and their records will remain strictly confidential as required by Federal law in accordance with the Health Insurance Portability and Accountability Act (HIPAA) to ensure privacy. There is a possibility that the FDA staff may review pertinent medical records associated with this study. All consent forms will be also kept and treated as private medical records. As part of data collection the mothers' and babies' names will be removed from the medical information gathered and assigned a random number. The privacy of this information will be further protected by maintaining all gathered information in a locked file at ATSU-KCOM and available only the investigators and the research coordinator.

In the case of any unforeseen side effects that my child may experience as part of his/her participation I should contact Erica Waddington, D.O. (primary investigator) or the research coordinator Patty Lyons at (660) 626-2537 for recommendation regarding treatment. Neither ATSU-KCOM nor NRMC assumes liability for this research project nor makes any commitment to provide compensation for such injuries.

My newborn's participation in this study may or may not have direct benefits. The information gained in this study will be used by the osteopathic medical community to enhance the understanding of the presence of somatic dysfunction in newborns. This could have important implications for future clinical trials.

My newborn's participation is voluntary and refusal to participate will involve no penalty to me or loss of benefits to which my newborn is otherwise entitled. I also understand that I may withdraw from the research study at any time without any penalty or prejudice. I may also cancel authorization to use my newborn's and his/her mother's identifiable health information at any time, though the research team may continue to use non-identifiable information that has already been collected. The investigators with or without my consent may terminate my newborn's participation. Any questions that I may have will be answered by Erica Waddington, D.O., who may be reached by telephone at 660-626-2304 (after hours 660-785-1000) or any one of the other above mentioned investigators. If I have any questions about my rights as a research subject, the HIPAA notice of Privacy, or in the event I have suffered any injury as a result of my participation in the research project, I may contact the chair of the KCOM Institutional Review Board: Robert J. Theobald, Ph.D., (phone: 660-626-2320), 800 West Jefferson, Kirksville, MO 63501, who will discuss any questions or will be able to refer me to an individual who will review the matter with me, and/or identify other resources that may be available to me, and/or provide information as to how to proceed.

I have read the previous statements and have been able to ask questions and express concerns, which have been satisfactorily responded to by one of the above mentioned investigators or his/her designee. I believe I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent for my newborn to be a participant in this study and allow my newborn's and his/her mother's personal health information to be used by the Principal Investigator and the research team in this medical research project.

Signature of Subject_____ Date _____

Name _____

Address _____

Telephone _____

I certify that I have explained to the above individual the nature, purpose, potential benefits, and possible risks associated with participation in this research study; have answered all questions that have been raised; and have witnessed the above signature. These elements of Informed Consent conform to the assurance given by KCOM to the DHHS to protect the rights of human subjects in accordance with the HIPAA Privacy Rule. I have provided the subject/patient with a copy of this document.

Signature of Investigator or Designee_____ Date _____

PARTICIPANT'S COPY OF WRITTEN INFORMED CONSENT FOR RESEARCH ACTIVITIES

Subjects name (printed) _____

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