

MERITER IRB #: 2010-001

RESEARCH PROTOCOL TITLE: Determining PCOS-like traits in macaques and newborn human infants

PRINCIPAL INVESTIGATOR: David Abbott, Ph.D.

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STUDY PURPOSE

Polycystic ovary syndrome (PCOS) affects women and is associated with increased risk for infertility, type 2 diabetes, cardiovascular disease, and endometrial cancer. Because there are no current methods to identify girls at risk for PCOS earlier in childhood, PCOS is typically diagnosed at puberty when medical intervention is less than optimal. The purpose of this study is to determine if girls at risk for future PCOS can be identified just after birth. Earlier identification of at-risk girls may allow for the development of new interventions or treatments in the future.

RESEARCH PROCEDURES

Research procedures will be conducted at regularly scheduled prenatal care visits. For pregnant women, research procedures include a questionnaire about menstrual history and other medical & lifestyle information; an assessment of body hair by a clinician involved in their prenatal care; and a one-time blood collection.

At the time of birth, a hair sample will be collected from newborn infant girls, and a research sample of blood will be collected from the umbilical cord (after it has been cut).

ELIGIBILITY CRITERIA FOR SUBJECTS

Pregnant non-smoking women with or without PCOS, but with impaired oral glucose testing or gestational diabetes may be eligible to enroll if they are expecting to deliver a single female infant. Final eligibility will be determined based on questionnaire and body hair assessment.

COMPENSATION/REIMBURSEMENT

There is no compensation or reimbursement for participating in this study.

RESEARCH LOCATION AND CONTACT PERSON

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