OMB # 0925-XXXX
Expiration Date:

Stress and Cortisol Follow-Up Studies

Note to File – Description of Potential Follow-Up Studies

*** Future change requests will lay out protocol for each formative research project. ***

The following description pertains to Stress and Cortisol Follow-Up Studies (excerpted from Supporting Statement A):

There are a wide range of approaches and protocols available to assess maternal stress and stress biology during pregnancy, with different opinions among experts regarding their relative feasibility and acceptability. Because cortisol is not secreted continuously and at the same levels, multiple approaches to its measurement are needed to estimate the trajectory of cortisol secretion over time, in the absence of continuous monitoring. Blood permits measurement of cortisol at a single point in time. Urine provides an estimate of cortisol secretion over an overnight or, in some cases, a 24-hour period of time. Hair provides for not only quantification of levels of stress over a period of approximately 30 days, but also for a measurement of cortisol levels at times up to six months prior to collection time, and of multiple exposures relating to cortisol. Saliva permits for cortisol collection at multiple time points within a 24-hour period, and allows for a relatively noninvasive estimation of the cortisol secretion trajectory for a given day. Specifically, replication of previous protocol demonstrations of cortisol measurement in hair is necessary for NCS biomarker prioritization. Information regarding a number of health, demographic, and other variables will be collected and analyzed to evaluate their role as potential covariates in the measurement of cortisol and stress, and relevance for the development of a reduced item questionnaire. Depending upon the results observed, further testing in a broader or more diverse population may be necessary to produce a standardized, validated, scientifically robust measure of chronic stress. Further testing, if needed, would be accomplished by requesting a non-substantive change to the regular clearance once it is established. Approximately 2,100 burden hours are requested in A.12 for “follow-up studies.”

Activity	Time Schedule
Participant Recruitment & Screening	1-2 months after OMB approval
Data Collection Activities	4-10 months after OMB approval
Validation	10-22 months after OMB approval
Analyses	10-22 months after OMB approval
Follow-up Studies	12-36 months after OMB approval