Attachment 2f Goal II IRB Approval Letter

JOHNS HOPKINS
MEDICINE

Office of Human Subjects Research
Institutional Review Boards

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Date: July 22, 2011

NEW APPLICATION APPROVAL

Review Type:	Expedited
PI Name:	Douglas Granger
Study #:	NA_00046970
Study Name:	Evaluating the potential of saliva as a research specimen for use in the National Children's Study: Part II. Sampling Feasibility
Committee Chair:	Susan Bassett
Committee:	JHM-IRB X

Date of review: July 21, 2011

Date of approval: July 21, 2011

Date of expiration: July 20, 2012

The JHM IRB approved the above-referenced New Application.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of one parent is required.

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with treatment interventions.

Changes in Research: All proposed changes to the research must be submitted using an eIRB Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: You must inform the IRB of any unanticipated problems involving risks to participants or others.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

Written Consent:

Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of protocol records, and consent documentation is part of such monitoring.
FINAL_Granger NA_00046970_CF_072111_No Logo.docx

Recruitment Materials:
FINAL_Granger_NA_00046970_Recruitment-TelephoneScreeningScript _07212011_NOLOGO.docx

Additional Supplemental Study Documents:
NA_00046970_Follow Up Telephone Interview 07-11-2011.docx
NA_00046970_Home Visit Demographics Questionnaire 07-11-2011.docx

Protocol:
Protocol and Questionnaire 3/22/11
eFormA:
NA_00046970_eIRB eFormA 07-11-2011.docx

Study Team Members:
Anjali Sivan, Jessica Scarpola, Kimberly Hill, Andrea Escobar, Hibest Assefa, Tina Cheng, Jessica Bayer, TRACEY HAND, Margaret Denny