



11000 Kinross Avenue, Suite 102
Los Angeles, CA 90095-1694

<http://ohrpp.research.ucla.edu>

GC-IRB: (310) 825-7122

M-IRB: (310) 825-5344

APPROVAL NOTICE

New Study

DATE:	3/15/2011
TO:	LENORE ARAB MEDICINE-GENERAL MEDICINE & HLTH SRVCS.
FROM:	ALISON MOORE Chair, SGIRB
RE:	IRB#10-001535 Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study Version: LOI-2-14

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. The UCLA IRB's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642 (IRB00004474).

Submission and Review Information

Type of Review	Full Board Review
Approval Date	3/15/2011
Expiration Date of the Study	1/10/2012
Funding Source(s)	1) NIH/NATIONAL INST OF CHILD HEALTH AND HUMAN DEVELOPMENT <i>Grant Title:</i> Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study <i>Grant Number:</i> LOI-2-14

Regulatory Determinations

- The UCLA IRB waived the requirement for signed informed consent for the screening under 45 CFR 46.117(c)(2).
- The UCLA IRB waived the requirement for obtaining the assent of the children under 45 CFR 46.116(d) for the entire study.
- The UCLA IRB determined that the research meets the requirements of 45 CFR 46.404 for research involving children as subjects.

Documents Reviewed included, but were not limited to:

Document Name	Document Version #
Craigslit Text.Child Chinese CLEAN.pdf	0.01
Craigslit Text.Pregnant Indian CLEAN.pdf	0.01
Eligibility Screener Script (preschooler) .pdf	0.01
Flyer Pregnant Chinese CLEAN 2.28.11.pdf.pdf	0.01
Craigslit Text.Child Indian CLEAN.pdf	0.01
Consent form Pregnant women.pdf	0.01
Flyer Children Chinese CLEAN 2.28.11.pdf.pdf	0.01
Consent form preschoolers.pdf	0.01
Flyer Pregnant SouthEastIndian CLEAN 2.28.11.pdf.pdf	0.01
Flyer Pregnant Filipino CLEAN 2.28.11.pdf.pdf	0.01
Craigslit Text.Child Filipino CLEAN.pdf	0.01
Recruitment Flyer (Children Filipino) CLEAN.pdf	0.01
Eligibility Screener Script (pregnant).pdf	0.01

Craigslit Text.Pregnant Filipino CLEAN.pdf	0.01
Flyer Children South East Indian CLEAN 2.28.11.pdf.pdf	0.01
Craigslit Text.Pregnant Chinese CLEAN.pdf	0.01

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval

As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.



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Consent form preschoolers.pdf	0.01
Flyer Pregnant SouthEastIndian CLEAN 2.28.11.pdf.pdf	0.01
Flyer Pregnant Filipino CLEAN 2.28.11.pdf.pdf	0.01
Craigslit Text.Child Filipino CLEAN.pdf	0.01
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- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.

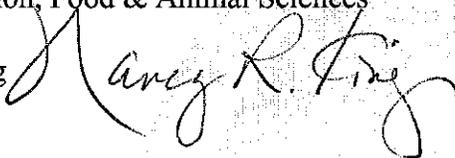
UNIVERSITY OF HAWAII

Committee on Human Studies

MEMORANDUM

December 9, 2011

TO: Rachel Novotny, Ph.D.
Principal Investigator
Human Nutrition, Food & Animal Sciences

FROM: Nancy R. King 
Director

SUBJECT: CHS #18622- "Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study"

Under an expedited review procedure, the research project identified above was approved for one year on December 9, 2011 by the University of Hawaii (UH) Committee on Human Studies (CHS). The application qualified for expedited review under CFR 46.110 and 21 CFR 56.110, Category (8c).

This memorandum is your record of CHS approval of this study. Please maintain it with your study records.

CHS approval for this project will expire on December 8, 2012. If you expect your project to continue beyond this date, you must submit an application for renewal of this CHS approval. CHS approval must be maintained for the entire term of your project.

If, during the course of your project, you intend to make changes to this study, you must obtain CHS approval prior to implementing them. Unanticipated problems that are likely to affect study participants must be promptly reported to the CHS.

You are required to maintain complete records pertaining to the use of humans as participants in your research. This includes all information or materials conveyed to and received from participants as well as signed consent forms, data, analyses, and results. These records must be maintained for at least three years following project completion or termination, and they are subject to inspection and review by CHS and other authorized agencies.

Please notify this office when your project is complete. Upon notification, we will close our files pertaining to your project. Reactivation of CHS approval will require a new CHS application.

Please contact this office if you have any questions or require assistance. We appreciate your cooperation, and wish you success with your research.

UNIVERSITY OF HAWAII

Committee on Human Studies

MEMORANDUM

December 12, 2011

TO: Rachel Novotny, Ph.D.
Principal Investigator
Human Nutrition, Food & Animal Science

FROM: Nancy R. King
Director



SUBJECT: CHS #18622 – “Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study”

Your application for CHS approval of a proposed change for the study identified above was approved by the Committee on Human Studies (CHS) on December 9, 2011. The approved change was for the recruitment flyer. This application qualified for Expedited Review under CFR 46.110 and 21 CFR 56.110, Category (b).

If future revisions to your study are required, please seek CHS approval prior to their implementation. If a change is necessary to protect the safety or welfare of study participants, it is permissible to make the change without prior approval. However, you must notify the CHS as soon as possible, requesting approval for the change.

When seeking approval to modify a CHS-approved document, please submit the document using “Track Changes” to identify the proposed modifications. Clearly explain the reason for the change on the CHS Modification form.

Please contact the CHS office at 956-5007 if you have any questions or require assistance.



EXPEDITED – APPROVAL

February 2, 2012

Tracie Miller, M.D.
University of Miami
Department of Pediatrics, Pediatric Clinical Research
Medical Campus, Locator Code: D 820
1580 NW 10th Avenue, Room 542
Miami, FL 33136

HSRO STUDY NUMBER: **20100921**
STUDY TITLE: **National Children's Study Diet Data Collection**
IRB ACTION DATE: **1/28/2012**
STUDY APPROVAL
EXPIRES: **1/4/2013**
FWA #: **FWA00002247**
SPONSOR NAME: **The Eunice Kennedy Shriver National Institute of Child Health and
Human Development**

On 1/28/2012 an IRB Designee approved the following items under the expedited review process.

APPROVAL INCLUDES:

Amendment (20100921-02)

- Addition of the University of Hawaii and John Hopkins approval letter
- Removal of UCLA as a performance site.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Sincerely,

*[This is a representation of an electronic record
that was signed electronically and this page is
the manifestation of the electronic signature]*

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/ar

cc: IRB File
There are no items to display

From: stang002 [stang002@umn.edu]
Sent: Wednesday, June 27, 2012 3:04 PM
To: Fuller, Jill E
Cc: Grace Fung
Subject: Fwd: 1012S93872 - PI Stang - IRB - APVD
Continuing Review

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Jill,

I am forwarding our IRB continuation letter - they only send an email. If you need a copy of the original IRB approval letter, I can find that as well. Thanks. jamie

PS Looks like the budget for the expanded recruitment will be about \$146k

Jamie Stang, PhD, MPH, RD, LN
Director, Leadership Education & Training Program in MCH Nutrition
Co-Director, Midwest Center for Lifelong-Learning in Public Health
University of Minnesota, School of Public Health

----- Original Message -----

Subject: 1012S93872 - PI Stang - IRB - APVD Continuing Review

Date: Thu, 22 Dec 2011 23:19:39 -0600 (CST)

From: irb@umn.edu

To: stang002@umn.edu

TO : helle023@umn.edu, stang002@umn.edu, deb@cccs.umn.edu, ukest001@umn.edu,

The IRB: Human Subjects Committee renewed its approval of the referenced study listed below:

Study Number: 1012S93872

Principal Investigator: Jamie Stang

Expiration Date: 12/19/2012

Approval Date: 12/21/2011

Title(s):

Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study

This e-mail confirmation is your official University of Minnesota HRPP notification of continuing review approval. You will not receive a hard copy or letter. This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

You may go to the View Completed section of <http://eresearch.umn.edu/> to view or print your continuing review submission.

For grant certification purposes you will need this date and the Assurance of Compliance number, which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Childrens Specialty Healthcare FWA00004003). Approval will expire one year from that date. You will receive a report form two months before the expiration date.

In the event that you submitted a consent document with the continuing review form, it has also been reviewed and approved. If you provided a summary of subjects' experience to include non-UPIRTSO events, these are hereby acknowledged.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems and adverse events should be reported to the IRB as they occur. Results of inspections by any external regulatory agency (i.e. FDA) must be reported immediately to the IRB. Research projects are subject to continuing review.

If you have any questions, please call the IRB office at (612) 626-5654.

The IRB wishes you continuing success with your research.



**Office of Human Subjects Research
Institutional Review Boards**

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
410-955-4367 Fax
e-mail: jhmirb@jhmi.edu

Date: January 12, 2012

CONTINUING REVIEW APPROVAL

Review Type: Expedited
PI Name: Frank Witter
Study #: NA_00043877
Study Name: Improving Dietary Assessment in Pregnant Women and Children in the National Children's Study
Committee Chair: Susan Bassett
Committee: JHM-IRB X

Date of review: January 9, 2012

Date of approval: January 9, 2012

Date of expiration: January 8, 2013

The JHM IRB approved the above-referenced Continuing Review.

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.

The Johns Hopkins Institutions operates under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, The Johns Hopkins University School of Nursing - FWA00006088, The Johns Hopkins Hospital and Johns Hopkins Health Systems - FWA00006087, Johns Hopkins Bayview Medical Center - FWA00006089, Howard County General Hospital - FWA00005743, Hugo W. Moser Research Institute at Kennedy Krieger, Inc. - FWA00005719, Johns Hopkins Community Physicians - FWA00002251, Suburban Hospital and Health System - FWA00005924

The National Children's Study

12 Month Follow-up Questionnaire



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Centers for Disease Control and Prevention
U.S. ENVIRONMENTAL PROTECTION AGENCY



THE NATIONAL
CHILDREN'S
STUDY

HEALTH GROWTH ENVIRONMENT

Thank you for agreeing to participate in the National Children's Study. This self-administered questionnaire will take about 10 minutes to complete. There are questions about your relationships and questions about your child's diet.

Your answers are important to us. There are no right or wrong answers. You can skip over any question. We will keep everything that you tell us confidential.

If you are married or have a partner, please read the instructions below.

If you are not married or do not have a partner, go to the instructions following Question 6.

The first set of items are about your relationship with your spouse or partner. Please indicate the extent to which you agree or disagree with each statement.

1. My spouse/partner listens to me when I need someone to talk to.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

2. I can state my feelings without him getting defensive.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

3. I often feel distant from my spouse/partner.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

4. My spouse/partner can really understand my hurts and joys.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

5. I feel neglected at times by my spouse/partner.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

6. I sometimes feel lonely when we're together.

- Strongly disagree
- Somewhat disagree
- Neither agree nor disagree
- Somewhat agree
- Strongly agree

The next questions will ask about the milk, formula, and food your child has eaten in the past 7 days. In answering include feedings by everyone who feeds the baby. Include snacks and night-time feedings. Use these guidelines in choosing how to respond:

- If the baby was fed this item once a day or more, write the number of feedings *per day* in the boxes and then mark the box before “Day.”
- If the baby was fed the item less than once a day, write the number of feedings *per week* in the boxes and then mark the box before “Week.”
- If the baby was not fed the item at all during the past 7 days, write “00” in the boxes.

7. In the past 7 days, how often was your baby fed breast milk (include breast fed and expressed or pumped breast milk)?

Number of times per (select one below)

- Day
 Week

8. In the past 7 days, how often was your baby fed formula?

Number of times per (select one below)

- Day
 Week

9. In the past 7 days, how often was your baby fed cow’s milk?

Number of times per (select one below)

- Day
 Week

10. In the past 7 days, how often was your baby fed other milk (soy milk, rice milk, goat milk)?

Number of times per (select one below)

- Day
 Week

11. Please tell me which best describes what your baby has been fed. My baby...

- ...is not drinking breast milk now, but was fed breast milk in the past
 ...is drinking breast milk now
 ...was never fed breast milk

If you answered “My baby is drinking breast milk now” for Question 11, go to Question 14.

If you answered “My baby was never fed breast milk” for Question 11, go to Question 15.

Otherwise go to Question 12.

12. How old was your baby when you completely stopped breastfeeding and pumping or expressing breast milk? (If your baby was less than one month, enter age in weeks. If your baby was older than one month, enter age in months.)

Number of (select one below)

Weeks

Months

13. Have you ever fed your baby pumped or expressed breast milk?

Yes

No → *Go to Question 15*

14. In the past 7 days, about how often was your baby fed pumped or expressed breast milk? Include feedings by everyone who feeds the baby and include snacks and nighttime feedings.

1 time per week

2 to 4 times per week

Nearly every day

1 time per day

2 to 3 times per day

4 to 6 times per day

More than 6 times per day

Not applicable/ I have not fed my baby breast milk in the past 7 days

15. How old was your baby when he/she was first fed formula on a daily basis?

less than 1 month old

1 to 2 months old

3 to 4 months old

5 to 6 months old

More than 6 months old

Not applicable (never fed formula to baby)

If you answered “00” to Question 8 and “Not applicable (never fed formula to baby)” for Question 15, go to the instructions following Question 21.

If you answered any number “01” or more to Question 8, go to Question 17.

If you were unable to answer Question 8, go to Question 16.

16. Has your baby had formula in the last seven days?

Yes

No → *Go to Instructions following Question 21*

Not applicable (never fed formula to baby) → *Go to Instructions following Question 21*

17. What kind of infant formula was your baby fed in the past 7 days? Select all of the formulas that you feed your baby. Include any formula the baby was fed in the past 7 days that is not included on the list under "Other."

- Baby's Only Organic Dairy
- Baby's Only Organic Soy
- Baby's Only Organic Lactose Free
- Bright Beginnings milk-based
- Bright Beginnings Gentle milk-based
- Bright Beginnings Organic
- Bright Beginnings milk-based 2
- Bright Beginnings NeoCare
- Earth's Best Organic Infant Formula with DHA & ARA
- Earth's Best Organic Soy Infant Formula with DHA & ARA
- EleCare®
- Enfamil® Premium with Triple Health Guard
- Enfamil® Premium Next Step
- Enfamil® ProSobee®
- Enfamil® RestFull
- Enfamil AR®
- Enfamil® Gentlease®
- Enfamil® Gentlease® Next Step
- Enfamil® Enfacare
- Enfamil® Premature
- Enfamil® Premium Vanilla or Chocolate
- Enfamil® Soy Next Step
- Gerber® Good Start® Gentle Plus
- Gerber® Good Start® Gentle Plus 2
- Gerber® Good Start® Protect Plus
- Gerber® Good Start® Protect Plus 2
- Gerber® Good Start® Soy Plus
- Gerber® Good Start® Soy Plus 2
- Nutramigen® with Enflora LGG
- Nutramigen® AA
- Pregestimil®
- Similac® Advance® EarlyShield
- Similac Isomil® Advance®
- Similac Isomil® DF
- Similac® Organic
- Similac® Go & Grow
- Similac® Go & Grow EarlyShield
- Similac® Sensitive
- Similac® Sensitive R.S.
- Similac® Alimentum®
- Similac® Neosure®
- Store brand Milk based (like Member's Mark, Kirkland, Target up & up)
- Store brand Gentle or partially broken down whey protein formula (like Member's Mark or Target up & up)
- Store brand Soy based (like Target up & up)
- Store brand Next step (like Target up & up)
- Store brand Lacto sensitive (like Target up & up)
- Store brand Prebiotic (like Target up & up)
- Other _____

18. Was the formula ready-to-feed, liquid concentrate, powder from a can that makes a single serving, or powder from single serving packets? Select all of the formulas you feed your baby.

- Ready-to-feed
- Liquid concentrate
- Powder from a can that makes more than one bottle
- Powder from single serving packets

If your baby was ONLY fed ready-to-feed formula, go to Question 21.

Otherwise, go to Question 19.

19. During the past 7 days, what types of water have you and others who care for your baby used for mixing your baby's formula? Select all of the types of water you have used for mixing your baby's formula. If you have used any other type of water, please list the water type on the line below.

- Tap water from the cold faucet
- Warm tap water from the hot faucet
- Bottled water
- Other type of water used _____

20. Was the water used to mix the formula boiled?

- Yes
- No

21. In the past 7 days, on the average, how many ounces of formula did your baby drink at each feeding?

Ounces.

In the past 7 days, about how often did your baby drink from each of the following types of bottles and cups?

22. Plastic baby bottle with disposable bottle liner.

- Never
- Sometimes
- Most of the time
- Always

23. Plastic baby bottle without disposable liner.

- Never
- Sometimes
- Most of the time
- Always

24. Other plastic bottle (for example, a water bottle).

- Never
- Sometimes
- Most of the time
- Always

25. Glass baby bottle.

- Never
- Sometimes
- Most of the time
- Always

26. Plastic “no spill” cup.

- Never
- Sometimes
- Most of the time
- Always

27. Has your baby used a pacifier in the past 7 days?

- Yes
- No

28. Has your baby ever been fed cow’s milk that was not sold especially for babies? (This includes whole, low-fat, nonfat, or chocolate milk.)

- Yes
- No → *Go to Question 30*

29. How old was your baby when he/she was first fed cow’s milk that was not sold especially for babies?

Age in months.

30. How old was your baby when he/she was first fed cereal, including baby cereal, on a daily basis?

- less than 1 month old
- 1 to 2 months old
- 3 to 4 months old
- 5 to 6 months old
- More than 6 months old
- Not applicable (never fed cereal)

31. How old was your baby when he/she was first fed pureed baby food on a daily basis? Please include commercial (store bought) and homemade baby food.

- less than 1 month old
- 1 to 2 months old
- 3 to 4 months old
- 5 to 6 months old
- More than 6 months old
- Not applicable (never fed pureed baby food)

32. How old was your baby when he/she was first fed table food such as eggs, cheese, or potatoes on a daily basis?

- less than 1 month old
- 1 to 2 months old
- 3 to 4 months old
- 5 to 6 months old
- More than 6 months old
- Not applicable (never fed table food)

33. Which of the following supplements was your child given at least 3 days a week during the past 2 weeks? Select all of the supplements your child has taken during the past 2 weeks for at least 3 days a week. If your child has taken any other vitamins or supplements, please list them on the line beside “Other vitamins or supplements.”

- Fluoride
- Iron
- Vitamin D
- Other vitamins or supplements _____
- Not applicable (child not given supplements)

34. Was your baby given any herbal or botanical preparations or any kind of tea or home remedy in the past 7 days? Do not count preparations put on the baby's skin or anything the baby may have gotten from breast milk after you took an herbal or botanical preparation.

Yes

No

Thank you for participating in the National Children's Study and for taking the time to complete this survey.

For Office Use Only: