Human Subjects Protection Office
Penn State College of Medicine | Penn State Milton S. Hershey Medical Center
600 Centerview Drive, PO Box 855, Mail Code A115
Hershey, PA 17033-0855 | 717-531-5687 | hspo@psu.edu

Submitted by: Jessica Beiler
Date Submitted: August 27, 2010 12:24:03 PM
Date: August 27, 2010
IRB#: 34493
PI: IAN M PAUL

Study Title

1>Study Title
Intervention Nurses Start Infants Growing on Healthy Trajectories (INSIGHT) Study

2>Type of eSubmission
New

Home Department for Study

3>Department where research is being conducted or if a student study, the department overseeing this research study.
General Pediatrics (HMC)

Review Level

4>What level of review do you expect this research to need? NOTE: The final determination of the review level will be determined by the IRB Administrative Office.
Choose from one of the following:
Full

Basic Information: Association with Other Studies

5>Is this research study associated with other IRB-approved studies, e.g., this study is an extension study of an ongoing study or this study will use data or tissue from another ongoing study?
No

6>Is this an investigator-initiated clinical trial (i.e., the protocol was written by a PSU/HMC investigator and it prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes)?
Yes

7>Is this a clinical trial* that is required by law to be registered in the ClinicalTrials.gov registry?
Yes

***All clinical trials of devices, drugs and biologics (except for preliminary, early Phase 1 or feasibility trials), which are subject to FDA regulations must be registered in ClinicalTrials.gov.**

In addition, clinical trials require registration in a public registry in order to be considered for publication according to a policy of the International Committee of Medical Journal Editors (ICMJE). Details of the ICMJE requirement are described at the ICMJE website

at http://www.icmje.org

For additional information about clinical trial registration, see http://prsinfo.clinicaltrials.gov.

8>Provide the study registration number from ClinicalTrials.gov (NCT#). For industry-sponsored multi-center trials, obtain this number from the sponsor.
NCT01167270

9>Where will this research study take place? Choose all that apply.

[X] University Park
[X] Hershey Medical Center

10>Specify the building, and room at University Park where this research study will take place. If not yet known, indicate as such.
Center for Childhood Obesity Research (CCOR)

11>Does this research study involve any of the following centers?

[X] General Clinical Research Center at the Hershey Medical Center
[X] Diet Assessment Center

12>Does this research study involve the use of Hershey Medical Center hospital and/or clinic facilities, equipment or staff?
Yes

NOTE: If Yes, the study must be registered with the Office of Research Affairs using the Propsal Internal Approval Form and the Hershey Blue Form. These forms are available at http://www.hmc.psu.edu/ora/grants/forms/HersheyBlue.pdf.

Personnel

13>Personnel List

PSU User ID	Name	Department Affiliation	Role in this study	Point of Contact
imp101	PAUL, IAN M	GENERAL PEDIATRICS	Principal Investigator	

PSU User ID	Name	Department Affiliation	Role in this study	Point of Contact
llb15	Birch, Leann	Human Development and Family Studies	Co-Investigator	
jfs195	SAVAGE, JENNIFER SAVAGE	Center for Childhood Obesity Research	Co-Investigator	
sla197	ANZMAN, STEPHANIE L	HUMAN DEVELOP & FAMILY STUDIES	Co-Investigator	
mem44	MARINI, MICHELE EVA	CNTR FOR CHILDHOOD OBESITY RES	Co-Investigator	
mr7	ROVINE, MICHAEL ROVINE	HUMAN DEVELOP & FAMILY STUDIES	Co-Investigator	
jsb22	Beiler, Jessica	General Pediatrics (HMC)	Project Coordinator	Yes
jle126	STOKES, JENNIFER L	PEDIATRICS SUPPORT SERVIC	Co-Investigator	
dcm1	Mitchell, Diane	Nutritional Sciences	Co-Investigator	

- **Role in this study** Principal Investigator
  First Name IAN M **Middle Name** **Last Name** PAUL **Credentials** MD, MSc
  [ ] Point of Contact
  PSU User ID imp101 **Email Address** imp101@psu.edu **PSU Employment Status** Employed
  [X] Person should receive emails about this application
  Mailing Address PO Box 850
  Address (Line 2) Department of Pediatrics
  Mail Code **City** Hershey **State** Pennsylvania **ZIP Code** 17033
  Phone Number 717 531 8006 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation GENERAL PEDIATRICS
  Describe this person's qualifications and role in the project: Dr. Paul is an experienced general pediatrician. He is experienced as both a Principal Investigator and as a sub-investigator.

- **Role in this study** Co-Investigator
  First Name Leann **Middle Name** **Last Name** Birch **Credentials** PhD
  [ ] Point of Contact
  PSU User ID llb15 **Email Address** llb15@psu.edu **PSU Employment Status** Employed
  [X] Person should receive emails about this application
  Mailing Address 129 Noll Laboratory
  Address (Line 2)
  Mail Code **City** University Park **State** Pennsylvania **ZIP Code** 16802
  Phone Number 814 863 0053 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation Human Development and Family Studies
  Describe this person's qualifications and role in the project: Dr. Birch is an expert on childhood nutrition and obesity. She has many years experience as a principal investigator.

- **Role in this study** Co-Investigator
  First Name JENNIFER SAVAGE **Middle Name** **Last Name** SAVAGE **Credentials** PhD
  [ ] **Point of Contact**
  PSU User ID jfs195 **Email Address** jfs195@psu.edu **PSU Employment Status** Employed
  [ ] **Person should receive emails about this application**
  Mailing Address
  Address (Line 2)
  Mail Code **City** **State** **ZIP Code**
  Phone Number **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation Center for Childhood Obesity Research

Describe this person's qualifications and role in the project: Dr. Savage is experienced investigator and has worked with Dr. Birch on other similar studies.

- **Role in this study** Co-Investigator
  First Name STEPHANIE L **Middle Name** **Last Name** ANZMAN **Credentials** MS
  [ ] Point of Contact
  PSU User ID sla197 **Email Address** sla197@psu.edu **PSU Employment Status** Employed
  [ ] Person should receive emails about this application
  Mailing Address
  Address (Line 2)
  Mail Code **City** **State** **ZIP Code**
  Phone Number **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation HUMAN DEVELOP &FAMILY STUDIES
  Describe this person's qualifications and role in the project: Stephanie is an experienced investigator and has worked with Dr. Birch on similar studies.

- **Role in this study** Co-Investigator
  First Name MICHELE EVA **Middle Name** **Last Name** MARINI **Credentials** MS
  [ ] Point of Contact
  PSU User ID mem44 **Email Address** mem44@psu.edu **PSU Employment Status** Employed
  [ ] Person should receive emails about this application
  Mailing Address 0129 NOLL LAB
  Address (Line 2) UNIVERSITY PARK
  Mail Code **City** **State** **ZIP Code**
  Phone Number +1 814 863 0607 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation CNTR FOR CHILDHOOD OBESITY RES
  Describe this person's qualifications and role in the project: Michele is an experienced statistician and has worked with Dr. Birch on similar studies.

- **Role in this study** Co-Investigator
  First Name MICHAEL ROVINE **Middle Name** **Last Name** ROVINE **Credentials** PhD
  [ ] Point of Contact
  PSU User ID mr7 **Email Address** mr7@psu.edu **PSU Employment Status** Employed
  [ ] Person should receive emails about this application
  Mailing Address 0119 HENDERSON BLDG
  Address (Line 2) UNIVERSITY PARK
  Mail Code **City** **State** **ZIP Code**
  Phone Number +1 814 865 7094 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation HUMAN DEVELOP &FAMILY STUDIES
  Describe this person's qualifications and role in the project: Dr. Rovine has experience as an investigator and with a wide variety of research studies.

- **Role in this study** Project Coordinator
  First Name Jessica **Middle Name** **Last Name** Beiler **Credentials** MPH
  [X] Point of Contact
  PSU User ID jsb22 **Email Address** jbeiler@hmc.psu.edu **PSU Employment Status** Employed
  [X] Person should receive emails about this application
  Mailing Address Pediatrics
  Address (Line 2) HERSHEY MEDICAL CENTER
  Mail Code **City** HERSHEY **State** Pennsylvania **ZIP Code** 17033
  Phone Number 1 717 531 1260 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation General Pediatrics (HMC)
  Describe this person's qualifications and role in the project: Jessica is an experienced investigator and has worked with Drs. Birch and Paul on similar studies.

- **Role in this study** Co-Investigator
  First Name JENNIFER L **Middle Name** **Last Name** STOKES **Credentials** RN
  [ ] Point of Contact
  PSU User ID jle126 **Email Address** jle126@psu.edu **PSU Employment Status** Employed
  [ ] Person should receive emails about this application
  Mailing Address H085 DERRY TOWNSHIP
  Address (Line 2)
  Mail Code **City** HERSHEY **State** Pennsylvania **ZIP Code** 17033-0850
  Phone Number +1 717 531 7765 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation PEDIATRICS SUPPORT SERVIC
  Describe this person's qualifications and role in the project: Jennifer is an experienced investigator and nurse. She has worked with Drs. Birch and Paul on similar studies.

- **Role in this study** Co-Investigator
  First Name Diane **Middle Name** **Last Name** Mitchell **Credentials** MS
  [ ] Point of Contact
  PSU User ID dcm1 **Email Address** dcm1@psu.edu **PSU Employment Status** Employed
  [ ] Person should receive emails about this application
  Mailing Address 108 Chandlee Laboratory
  Address (Line 2)
  Mail Code **City** University Park **State** Pennsylvania **ZIP Code** 16802
  Phone Number 814 863 5955 **Fax number** **Pager Number** **Alternate Telephone**
  Department Affiliation Nutritional Sciences
  Describe this person's qualifications and role in the project: Diane Mitchell will be a sub-investigator and has experience in nutrition research.

14>Is the Clinical Trials Office being used for HMC Regulatory Service for Initial Review?
No

Funding Source

15>Is this research study funded? Funding could include the sponsor providing drugs or devices for the study.
Pending

NOTE: If the study is funded or funding is pending, submit a copy of the grant proposal or statement of work for review.

16>Sponsor List
Sponsor Name
NIH/National Institutes of Diabetes and Digestive and Kidney Disorders

- **Sponsor Name**
  NIH/National Institutes of Diabetes and Digestive and Kidney Disorders
  Sponsor address or other contact information
  National Institute of Diabetes and Digestive and Kidney Diseases
  6707 Democracy Blvd
  Bethesda, MD 20892-5450

17>Is the funding awarded through a subcontract?
No

18>Is the sponsor providing drug, device, etc, free of charge?
No

19>If funding is not awarded, will the research still be conducted?
No

20>Does this research study involve prospectively providing treatment or therapy to participants?
No

Conflict of Interest

21>Do any of the investigator(s), key personnel, and/or their spouses or dependent children have a financial or business interest(s) as defined by PSU Policy RA20, "Individual Conflict of Interest," associated with this research? NOTE: There is no de minimus in human participant research studies (i.e., all amount must be reported).
No

Multi-Center Study

22>Is this a multi-center study (i.e., study will be conducted at other institutions each with its own principal investigator)?
No

Participant Numbers

23>Maximum number of participants/samples/records to be enrolled by PSU investigators. NOTE: Enter one number – not a range. This number should include the estimated number that will give consent but not qualify after screening or who will otherwise withdraw and not qualify for inclusion in the final data analysis. This number should be based on a statistical analysis, unless this is a pilot study, and must match the number of participants listed in the consent form.
976

24>Was a statistical/power analysis conducted to determine the adequate sample size?
Yes

25>Name of person responsible for the statistical/power analysis and his/her affiliation (if any):
Michele Marini, MS Penn State University: Center for Childhood Obesity Research

Age Range of Participants

26>Age range of participants
infants

Participant Information: Participant Categories

27>Choose all categories of participants who will be involved in this research study.

[X] Healthy volunteers
[X] Children – Federal law defines "children" as persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. Under Pennsylvania law, persons under the age of eighteen (18) generally meet the definition of "children" with a few exceptions.

28>Will assent be obtained from the children enrolled in this research study?
Choose only one.

[X] Assent will not be obtained

29>Provide a justification for the waiver of child assent.
All children enrolled in the study will be under the assenting age of 7.

30>Research involving children is limited to the following categories. Choose one category that applies to your study:

[X] Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants

31>Explain why the risk is justified by the anticipated benefit to the child.
This study aims to teach parents soothing and feeding techniques, hypothesizing that use of these interventions will result in children with healthier eating habits and less obesity. It is theoretically possible that behavioral interventions designed to prevent early life obesity could result in underfeeding by parents and insufficient growth. The educational intervention focuses on responsive infant feeding cues and heathly dietary choices, not witholding food. Infant weight and length will be monitored throughout the study (2 weeks, 4 months, 8 months, 12 months, 2 years, and 3 years) by experienced research nurses. Parents will be told that they can contact the research nurse with any questions or concerns about their infant's health. Dr. Paul the PI of the study is an experienced general pediatrician and will be available to both the parents and the research staff to address any questions or concerns. Dr. Paul will review the participant's growth chart within one week of the home visits to indentify any growth concerns.

Participant's primary care physicians will be sent a letter summarizing the study, informing them of their patient's study participation and whether they are in the intervention group (obestity prevention program) or the control group (infant home safety information based on the American Academy of Pediatrics guidelines). The letter will also give the physician contact information for the study staff to report any growth concerns or questions.

The study does not use any invasive testing or medications.

32>Explain why the relation of the anticipated benefit to the risk is at least as favorable to the participants as the available alternatives.

The risk for this study is theoretical. Because insufficient weight was a concern, this outcome was evaluated in our pilot study (SLIMTIME IRB 22165EP) using two standard definitions, downward crossing of two major weight-for-age growth chart percentile lines between birth and age 1 year and weight less than the 5th percentile at age 1 year. No significant differences were detected among treatment groups for either definition of insufficient weight gain. Further, while the combined interventions had a significant impact on weight-for-length percentile, there was no impact on linear growth. We do not anticipate any risk of insufficent weight gain in this study since the educational intervention focuses on responsive infant feeding cues, improving infant sleep, and healthy dietary choices, not witholding food.

Parents will either be given timely personalized safety information or an educational intervention that may help prevent obesity. Regardless of the assigned treatment group, parents will be given healthy parenting strategies. Parents will also have access to a study nurse to answer any questions and provide support during their study involvement.

33>Describe the provisions made to solicit the child's assent and parent's/guardian's permission OR indicate that a waiver of child assent and parent/guardian permission has been requested.
Parents of infants delivered at the Hershey Medical Center will be approached during the post-partum hospital stay. Eligible parent(s) will have the study described to them and any questions answered by experienced research coordinators. Since the children enrolled in the study are all infants assent will only be obtained after the children are age 7.

34>Is there a possibility that any of the children will be wards of the State or any other agency or institution?
No

35>Will this study be conducted within a school district and/or other learning environment (i.e., charter school, daycare)?
No

The IRB requires that research conducted in schools with children be approved by schools, school district authorities or research evaluation committee(s). At HMC, documented approval is required. At University Park, the letters of agreement do not need to be submitted with the application. However, the researcher must have the letters on file and available for IRB or ORP review at any time.

36>Will participants be currently enrolled in a course/class of any personnel listed on this application?
No

37>Will participants be employees of any personnel listed on this application?
No

38>Does this research exclude any particular gender, ethnic or racial group, and/or a person based on sexual identity?
No

39>Could some or all participants be vulnerable to coercion or undue influence due to special circumstances (do not include children, decisionally impaired, and prisoners in your answer)?

No

Recruitment

40>Describe the specific steps to be used to identify and/or contact prospective participants, records and/or tissue. If applicable, also describe how you have access to lists or records of potential participants.

Research coordinators will use mother/infant charts of infants delivered at the Hershey Medical Center to determine eligibility. Eligible mothers will be approached by research coordinators during their post-partum hospital stay.

41>Will recruitment materials be used to identify potential participants?

No

42>Before potential participants sign a consent document, are there any screening/eligibility questions that you need to directly ask the individual to determine whether he/she qualifies for enrollment in the study?

[X] Yes

43>Will researchers who are not involved in the care of potential participants review and/or use protected health information before a consent/authorization form is signed in the course of screening/recruiting for this research study (e.g., reviewing medical records in order to determine eligibility)?

Yes

44>Indicate why pre-review has to be done prior to the participant's authorization.

Research coordinators want to ensure the privacy and confidentiality of new mothers delivering at the Hershey Medical Center. To that end, it is important to make sure that only mother/infant pairs that are eligible for the study are approached for participation. Review of the mother/infant chart will allow coordinators to determine some of the key eligibility criteria essential to protecting the privacy of the mothers, i.e. Is the baby being put up for adoption, multiple birth etc.

45>Investigators are required to only obtain the minimum necessary data in order to achieve the goals of the research. Provide a list of the information intended to be used.

Research coordinators will collect eligibility criteria and some descriptive information. Eligibility questions are in a "Yes/No' format and do not collect any identifying information. Eligibility questions include: adoption, mother/baby health problems, gestational age, maternal age, para, area of residence, evidence of IUGR, and extended hospital stay.

46>Explain why the data being obtained is the minimum necessary to achieve the goals of this research study.

To assure the integrity of the study and recruitment practice it is essential to minimally describe the patients delivering at the Hershey Medical Center. The study needs to report, the number of deliveries, the number of eligible mother/infant pairs, and then the number of mother/infant pairs that actually enroll in the study and any basic differences between those groups. These details are necessary to accurately complete the CONSORT diagram encouraged by ICMJE.

47>Provide a description of the pre-review and the plan for prescreening the information.

Experienced research coordinators will review the mother/ infant chart for eligibility and minimal descriptive information. Eligible mothers will be approached about the study. If the mother agrees to participate and signs the consent form, her pre-screen information will be identified with a study ID number along with her other study information. If the mother declines to participate, any screening information will remain de-indentified and will not be linked to her or her infant(s) in any way.

48>The approval of this request is contingent upon the principal investigator's agreement to the following statements. Check the box if the principal investigator agrees that:

[X] The use or disclosure is sought solely to review protected health information as necessary to prepare a research study or for similar purposes preparatory to research.
[X] No protected health information is to be removed from the covered entity by the research in the course of the review.
[X] Use or access to the protected health information is necessary for the research purposes.
[X] The use of the protected health information is in accord with the "minimum necessary" standard per federal requirements. NOTE: 'Minimum necessary' standard is the information reasonably necessary to accomplish the purpose [of the sought or requested use or disclosure].
[X] Research team members will sign a Confidentiality Agreement. NOTE: All PSUCOM and HMC employees and students have signed such a form as part of their employment/enrollment.)
[X] Access to the information will be limited to the greatest extent possible within the research team.

49>Does this research study use health information within the study?

Yes

(1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

50>Are any identifiers (according to HIPAA regulations) attached or linked to the health information, e.g., name, initials, address, phone/fax numbers, email address, dates, medical record number, social security number, linking code list?

Yes

Based on your answers to the preceding questions, you ARE using Protected Health Information in your research study.

51>Choose one or more of the following:

[X] Authorization will be obtained and documented as part of the consent process

52>Indicate which of the following identifiers will be used:

[X] Name
[X] Any geographic subdivisions smaller than a state, including street address, city, county, precinct,

zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
[X] Any elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
[X] Telephone numbers
[X] Electronic mail addresses
[X] Social Security numbers
[X] Medical record numbers
[X] Full-face photographic images and any comparable images
[X] Link to identifier code (a list kept separate from the data set that links participants' identifier(s) to a code number in the data set)

Informed Consent/Parental Permission and Authorization Information

NOTE: Per federal regulations, (45 CFR 46.117), the informed consent process must be followed by documentation using a written consent form approved by the IRB and signed by the participant or the participants' legally authorized representative. A copy must be given to the person signing the form. (Refer to the IRB web site for the general instructions, the required elements for the informed consent process and the format for the written consent form.)

In some instances, however, the IRB has authority to waive the requirement to obtain informed consent from participants or the requirement to have participants sign a consent document.

53>Informed consent requirement: Choose all that apply:

[X] Informed consent will be sought and documented with a written consent form or parental permission form

54>Indicate who will be responsible for obtaining consent from participants.
Experienced research coordinators will obtain consent.

55>Describe when and where participants will be approached to obtain informed consent (include the timing of obtaining consent in the response).
Eligible mothers will be approached about the study during their post partum stay, in their hospital room. Mothers will be given ample time to ask questions and consider study participation. If the mother agrees to participate she will consent form and be given a copy for her records.

56>Describe the steps taken to minimize the possibility of coercion or undue influence.
Experienced research coordinators will approach the parents, explain the study, and give time to ask questions before obtaining consent. It will be explained that study participation will not affect the patients care.

57>Will consent be solicited from non-English or limited English speaking participants?

[X] No

58>Provide a justification for excluding non-English or limited English speaking participants. Choose all that apply.

[X] Research is using an unvalidated instrument (survey or questionnaire)

Cost to Participants: Compensation

59>Will the participant bear any costs which are not part of standard of care?

No

60>Will individuals be offered compensation for their participation?

Yes

61>Indicate the type(s) of compensation that will be offered. Choose all that apply.

[X] Money
[X] Other (e.g., items such as iPODs)

62>How much money will be offered to participants?

$500

63>Describe the 'other' type of compensation that will be offered.

American Academy of Pediatrics Book, "Your Baby's First Year".

64>Explain the schedule for any compensation that will be offered (e.g., money per visit, gift card at the end of the study, etc.)

Participants will receive a total of $500. $250 during the first year ($25 after the first home visit, and $75 each for the home visit at 4 and 8 months, and the research clinic visit at 1 year). $125 each for the research visits at 2 and 3 years.

Data Collection Measures/Instruments

65>Choose any of the following data collection measures/instruments that will be used in this study. Submit a copy of all instruments, measures, interview questions, and/or focus group topics/questions for review.

[X] Review of private, identifiable information (e.g., review of medical records)
[X] Educational research
[X] Questionnaires, surveys, diaries or journals

66>What is the source of the information? Choose all that apply.

[X] Medical records

67>Is all of the information existing data at the time of the IRB application (e.g., retrospective chart review study)?

No

68>Provide a description of the educational research.

There are 2 programs (intervention and control) that parents will be randomized to receive in this study:

The obesity intervention program contains messages on responsive feeding, division of feeding responsibility, and healthy dietary choices designed for the prevention of obesity that extend from infancy through age 3 years (See protocol for more details). This intervention program will be delivered at 3 home visits and 2 Clinical Research Office visits over the first 24 months after birth. Training material examples for parents are attached to this application.

The control group will receive an equal number of visits, but the content will be a child safety intervention with messages focused on the infant's environment and interactions with parents. They will be guided by The Injury Prevention Program (TIPP) from the American Academy of Pediatrics (see attached) as well as the Academy's guide for health supervision, Bright Futures. The information covered by the safety intervention is typically presented as part of standard pediatric office care, but will be delivered in a more hands-on fashion at the home visits. Parents will be encouraged to modify the environment to prevent falls, suffocation, motor vehicle-related injuries, burns, etc.

69>List the titles of the surveys, diaries or questionnaires that will be used.

See Protocol Page 15 Table 4.

Drugs/Medical Devices/Other Substances

70>Does this research study involve the use of any of the following? Choose all that apply.

[X] None of the above will be used in this research study

Biological Specimens

71>Will biological specimens (including blood, urine and other human-derived samples) be used in this study?

No

Recordings - Audio, Video, Digital, Photographs

72>Will any type of recordings (audio, video or digital) or photographs be made during this study?

Yes

73>What type of recordings will be made (including digital)? Choose all that apply.

[X] Video

74>What will be recorded or photographed (i.e., the interview, the focus group, the observations)?

Infants and a parent will be videotaped during the "unfamiliar food tasting". Permission to do this videotaping will be requested as part of the informed consent process.

75>Where will the recordings/photographs be stored?

Video recordings will be stored in Dr. Paul, the PIs academic office.

76>Who will have access to the recordings/photographs?

Research staff at the Hershey Medical Center and at University Park.

77>How will the recordings/photographs be labeled?

The video recordings will be labeled with the subject ID number. None of the video recordings that are sent to University Park for coding will be labeled with any additional identifying information other than the subject ID.

78>Can participants' identities be determined from the recording or image (i.e., facial image, name)?

Yes

79>How will the recordings be transcribed, coded and by whom?

Research coordinators at the Hershey Medical Center will copy the video onto a CD with the subject ID as the identifier. Blinded coders from the Center for Childhood Obesity will review and code the videos.

80>Will the recordings/photographs be destroyed?

Yes

81>How and when will the recordings/photographs be destroyed?

Videos will be kept until the study and any analyses, research papers from this study are completed.

82>Will the recordings/photographs be used outside of this research study?

No

Computer/Internet

83>Will any data collection for this study be conducted on the Internet or via email (e.g. on-line surveys, observations of chat rooms or blogs, on-line interviews surveys via email)?

No

84>Will a commercial service provider (i.e., SurveyMonkey, Psych Data, Zoomerang) be used to collect data or for data storage?

No

Risks: Summary

85>Summarize the major discomforts and risks of interventions that are part of the experimental portion of the study. This description should include physical, psychological, legal, social and/or financial risks. (Note: For studies presenting no more than minimal risk, loss of confidentiality may be the main risk associated with the research.)

Because behavioral interventions aimed at obesity prevention could theoretically cause infants to gain insufficient weight. This outcome was evaluated in our pilot study (SLIMTIME IRB 22165EP) using two standard definitions, downward crossing of two major weight-for-age growth chart percentile lines between birth and age 1 year and weight less than the 5th percentile at age 1 year. No significant differences were detected among treatment groups for either definition of insufficient weight gain. Further, while the combined interventions had a significant impact on weight-for-length percentile, there was no impact on linear growth. We do not anticipate any risk of insufficient weight gain in this study since the educational intervention focuses on responsive infant feeding cues and healthy dietary choices, not withholding food. The study has a comprehensive DSMP (attached) to manage and prevent any potential risks.

Loss of privacy and confidentiality and encountering social issues with entering the home are other potential risks.

86>Describe how the discomforts and risks will be minimized and/or how participants will be protected against potential discomforts/risks throughout the study (e.g., label research data/specimens with code numbers, screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).

Infant weight and length will be monitoring throughout the study (2 weeks, 4 months, 8 months, 12 months, 2 years, and 3 years) by experienced research nurses. Parents will be told that they can contact the research nurse with any questions or concerns about their infant's health. Dr. Paul the PI of the study is an experienced general pediatrician, will be available to both the parents and the research staff to address any questions or concerns. Dr. Paul will review the participant's growth chart within one week of the home visits to identify any growth concerns.

Participant's primary care physicians will be sent a letter summarizing the study, informing them of their patient's study participation and whether they are in the intervention group (obesity prevention program) or the control group (infant home safety information based on the American Academy of Pediatrics guidelines). The letter will also give the physician contact information for the study staff to report any growth concerns or questions.

This study has a comprehensive data safety plan that describes the tracking of any adverse events, including any growth concerns. The study DSMP is attached to this application.

Experienced research coordinators will collect the diaries, ask questions, and perform the home visits. These are experienced coordinators that are trained in protecting participate information. Participant's information will be labeled only with their subject ID number.

Any Illegal activities like abuse that are discovered as part of the home visits will be reported to the proper authorities. Study staff are required to report any illegal activity or abuse to the PA Youth Services through ChildLine.

87>Is it possible that you will discover a participant's previously unknown condition (e.g., disease, suicidal thoughts, wrong paternity, etc.) as a result of the study procedures?

Yes

88>Explain how and when a discovery of a participant's previously unknown condition will be handled.

Mother's will be screened for post-partum depression. If mother is suspected of being depressed then, the mother will be referred to the HMC Women's Health group. Conditions discovered in the infants will be treated per standard of care by the child's PCP, who will be notified by study staff.

89>Is it possible that, as a result of the study procedures, you will discover a participant is engaging in illegal activities (e.g., drug use, domestic violence, child abuse/neglect, underage drinking, etc.)?

Yes

90>Explain how and when a discovery of a participant's illegal activities will be handled.

Any Illegal activities like abuse that are discovered as part of the home visits will be reported to the proper authorities. Study staff are required to report any illegal activity or abuse to the PA Youth Services through ChildLine.

91>Does this research involve greater than minimal risk to the participants?

Yes

92>Describe how the risks to participants are reasonable in relation to anticipated benefits.

The risk for this study is theoretical. Because insufficient weight was a concern, this outcome was evaluated in our pilot study (SLIMTIME IRB 22165EP) using two standard definitions, downward crossing of two major weight-for-age growth chart percentile lines between birth and age 1 year and weight less than the 5th percentile at age 1 year. No significant differences were detected among treatment groups for either definition of insufficient weight gain. Further, while the combined interventions had a significant impact on weight-for-length percentile, there was no impact on linear growth. We do not anticipate any risk of insufficient weight gain in this study since the educational intervention focuses on responsive infant feeding cues, improving infant sleep, and healthy dietary choices, not withholding food.

Parents will either be given timely personalized safety information or an educational intervention that may help prevent obesity. Regardless of the assigned treatment group, parents will be given healthy parenting strategies. Parents will also have access to a study nurse to answer any questions and provide support during their study involvement.

93>Will continuous emergency medical or psychological care be available for participants who may require it as a result of the study?

Yes

94>List the source of the emergency medical or psychological care available.

Penn State Hershey Medical Center Emergency Department or the Pediatric Resident on call.

95>Will participants be withdrawn from or denied standard care for any condition in order to participate in the study?

No

96>All research studies involving greater than minimal risk must include a data safety monitoring plan (DSMP) as part of the proposed research study. Is a description and assessment of research-related risks included in the data safety monitoring plan?
Yes

97>Provide the protocol section or describe.
This study's DSMP is a separate document, attached to this application.

98>Is a description of anticipated adverse events and how they will be graded included in the data safety monitoring plan?
Yes

99>Provide the protocol section or describe.
DSMP Section D, Pages 4-5

100>Is a description of reporting mechanisms for internal adverse events included in the data safety monitoring plan?
Yes

101>Provide the protocol section or describe.
DSMP Section A, page 5

102>Is a description of the procedures which will be utilized to monitor participant safety included in the data safety monitoring plan?
Yes

103>Provide the protocol section or describe.
DSMP Section D pages 4-5

104>Is a description of stopping rules or critical thresholds for stopping or modifying the study included in the data safety monitoring plan?
Yes

105>Provide the protocol section or describe.
DSMP Section E page 7

106>Who will perform the data and safety monitoring? Choose only one:

[X] Formally constituted independent Data Safety Monitoring Board (DSMB)

107>Indicate the formally constituted DSMB that will perform the data and safety monitoring. Choose only one.

[X] DSMB at the Hershey Medical Center

108>Provide the protocol section which describes the DSMB or describe.

The study DSMB is a separate document. Please see attached.

109>Describe the schedule of interim analysis.

Not planned at this time

110>Describe plans for assuring data accuracy and protocol compliance.

Investigators at University Park will review the data and work with the Hershey staff to ensure compliance and accuracy.

Benefits to Participants

111>What are the potential benefits to the individual participants of the proposed research study? (If none, state "None.") NOTE: Compensation cannot be considered a benefit.

Parents will either be given timely personalized safety information or an educational intervention that may help prevent obesity and promote healthy eating and sleeping habits. Regardless of the assigned treatment group, parents will be given healthy parenting strategies. First-time parents will also have access to a study nurse to answer any questions and provide support during their study involvement.

112>What are the potential benefits to others from the proposed research study?

The study may provide insight into an educational intervention that will increase responsive feeding, alternative soothing techniques, and parenting self-efficacy that may be linked to healthier patterns of weight gain during the first years of life.

Deception

113>Does this study involve giving false or misleading information to participants or withholding information from them such that their "informed" consent is in question?

No

Confidentiality

114>Describe the provisions made to maintain confidentiality of the data, including medical records and specimens. Choose all that apply.

[X] Password protected computer files
[X] Locked file cabinets
[X] Locked offices
[X] Identification coding system.

115>Describe the provisions made to protect the privacy interests of the participants and minimize intrusion.

Only the code list will have any identifying information. Coordinators will pre-screen potential

participants to limit unnecessary intrusion on non-eligible participants. Data from this prescreen will not contain indentifying information. Potential participants will be approached in the privacy of the examination room for study explanation, consenting, and study procedures.

The security of the project data will be maintained through the ISS network hardware and user authentication (usernames and passwords). The project directory will be restricted to only staff in the Center working on the project. Back-ups of the project data files will occur every night, with user data backed-up incrementally Monday through Thursday and complete back-ups every Friday. Archival back-ups, stored indefinitely, are cut on the last weekend of every month. All back-up data are stored in a secure off-site location. The number and variety of back-ups ensure ample data redundancy and protection. In addition, Center staff will never receive any identifying personal information on the research participants. Each participant will be assigned a unique subject identification number. Only the study research staff will have the log linking this number with the participant's personal information.

116>Will the study data and/or specimens contain identifiable information?

Yes

117>List the identifiers that will be recorded for the research.

DOB (maternal, paternal, and child), name, address, phone number, email, MRN, soc security (for payment only), video recording.

118>Who will have access to the study data and/or specimens?

Study coordinators and staff

119>Will identifiers be disclosed to a sponsor or collaborators at another institution?

No

120>Will a record or list containing a code (i.e., code number, pseudonym) and participants identity be used in this study?

Yes

121>Where will the list linking the code numbers to participants be stored?

Dr. Paul's office, Long Lane Building 111

122>How will the list linking the code numbers to participants be secured?

Locked cabinets and computer files in Dr. Paul's office

123>Who will have access to the list linking the code numbers to participants?

Study staff

124>When will the list linking the code numbers to participants be destroyed?

When the study is over and all of the papers have been written the PIs will determine that the list is no longer needed and can be destroyed.

125>What will happen to the data when the research has been completed? Choose one.

[X] Stored for length of time required by federal regulations/funding source and then destroyed [minimum of 3 years]

126>Is information being collected for this research that could have adverse consequences for participants or damage their financial standing, employability, insurability or reputation?
No

127>Will a "Certificate of Confidentiality" be obtained from the federal government?
No

Additional PSU Committee Approvals

128>Choose all that apply.

[ ] Human Use of Radioisotope Committee (HUIC)

Review by this committee is required if the study involves radiation procedures specifically for the research. The HUIC review letter is required before IRB approval will be issued.

[ ] Institutional Biosafety Committee (IBC)
IBC Registration Number:

Review by this committee is required if the research involves the use of human biological specimens, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA, or gene therapy. The IBC registration number is required before IRB approval will be issued.

[ ] Departmental Scientific Review Committee

For example, review by the Penn State Cancer Institute Scientific Review Committee is required if the study involves cancer patients, records and/or tissues. Include a copy of the committee's report with the application materials.

[ ] Anatomic Pathology

Protocols involving the collection of tissues or use of pathologic specimens must receive approval from Anatomic Pathology. Include a copy of the Human Tissue for Research Form with the application materials.

[ ] Conflict of Interest Review Committee (CIRC)

Review by this committee is required if a significant financial or business interest or PSU intellectual property interest is indicated. The CIRC report is required before IRB approval will be issued.

Radiation

129>Will any participants be asked to undergo a diagnostic or therapeutic radiation procedure (including radiographic, nuclear medicine, DEXA) while enrolled in this study?
No

Abstract

130>Background and Rationale: Provide background information and explain why the study hypothesis needs to be addressed. For studies using drugs, summarize the drug's class and mechanism.
Overweight and rapid weight gain during infancy are associated with increased later risk of overweight, as well as numerous co-morbidities. Because infancy is a critical period of developmental plasticity with long-lasting metabolic and behavioral consequences, interventions developed for delivery during this period may alter long-term risk for obesity and associated co-morbidities. However, while modifiable factors promoting overweight and rapid growth during infancy have been identified,preventive interventions addressing these factors have not been developed and tested. Most attempts to address childhood obesity have tried to impact the obesity epidemic through interventions in schools, communities, and childcare settings. Unfortunately, a recent Cochrane analysis of these efforts found limited success in preventing or treating obesity for children in these age groups. An innovative approach to the epidemic is to begin preventive efforts before age 2, a period of metabolic and behavioral plasticity

The intervention we propose to test is informed by research conducted within an ecological/developmental framework by co-PI Birch that has revealed links between parental feeding practices and the developing controls of food intake and weight outcomes in children. We propose an innovative intervention to alter traditional feeding practices by teaching parents to interact with their child in ways that are responsive, appropriate, and contingent. This approach is supported by extensive evidence showing that responsive parenting has positive effects on social, emotional, cognitive, and health outcomes. Responsive feeding can promote self-regulation and shared parent-child responsibility for feeding, reducing risk for overeating and overweight.

131>Key Objectives: List the study's objectives, aims or goals.
Specific Aim 1: To test the efficacy of an intervention designed to prevent rapid weight gain in infancy and overweight at age 3 years by providing guidance on responsive feeding, division of feeding responsibility, and healthy dietary choices.

Specific Aim 2: To test how intervention effects on primary growth and weight outcomes are mediated by parental and infant behaviors and infant diet.

132>Study Population: Health volunteers or participants with a specific illness? Students? Include the age range of the participants. Include controls, if any.
350 healthy newborns and mothers will be recruited during the maternity hospitalization.

133>Major Inclusion & Exclusion Criteria: List the characteristics required to be in the study and those which would make an individual ineligible. For studies with a research protocol, describe only the major criteria).
Inclusion criteria include: 1) singleton infant born at >37 weeks gestation, 2) primiparous mother, 3) English-speaking mother 4) nursery or NICU stay of 7 days or less 5) lives within 50 miles (1 hour) of HMC

Exclusion criteria include: 1) Maternal age <18 years, 2) presence of a congenital anomaly or neonatal condition that significantly affects a newborn's feeding (e.g. cleft lip, cleft palate, metabolic disease), 3)

any major maternal morbidities and/or pre-existing condition that would affect postpartum care or her ability to care for her newborn such as cancer, multiple sclerosis, lupus, etc. 4) Prenatal ultrasound presence of intrauterine growth retardation (IUGR)

134>Method of Identification of Participants, Samples and/or Medical Records: Indicate how potential participants, samples or medical records will be identified for this research. Describe any recruitment materials.

Research coordinators will use mother/infant charts of infants delivered at the Hershey Medical Center to determine eligibility. Eligible mothers will be approached by research coordinators during their post-partum hospital stay.

135>Consent Process and Documentation: Who will conduct the consent discussion? Briefly describe the process [e.g., when and where consent will be obtained].

Experienced research coordinators will review the mother/ infant chart for eligibility and minimal descriptive information. Eligible mothers will be approached about the study in the privacy of their hospital room. If the mother agrees to participate and signs the consent form, her pre-screen information will be identified with a study ID number along with her other study information. If the mother declines to participate, any screening information will remain deindentified and will not be linked to her or her infant(s) in any way.

136>Study Design: Describe the study design [e.g., case series, retrospective case-control study, etc.] Include the method of group assignment including randomization process and study comparison groups, if applicable. For case-control studies, provide the criteria used to identify participants for the control group. For simple research, this section may describe observational methods, medical chart review, etc.

Randomized control trial. Participants will be randomized to either the obesity prevention program or the child safety control group, stratifying on birth weight for gestational age quartile and intended feeding mode (breastfeeding or formula feeding) 10-14 days after delivery. The randomization scheme will use permuted blocks.

137>Summary of Procedures: Describe the procedures involving the participants, how they will be done and when as well as any post-treatment follow-up. For chart review studies, list the data elements to be recorded for research.

Over the 3-year study period, numerous study visits or telephone calls will occur; beginning with a visit during the maternity and nursery hospitalization. Participation by the mother/infant dyad after maternity and nursery discharge will consist of 4 home visits where intervention procedures will be explained to parents, 9 telephone interviews, and 3 study visit at the HMC GCRC (at 1,2, and 3 years). Infant's length and weight will be measured at each of the home and GCRC visits. Mothers will have their weights taken at each of the home visits and their height taken at the 2 weeks home visit. Father's (if they agree to participate) will have their heights and weights taken one time at a home visit. Parents will be asked questions about their infant's sleep, feeding, temperament, and other parenting questionnaires (see attached). A video recorded unfamiliar food tasting will be conducted at the 3 GCRC visits.

Interventions include:
Obesity prevention program -instructions on infant sleeping and soothing, responsive feeding and repeated food exposure.

Child safety control group-safety instructions are focused on the infant's environment and interactions with parents. Instructions are guided by The Injury Prevention Program (TIPP) from the American Academy of Pediatrics and the Academy's guide for health supervision, Bright Futures.

138>Outcome Measures: Describe the endpoints used to answer the aims of the study. For studies with a research protocol, state "See protocol section X."
See Protocol Section III E, page 13. Outcome Measures and the Rationale for Choosing Them

139>Statistical Plan and Sample Size Justification: Give details of the power analysis used to justify the sample size for the study. Provide a data analysis plan including statistical methods to be used for each aim of the study. For studies with a research protocol, state "See protocol section X."
Section VIII. C, page 27: Sample Size, Power Calculations, and Statistical Analysis

140>Major Risks & Discomforts: Describe the risks and discomforts that are reasonably foreseeable.
Because behavioral interventions aimed at obesity prevention could theoretically cause infants to gain insufficient weight. This outcome was evaluated in our pilot study (SLIMTIME IRB 22165EP) using two standard definitions, downward crossing of two major weight-for-age growth chart percentile lines between birth and age 1 year and weight less than the 5th percentile at age 1 year. No significant differences were detected among treatment groups for either definition of insufficient weight gain. Further, while the combined interventions had a significant impact on weight-for-length percentile, there was no impact on linear growth. We do not anticipate any risk of insufficient weight gain in this study since the educational intervention focuses on responsive infant feeding cues and healthy dietary choices, not withholding food. The study has a comprehensive DSMP (attached) to manage and prevent any potential risks.

Loss of privacy and confidentiality and encountering social issues with entering the home are other potential risks.

141>Potential Benefits: Describe the anticipated benefits for the participants and/or others.
Parents will either be given timely personalized safety information or an educational intervention that may help prevent obesity and promote healthy eating and sleeping habits. Regardless of the assigned treatment group, parents will be given healthy parenting strategies. First-time parents will also have access to a study nurse to answer any questions and provide support during their study involvement.

The study may provide insight into an educational intervention that will increase responsive feeding, alternative soothing techniques, and parenting self-efficacy that may be linked to healthier patterns of weight gain during the first years of life.

142>Privacy & Confidentiality: Indicate measures to protect participant privacy and maintain confidentiality of the research data. Indicate whether information or a code will be linkable to participants in anyway. Who will have access to the identifiers, codes or the key? How will information be protected? Will participant identifiers or codes leave the institution?
Coordinators will pre-screen potential participants to limit unnecessary intrusion on non-eligible participants.Coordinators will only approach mothers meeting the initial (chart review) eligibility criteria for study participation. Data from this prescreen will not contain indentifying information. Potential participants will be approached in the privacy of the examination room for study explanation, consenting, and questions.
Research staff will have access to identifying information. A code list will be used for any information sent to University Park for analyses. No data will be sent outside Penn State University. See Protocol

Section VIII A, page 26 for more data security detail.

143>Qualifications & Research Experience of Principal Investigator: Briefly summary the PI's qualifications and relevant research experience.

Dr. Paul is an experienced pediatrician and was the PI for the pilot study to this grant (IRB# 22165EP).

144>Study Site Location(s): List all sites to be involved.

Penn State Hershey Medical Center

Penn State University (data analysis/entry)

145>References: List a few of the most relevant references. For studies with a research protocol, state "See protocol section X."

Please see page 28-33.

Document Upload

APPROVAL LETTER

Document 1001 Received 08/27/2010 12:23:20 - PI response to memo

CONSENT FORMS

Document 1001 Received 08/27/2010 12:14:06 - Parent Permission Form PPF and consent redline with IRB

DATA COLLECTION INSTRUMENTS

Document 1001 Received 08/02/2010 13:41:00 - Intervention materials
Document 1002 Received 08/02/2010 13:41:30 - Data collection forms
Document 1003 Received 08/02/2010 13:42:24 - Evaluation instruments
Document 1004 Received 08/05/2010 15:30:42 - Letter to physician's notifying of patient participatio

PROTOCOL DOCUMENTS

Document 1001 Received 07/30/2010 15:48:46 - Data Safety Monitoring Plans Data Safety Plan
Document 1002 Received 08/27/2010 12:13:22 - Protocol redline version of protocol per IRB requested

REVIEW - REQUEST INFO

Document 1001 Received 08/03/2010 03:29:08 PM - Returned for Additional Information
Document 1002 Received 08/06/2010 11:41:36 - PI Response Clarification Memo for Prereview changes
Document 1003 Received 08/27/2010 09:08:20 AM - IRB Edits 8-23-10
Document 1004 Received 08/27/2010 09:10:51 AM - Returned for Additional Information

SUBMISSION FORMS

Document 1001 Received 08/02/2010 13:44:03 - Signature Pages HMC signatures

Document 1002 Received 08/02/2010 13:44:30 - Signature Pages UP signatures
Document 1003 Received 08/06/2010 11:44:34 AM - Application Auto-generated by eSubmission Approval
Document 1004 Received 08/06/2010 11:44:38 AM - Abstract Auto-generated by eSubmission Approval