

6036

CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):

R. Iannotti

PROTOCOL TITLE:

Health Behaviors in School-age Children: 2009/2010

ABBREVIATED TITLE (30 characters or less): HBSC 2009/2010

PROPOSED START DATE: 3/1/2009

END DATE: 7/31/2011

TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 14,672

MULTI-SITE COLLABORATION:

Is this a multi-site collaboration? Yes (complete this section) No

Will subjects participate on the protocol at the NIH CC? Yes No

Will subjects participate on the protocol at other sites? Yes No

If yes, are the sites Domestic Foreign Both

Is NIH the coordinating site?

Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.

No. Coordinating Site is

REQUESTED ACCRUAL EXCLUSION (Check all that apply):

- None Asian
- Male Black or African American
- Female White
- Children <18 Hispanic or Latino
- American Indian/ Alaskan Native Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:

Minimum Age Permitted 0

Maximum Age Permitted 10

Pediatric None <2 Yr. 2-6 Yrs. 7-17 Yrs.

Protocol involves healthy volunteers? Yes No

Are Healthy Volunteers NIH Employees? Yes No

Does the protocol permit self referral? Yes No

Will the protocol involve adults unable to give informed consent? Yes No

PROTOCOL TYPE: (Check one):

- Screening
- Training
- Natural History - Disease Progression/ Physiology
- Natural History - Sample/Data Collection or Analysis (Recruiting Patients)
- Natural History - Sample/Data Collection or Analysis (Not Recruiting Patients)
- Pharmacokinetics/Dynamics
- Clinical Trial: Identify Phase (Check one)
 - Phase 0 Phase 1 Phase 1-2
 - Phase 2 Phase 3 Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? Yes No N/A

KEY WORDS (Words or phrase that describe the protocol.)

- 1. Adolescence
- 2. Obesity
- 3. Substance use
- 4. Prevalence
- 5. Social and Environmental Contexts

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
 None Medically indicated Research indicated*

*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review.

INVESTIGATIONAL NEW DRUG/DEVICE: None IND IDE

*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _

IND/IDE Name: _

Sponsor: _

Who is the manufacturer of the above entity: _

Does the protocol involve a Tech Transfer Agreement? Yes No

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?

Yes (Append a statement of disclosure)

No

Has the NIH IRP COI Guide been distributed to NIH Investigators?

Yes No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators?

Yes No N/A

CONFLICTS OF INTEREST REVIEW:

Date submitted to IC DEC: 10/07/08 Date cleared by IC DEC: _

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? Yes No

Name of Adjunct PI: _

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:

LEAD ASSOCIATE INVESTIGATOR - Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:

_

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:

_

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.

- 1. Bruce Simons-Morton NICHD/DESPR/PRB.
- 2. Tonia Nansel. NICHD/DESPR/PRB.
- 3. Denise Havnin. NICHD/DFSPR/PRB.
- 4. _
- 5. _

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE		Ronald J. Iannotti	Date		Send to Accountable Investigator
RECOMMENDATION		Ronald J. Iannotti	Date		Send to Branch Chief, or CC Dept. Head of Accountable Investigator
		Bruce Simons-Morton	Date		Send to Institute/Center Scientific Review Committee
APPROVALS		S. KALER	Date	10/7/08	Send to Clinical Director
		K. Calis	Date	10/24/08	Send to Chair, Institutional Review Board
		John Gallin	Date	11/19/08	Send to Office of Protocol Services, through IRB Protocol Coordinator
PATIENT SAFETY/ RESOURCE REVIEW		Ramya Rao	Date	11/21/08	Return to Office of Protocol Services, (10/1S231B)
COMPLETION					PROTOCOL NO. 09 CH-N023

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CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):
 Ronald J. Iannotti, PhD, NICHD/DESPR/PRB, 6100 7B05, 301-435-6951

PROTOCOL TITLE:
Health Behaviors in School-age Children: 2009/2010

ABBREVIATED TITLE (30 characters or less): **HBSC 2009/2010**

PROPOSED START DATE: **3/1/2009** END DATE: **7/31/2011** TOTAL SUBJECTS TO BE ACCRUE: **14,572**

MULTI-SITE COLLABORATION:
 None Foreign site(s) only*
 Domestic site(s) only* Foreign & domestic sites*
 *Include in the protocol the full name and address of each site and identify whether each holds a FWA or MPA. For more information, contact the Office of Human Subjects Research (301-402-3444).

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
 None Asian
 Male Black or African American
 Female White
 Children Hispanic or Latino
 American Indian/ Alaskan Native Native Hawaiian or Pacific Islander
 *Attach detailed statement describing the rationale for any requested exclusion(s).

SUBJECT ACCRUAL CHARACTERISTICS:
 Minimum Age Permitted 10 Yr
 Maximum Age Permitted 12 Yr
 Pediatric None <1 Yr. 1-3 Yrs. 4-17 Yrs. 18-20 Yrs
 Healthy Volunteers Yes No
 Are Healthy Volunteers NIH Employees? Yes No
 Subject Remuneration Yes No

NOTE: Each Protocol must include a discussion of the rationale for subject selection including gender and ethnicity of the population at risk. Recruitment plans and procedures must also be described.

PROTOCOL TYPE: (Check one):
 Screening
 Training
 Natural History
 Natural History - Specimen Procurement Only
 Clinical Trial: Identify Phase (Definitions on Reverse) (Check one)
 Phase I Phase II Phase III Phase IV

IS TISSUE BEING COLLECTED FOR RESEARCH PURPOSES? Yes No
 PATIENT SELF REFERRAL ALLOWED? Yes No
 LIST ON WEB Yes No

KEY WORDS (Enter 5 words, not contained in the protocol title, particularly salient in describing the protocol):
 1. Adolescence
 2. Obesity
 3. Substance use
 4. Prevalence
 5. Social and Environmental Contexts

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.):
 None
 Medically indicated
 Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).

INVESTIGATIONAL NEW DRUG/DEVICE: None IND IDE
 FDA No. _____
 Name: _____
 Sponsor: _____

List all commercial or other entities providing investigational drug/device: (Explanation/examples on reverse side)

Do any investigators have equity, consultative, or other financial relationship with a non-NIH source related to this protocol which might be considered a conflict of interest?
 No Yes (Append a statement of disclosure)

MEICAI ADVISORY INVESTIGATOR (if necessary):
 (Name) (Institute/Branch) (Telephone)

RESEARCH CONTACT:
 (Name) (Institute/Branch) (Address, Telephone, Fax)

ASSOCIATE INVESTIGATOR(S) (Name, Institute/Branch, Telephone) Initial:
 1. Bruce Simons-Morton, NICHD/DESPR/PRB 496-5674 *BSM*
 2. Tonja Nansel, NICHD/DESPR/PRB, 301-435-6950 *TN*
 3. Denise Haynie, NICHD/DESPR/PRB, 301-435-6933 *DH*
 4. _____
 5. _____
 6. _____
 7. _____
 8. _____
 9. _____

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE	<u>Ronald J. Iannotti</u> Principal Investigator	Ronald J. Iannotti	Date	<u>08/28/2008</u>	Send to Accountable Investigator
RECOMMENDATION	<u>Ronald J. Iannotti</u> Accountable Investigator	<u>RONALD J. IANOTTI</u> Print/Type Name	Date	<u>8/28/08</u>	Send to Branch Chief, or CC Dept. Head of PI
APPROVALS	<u>Bruce Simons-Morton</u> Branch Chief or CC Dept. Head of P.I.	<u>SIMONS-MORTON</u> Print/Type Name	Date	<u>8/28/2008</u>	Send to Institute/Center Scientific Review Committee
	<u>Owen M. Rennert</u> For Institute/Center Scientific Review Comm.	<u>Owen M. Rennert</u> Print/Type Name	Date	<u>10/1/08</u>	Send to Clinical Director
	<u>S. KALER</u> Clinical Director	<u>S. KALER</u> Print/Type Name	Date	<u>10/2/08</u>	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Print/Type Name	Date	Protocol & Consent Approval Completed	Send to Office of Protocol Services, through IRB Protocol Coordinator
PATIENT SAFETY/ RESOURCE REVIEW	Director, Clinical Center	Print/Type Name	Date		Return to Office of Protocol Services, (10/1S231B)
COMPLETION	Protocol Specialist	Date			

Clinical Research Protocol Initial Review Application
 NIH-1195 (6-04)

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The following data elements are required by the National Library of Medicine for posting on [clinicaltrials.gov](http://www.clinicaltrials.gov) and meets the registration requirements set forth by the International Committee of Medical Journal Editors (ICMJE) for publishing. <http://www.clinicaltrials.gov/>

CONDITIONS: Select up to 5 primary diseases or conditions being studied, using NLM Medical Subject Heading (MeSH) controlled vocabulary. The conditions are used to index studies. <http://www.nlm.nih.gov/mesh/MBrowser.htm>

- | | | |
|--------------------|------------------|-------|
| 1. Minors | 4. Violence | _____ |
| 2. Obesity | 5. Mental Health | _____ |
| 3. Substance abuse | | |

STUDY TYPE: Nature of the investigation. Select Interventional or Observational, in addition to the most appropriate term describing the protocol for each of the corresponding categories.

<input type="checkbox"/> Interventional Studies	<input checked="" type="checkbox"/> Observational Studies
Purpose: Reason for the protocol <input type="checkbox"/> Treatment <input type="checkbox"/> Prevention <input type="checkbox"/> Diagnosis <input type="checkbox"/> Educate/Train	Purpose: reason for the protocol <input type="checkbox"/> Natural History <input type="checkbox"/> Screening <input checked="" type="checkbox"/> Psychosocial
Study Design: participant selection <input type="checkbox"/> Randomized Trial <input type="checkbox"/> Non-randomized Trial	Duration of Sampling: protocol sample in <input type="checkbox"/> Longitudinal <input checked="" type="checkbox"/> Cross-sectional
Masking: knowledge of intervention <input type="checkbox"/> Open <input type="checkbox"/> Single Blind <input type="checkbox"/> Double Blind	Selection Method: sample selection <input type="checkbox"/> Targeted Population <input checked="" type="checkbox"/> Random Sample <input type="checkbox"/> Case Control
Control: nature of the interventional control <input type="checkbox"/> Placebo <input type="checkbox"/> Active <input type="checkbox"/> Uncontrolled <input type="checkbox"/> Historical <input type="checkbox"/> Dose Comparison	Timing: data collection period <input checked="" type="checkbox"/> Retrospective <input type="checkbox"/> Prospective <input type="checkbox"/> Both
Assignment: intervention groups <input type="checkbox"/> Single Group <input type="checkbox"/> Parallel <input type="checkbox"/> Cross-over <input type="checkbox"/> Factorial <input type="checkbox"/> Expanded Access	
Endpoint: primary outcome that the protocol is designed to evaluate <input type="checkbox"/> Safety <input type="checkbox"/> Efficacy <input type="checkbox"/> Safety/Efficacy <input type="checkbox"/> Bio-equivalence <input type="checkbox"/> Bio-availability <input type="checkbox"/> Pharmacokinetics <input type="checkbox"/> Pharmacodynamics <input type="checkbox"/> Pharmacokinetics/pharmacodynamics	

COMPLETE FOR INTERVENTIONAL STUDIES ONLY

INTERVENTIONS: Provide up to 10 primary interventions identifying a category for each. Category selections are: Drug, Gene Transfer, Vaccine, Behavior, Device, and Procedure.

Category	Intervention	Category	Intervention
<u>Ex. Drug</u>	<u>AZT</u>	<u>Ex. Behavior</u>	<u>Hypnosis</u>
1. _____	_____	6. _____	_____
2. _____	_____	7. _____	_____
3. _____	_____	8. _____	_____
4. _____	_____	9. _____	_____
5. _____	_____	10. _____	_____

OUTCOME MEASURE(S)/ENDPOINT(S): Examples – changes in cardiac output, changes in cognitive function, changes in drug or antibody.

Primary: main outcome representing a primary study question(s). (limit 250 char) _____

Secondary: outcome(s) of interest to a study, but not representing the primary study question(s). (limit 250 char) _____