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
☐ Male
☐ Female
☐ Children <18
☐ American Indian/ Alaskan Native
☐ Asian
☐ Black or African American
☐ White
☐ Hispanic or Latino
☐ 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 Haynie. NICHD/DESPR/PRB.
4. ☐ _
5. ☐ _

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

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

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 ACCRUED: 14,372

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 17 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)

MEDICAL 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 TRN
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	Principal Investigator	Ronald J. Iannotti (Print/Type Name)	Date 08/28/2008	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	RONALD J. IANNOTTI (Print/Type Name)	Date 8/28/08	Send to Branch Chief, or CC Dept. Head of PI
	Branch Chief or CC Dept. Head of P.I.	Simons-Morton (Print/Type Name)	Date 8/28/2008	Send to Institute/Center Scientific Review Committee
APPROVALS	For Institute/Center Scientific Review Comm.	Owen M. Rennert (Print/Type Name)	Date 10/1/08	Send to Clinical Director
	Clinical Director	S. KALER (Print/Type Name)	Date 10/2/08	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	PROTOCOL NO.	

The following data elements are required by the National Library of Medicine for posting on clintrials.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.html

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

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.

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