

**New Jersey Department of Health
Office of Commissioner
INSTITUTIONAL REVIEW BOARD**

APPLICATION TO CONTINUE HUMAN SUBJECTS RESEARCH

Project ID Number	Project Title		
Principal Investigator		Affiliation	
Address		City, State, Zip Code	
Telephone Number	Fax Number	Email Address	

I certify that the information provided below is accurate and complete.

Signature	Date
-----------	------

SECTION I – PROJECT STATUS (Check all that apply)

- Not Started** (Anticipated Start Date:)
- Active: Analysis of Secondary Data Only** (Project Does Not Include Interactions or Interventions)
- Active: Interactions or Interventions Are Ongoing**
 - Research Subject Enrollment: Not Started (Anticipated Start Date:) Ongoing Completed
 - Research Subject Interaction(s): Ongoing Follow-up Only Completed
 - Type(s): Interview: In Person Telephone
 - Questionnaire: In Person Telephone Mail
 - Survey: In Person Telephone Mail
 - Record Review: Patient Charts Other:
 - Research Subject Intervention(s): None Ongoing Follow-up Only Completed
 - Type(s): Obtaining Biologic Sample: Blood Sputum Cheek Cells Saliva
 - Genetic Testing HIV Testing Physical Measurements Behavior Modification
 - Other
- Active: Conducting Data Analysis Only** (All Interactions or Interventions Have Been Completed)
- Closed:** Date Closed: Explanation:
- Transferred to UMDNJ/Cancer Institute of NJ Institutional Review Board:** Date Transferred:

SECTION II – USE OF DEPARTMENT DATA

- | | | |
|---|--|---|
| <input type="checkbox"/> Cancer Registry | <input type="checkbox"/> TB Registry | <input type="checkbox"/> Special Child Health Services Registry |
| <input type="checkbox"/> Birth Certificates | <input type="checkbox"/> WIC | <input type="checkbox"/> Communicable Disease Registry |
| <input type="checkbox"/> Death Certificates | <input type="checkbox"/> HIV/AIDS Registry | <input type="checkbox"/> Child Immunization Registry |
| <input type="checkbox"/> Hospital Discharge | <input type="checkbox"/> Lead Poisoning | <input type="checkbox"/> Other: |

**APPLICATION TO CONTINUE HUMAN SUBJECTS RESEARCH
(Continued)**

SECTION III – PROJECT DESCRIPTION AND SUMMARY OF RESULTS TO DATE (Maximum: 300 words)

Empty space for project description and summary of results to date.

SECTION IV – CONSENT PROCESS AND DOCUMENTATION

	<u>Obtained</u>	<u>Waived</u>	<u>Not Applicable</u>
Consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation of Consent.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Assent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation of Assent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Parental Permission	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation of Parental Permission.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Legally Authorized Representative (e.g., surrogate/proxy, guardian) Permission ..	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation of Legally Authorized Representative Permission	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION V – RESEARCH SUBJECT DEMOGRAPHICS

ADULT DEMOGRAPHICS **Collected** **Not Collected**

	White-Non-Hispanic	White-Hispanic	Black	Black-Hispanic	Asian/Pacific Islander	American Indian	Alaskan Native	Other	Unknown	TOTAL	Age-Range
Male											
Female											
TOTAL											

CHILDREN DEMOGRAPHICS **Collected** **Not Collected**

	White-Non-Hispanic	White-Hispanic	Black	Black-Hispanic	Asian/Pacific Islander	American Indian	Alaskan Native	Other	Unknown	TOTAL	Age-Range
Male											
Female											
TOTAL											

**APPLICATION TO CONTINUE HUMAN SUBJECTS RESEARCH
(Continued)**

SECTION VI – RESEARCH SUBJECTS				
Total Number	PRIMARY SITE		ALL OTHER SITES ²	
	Since Last Approval ¹	Overall	Since Last Approval	Overall
Individuals initially screened for eligibility				
Individuals who were eligible based on initial screening				
Individuals who were ineligible based on initial screening				
Eligible individuals who were contacted				
Eligible individuals who were not contacted:				
- because they could not be located.				
- because they did not respond.				
- because we were advised not to contact them.				
- because they no longer met the inclusion criteria.				
- other:				
Individuals who were contacted and eligible based on a secondary screening				
Individuals who were contacted and ineligible based on a secondary screening				
Individuals who were eligible based on secondary screening that consented				
Individuals who were eligible based on secondary screening that did not consent				
Interactions that have been completed ³				
Interactions that have been completed ³				
Interactions that have been completed ³				
Interventions that have been completed ⁴				
Interventions that have been completed ⁴				
Interventions that have been completed ⁴				
Medical records that have been obtained				
Biological or genetic samples that have been obtained				
Biological or genetic samples that have been obtained and are usable				
Biological or genetic samples that have been analyzed				
Research subjects who actively withdrew from participating ⁵				
Research subjects whose participation was terminated by the investigator ⁵				
Research subjects who were "lost" prior to completing all research activities				
¹ "Since last approval" covers the time period from the project's initial approval (or most recent continuing review approval) to the present. ² For multi-site projects, "All Other Sites" refers to the sum of research activities conducted at all locations <u>outside</u> of New Jersey. If all research activities are conducted within New Jersey but at different locations, provide the required information for each individual location where research activities are conducted (attach additional sheets as needed). ³ Insert all research interactions that have been conducted (e.g., interviews, surveys, questionnaires, follow-up questionnaires). ⁴ Insert all research interventions that have been performed (e.g., obtaining biologic sample, genetic testing, HIV testing, physical measurements, behavior modification). ⁵ Attach an explanation for each research subject who withdrew from participating or whose participation was terminated by the investigator. <u>DO NOT</u> provide any information that could identify the research subject; refer to research subjects by their ID Number.				
SECTION VII – NEW FINDINGS				
Has new literature been published, or has anything occurred since last renewal, that may affect the project's risk/benefit ratio, goals or hypotheses? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, explain:				
Has new literature been published, or has anything occurred since last renewal, that may affect the research subjects' willingness to continue participating? <input type="checkbox"/> No <input type="checkbox"/> Yes If Yes, explain:				

**APPLICATION TO CONTINUE HUMAN SUBJECTS RESEARCH
(Continued)**

SECTION VIII / PART A – INCIDENTS AT PRIMARY SITE SINCE LAST APPROVAL

Type of Incident	Total Number	Date(s) Occurred	Date(s) Submitted to IRB
<input type="checkbox"/> Adverse Event *			
<input type="checkbox"/> Complaints *			
<input type="checkbox"/> Unexpected Problem *			

**Submit an Adverse Event Report Form if you have not already done so.*

SECTION VIII / PART B – INCIDENTS AT OTHER SITES SINCE LAST APPROVAL
 Not a Multi-Site Project

Name ¹		Affiliation	
Address		City, State, Zip Code	
Telephone Number	Fax Number	Email Address	

Type of Incident ²	Total Number	Site Where Incident Occurred
<input type="checkbox"/> Adverse Event ³		
<input type="checkbox"/> Complaints ³		
<input type="checkbox"/> Unexpected Problem ³		

¹ If project is being conducted nationally, provide contact information for the National Principal Investigator.

² This information must be obtained from the National Principal Investigator.

³ Attach a complete description of each incident (e.g., what happened, when it happened, site involved, corrective actions taken and name and contact information for the local investigator involved in the incident). DO NOT provide any information that could identify the research subject; refer to research subjects by their ID Number.

SECTION IX – MODIFICATIONS

No Modifications since Initial or Last Continuing Review Approval (whichever is more recent)

Modification Type	Number of Modifications Since Last Approval	Date(s) Approved
<input type="checkbox"/> Design		
<input type="checkbox"/> Procedure		
<input type="checkbox"/> Methodology		
<input type="checkbox"/> Instrument		
<input type="checkbox"/> Study Site		
<input type="checkbox"/> Recruitment Materials		
<input type="checkbox"/> Personnel		
<input type="checkbox"/> Funding		
<input type="checkbox"/> Consent		
<input type="checkbox"/> Research Subjects		
<input type="checkbox"/> Other		

**APPLICATION TO CONTINUE HUMAN SUBJECTS RESEARCH
(Continued)**

SECTION XI – PROJECT DOCUMENTS (Provide One Copy)		
Document Type	N/A	Document Title and Version Number / Date
<input type="checkbox"/> Protocol	<input type="checkbox"/>	
<input type="checkbox"/> Instruments (surveys, questionnaires, etc.)	<input type="checkbox"/>	
<input type="checkbox"/> Data Collection Forms	<input type="checkbox"/>	
<input type="checkbox"/> Informed Consent Document(s)	<input type="checkbox"/>	
<input type="checkbox"/> Assent Document(s)	<input type="checkbox"/>	
<input type="checkbox"/> Parental Permission Document(s)	<input type="checkbox"/>	
<input type="checkbox"/> Surrogate/Proxy Permission Document(s)	<input type="checkbox"/>	
<input type="checkbox"/> Letter(s)	<input type="checkbox"/>	
<input type="checkbox"/> Script(s)	<input type="checkbox"/>	
<input type="checkbox"/> Advertising (brochures, etc.)	<input type="checkbox"/>	
<input type="checkbox"/> Certificate of Confidentiality	<input type="checkbox"/>	Expiration Date:
<input type="checkbox"/> Other	<input type="checkbox"/>	

SECTION XII – PROJECT PERSONNEL			
Name	I¹	E¹	Role²
1.	<input type="checkbox"/>	<input type="checkbox"/>	
2.	<input type="checkbox"/>	<input type="checkbox"/>	
3.	<input type="checkbox"/>	<input type="checkbox"/>	
4.	<input type="checkbox"/>	<input type="checkbox"/>	
5.	<input type="checkbox"/>	<input type="checkbox"/>	
6.	<input type="checkbox"/>	<input type="checkbox"/>	
7.	<input type="checkbox"/>	<input type="checkbox"/>	
8.	<input type="checkbox"/>	<input type="checkbox"/>	
9.	<input type="checkbox"/>	<input type="checkbox"/>	
10.	<input type="checkbox"/>	<input type="checkbox"/>	

¹ [I] Intramural: NJDOH Employee or [E] Extramural: Non-NJDOH Employee

² Provide the specific activities/tasks the individual will perform.