New Jersey Department of Health
Office of Human Protections
Institutional Review Board
P.O. Box 360, Trenton, NJ 08625-0360
http://www.nj.gov/health/hrep
(866) 780-4121

APPLICATION FOR INITIAL REVIEW

NJDOHIRB#:	**Project Title:**
Office Use only	

Principal Investigator:				Title/Position:	Department/Division/Program
(Last)	*(First)*	*(MI)*	*(Sfx)*		

Institution or Affiliation:				Sponsoring Institution (if different)			
Addr1:				Addr1			
Addr2:				Addr2:			
City:		ST:	Zip:	City:		ST:	Zip:
Tel:	*Fax:*	*Email*		*Tel:*	*Fax:*	*Email*	

Action Requested:		
Exemption:	☐ Not Research	☐ Not Human Subjects Research
IRB Review:	☐ Expedited IRB Review	☐ Full Board IRB Review
Vital Statistics:	☐ Death Certificates	Defer to External IRB? ☐ Yes ☐ No ☐ Birth Certificates

Checklist of Contents of Review Application *[Requests for Exemption need only include items marked with (*) as needed]*

- ☐ IRB Application (this document)*
- ☐ Research Protocol*
- ☐ Institutional Approval of Research - Intra-Mural Research (Form OC-37); Extra-Mural Research (Form OC-39)*

  Research Liaison: _____ Signature: _____
- ☐ Research Personnel documents - (OC-41; OC-45 [Fed];Research Ethics Training Certification; CV/Resumes
- ☐ Informed Consent Documents (consent/assent forms, scripts, etc.)
- ☐ Instruments (survey, questionnaire, abstraction form, rating scale, etc.)
- ☐ Documentation of any action by other IRBs or similar review boards, if any.*
- ☐ Documentation of data handling procedures, security measures and disposition.*
- ☐ Grant Award, Contract or other Documentation of funding or support.
- ☐ Contracts, approvals, etc., from third party service providers, additional performance sites, etc., if any.
- ☐ Additional documentation for research under a New Drug Application (NDA) or Investigational Drug Application (IND) or involving a food, drug, device, biologic or cosmetic approved or regulated by the FDA.

Proposed start date:	Proposed end date:

I, _____ (PI or Co-PI) hereby certify that the information contained in this IRB application is accurate and complete and reflects the responsibilities agreed to by myself and each person listed herein.

Signature:_____ Date:

I, _____ (PI or Co-PI) hereby certify that the information contained in this IRB application is accurate and complete and reflects the responsibilities agreed to by myself and each person listed herein.

Signature:_____ Date:

INSTITUTIONAL REVIEW BOARD
APPLICATION FOR INITIAL REVIEW, CONTINUED

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PROJECT OVERVIEW

Please indicate all research activities proposed to be conducted at all research sites:

- ☐ Children as research subjects
- ☐ Medical record/chart review
- ☐ Biologic samples
- ☐ HIV/AIDS screening or testing
- ☐ Genetic testing
- ☐ In-person interview
- ☐ Phone interview
- ☐ In-person questionnaire/survey
- ☐ Phone questionnaire/survey
- ☐ Mail questionnaire/survey
- ☐ Manipulation of social or psychological variables
- ☐ Psychological tests or inventories
- ☐ Photography, video, or audio recording of subjects
- ☐ Probing for personal or sensitive information
- ☐ Physical or psychological stress
- ☐ Investigators will recruit their own patients or clients
- ☐ Prisoners or incarcerated individuals as research subjects
- ☐ Other (describe):

Please indicate the extent of researcher involvement with subjects
Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

- ☐ Interaction with research subjects
- ☐ Intervention with research subjects
- ☐ NO interaction with research subjects
- ☐ NO intervention with research subjects

Please indicate Proposed Informed Consent/Assent Procedures

- ☐ Informed consent/assent will be obtained
  - ☐ Documented OR ☐ Not Documented
- ☐ Informed consent/assent will be waived

Please identify NJDOH Data Sources Requested:

- ☐ Cancer data
- ☐ Birth records
- ☐ Death records
- ☐ HIV/AIDS data
- ☐ Hospital discharge data
- ☐ Birth defects data
- ☐ TB data
- ☐ WIC data
- ☐ Medicaid records
- ☐ Other NJDOH Registry or data (specify):

Identify funding source for the proposed research:

Has this research been submitted to another IRB?

- ☐ **No**
- ☐ **Yes-Approved.** Date and type of approval: _____ (attach a copy of most recent IRB approval letter)
- ☐ **Yes-Pending.** Date of submission and expected date of decision:
- ☐ **Yes-Disapproved or terminated.** Provide full details and documentation (use additional sheets if necessary.)

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RESEARCH AIMS, DESIGN AND METHODS
(Excerpts from Research Protocol and other documents may inserted in response to the following questions)

Lay Summary
(Provide a brief summary of the project in non-scientific terms, describing the aims, methods and expected benefits - maximum 500 words).

Technical Abstract
Describe the research in scientific terms, identifying goals, aims, hypotheses, research design, methods, and procedures.

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RESEARCH AIMS, DESIGN AND METHODS (Continued)

DOH Data or Resources Requested

Identify and describe the DOH data set or source requested including selection criteria, sampling technique(s), years requested, variables, fields, etc, or other DOH resources requested.

Data Use and Security

Describe procedures for the secure handling and maintenance of personal health information (PHI) and other confidential data, records and/or biological samples. Specifically state where such information will be maintained, how it will be secured, who will have access, how long it will be maintained, documentation of chain of custody, and procedures for delinking of identifiers and final disposition.

Risk Assessment

State the overall risk/benefit ratio of the research project, potential risks for harm or detriment to research subjects, potential benefits to research subjects, benefits to other individuals, groups and/or society, advancement in knowledge or learning expected, and measures designed to mitigate minimize risk and maximize benefit.

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(Last)	*(First)*	*(MI)*	*(Sfx)*		

RESEARCH SUBJECTS

Please indicate below if the inclusion criteria specifically **target** subjects in any of the following categories:

☐ Male	☐ Physically Disabled	☐ Caucasian/non-Hispanic
☐ Female	☐ Developmentally Disabled	☐ Caucasian/Hispanic
☐ Minors	☐ Psychologically Disabled	☐ Black/non-Hispanic
☐ Pregnant Females	☐ Emotionally Impaired/Traumatized	☐ Black/non-Hispanic
☐ Fetuses	☐ Stigmatized Health Condition ( )	☐ Asian/Pacific Islander
☐ Neonates	☐ Chronic Condition ( )	☐ American Indian
☐ Wards	☐ Poor/Uninsured/Underinsured	☐ Other racial classification ( )
☐ Students (Sponsor)	☐ Seriously or Terminally Ill	☐ Non-English Speaking Subjects
☐ Elderly	☐ Prisoners	☐ Individuals with Limited Literacy/Illiteracy
☐ Foster Children	☐ Institutionalized (non-criminal)	☐ Other (please specify): ( )
☐ Employees (Sponsor)	☐ Homeless	

Please indicate below if the inclusion criteria specifically exclude subjects in any of the following categories:

☐ Male	☐ Physically Disabled	☐ Caucasian/non-Hispanic
☐ Female	☐ Developmentally Disabled	☐ Caucasian/Hispanic
☐ Minors	☐ Psychologically Disabled	☐ Black/non-Hispanic
☐ Pregnant Females	☐ Emotionally Impaired/Traumatized	☐ Black/non-Hispanic
☐ Fetuses	☐ Stigmatized Health Condition ( )	☐ Asian/Pacific Islander
☐ Neonates	☐ Chronic Condition ( )	☐ American Indian
☐ Wards	☐ Poor/Uninsured/Underinsured	☐ Other racial classification: ( )
☐ Students (Sponsor)	☐ Seriously or Terminally Ill	☐ Non-English Speaking Subjects
☐ Elderly	☐ Prisoners	☐ Individuals with Limited Literacy/Illiteracy
☐ Foster Children	☐ Institutionalized (non-criminal)	☐ Other (please specify): ( )
☐ Employees (Sponsor)	☐ Homeless	

Estimated number of subjects to be enrolled or included:	Age range of subjects to be enrolled or included:
( )	**( )**

Inclusion Criteria

*Describe the inclusion/exclusion criteria, relevance to the purpose of research, randomization procedures; **justification for any inclusion or exclusion of vulnerable populations, minorities or sub-groups** as potential research subjects, available languages of consent forms; procedures for identifying, approaching and screening potential subjects, and ensuring respect for and protection of their rights and welfare.*

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RESEARCH SUBJECTS (Continued)

Informed Consent/Assent Procedures

Describe or reference procedures for obtaining and documenting informed consent/assent, recruitment venues, scripts, procedures, and criteria for determining comprehension and ability to consent/assent, and where and how the consent forms will be secured.

Continuing Consents

If the project is a multi-year or tracking study, describe procedures for maintaining and documenting continuing consents.

Requests for Waiver and/or Alteration of Informed Consent Requirements

(If requesting a waiver of informed consent, all four conditions below must be satisfied. Please supply a justification for each item.)

- ☐ The research involves no more than minimal risk to the subjects;
- ☐ The waiver or alteration will not adversely affect the rights or welfare of the subjects;
- ☐ The research could not practicably be carried out without the waiver or alteration; and
- ☐ If appropriate, research subjects will be provided with pertinent information after their participation.

Details:

Requests for Waiver of Informed Consent Documentation:

- ☐ The only record linking the subject to the research would be the consent document and the principal risk is the harm resulting from a breach of confidentiality, **OR**
- ☐ The research involves no more than minimal risk to the subjects and involves no procedures for which written consent is normally required outside of the research context

Details:

Participant Expenses (if any)

Indicate type and amount of any research-related costs and expenses costs to be borne by subjects and procedures for reimbursement.

Compensation

Indicate type and amount of any compensation to be paid or offered subjects for enrolling or participating in research:

INSTITUTIONAL REVIEW BOARD
APPLICATION FOR INITIAL REVIEW, CONTINUED

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PERFORMANCE SITE(S)

If any human subjects research activities will take place at locations other than the Principal Investigator's home institution or organization (such as at clinics, schools, hospitals, nursing homes, healthcare facilities, etc.) please provide the information below requested for each site.

(Make additional copies as needed for each site)

Institution:				**Contact person responsible for on-site research activities:**			
				(last)	*(first)*	*(mi)*	*(sfx)*
Addr1:				Tel:			
Addr2:				Fax:			
City:	State:	Zip:		Email:			

Estimated and maximum number of subjects to be enrolled at this site:

Describe and provide copies of documentation approving and authorizing research activities at this site:

Describe and provide copies of policies and procedures governing research activities at this site:

Describe procedures for ensuring compliance with the protocol and IRB requirements for activities at this location:

Identify and describe any features of the research setting that may expose the subjects to undue or inappropriate pressure to participate or enroll, and procedures and measures to be implemented to mitigate any potential for such undue influence

Describe any recruitment or research services to be provided by a third party organization and procedures to ensure compliance with the project protocol and IRB requirements: (Attach a copy of the relevant agreement or contract.)

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INVESTIGATORS AND RESEARCH PERSONNEL
(Clerical and administrative personnel without access to human subjects information need not be listed.)
(Insert additional pages as needed)

Investigator or Researcher:				**Title/Position:**	**Role on Project**
(last)	*(first)*	*(MI)*	*(sfx)*		
(Institution or Affiliation)				*(Department/Division/Program)*	
Addr1:				Tel:	
Addr2:				Fax:	
City:	State:	Zip:		Email:	

☐ Research Ethics Training completed within last 3 years. (Certificate attached)
☐ Agreement for the Ethical Conduct of Human Subjects Research - DOH Form OC-41/OC-45 (Federal) attached
☐ CV/Resume/BioSketch attached

Does the proposed research present any potential for an actual or apparent personal, professional, financial, or other conflict of interest? See OHRP Final Guidance on Conflict of Interest (http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf)
☐ No ☐ Yes (if Yes, provide details)

Have you ever been the subject of a professional inquiry, audit, or disciplinary action by any board, authority, state or federal agency in connection with your practice or research conduct?
☐ No ☐ Yes (if Yes, provide details)

Investigator or Researcher:				**Title/Position:**	**Role on Project**
(last)	*(first)*	*(MI)*	*(sfx)*		
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(Last)	*(First)*	*(MI)*	*(Sfx)*		

INVESTIGATORS AND RESEARCH PERSONNEL (Continued)

Investigator or Researcher:				**Title/Position:**	**Role on Project**
(last)	*(first)*	*(MI)*	*(sfx)*		
(Institution or Affiliation)				*(Department/Division/Program)*	
Addr1:				Tel:	
Addr2:				Fax:	
City:	State:	Zip:		Email:	

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Investigator or Researcher:				**Title/Position:**	**Role on Project**
(last)	*(first)*	*(MI)*	*(sfx)*		
(Institution or Affiliation)				*(Department/Division/Program)*	
Addr1:				Tel:	
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☐ No ☐ Yes (if Yes, provide details)