ATTACHMENT 3

PROTOCOL #_____
IRB Office Use Only

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF THE INSPECTOR GENERAL
INSTITUTIONAL REVIEW BOARD
FORM 1 (DHMH 2124)

PROTOCOL STATUS: ____NEW APPLICATION
____ DISSERTATION/____STUDENT RESEARCH
____ RE-APPLICATION (new application resulting from approval lapse)

TITLE OF STUDY: _____
_____
_____

PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

CO-PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

STUDENT INVESTIGATOR: _____ _____
(Academic Advisor should be PI) **SIGNATURE** **PRINT OR TYPE NAME**

MAILING ADDRESS: _____
(Include organizational affiliation, e.g. University or DHMH Program) _____
_____
_____

PHONE # _____FAX #_____E-MAIL_____

FUNDING SOURCE: ____FEDERAL _____
(Provide the name of the agency on the line next to the source) ____STATE_____
____OTHER_____

IF NO FUNDING SOURCE EXPLAIN _____
HOW THIS STUDY WILL BE _____
SUPPORTED FINANCIALLY _____
_____

PROVIDE THE NAME(S) OF THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE'S (DHMH) ADMINISTRATION(S) OR PROGRAM(S) PROVIDING DATA OR ALLOWING RECRUITMENT OF SUBJECTS FOR THIS STUDY:

1._____ 3._____

2._____ 4._____

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HAVE YOU CONTACTED THIS/THESE DHMH PROGRAM(S) REGARDING YOUR STUDY?
____YES ____NO

HAVE THEY APPROVED YOUR STUDY?___YES ___NO IF YES, HAVE THEM SIGN BELOW

NAME OF DHMH PROGRAM ADMINISTRATOR(S) AUTHORIZING INVOLVMENT IN THIS STUDY:
(Obtain signature(s) prior to submission to the IRB for review. *Protocols will not be reviewed without signature(s))

1._____ SIGNATURE_____
(PRINT) (DATE)

2._____ SIGNATURE_____
(PRINT) (DATE)

3._____ SIGNATURE_____
(PRINT) (DATE)

4._____ SIGNATURE_____
(PRINT) (DATE)

DOES THIS STUDY INVOLVE INTERACTION OR INTERVENTION WITH HUMAN SUBJECTS? ___YES ____NO

DOES THIS STUDY REQUIRE THE USE OF DHMH DATA/DATA SET? ____YES ____NO

DOES THIS STUDY INVOLVE? (Provide details in protocol for any "yes" response)

MINORS (UNDER 18 YEARS OF AGE)	___YES	___NO	MENTALLY ILL INDIVIDUALS	___YES	___NO
ELDERLY	___YES	___NO	FETAL TISSUE OR ABORTUS	___YES	___NO
PRISONERS	___YES	___NO	RADIOACTIVE MATERIAL	___YES	___NO
DEVELOPMENTALLY DISABLED INDIVIDUALS	___YES	___NO	INFECTIOUS AGENTS	___YES	___NO
			PREGNANT WOMEN	___YES	___NO

DOES THIS STUDY POTENTIALLY INVOLVE? (Provide details in protocol for any "yes" response)

PHYSICAL RISK TO SUBJECT	___YES	___NO	SOCIAL RISK	___YES	___NO
PSYCHOLOGICAL RISK TO SUBJECT	___YES	___NO	PHYSICAL OR MENTAL DISCOMFORT TO SUBJECT	___YES	___NO
RISK OF DISCLOSURE OF INFORMATON POSSIBLY DAMAGING TO SUBJECT OR OTHERS	___YES	___NO	INVASION OF PRIVACY	___YES	___NO

WILL INFORMED CONSENT BE OBTAINED? ___YES ___NO

ARE YOU REQUESTING A WAIVER OF INFORMED CONSENT? ___YES ___NO

IF YES, PROVIDE THE BASIS (ACCORDING TO 45 CFR 46.116) FOR YOUR REQUEST

_____
_____
_____
_____

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ARE YOU REQUESTING A WAIVER OF DOCUMENTATION OF INFORMED CONSENT (MUST MEET THE REQUIREMENT OF 45 CFR 46.117)? ____YES ____NO

ARE YOU REQUESTING A HIPAA WAIVER? ____YES ____NO

ARE YOU REQUESTING A PARTIAL HIPAA WAIVER? ____YES ____NO

HAS THIS STUDY BEEN REVIEWED BY ANOTHER IRB? ____YES ____NO

IF YES, PLEASE PROVIDE COPIES OF THE IRB APPROVALS

IF NO, EXPLAIN WHY_____
_____
_____

HAVE YOU RECEIVED ETHICAL/INVESTIGATOR RESEARCH TRAINING? ___YES ___NO

IF YES, WHEN WAS YOUR LAST TRAINING _____

IF NO, EXPLAIN WHY_____

IN ORDER FOR THE IRB TO APPROVE A PROTOCOL, THE FOLLOWING CONDITIONS MUST BE MET. PLEASE ENURE THAT YOUR PROTOCOL ADDRESSES EACH OF THESE ITEMS.

- RISKS ARE MINIMIZED THROUGH SOUND RESEARCH DESIGN, NO UNNECESSARY EXPOSURE TO RISK, AND WHENEVER APPROPRIATE, USE DIAGNOSITIC OR TREATMENT PROCEDURES FAMILIAR TO SUBJECT
- RISKS ARE REASONABLY RELATIVE TO ANTICIPATED BENEFTS
- SELECTION OF SUBJECTS IS EQUITABLE
- INFORMED CONSENT IS OBTAINED (copy provided to participant)
- INFORMED CONSENT WILL BE DOCUMENTED (IF APPLICABLE)
- PROVISIONS TO PROTECT THE PRIVACY OF SUBJECTS AND CONFIDENTIALITY OF DATA ARE ADEQUATE
- ADEQUATE PROVISIONS FOR MONITORING DATA COLLECTION TO ENSURE SAFETY OF SUBJECTS
- APPROPRIATE SAFEGUARDS ARE INCLUDED FOR VULNERABLE SUBJECTS
- *ALL APPROPRIATE SIGNATURES