STATE OF MARYLAND

# DHMH

Maryland Department of Health and Mental Hygiene

## INSTITUTIONAL REVIEW BOARD

201 W. Preston Street • Baltimore Maryland 21201

Patricia M. Alt, Ph.D., Chairperson

The Maryland Department of Health and Mental Hygiene (DHMH) Institutional Review Board (IRB) is responsible for reviewing and approving all proposed research projects involving human subjects, covered by 45 Code of Federal Regulations (CFR) Part 46, occurring in any DHMH facility. Projects involving data collection in which there is identifiable linkage to the subject or involving physical, social, psychological, or privacy risks to the subject require IRB review. The IRB is charged with the responsibility of determining if a project qualifies as being exempt from IRB review requirements.

**Research involving any DHMH unit or facility must be signed off by the Director or Administrator of the unit or facility prior to submitting to the IRB office. The Director's signature should appear on the line designated for the "DHMH program administrator" on IRB form 1 (DHMH 2124, Attachment 3)** Any research involving Mental Hygiene Administration (MHA) programs or facilities must be signed off by Brian Hepburn, M.D, Medical Director for MHA. Five DHMH facilities have individual research approval committees. Any proposal that involves research in one of these facilities must be approved by that facility's review board. See Attachment 1.

Any proposal that involves another collaborating institution or agency must be approved by all the collaborating institutions or agencies. Any research submitted by a student must be approved by the student's educational institution.

The IRB meets the third Thursday of each month. The deadline for proposals to be included for each meeting's agenda is 10 calendar days prior to the meeting date. Proposals will be reviewed in the order received. No more than five proposals can be considered at any one meeting. See Attachment 2 for schedule. Any proposal in excess of five or received after the cut- off date will be placed on the next month's agenda.

Proposals should include the following:

1. A complete form DHMH 2124 (Attachment 3);

2. An abstract summary (For outline, see Attachment 4);

3. Narrative including:

   a. Pertinent background information; and
   b. A detailed protocol

4. Copies of all instruments to be used, e.g., record abstraction form, interview form, questionnaire, etc.

5. Copies of all informed consents or disclosure statement when applicable (See Attachment 5 for elements of informed consent).

6. Assurance that an evaluation of ability to consent will be utilized if the proposed research involves cognitively impaired or mentally ill subjects. (See Attachment 6 for example).

7. Copies of IRB approvals from other involved institutions.

**SEND AN ORIGINAL PROPOSAL AND TEN COPIES OF THE PROPOSAL TO:**
(If your complete packet is more than 100 pages the copies should be in the form of cds)

Institutional Review Board
201 W. Preston Street
Baltimore MD 21201

When your proposal has been scheduled for review, you will be informed of the date and approximate time of the review. Although it is not required that the principal investigator attend the IRB meeting, his or her doing so can facilitate the process should the Board members have questions regarding the protocol to be followed to carry out the proposal.

Should you have any questions as you prepare your proposal for submission, please feel free to contact Ms. Gay Hutchen, IRB Administrator. She can be reached at (410) 767-8448.

****PROTOCOL SUBMITTED WITHOUT THE "DHMH PROGRAM ADMINISTRATOR'S" SIGNATURE <u>WILL NOT</u> BE REVIEWED UNTIL THE SIGNATURE IS OBTAINED****

MENTAL HEALTH INSTITUTIONS RESEARCH APPROVAL COMMITTEE

Walter P. Carter Center
Dr. DeVang Gandhi
(410) 328-5793

Springfield Hospital Center
Dr. Jonathan D. Book
(410) 970-7000

Spring Grove Hospital Center
Dr. Charles Richardson
(410) 402-6871

Clifton T. Perkins
Dr. Robert Wisner-Carlson
(410) 724-3075

**ATTACHMENT 2**

IRB MEETING SCHEDULE FOR JANUARY, 2011- DECEMBER 2011

**All proposals must be in this office 10 days prior to the third Thursday of each month. Each proposal submission must have an original and 10 copies.**

| **Proposal Due Dates** | **IRB Meeting Dates** |
|---|---|
| January 10, 2011 | January 20, 2011 |
| February 7, 2011 | February 17, 2011 |
| March 7, 2011 | March 17, 2011 |
| April 11, 2011 | April 21, 2011 |
| May 9, 2011 | May 19, 2011 |
| June 6, 2011 | June 16, 2011 |
| July 11, 2011 | July 21, 2011 |
| August 8, 2011 | August 18, 2011 |
| September 5, 2011 | September 15, 2011 |
| October 10, 2011 | October 20, 2011 |
| November 7, 2011 | November 17, 2011 |
| December 5, 2011 | December 15, 2011 |

**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._____

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 NEXT ITEM

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)

2._____ SIGNATURE_____
(PRINT)

3._____ SIGNATURE_____
(PRINT)

4._____ SIGNATURE_____
(PRINT)

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 |

ARE YOU REQUESTING A WAIVER OF INFORMED CONSENT? ___YES ___NO

IF YES, PROVIDE THE BASIS (ACCORDING TO 45 CFR 46.116) FOR YOUR REQUEST (45 CFR PART 46)
**(click to link)**

_____

_____

_____

_____

IF NO, WILL INFORMED CONSENT BE OBTAINED _____ORALLY OR _____ WRITTEN?
(check one)

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

## GUIDELINES FOR PREPARING THE ABSRACT SUMMARY

An abstract summarizing each of the following items must be included with each application before it will be processed for Board review. The Abstract Summary must be single spaced and limited to no more than three pages. If an item is not applicable, please note accordingly.

**AN ABSTRACT SUMMARY MUST ALSO BE PREPARED FOR RESEARCH SUBMITTED AS EXEMPT**

1. Briefly summarize the purpose of this study including the methods and procedures to be used.

2. Describe the source for the study population and what is required of the subjects. (when the population consists of special groups such as prisoners, children and the mentally disabled or other groups whose ability to give voluntary informed consent may be in question, it is necessary to provide the rationale for using this particular population.)

3. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, a fetus or an abortus.

   If identifying information is to be collected from records, indicate the type of data to be retained, the purpose for which the data will be used, how long it will be retained in identifiable form, and how the disposition of the data will be handled.

4. Describe and assess any potential risks - physical, psychological, social, legal or other and assess the likelihood and seriousness of such risks.

   a. Describe procedures for protecting against or minimizing potential risks and assess their likely effectiveness.

   b. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

5. Assess the potential benefits to be gained by the individual subjects as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.

6. Describe consent procedures to be followed, including how and where informed consent will be obtained. When there are potential risks to the subject, or the privacy of the individual is involved, the investigator is required to obtain a signed informed consent statement from the subject. For subjects who are not able to give informed consent, signed informed consent must be obtained from the parent or authorized legal guardian of the subject. These subjects should be provided with information clearly stating what is to be expected in order that they may assent to participation. Furnish an actual copy of the disclosure statement and/or the informed consent statement.

   a. If signed informed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.

   b. If information is to be withheld from a subject, justify this course of action.

7. Describe the method for safeguarding confidentiality and/or measures for protecting anonymity. (Inform the Board where the data will be kept and plans for disposition at the completion of the study.)

8. If the study will involve an interview, describe where and in what context the interview will take place. (The approximate length of time required for the interview should be stated in the consent form.)

9. If the final survey instrument is not submitted with the IRB Form I (Attachment 3), the following information should be included in the abstract summary:

   a. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy;

   b. Examples of the type of specific questions to be asked in the sensitive areas; and

   c. Indicate when the questionnaire will be presented to the Board for review.

## COMPONENTS OF INFORMED CONSENT

1. Invitation to participate in study.
2. Explanation of purpose of study.
3. Explanation of study procedures (as they relate to subject).
4. Assurance that subject has the right to refuse to participate, and that refusal will not place subject in jeopardy.
5. Assurance that subject has the right to withdraw from participation and that withdrawal will not place the subject in jeopardy.
6. Description of potential risks, discomforts, inconveniences, or threats to dignity involved in study.
7. Description of potential benefits of participation in study.
8. Description of compensation to be expected, whether monetary or otherwise (if applicable).
9. Disclosure of available alternatives (if applicable).
10. Assurance of confidentiality or anonymity.
11. Statement regarding contact person and an offer to answer questions about the protocol.
12. Statement regarding IRB contact person to answer questions about rights as a research participant.
13. Concluding statement noting that subject indicates by signature (or, in certain studies, return of completed questionnaire) that he/she has read the information and has decided to participate.
14. Individual agency may require statement that agency will not provide compensation in case of injury resulting from participation.
15. Language should be clear, unambiguous and appropriate for subject's age, educational level, etc.
16. Special restrictions apply to minors or individuals whose ability to give informed consent may be compromised. In these cases, if participant consents to participation, an "ability to consent" evaluation must be included in the consent procedures. If proxy, surrogate, parental or guardian consent is obtain, prospective participants should assent to participation whenever possible.

**ATTACHMENT 6**

## EVALUATION TO SIGN CONSENT FORM

PATIENT DATA:

Name:_____

Birthdate:_____

Procedures:
Make a subjective judgement regarding item 1 below. Ask the patient questions 2 through 5. The Evaluator may select the language to use in asking the questions in order to help the patient understand them.

Items:

1. Is the patient alert and able to communicate with the examiner?

   ___Yes ___No

2. Ask the patient to name at least two (2) potential risks incurred as a result of participating in the study.

   _____

   _____

3. Ask the patient to name at least two things that will be expected of (him/her) in terms of patient cooperation during the study.

   _____

   _____

4. Ask the patient to explain what (he/she) would do if (he/she) decides that they no longer wish to participate in the study.

   _____

   _____

   _____

5. Ask the patient to explain what (he/she) would do if (he/she) is experiencing distress or discomfort.

   _____

   _____

   _____

Signatures:

I hereby certify that the above patient is alert, able to communicate and able to give acceptable answers to items 2, 3, 4, and 5 above.

_____ _____

Evaluator Date Witness Date

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