



MARYLAND Department of Health

Institutional Review Board · 201 W. Preston St. · Baltimore, MD 21201
Carol Johnston, APRN, PMH, BC, Chair

The Maryland Department of Health (MDH) 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 MDH 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 MDH unit or facility must be signed off by the Director or Administrator (research involving local health departments requires “Health Officer” signature) of the unit or facility prior to submitting to the IRB office. The Director's signature should appear on the line designated for the "MDH program administrator" on IRB Form 1 (MDH 2124, Attachment 3). Any research involving Behavioral Health Administration (BHA) programs or facilities must be signed off by Dr. Barbara Bazron, Executive Director for BHA. Spring Grove Hospital Center and Clifton T. Perkins Hospital Center both have an independent research approval committee. Any proposal that involves research at 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. Student research 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 new proposals can be considered at any one meeting. See Attachment 2 for schedule. All proposals 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: (DO NOT INCLUDE COPIES OF ATTACHMENTS 1, 2, 4, OR 5, WITH YOUR SUBMISSION)

1. A completed form MDH 2124 (Attachment 3), must have signature of MDH Program Administrator (;
2. An abstract summary (For guideline, 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.
7. Copies of IRB approvals from other involved institutions.
8. If your proposed research involve prisoners complete “Attachment 6” and include with your submission.

SEND AN ORIGINAL PROPOSAL AND TEN COPIES OF THE PROPOSAL TO:

**If a single copy of a proposal is less than 50 pages (double-sided), copies are not needed*

***If a single copy of a proposal is 100 pages or more (double-sided), copies required on individual flash drives*

**** If a single copy of a proposal is between 50 and 99 pages (double sided), regular copies*

Institutional Review Board
201 W. Preston Street
Baltimore MD 21201

If your proposal is scheduled for a convened meeting 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 or gay.hutchen@maryland.gov.

****PROTOCOLS SUBMITTED WITHOUT THE “MDH PROGRAM ADMINISTRATOR’S” SIGNATURE WILL NOT BE REVIEWED UNTIL THE SIGNATURE IS OBTAINED****

BEHAVIORAL HEALTH INSTITUTIONS WITH RESEARCH APPROVAL COMMITTEE

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

Clifton T. Perkins Hospital Center
Monica Chawla
(410) 724-3140

IRB MEETING SCHEDULE FOR JANUARY 2019 - DECEMBER 2019

Proposal Due Dates

January 7, 2019

February 11, 2019

March 11, 2019

April 8, 2019

May 6, 2019

June 10, 2019

July 8, 2019

August 5, 2019

September 9, 2019

October 7, 2019

November 11, 2019

December 9, 2019

IRB Meeting Dates

January 17, 2019

February 21, 2019

March 21, 2019

April 18, 2019

May 16, 2019

June 20, 2019

July 18, 2019

August 15, 2019

September 19, 2019

October 17, 2019

November 21, 2019

December 19, 2019

PROTOCOL # _____ IRB Office Use Only

MARYLAND DEPARTMENT OF HEALTH
 OFFICE OF THE INSPECTOR GENERAL
 INSTITUTIONAL REVIEW BOARD
FORM 1 (MDH 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 MDH Program): [_Click or tap here to enter text.](#)

PHONE # _____

FAX # _____

E-MAIL: _____

FUNDING SOURCE: FEDERAL _____
 (Provide the name of the agency STATE _____
 on the line next to the source) OTHER _____

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

PROVIDE THE NAME(S) OF THE MARYLAND DEPARTMENT OF HEALTH 'S (MDH) ADMINISTRATION(S) OR PROGRAM(S) PROVIDING DATA OR ALLOWING RECRUITMENT OF SUBJECTS FOR THIS STUDY:

1. _____

3. _____

2. _____

4. _____

HAVE YOU CONTACTED THIS/THESE MDH PROGRAM(S) REGARDING YOUR PROTOCOL?

YES NO

HAVE THEY APPROVED YOUR PROTOCOL? YES NO (IF YES, SIGNATURE REQUIRED BELOW)

NAME OF MDH 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. _____ (PRINT)	SIGNATURE _____ (DATE)
2. _____ (PRINT)	SIGNATURE _____ (DATE)
3. _____ (PRINT)	SIGNATURE _____ (DATE)
4. _____ (PRINT)	SIGNATURE _____ (DATE)

DOES THIS STUDY INVOLVE INTERACTION OR INTERVENTION WITH HUMAN SUBJECTS? YES NO

DOES THIS STUDY REQUIRE THE USE OF MDH DATA/DATA SET? YES NO

DOES THIS STUDY INVOLVE:

- THE STORAGE, MAINTENANCE AND SECONDARY RESEARCH USE OF IDENTIFIABLE PRIVATE INFORMATION? YES NO
- IDENTIFIABLE BIOSPECIMENS COLLECTED FOR EITHER RESEARCH STUDIES OTHER THAN THIS PROPOSED RESEARCH OR NON-RESEARCH PURPOSES ? YES NO

DOES THIS STUDY INVOLVE? (Check all that apply and provide details in protocol)

MINORS (UNDER 18 YEARS OF AGE)	<input type="checkbox"/>	INTELLECTUAL DISABILITY	<input type="checkbox"/>
ELDERLY (≥65)	<input type="checkbox"/>	FETAL TISSUE OR ABORTUS	<input type="checkbox"/>
PRISONERS	<input type="checkbox"/>	RADIOACTIVE MATERIAL	<input type="checkbox"/>
DEVELOPMENTALLY DISABLED	<input type="checkbox"/>	INFECTIOUS AGENTS	<input type="checkbox"/>
INDIVIDUALS	<input type="checkbox"/>	PREGNANT WOMEN	<input type="checkbox"/>
INDIVIDUALS WITH LEGAL GUARDIAN	<input type="checkbox"/>		

DOES THIS STUDY POTENTIALLY INVOLVE? (Check all that apply and provide details in protocol)

PHYSICAL RISK TO SUBJECT	<input type="checkbox"/>	SOCIAL RISK	<input type="checkbox"/>
PSYCHOLOGICAL RISK TO SUBJECT	<input type="checkbox"/>	PHYSICAL OR MENTAL DISCOMFORT	
RISK OF DISCLOSURE OF INFORMATION POSSIBLY DAMAGING TO SUBJECT OR OTHERS	<input type="checkbox"/>	TO SUBJECT	<input type="checkbox"/>
		INVASION OF PRIVACY	<input type="checkbox"/>

WILL INFORMED CONSENT BE OBTAINED? YES NO
 IF YES, HAVE YOU MET REQUIREMENTS OF 45 CFR 46.116 YES NO
 (see attachment 5)

ARE YOU REQUESTING A WAIVER OF INFORMED CONSENT? YES NO

IF YES, PROVIDE THE BASIS (IN ACCORDANCE WITH [45 CFR 46.116](#)) FOR YOUR REQUEST: _____

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 IF YES, FULL PARTIAL

HAS THIS STUDY BEEN REVIEWED BY ANOTHER IRB? YES NO

IF YES, PLEASE PROVIDE COPY OF IRB APPROVAL

IF NO, EXPLAIN WHY _____

ATTACH LIST OF ALL RESEARCH STAFF (INCLUDING PI) INDICATING DATE OF LAST ETHICAL/RESEARCH TRAINING (Training should be within the last three years)

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

- RISKS ARE MINIMIZED THROUGH SOUND RESEARCH DESIGN, NO UNNECESSARY EXPOSURE TO RISK, AND WHENEVER APPROPRIATE, USE DIAGNOSTIC OR TREATMENT PROCEDURES FAMILIAR TO SUBJECT
- RISKS ARE REASONABLY RELATIVE TO ANTICIPATED BENEFITS
- 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 ABSTRACT SUMMARY

Attach abstract summary addressing each of the following items. Items that are not applicable to your protocol indicate with N/A

1. Summarize the purpose of this study including the research questions and hypothesis to be evaluated.
2. Describe methods and procedures to be used, include recruitment details and duration of participation (if applicable).
3. Describe the inclusion/exclusion criteria for the study population (if applicable).
4. Describe source and collection details for research that involves the collection of identifiable private information or identifiable biospecimens, indicate if the research is limited to the **storage or maintenance** of identifiable private information or identifiable biospecimens for secondary research use (if applicable).
5. Describe and assess any potential risks (physical, psychological, social, legal or other and assess the likelihood and seriousness of such risk. Provide procedures for protecting against or minimizing potential risk and assess their likely effectiveness.
6. Assess the potential benefit to be gained by the individual subjects as well as the benefit which may accrue to society in general resulting from the planned protocol. Indicate how the benefits outweigh the risks.
7. Describe **consent procedures to be followed if appropriate, including how and where informed consent will be obtained**. If documented informed consent will not be obtained, a disclosure statement may be furnished to participants (if applicable assent must be obtained for participants under the age of 18). Protocols which involve the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens may obtain broad consent. Provide actual copy of consent form or disclosure statement.
8. Describe the methods for safeguarding confidentiality and/or measures for protecting anonymity (**provide clear and precise information on where data will be stored, who has access and disposition plans for confidential data**).
9. If the study involves an interview, describe where and in what context the interview will take place. (The approximate length of time required for the interview should also be stated in the consent form.)
10. Include final study instrument(s) with IRB application. (If final is not submitted, data collection cannot begin until instruments are review and approved by Board.)

COMPONENTS OF INFORMED CONSENT

The consent form must:

- **Be in a language understandable to the subject or the legally authorized representative;**
- **Be sufficient in details relating to the research and must be organized and presented in a way that does not merely list isolated facts;**
- **Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reason why one might or might not want to participate in the research; and**
- **Not contain any exculpatory language that through which subject or legal authorized representative is made to waive or appear to waive any of the subject's legal rights.**

1. Invitation to participate in study.
2. Clear and concise purpose of study
3. Explanation of study procedures organized and presented in a way that facilitates comprehension by perspective subjects to determine participation . Include expected duration of participation and if any procedures are experimental. Approximate number of subjects involved.
4. Assurance that subject has the right to refuse to participate, and that refusal will not place subject in jeopardy or loss of any benefits otherwise entitled.
5. Assurance that subject has the right to withdraw from participation and that withdrawal will not place the subject in jeopardy or loss of any benefits otherwise entitled.
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. resulting from participation.
15. 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 legally authorized representative or parental or guardian consent is obtained, prospective participants should assent to participation whenever possible.

16. Research that involves the collection of identifiable private information or identifiable biospecimens must include one of the following of statements:
- Statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and once removed could be used for future research or distributed to another investigator for future research studies without additional informed consent from the subject or legal authorized representative; or
 - Statement that even if the identifiers are removed from the subject's information or biospecimen, it will not be used for future research or distributed for future research studies.

Additional Elements of Informed Consent

One or more of the following elements of information shall be provided to subject or legal authorized representative when appropriate:

- Statement regarding possible unforeseeable risk from a particular treatment or procedures to subject (or embryo or fetus if subject is or may become pregnant);
- Circumstance which participation may be terminated by the investigator;
- Any cost to subject resulting from participation;
- Consequences of a subject's decision to withdraw from research and procedures for termination of participation;
- Information on significant new findings developed during the course of the research that may relate to subject's willingness to continue participation will be provided;
- Approximate number of participants;
- Statement regarding possible commercial profit from use of biospecimens and whether subject will or will not benefit from such profit;
- Statement indicating whether clinically relevant research results (including individual results) will be shared with subject and if so under what circumstances; and
- For research involving biospecimens, indicate whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with an intent to generate the genome or exome sequence of that specimen).

Maryland Department of Health Institutional Review Board Prisoner Research Checklist

Permitted research involving prisoners - please check from the list below the category that describes your research:

45 CFR 46.306(a)(2)

- (i) Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- (ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study present no more than minimal risk and no more than inconvenience to the subjects;
- (iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of this intent to approve such research; or
- (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consist with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics and publish notice, in the Federal Register of the intent to approve such research.

In accordance with 45 CFR 46.305, in addition to the research representing one of the categories listed above, the following conditions must be met for approval of research involving prisoners:

- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be

selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;

- The information is presented in language that is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.