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. James Yoe, Director of Applied Research and Evaluation. 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 new 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:

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.

***DURING THE CURRENT PANDEMIC, ALL PROPOSALS SHOULD BE SUBMITTED VIA EMAIL TO ONLY ONE OF THE FOLLOWING E-MAIL ADDRESSES:**

gay.hutchen@maryland.gov or fannie.hawkins@maryland.gov

If your protocol 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****

ATTACHMENT I

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

ATTACHMENT 2

IRB MEETING SCHEDULE FOR JANUARY 2021 - DECEMBER 2021

All proposals must be in the IRB's office 10 days prior to the third Thursday of each month.

Proposal Due Dates	IRB Meeting Dates
January 11, 2021	January 21, 2021
February 8, 2021	February 18, 2021
March 8, 2021	March 18, 2021
April 5, 2021	April 15, 2021
May 10, 2021	May 20, 2021
June 7, 2021	June 17, 2021
July 5, 2021	July 15, 2021
August 9, 2021	August 19, 2021
September 6, 2021	September 16, 2021
October 11, 2021	October 21, 2021
November 8, 2021	November 18, 2021
December 6, 2021	December 16, 2021

ATTACHMENT 3

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 on the line next to the source)
☐ STATE _____
☐ 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._____ 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 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)	☐	INTELLECTUAL DISABILITY	☐
ELDERLY (≥65)	☐	FETAL TISSUE OR ABORTUS	☐
PRISONERS	☐	RADIOACTIVE MATERIAL	☐
DEVELOPMENTALLY DISABLED INDIVIDUALS	☐	INFECTIOUS AGENTS	☐
		PREGNANT WOMEN	☐
INDIVIDUALS WITH LEGAL GUARDIAN	☐		

ATTACHMENT 3

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

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

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 TRAINING FOR THE PROTECTION OF RESEARCH PARTICIPANTS (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 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)

ATTACHMENT 3

- 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

ATTACHMENT 4

GUIDELINES FOR PREPARING THE ABSRACT 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.)

ATTACHMENT 5

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.**
- **Provide and "ability to consent for individuals or minors 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**.

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.

14. 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).