PROTOCOL#\_\_\_\_\_

IRB Office Use Only

MARYLAND DEPARTMENT OF HEALTH

**INSTITUTIONAL REVIEW BOARD**

**REQUEST FOR RESEARCH EXEMPTION**

Research is defined as a systematic investigation, including research development, test, and evaluation designed to develop or contribute to generalizable knowledge. **Complete this form only if your project meet this definition**.

Title of Protocol:

 Principal Investigator (PI) (include credentials):

 PI Signature: Date:

Phone:       Email:

Mailing Address (include organization affiliation, if applicable):

Co PI:

Student Investigator:        Dissertation - Yes [ ]  No [ ]

 **ATTACH LIST OF ALL RESEARCH STAFF (INCLUDING PI) INDICATING DATE OF LAST TRAINING FOR THE**

Research Funding Source:

Federal [ ]  State [ ]  Other [ ]  None [ ]

Name of Funding Source (if applicable):

 **PROTECTION OF HUMAN RESEARCH PARTICIPANTS** (Training should be within the last three years)

Approved by Another IRB [ ]  Yes (provide copy of approval) [ ]  No

MDH Administration Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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The IRB will ultimately determine if research qualifies for exemption, PIs are asked to select from the categories below that describes their research. If the Board determines that your protocol does not qualify for exemption, you will be required to complete a standard IRB application packet (MDH 2124 <https://health.maryland.gov/oig/irb/Pages/Forms.aspx#IRB_Forms>)

**Please note: Exemptions do not apply to research involving prisoners Except for research aimed at involving a broader subject population that only incidentally include prisoners. Children are allowed in categories 1, 4, 5, 6, 7 and 8; limitations and exclusion of children in categories 2 (with limitations) and 3 (no children).**

 \*IF YOUR RESEARCH DOES NOT FIT IN ONE OF THE CATEGORIES BELOW COMPLETE STANDARD APPLICATION \*

[ ]  1. Research in established or commonly acceptable educational setting, involving normal educational practices that are not likely to adversely impact students’ opportunity to learn or the assessment of educators who provide instruction. This includes most regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[ ]  2. Research that only involves educational tests (cognitive diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior (including visual or auditory recording) if at least **one** of the following criteria is met:

1. Information recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual); or
2. Disclosure of the information could not reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation; or
3. Information is recorded in a manner that individuals **can** be identified (directly or through identifiers) (IRB must conduct privacy and confidentiality review).

[ ]  3. Research involving benign behavioral interventions through verbal or written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agrees and **one** of the following is met:

1. Recorded information **cannot** readily identify the subject (directly or indirectly/linked); or
2. Any disclosure of responses outside of the research would not reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); or
3. Information is recorded **with identifiers** (IRB must conduct privacy and confidentiality review).

[ ]  4. Secondary research for which consent is not required: use of identifiable information or identifiable biospecimens that have been or will be collected for some other “primary” or “initial”, if **one** of the following criteria is met:

1. Biospecimens or information is publicly available; or
2. Information recorded so that the subject cannot be identified directly or indirectly (link), investigator does not contact or re-identify subject;
3. Collection and analysis of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes; or
4. Research information is collected by or on behalf of federal government using government generated or collected information obtained for non-research activities.

[ ]  5. Research and demonstration projects that are conducted or supported by a federal department or agency designed to study, evaluate or improve public benefit or service programs. (must meet entire exemption requirement at 45 CFR 46.104.(5) <https://gov.ecfr.io/cgi-bin/text-idx?mc=true&node=pt45.1.46&rgn=div5>

[ ]  6. Taste and food quality evaluation.

[ ]  7. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent was obtained. Broad consent should include tracking mechanisms and broad consent verification.

[ ]  8. Secondary research involving the use of identifiable private information or identifiable biospecimens for which broad consent was obtained. Broad consent should include tracking mechanisms and broad consent verification.

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**Attachment 1**

**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.

Explain how the results will be used.

1. Describe methods and procedures to be used, include recruitment details and duration of participation (if applicable).
2. Describe the inclusion/exclusion criteria for the study population (if applicable).
3. 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).
4. 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.
5. 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.
6. 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.
7. 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**).
8. 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.)
9. 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 2**

**General Guidance for Informed Consent (written or oral)**

* Provide information that a typical prospective participant or legal authorized representative would want to know to make an informed decision whether to participate and provide an opportunity to discuss study details
* Begin with a concise statement that presents the key information in an organized manner that will help prospective participant understand why they would or would not want to participate
* Do not use exculpatory language that may appear to waive any of the subject’s legal rights or release investigator from liability for negligence

**Components of Informed Consent**

* Invitation to participate in research study
* Number of prospective participants
* Explanation of the purpose of study
* Explanation of study procedures (as they relate to subject)
* Assurance that subject has the right to refuse to participate, and that refusal will not place subject in jeopardy
* Description of potential risk, discomforts, inconveniences or threats to dignity involved in study
* Description of potential benefits of participation in study
* Description of compensation to be expected, whether monetary or otherwise (if applicable)
* Disclosure of available alternatives (if applicable)
* Assurance of confidentiality or anonymity
* Statement regarding contact person to answer question about the protocol
* Statement that participation can be refused or stopped at any time with no penalty or loss of benefits
* Statement regarding IRB contact person to answer questions about rights as a research participant
* Statement indicating whether identifiable private information or identifiable biospecimens collected will be used for future research with or without identifiers removed (if applicable)
* Statement that biospecimens (even if identifiers are removed) may be used for commercial profit and indicate whether participant will share in the profit (if applicable)
* Explain under what conditions will clinically relevant research results will be shared with participants, if shared at all
* Explain whether biospecimen research will or might include whole genome sequencing
* Anticipated circumstances for which participants may be terminated
* Certificate of Confidentiality language (if applicable)