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**JHM IRB eForm E – Exempt Protocol**

* **Please use this form to describe a research protocol that may qualify for an exemption. Types of research that may meet the criteria for exempt review include: educational research, survey/interviews, benign behavioral interventions, and secondary research.**
* **PLEASE NOTE:** If the project is ONLY comprised of **secondary research** data analyses (retrospective or prospective medical record/biospecimen review, secondary analysis of approved study data), please do NOT use this form and instead use the eForm S for your research protocol template.
* **Please provide complete information for each item below. If an item is inapplicable to your research study, explain why.**
* **When submitting JHM IRB eForm E (new or revised), enter the date submitted, the name of the PI, and the eIRB application number in the header at the top of the form.**
1. **Purpose/Aims**
2. **Background** (briefly summarize literature including current practice or educational guidelines, current institutional practice or standard of care, and any other relevant information to justify the research)
3. **Population:**
	1. Sample (i.e., target population, age range, study site(s)):
	2. Does the study include vulnerable populations (i.e., prisoners**, adults lacking capacity to consent, pregnant women, Non-viable neonates/neonates of uncertain viability, Non-English speakers,** ch**ildren who are in foster care or wards of the state**)?
	3. Inclusion criteria:
	4. Exclusion criteria:
	5. Setting: Describe study sites. If a single institutional project, please specify one unit or multiple units as study sites.
4. **Methods**
	1. Study design: Please select one or more categories and provide additional detail as needed:

[ ]  Research conducted in an educational setting

[ ]  Survey/interviews (**If the target sample includes children, this study may require expedited review**.)

[ ]  Educational tests [e.g. cognitive diagnostic, aptitude, achievement] (**If the target sample includes children, this study may require expedited review**.)

[ ]  Public observations (**If the target sample includes children, this study may require expedited review**.):

[ ]  Benign behavioral intervention (**A** benign behavioral intervention must be brief in duration (although data collection may take longer). The intervention must be harmless, painless, and not physically invasive. If the study will include a benign behavioral intervention, please provide **justification/rationale for the intervention to be considered benign/non-significant risk.** (**If the target sample includes children, this study will require expedited review and the eForm A should be used**.):

[ ]  Research and demonstration project conducted or supported by Federal department or agency for Public benefit or service

* 1. Timeline (from implementation to completion of project)
	2. Analyses
1. **Research Procedures**
2. Describe sequence and timing of all study activities. Be sure to distinguish research procedures from those that are part of standard clinical care or curriculum.
3. Include how participants are recruited and by whom. If this is a study with students or employees as participants, describe whether the recruiter is in an evaluator position. **(**If directly recruiting participants, for example, email or web post recruitment, please upload the recruitment documents within *Section 13,*

*Q 7 of the application).*

1. Discuss data collection procedures including measures/assessment tools. [Does the data collection involve audio or audiovisual recording? If recording, please include permission to record language in interview guide or consent script].
2. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies.  Please note:  Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016.  If this situation applies, Section 36, question 4 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.
3. **Data Management/Security**
4. Describe your plan for recording and storing research data.
5. Discuss if the participant data will be de-identified and, if not, how the data will be secured. Is data recorded or links maintained such that participants can be identified, directly or through identifier links? If so, please describe how data will be secured.
6. Identify who has access to the data.
7. **Risks and Potential Benefits**
8. Address the risk of loss of confidentiality and/or any other risks.
9. Discuss the steps you are taking to minimize risks
10. Discuss any potential benefits of the study.
11. **Payment and Remuneration (**Detail compensation for participants)
12. **Survey and Interview Study Forms (**Upload your survey(s) and/or interview guides in Section 20, Q 2 of the application)