HML IRB
RESEARCH & ETHICS

| IRB Review of Research Ethics Protocols for the Protection of Human Subjects<br>EXEMPTION FROM ON-GOING REVIEW | |
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| **Project Title:** | ***Building Usage, Improvement, and Learning with Data in Healthy Marriage and Responsible Fatherhood Programs (BUILD HMRF)*** |
| **HML IRB Review ID#:** | 837MATH21x |
| **Principal Investigator:**<br>Degree(s), address, email | Grace Roemer, M.S.,<br>Project Director<br>Mathematica<br>600 Alexander Park, Princeton, NJ 08540<br>groemer@mathematica-mpr.com |
| **Other Key Personnel:**<br>Title, degree(s): | Mathew Stange, deputy project director, Ph.D. |
| **Primary study site(s):** | Administrative data only for human subjects participating in federal grant programs from 4/1/2021-9/30/2025 |
| **Participation of Human Subjects**<br>From – to dates | NA |
| **Funding Source:** | Administration for Children and Families (ACF) |
| **PO Number:**<br>or other billing info required by your organization | Purchase Order number 310369 |

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| **Date of IRB Request** | 28 January 2021 |
| **Date(s) IRB Comments Returned** | None |
| **Date Final Documents Received** | None |
| **DATE OF IRB APPROVAL** | 29 January 2021 |

| **Exemptions from IRB Review**<br>*Check all that apply* | **Check (X) here** |
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| 1. Research conducted in educational settings that involves educational practices not likely to adversely affect students' opportunity to learn required content, or educators who provide instruction. This includes research on instructional strategies, on the effectiveness or comparison of instructional techniques, curricula, or classroom management methods. | |
| 2. Research involving educational tests, survey procedures, interview procedures, or observations of public behavior, if at least one of the following criteria is met: | |
| a. Data are obtained in a way that identity of the subjects cannot be ascertained, directly or through identifiers linked to the subjects; or | |
| b. Disclosure of subjects' responses will not place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, education, or reputation; or | |
| c. Data are obtained in a way that identity of the subjects can be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination that confidentiality is maintained. | |

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| 3. Research involving benign behavioral interventions in conjunction with data collection from consenting adult subjects, if at least one of the following criteria is met:<br><br>a. Data are recorded in a way that identity of the subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or<br><br>b. Disclosure of subjects' responses will not place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, education, or reputation; or<br>c. Data are obtained in a way that identity of the subjects can be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination that confidentiality is maintained.<br>Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the investigator has no reason to think subjects will find the interventions offensive or embarrassing. Examples of benign behavioral interventions include having subjects play an online game, solve puzzles under various noise conditions, or having them decide how to allocate cash between themselves and someone else.<br>If the research involves deceiving subjects regarding the nature or purpose of the research, this exemption is not applicable unless subjects authorize the deception through a pre-agreement to participate in research where they are informed that they will be misled regarding the nature or purpose of the research. | |
| 4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:<br><br>a. The identifiable private information or biospecimens are publicly available;<br><br>b. Data are recorded in a way that identity of subjects cannot readily be ascertained, directly or through identifiers linked to subjects, investigators do not contact subjects, and investigators will not re-identify subjects; or | X |

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| c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is a part of public health or medical surveillance.<br><br>d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with storage and privacy regulations of that department or agency. | |
| 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, and are designed to study, evaluate, improve, or examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits or services under those programs. These projects include, but are not limited to, internal studies by Federal employees, as well as studies under contracts or consulting arrangements, cooperative agreements, or grants.<br><br>Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.<br>Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or as the department or agency head may determine, a list of their research and demonstration projects conducted or supported under this provision. The project must be published on this list prior to commencing the research involving human subjects. | |
| 6. Taste and food quality evaluation and consumer acceptance studies:<br><br>a. If wholesome foods without additives are consumed, or | |

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| b. If a food is consumed that contains an ingredient at or below the level found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA, or approved by the EPA or the Food Safety and Inspection Service of the USDA. | |
| 7. Storage or maintenance for secondary research where broad consent is required:<br>Storage or maintenance of identifiable private information or biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations that risks to subjects have been minimized, are reasonable in relation to benefits, that subject selection is equitable, that informed consent is sought, and that monitoring and storage of data is secure. | X |
| 8. Secondary research where broad consent is required. Research involving the use of identifiable private information or biospecimens for secondary research use, if the following criteria are met:<br><br>a. Consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens is obtained.<br><br>b. Documentation of informed consent or waiver of documentation of consent is obtained.<br><br>c. An IRB conducts a limited review and makes the determination that the research is within the scope of the consent; and the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. | X |

**→ PROCESS: HML IRB will conduct a research ethics review of submitted materials and determination of exemption status, and make comments below.**
**We will then return this template for responses from researchers.**
**Please reply in the right-side column, and we will issue a letter of approval or ask for further clarification.**

| | Ethics Review Board Criteria of Interest | IRB OK | Reviewer Comments or Requests for More Information |
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| **Section 1** | ***Research Risk*: Do submitted materials address potential risks to subjects?** | | **Researchers: Please respond to IRB's red comments in another color** |
| 1.1 | Minimal Risk Only: The probability and magnitude of anticipated harm or discomfort is not greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests | NA | Please keep us informed of any subject protection protocol or research design changes that need to take place in adaptation to the COVID-19 pandemic |
| 1.2 | Research may be approved as exempt if it is not greater than minimal risk and fits one of the exempt review categories as defined by federal regulation 45 CFR 46, above. | X | |
| 1.3 | Exemption category or categories from above = | X | |
| 1.4 | Comments, amendments, additions, or revisions | X | |
| **Section 2** | ***Research Design:* Do submitted materials describe the proposed research?** | | |
| 2.1 | Background and rationale | X | |
| 2.2 | Description of methodology | X | |
| 2.3 | Are all documents final versions? | NA | Please respond. |
| 2.4 | Does study involve an intervention or treatment group? | X | |
| 2.5 | Does study involve a comparison or control group? | X | |

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| 2.6 | Type of data collection:<br>a. survey questionnaire……..……..<br>b. subject interview……<br>c. key informant interview (KII)……..……<br>d. focus group discussion (FGD)……..…..<br>e. document review……..……<br>f. on-site observation……..……..<br>g. case study……<br>h. physical measurements ……<br>i. biological specimen ……..……..…<br>j. other..……..…..……<br>Secondary data analysis | | |
| 2. | Number of Data Collections:<br>a. one-time (no follow-up)…….<br>b. two or more (follow-up) ……..……... | X | |
| 2.8 | Sample size: Total *n* or approximate *n* = | NR | |
| 2.9 | Are any subjects children (<18 years old)?<br>13 – 17 yo | X | |
| 2.10 | Comments, amendments, additions, or revisions | X | |
| **Section 3** | ***Recruitment:*** **Do submitted materials describe subjects and the recruitment process?** | | |
| 3.1 | Subject identification:<br>a. subjects' names are recorded …….<br>b. no names are recorded ……..….<br>c. other personally identifiable information (PII) is recorded ……..……<br>d. no PII is recorded ……..…<br>e. subjects are given a unique identifier.....X | X | |
| 3.2 | If name or any other PII is recorded, are procedures | X | |

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| | included for how this info will be kept separate from responses? | | |
| 3.3 | Are sampling strategy & subject recruitment procedures adequately described? | X | |
| 3.4 | Do recruitment procedures show any indication of coercion, intimidation, compulsion, pressure, or force? | X | |
| 3.5 | If subjects are children, do materials adequately describe ages and why these ages are appropriate? | X | |
| 3.6 | If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) appropriate based upon age? | X | |
| 3.7 | If subjects are children or other vulnerable groups, is recruitment done in a manner sensitive to potential vulnerabilities or weaknesses (real or perceived) subjects may have? | X | |
| 3.8 | If subjects are paid, compensated, or provided a gift for participation, is the incentive described and justified as being non-coercive? | X | |
| 3.9 | If future contact with subjects is planned, does it provide for subject safety and data security through the research period and beyond? | X | |
| 3.10 | Comments, amendments, additions, or revisions | X | |
| **Section 4** | ***Informed Consent:* IC is a negotiation whereby subjects are informed about the study and their rights, and they agree to participate voluntarily. IC must be sought from each subject or the subject's authorized representative confirming this process.** | | |
| 4.1 | Type of Informed Consent:<br>a. written & signed ……..……<br>b. written not signed ……..……X | X | |

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| | c. written & signed by authorized representative……<br>d. verbal & signed or recorded……..……...<br>e. verbal & signed by authorized representative…..…<br>f. verbal not signed or recorded……..……<br>g. active……..<br>h. passive……<br>i. other …….. | | |
| 4.2 | Are procedures for obtaining IC adequately described? | X | |
| 4.3 | Are written IC documents, using clear and simple wording, included? | X | |
| 4.4 | Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language? | X | |
| 4.5 | Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw without consequences? | X | |
| 4.6 | Does IC include a description of any risks or benefits to subjects? | X | |
| 4.7 | Does IC include a statement describing how confidentiality (or anonymity) of subjects and data will be maintained, and any limitations to confidentiality? | X | |
| 4.8 | Does IC include the expected duration of the subject's participation (hours/minutes)? | X | |
| 4.9 | Does IC provide identity and contact info of investigators? | X | |
| 4.10 | Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group? | NA | |

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| 4.11 | Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type? | X | |
| 4.12 | Where data collection differs by method (e.g.: survey, FGD, interview), do IC materials cover each method? | X | |
| 4.13 | For child subjects, is there provision for obtaining consent from parent, guardian, caregiver, or responsible person? | X | |
| 4.14 | For child subjects, is their role in the study described adequately for them to provide written or verbal assent? | X | |
| 4.15 | If IC is written, is a copy left with subjects or there is explanation for not doing so? | X | |
| 4.16 | Comments, amendments, additions, or revisions | X | |
| **Section 5** | ***Subject Protections:*** **Do submitted materials clearly identify protection against risk?** | | |
| 5.1 | Do materials describe the use of information collected? | X | |
| 5.2 | Are subjects given a clear indication of who will have access to their responses and in what form? | X | |
| 5.3 | If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protections? | X | |
| 5.4 | If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive? | X | |
| 5.5 | Have personnel collecting data from subjects had ethical training specific to the target group? | X | |
| 5.6 | Are personnel collecting data aware of ethical issues that may arise and their mitigation strategies? | X | |
| 5.7 | Comments, amendments, additions, or revisions | X | |

| Section 6 | ***Subject Risks:*** **Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?** | | |
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| 6.1 | Do study objectives show that risk is reasonable in relationship to expected gains? | X | |
| 6.2 | Does study deliver potential benefits to subjects through provision of information or services? | X | |
| 6.3 | In event of physical, psychological, social, or legal risk, do protocols describe and outline clear strategies to mitigate against these risks? | X | |
| 6.4 | If a subject discloses or is suspected to be at risk outside of the study, are procedures in place to address or report risk? | X | |
| 6.5 | Comments, amendments, additions, or revisions | X | |
| **Section 7** | ***Data Protection:*** **Do data collection and storage protocols adequately ensure subject & data safety?** | | |
| 7.1 | Are data collection tools appropriate and constructed to assure subject privacy, confidentiality, or anonymity? | X | |
| 7.2 | Do data collection procedures and environment ensure subject safety and data security? | X | |
| 7.3 | Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type? | X | |
| 7.4 | Is chain of custody of data, from collection, transfer, analysis, de-identification, storage, to destruction, clearly described? | X | |
| 7.5 | Will a data set be created for storage, dissemination and/or use either publicly or restricted at the completion of this project? If yes, please describe the data set, | X | |

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| | where it will be stored, with whom it will be shared, and its intended use. | | |
| 7.6 | Is future contact with subjects, if any, planned in a way that ensures data security? | X | |
| 7.7 | Comments, amendments, additions, or revisions | X | |