BATTELLE

HUMAN SUBJECTS RESEARCH EVALUATION REPORT — IRB HSRE-230, Rev 1.0

Battelle Institutional Review Board

Federalwide Assurance FWA00004696 / Registration No. 00000284

Battelle Principal Investigator/Project Manager/Director: **Robyn Sagatov, Ph.D., MHS, RDN**	
Phone Number: **410-372-2719**	Organization Code: **4078**
Opportunity ID/Proposal or Purchase Order Number: **Contract: CON00020476 / OPP115933**	
Project Number, if known (include Task Order/ Delivery Order #): **100088602 (historically 100061734-IRB)**	
Start Date, known or anticipated: **To be determined**	
Full Title of Proposed Research Study: **Assessment and Monitoring of Breastfeeding-Related Maternity Care Practices: Maternity Practices in Infant Nutrition and Care (mPINC)**	
Client and/or Funding Agency: **DHHS Centers for Disease Control and Prevention (CDC)**	Battelle will issue a subcontract to : **Group Voxco**

	Criterion	Yes	No	N/A
OHRP	1. The proposed research study includes a systematic investigation, including research development and/or testing and evaluation, designed to develop or to contribute to generalizable knowledge. [45 CFR 46.102 (d)]	☒	☐	☐
OHRP	2. The proposed study includes a living individual ABOUT WHOM an investigator conducting research obtains information [45 CFR 46.102(f)]	☐	☒	☐
OHRP	3. The proposed study involves intervention or interaction with the living individuals [45 CFR 46.102(f)(1)] *Non-Applicable. See Item #2.*	☐	☐	☒
OHRP	4. The information obtained in the study is individually identifiable. [45 CFR 46.102.(f)(2)] *Non-Applicable. See Item #2.*	☐	☐	☒
OHRP	5. The information obtained in the study is private information. [45 CFR 46.102.(f)(2)] *Non-Applicable. See Item #2.*	☐	☐	☒
FDA	6. Involves use of a DRUG (other than marketed drug(s) in the course of medical practice) [21 CFR 312].	☐	☒	☐
FDA	7. Involves determining the SAFETY or EFFECTIVENESS of a medical device AND involves individuals on whose specimen a medical device will be used or who will receive a test article or be used as a control [21 CFR 812/814].	☐	☒	☐
FDA	8. Results will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit [21 CFR 50.3(c)].	☐	☒	☐

Comments: Survey involves collection and analysis of facility-specific practices. Results of analysis are intended primarily for quality improvement and benchmarking purposes and to promote good practices across facilities that provide common services. No information is collected about living individuals. Facilities nominate designated respondents to provide information about the facility's practices for patient care, training, personnel and policy, and facility characteristics. All available response options within the survey are either factual or statistical in nature; no personal opinions from respondents are sought. It's reasonable to rule that survey respondents are not human subjects, nor are any facility service providers or patients. This survey activity does not meet requirements at 45 CFR 46.102(f) for categorization as human subjects research.

Reviewed RFTOP:APHIR-0030 to assure client's expectations for IRB review and approval. E-Data must be maintained in a FISMA compliant environment. Respondents' participation is entirely voluntary. Respondents are identified by a unique ID; IDs are provided to client so that individualized benchmarking report can be provided to each participating facility.

Revision 1.0 of this ruling pertains to the pending 2018 and 2020 data collection/analysis activities. Reviewed draft screeners/contact solicitations, amended MPINC survey script, follow-up correspondence, website content, OMB submission documents and other related information. Ruling continues as non-Human Subjects Research (HSRE-230, Rev 1.0)

If amendments to the proposed data collection activity are anticipated, including any proposed change to the Battelle scope of work, notify the IRB and submit the changes for review/approval before they are implemented.

Human Protections Administrator	Gary M. Sapp, MS, CIM	Gary M. Sapp	Digitally signed by Gary M. Sapp Date: 2017.03.21 13:04:29 -04'00'
Title	Name	Signature	Date