

## Attachment X - IRB Letter

## EXEMPT DETERMINATION

DATE: 29 Jun 2018

TO: Gerad O'Shea, MA

**Applied Curiosity Research** 

**PROJECT:** US Department of Agriculture - Food & Nutrition Service, Multicultural

Nutrition Education for Child Care (Pro00028248)

## **DOCUMENTATION REVIEWED:**

**Protocol Version:** Research Protocol: Multicultural Nutrition Education for Child Care

(Not Dated)

**Consent Forms:** • Provider Informed Consent Form (Not Dated)

Parent/Caregiver Consent for Child Participation (Not Dated)

**Recruitment Material:** Parent/Caregiver Focus Group Flyer and Follow Up Communications for Parent Focus Group Participants (Not Dated)

• Information about Pilot Opportunity for Child Care Providers Flyer (Not Dated)

Initial Recruitment E-mail, Follow-Up Email to Interested Sites, Initial Recruitment Phone Call, Follow Up Call with Interested Site Directors, Follow Up Call to Determine Interested Providers, Follow Up Interview Recruitment Email, and Follow Up Interview Recruitment Call Script

(Not Dated)

Other Material: Survey for 6-12 Year Old Children (Not Dated)

Storybook Interview Form for Children 3-5 (Not Dated)

Provider Follow Up Interview (Not Dated)

Parent/Caregiver Focus Group Guideline (Not Dated)

Child Care Provider Interview Guideline (Not Dated)

Child Care Provider Journal (Not Dated)

Child Taste Test Ballot (Not Dated)

Using the Department of Health and Human Services regulations found at 45 CFR 46.101(b)(1), the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

The IRB determined that the specific IRB contact information must be removed from the study materials.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this exemption with an understanding of the following:

- 1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.
- 2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.101(b), you will resubmit revised materials for IRB review.
- 3. It is the responsibility of the investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed that the activity involves research, a description of the procedures, participation is voluntary, and the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you have any questions or concerns, please use the Contact IRB activity on your Advarra CIRBI Platform .

Thank you for selecting Advarra IRB to review your research project.