

Appendix J: IRB Approval

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Food Safety Consumer Research Project
RTI Project Number: 0215472.001.002 RTI Proposal Number (if no Project Number):
Project Leader: Sheri Cates
Project Team Member Contact (if different from Project Leader): Kathy Kosa
Source of Funding for this Study: USDA
Date Submitted to IRB: September 20, 2017
Level of Review (check one):
Full , IRB Meeting Date:
Expedited , category: **7: Behavioral - surveys, focus groups, etc.**

Type of Review (check one):

- Preliminary review (For DHHS grants where RTI is prime, the grant application/contract proposal and protocol submitted to the IRB are in concordance (45 CFR 46.103(f)). **Do not involve human subjects or data until pretest or full study is approved.**)
- Amendment, describe:
- Add study site(s): _____
- Pretest/Pilot Test:
- Full Implementation
- Renewal
- Study Closure


IRB Approval of Special Conditions (check all that apply to this review):

- Waiver of Signed Informed Consent/Parental Permission
- Waiver of elements of Informed Consent or requirement for Informed Consent/Parental Permission
- Participation of Pregnant Women (**Worksheet B** submitted by project team)
- Participation of Prisoners (**Worksheet C** submitted by project team)
- Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement required)
- Participation of Minors (**Worksheet D** submitted by project team)
- IRB Agreement of Nonsignificant Risk Device Study Determination
- HIPAA Waiver of Authorization

Please note the following requirements:

- If **unexpected problems or adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: September 25, 2018
(No human subjects research can occur after this date without continuing review and approval.)



September 25, 2017

Signature - IRB Member or Chair

Date of IRB Approval

Juesta Caddell, PhD
Name - IRB Member or Chair (print or type)

- Copy sent to project leader on: September 25, 2017
- Entered into MIS
- OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on: _____



APPROVAL

June 1, 2020

Sheryl Cates
919-541-6810, x26810
scc@rti.org

Dear Sheryl Cates:

On 6/1/2020, the IRB reviewed the following submission:

Type of Review:	Continuing Review
Title:	Food Safety Consumer Research Project
Investigator:	Sheryl Cates
IRB ID:	CR00000597 for 14215
Funding Source:	USDA FSIS
Customer/Client Name:	USDA FSIS
Project/Proposal Number:	0215472.001.002
IND, IDE, or HDE:	None

The IRB approved continuing review from 6/1/2020 to 5/31/2021. Before 5/31/2021 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 5/31/2021, approval of this study expires on that date.

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,
The RTI Office of Research Protection