APPENDIX H

INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

INTEGREVIEW IRB

August 3, 2017

Principal Investigator: Paul Ruggiere, Ph.D., M.S., B.B.A.
Sponsor: United States Department of Agriculture Food and Nutrition Services
Protocol Number: 2016-001
Study Title: "Third National Survey of WIC Participants (NSWP-III)"

Dear Dr. Ruggiere:

The above-referenced study meets the requirements for a research study that may be reviewed through expedited review procedures set forth in federal regulations.

Utilizing the expedited review procedures, the following action was taken on the continuing review of the above referenced study on behalf of IntegReview by **Christina Walker, M.D.** on August 3, 2017.

Approved:
Principal Investigator
Investigative site(s) as previously approved by IntegReview
Protocol, Version 1.0 dated July 29, 2016

Upon evaluation of the request for Waiver of documentation of Informed Consent, the expedited reviewer has determined that the request meets the criteria as identified in 45 CFR 46.116(d).

IMPORTANT

- **The following changes in approved research may not be implemented until you have received approval from IntegReview <u>except</u> where necessary to eliminate apparent immediate hazards to the human subjects:**
  - **Protocol Amendments**
  - **Change in the Principal Investigator and/or Sub-investigators (only if the Sub-investigators will be performing study-related procedures that the PI is not qualified through expertise to perform)**
  - **Change in the address at the study site or the addition of a study site(s)**
- **Only Informed Consent documents <u>containing IntegReview's approval</u> stamp may be utilized:**
  - **There must be procedures in place to guarantee that consent has been voluntarily obtained and properly documented.**
  - **For participants that do not speak English, the informed consent document must be in a language understandable to them.**
  - **Only IntegReview staff may initiate modifications to Informed Consent documents. The Informed Consent document will be maintained in our computer files, and IntegReview will make all revisions following IRB approval.**
- **Only recruiting materials <u>containing IntegReview's approval</u> stamp may be utilized. All audio/video recording(s) must be submitted for IRB approval prior to broadcast.**
- **Revision requests should be submitted on IntegReview's forms, which are available in IRBManager.**
- **Visit our website at www.integreview.com for information on research regulations, reporting requirements, Sponsor training, Investigator and research personnel training, etc.**

IntegReview approval for this study expires **August 2, 2018**.

In order to obtain extended IRB approval, IntegReview must receive your form for continuing review two weeks prior to the IRB expiration date. Appropriate forms will be forwarded to you approximately four weeks prior to the approval expiration date. Should the study end before you receive notification, submit a Closure Notification form.

REPORTING REQUIREMENTS

To ensure compliance with the applicable federal regulations as well as International Conference on Harmonisation (ICH), E6: Good Clinical Practice: Consolidated Guideline, IntegReview requires notification of the following for review/approval:

- **Report immediately:**
  - Changes in research that were initiated without IRB review and approval to eliminate apparent immediate hazards to the human subjects to ensure the continued safety and welfare of subjects
  - Modifications to previously approved documents
  - Receipt of investigator/site 483, Determination letter or Warning letter
  - If your license is suspended, revoked, placed on probation or restricted in any state or country
  - Safety information that may help to provide additional protections for subject's safety and well-being, throughout the course of the study and after study completion.
  - Communication of results from a research study to subjects when those results directly affect their safety or medical care
  - Reports of pregnancy
- **Report within 10 days of discovery:**
  - Revisions to the report of prior investigations
  - Unanticipated adverse device effects
  - Non-compliance – Failure by an investigator and/or sponsor to follow IntegReview's requirements, applicable regulations or to protect human research subjects, including but not limited to the principles of the Belmont Report
  - Serious non-compliance issues - non-compliance as defined as above and as determined to be serious in a way that adversely affects the rights and welfare of human subjects following the investigation and review by the IRB
  - Continuing non-compliance issues – A pattern of repeated non-compliance or serious non-compliance as determined by the IRB
  - Significant deviations – Significant deviations are those that deviate from the approved protocol, informed consent process and affect or potentially affect the safety of subjects. IntegReview does not consider protocol deviations to be different from protocol violations.
  - Unanticipated problems should be reported regardless of whether they occur during the study, after the study completion, or after participant withdrawal or completion. Any unanticipated problems involving risks to human subjects or others that are (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or

social harm) than was previously known or recognized. Examples of problems or events that may meet the definition of unanticipated problems involving risk to subjects or others may include, but are not limited to the following:

- Imminent threat of a reportable event that has not yet occurred
- Information indicating a change to the risk/benefit ratio of the research
- Death
- Breach of confidentiality, including lost or stolen study documents/data

- **Report within 30 days of acquisition or discovery**
  - New or additional conflicts of interests
- **Submit prior to publication/distribution:**
  - Any modification(s) to the previously approved Informed Consent document
  - New and/or modifications to previously approved recruiting/miscellaneous materials to be seen or heard by subjects
- **Submit two weeks prior to IntegReview approval expiration date:**
  - Continuing review documents
- **Submit upon completion of the study:**
  - Notification of study closure

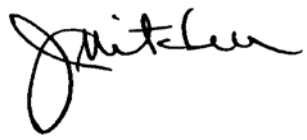
At its discretion, IntegReview IRB reserves the right to visit the study site.

IntegReview IRB is organized and operates in accordance with the applicable federal regulations, and ICH Guidelines for Good Clinical Practices, E6. In addition, Standard Operating Procedures have been created to ensure compliance with these regulations and guidelines.

If you have any questions regarding these procedures or if you wish to appeal the decision of IntegReview, you may address your comments to the IntegReview Co-chair.

Failure to comply with the Code of Federal Regulations or the requirements or determinations of IntegReview IRB can result in suspension or termination of IntegReview approval.

Sincerely,



Joseph Mitchell, LVN, CCRP
IRB Administrative Associate II

INTEGREVIEW IRB

November 14, 2017

Principal Investigator: Paul Ruggiere, Ph.D., M.S., B.B.A.
Sponsor: United States Department of Agriculture Food and Nutrition Services
Protocol Number: 2016-001
Study Title: "Third National Survey of WIC Participants (NSWP-III)"

Dear Dr. Ruggiere:

The following item(s) received IRB approval on November 14, 2017 via expedited review by Christina Walker, M.D.:

- One New Appendix A7. Denied Applicant Log Request Email
- One New Appendix B22.a Certification Survey Recruitment In-Person Script
- One New Appendix B23.a Denied WIC Applicant Survey Recruitment In-Person Script
- One New Appendix C5. Study Description for State and Local WIC Agencies
- One New Appendix C6. Certification End Date Verification Email
- One New Appendix C7.a Certification Survey Information Letter from State Agencies
- One New Appendix C8.a Denied WIC Applicant Information Letter from State Agencies
- One New Appendix C9.a PES Thank You Letter and Gift Card
- One New Appendix C10.a Former WIC Participant Case Study Interview Thank You Letter and Gift Card

If you have any questions, please contact me at (512) 326-3001.

Sincerely,

Anthony Mercado
IRB Administrative Associate I

INTEGREVIEW IRB

November 14, 2017

Principal Investigator: Paul Ruggiere, Ph.D., M.S., B.B.A.
Sponsor: United States Department of Agriculture Food and Nutrition Services
Protocol Number: 2016-001
Study Title: "Third National Survey of WIC Participants (NSWP-III)"

Dear Dr. Ruggiere:

The following item(s) received IRB approval on November 14, 2017 via expedited review by Christina Walker, M.D.:

- One Revised Appendix A1. State Agency Survey
- One Revised Appendix A2. Local Agency Survey
- One Revised Appendix A3.a Certification Survey Version A (Adult)
- One Revised Appendix A3.b Certification Survey Version B (Infant Child)
- One Revised Appendix A4.a Denied Applicant Survey Version A (Adult)
- One Revised Appendix A4.b Denied Applicant Survey Version B (Infant Child)
- One Revised Appendix A5.a Program Experiences Survey Version A (Adult)
- One Revised Appendix A5.b Program Experiences Survey Version B (Infant Child)
- One Revised Appendix A6.a Former WIC Participant Case Study Interview Guide
- One Revised Appendix B1. Notification Email to Regional and State Offices
- One Revised Appendix B2. Letter to State Agencies from Regional Offices
- One Revised Appendix B3. State Agency Survey Invitation Email
- One Revised Appendix B4. State Agency Survey Invitation Letter with Instrument
- One Revised Appendix B5. State Agency Survey Reminder Email
- One Revised Appendix B6. State Agency Survey Reminder Telephone Script
- One Revised Appendix B7. Local Agency Survey Invitation Email
- One Revised Appendix B8. Local Agency Survey Invitation Letter with Instrument
- One Revised Appendix B9. Local Agency Survey Reminder Email
- One Revised Appendix B10. Local Agency Survey Reminder Telephone Script
- One Revised Appendix B11.a Certification Survey Recruitment Telephone Script
- One Revised Appendix B12.a Text Message Reminder for Scheduled Certification Survey
- One Revised Appendix B13.a Telephone Reminder for Scheduled Certification Survey
- One Revised Appendix B14.a Denied WIC Applicant Survey Recruitment Telephone Script
- One Revised Appendix B15.a Text Message Reminder for Scheduled Denied Applicant Survey
- One Revised Appendix B16.a Telephone Reminder for Scheduled Denied Applicant Survey
- One Revised Appendix B17.a Program Experiences Survey Invitation Telephone Script
- One Revised Appendix B18.a Former WIC Participant Case Study Interview Invitation Telephone Script
- One Revised Appendix B19.a. Program Experiences Survey Invitation Letter
- One Revised Appendix B20.a. Program Experiences Survey Invitation Email
- One Revised Appendix B21.a Program Experiences Survey Invitation In-Person Script

- One Revised Appendix C1.a Participant Consent Form Certification Survey
- One Revised Appendix C2.a Participant Consent Form Denied Applicant Survey
- One Revised Appendix C3. State Agency Survey Thank You Letter
- One Revised Appendix C4. Local Agency Survey Thank You Letter

If you have any questions, please contact me at (512) 326-3001.

Sincerely,

Anthony Mercado
IRB Administrative Associate I

INTEGREVIEW IRB

November 21, 2017

Principal Investigator: Paul Ruggiere, Ph.D., M.S., B.B.A.
Sponsor: United States Department of Agriculture Food and Nutrition Services
Protocol Number: 2016-001
Study Title: "Third National Survey of WIC Participants (NSWP-III)"

Dear Dr. Ruggiere:

The following client translated documents received IRB approval on November 21, 2017 via expedited review by Christina Walker, M.D. for the above referenced study:

- One New Spanish Appendix A3.c Certification Survey Version A (Adult)
- One New Spanish Appendix A3.d Certification Survey Version B (Infant Child)
- One New Spanish Appendix A4.c Denied Applicant Survey Version A (Adult)
- One New Spanish Appendix A4.d Denied Applicant Survey Version B (Infant Child)
- One New Spanish Appendix A5.c Program Experiences Survey Version A (Adult)
- One New Spanish Appendix A5.d Program Experiences Survey Version B (Infant Child)
- One New Spanish Appendix A6.b Former WIC Participant Case Study Interview Guide
- One New Spanish Appendix B11.b Certification Survey Recruitment Telephone Script
- One New Spanish Appendix B12.b Text Message Reminder for Scheduled Certification Survey
- One New Spanish Appendix B13.b Telephone Reminder for Scheduled Certification Survey
- One New Spanish Appendix B14.b Denied WIC Applicant Survey Recruitment Telephone Script
- One New Spanish Appendix B15.b Text Message Reminder for Scheduled Denied Applicant Survey
- One New Spanish Appendix B16.b Telephone Reminder for Scheduled Denied Applicant Survey
- One New Spanish Appendix B17.b Program Experiences Survey Invitation Telephone Script
- One New Spanish Appendix B18.b Former WIC Participant Case Study Interview Invitation Telephone Script
- One New Spanish Appendix B19.b. Program Experiences Survey Invitation Letter
- One New Spanish Appendix B20.b. Program Experiences Survey Invitation Email
- One New Spanish Appendix B21.b Program Experiences Survey Invitation In-Person Script
- One New Spanish Appendix B22.b Certification Survey Recruitment In-Person Script
- One New Spanish Appendix B23.b Denied WIC Applicant Survey Recruitment In-Person Script
- One New Spanish Appendix C7.b Certification Survey Information Letter from State Agencies
- One New Spanish Appendix C8.b Denied WIC Applicant Information Letter from State Agencies
- One New Spanish Appendix C9.b PES Thank You Letter and Gift Card
- One New Spanish Appendix C10.b Former WIC Participant Case Study Interview Thank You Letter and Gift Card

If you have any questions please feel free to contact me at 512-326-3001.

Sincerely,

Jenna Rozacky, B.S.
IRB Administrative Associate II

INTEGREVIEW IRB

November 21, 2017

Principal Investigator: Paul Ruggiere, Ph.D., M.S., B.B.A.
Sponsor: United States Department of Agriculture Food and Nutrition Services
Protocol Number: 2016-001
Study Title: "Third National Survey of WIC Participants (NSWP-III)"

Dear Dr. Ruggiere:

The following document(s) received IRB approval on November 21, 2017 via expedited review by Christina Walker, M.D.:

- Revision to IntegReview currently approved Informed Consent Certification Survey document
- Revision to IntegReview currently approved Informed Consent Denied WIC Applicant Survey document

If you have any questions, please contact me at (512) 326-3001.

Sincerely,

Jenna Rozacky, B.S.
IRB Administrative Associate II