Certificate of Action

Investigator Name: Deborah G. Tatar, PhD	**Board Action Date:** 02/26/2019
Investigator Address: 2202 Kraft Dr. Room 1123 Blacksburg, VA 24060, United States	**Approval Expires:** 02/26/2020 **Continuing Review Frequency:** No CR Required
Sponsor: Virginia Polytechnic Institute and State University (Virginia Tech) **Institution Tracking Number:** 19-061	**Sponsor Protocol Number:** 19-061 **Amended Sponsor Protocol Number:**
Study Number: 1255150	**IRB Tracking Number:** 20190447
Work Order Number: 1-1156980-1	**Panel:** 3
Protocol Title: FamilySong - Longitudinal Study	

THE FOLLOWING ITEMS ARE APPROVED:
Investigator
Advertisement - FamilySong Be Together At A #23837242.0 - As Submitted
FamilySong Interview Information #23837244.0 - As Submitted
Protocol
Subject Recruitment Letter #23837243.0 - As Submitted
Consent Information Sheet [IN0]
Interview Script #23837247.0 - As Submitted
Screening Questionnaire #23933175.0 - As Submitted

Please note the following information:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

Under the revised common rule (effective 1-21-2019), continuing review by the Board of the above referenced research is not required; however, the IRB will maintain our records and continue responsibility for exercising administrative and regulatory oversight of this research. The IRB will automatically charge a maintenance fee for this administrative effort unless we are notified the research is closing. To avoid unnecessary fees due to closure, a closure form must be submitted for each site 30 days prior to expiration.

The Board found that this research meets the requirements for a waiver of documentation of consent under 45 CFR §46.117(c)(1)(ii) [2018 Requirements] 45 CFR 46.117(c)(2) [Pre-2018 Requirements]

Request for Alternative Consent Process

The Board noted that one or more enclosed ads, subject materials, or consent forms contain both English and Spanish. WIRB would like to remind you that the enclosed materials are approved only in so far as they relate to the English version of the documents referenced in the enclosed approval notice. The portions of the materials that contain Spanish were not reviewed.

If you have any questions or concerns, please contact Client Services at clientservices@wirb.com.

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Virginia Tech, 2202 Kraft Dr. Room 1123, Blacksburg, Virginia 24060

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - For research subject to federal oversight other than FDA:
        - No additional identifiable private information about the subjects is being obtained
        - Analysis of private identifiable information is completed
- If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.

If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by the IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. "

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

COA Template 01-03-2018

DISTRIBUTION OF COPIES:

Contact, Company

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