IRB ID Number: 13251

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

Title of Study: Develop and Implement UCARE4LIFE Message Library
RTI Project Number: 0213543.001.001 **RTI Proposal Number** (if no Project Number)
Project Leader: Jennifer Uhrig
Project Team Member Contact (if different from Project Leader): Jennie Harris
Source of Funding for this Study: Health Resources and Services Administration
Date Submitted to IRB: April 25, 2013 (revised)
Level of Review *(check one)*:
Full ☒, IRB Meeting Date: April 16, 2013
Expedited ☐**,** category: Choose an item.
Type of Review *(check one)*:
☐Preliminary review (The grant application/contract proposal and protocol submitted to the IRB are in concordance with regard to the scientific conduct of the study, informed consent content, and all other issues pertaining to the protection of human subjects. (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 _____ ☐Renewal
☒Full Implementation for adults and minors for whom 45CFR46.404 (Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research does *not* apply ☐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: 02-19-2014
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell

Signature - IRB Member or Chair

May 3, 2013
Date of IRB Approval

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

☒Copy sent to project leader on May 3, 2013
☐Entered into MIS
☐ OHRP acknowledgement received for participation of prisoners in DHHS-funded studies on:_____

Office of Research Protection and Ethics, Institutional Review Board
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