13251

RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: February 8, 2013 **RTI Project/Proposal No.:** 0213543.001.000/0281201.380

Project Title: Develop and Implement UCARE4LIFE Message

Project Manager: Jen Uhrig **Sponsor**: Health Resources and Services Administration (HRSA)

Date Participation of Human Subjects Scheduled to Begin: June 1, 2013

A. Brief Description of Study Procedures and Participant Population:

The purpose of the UCARE4LIFE study is to develop, implement, and evaluate short message service (SMS), or text messages, to improve retention in care and HIV medication adherence among racially and ethnically diverse HIV-positive youth who are receiving care at select Ryan White clinics throughout the United States. The primary aims of this contract are to: 1) develop, test, and maintain a message library that addresses topics of HIV disease self-management and risk reduction, and 2) develop, implement, and evaluate the text messaging. As part of Aim 2, we will interview up to three clinic staff members from each participating clinic to explore their experiences with and reactions to the project.

II. STUDY DESCRIPTION

Up to three clinic staff members from each participating clinic (N=10) will be selected to participate in an in-depth, semi-structured qualitative interview for a total of up to 30 interviews. The onsite study coordinator from each clinic will recommend staff for inclusion. The type of staff we plan to interview include health care providers (e.g., physicians, nurses, nurse practitioners, etc.), social service workers (e.g., case managers, social workers, etc.), and the onsite study coordinator. RTI will contact the recommended staff via email to assess their willingness and interest in participating (**Exhibit 1**). If someone should decline to be interviewed, we will ask the onsite study coordinator to recommend a suitable replacement. We will schedule 1-hour telephone interviews with those staff who accept our invitation.

Prior to initiating data collection, we will obtain verbal consent from participants (**Exhibit 2**). During the interview, the participants will be asked questions to assess organizational context and readiness to change, implementation policies and practices, facilitators and barriers to program implementation and sustainability, implementation climate, value-fit, and recommendations for improvement (**Exhibit 2**).

Interviews will be conducted by two-person teams: The interviewer and a note taker. The discussion will be audio recorded as a backup to the notes; however, the notes and audio recordings will not include participant or clinic names. The qualitative data will be summarized and aggregated in an analytic matrix by participant type and geographic region to assess variations in response patterns.

B. **Description of Physical, Psychological, Social or Legal Risks to Participants**:

We believe that the data collection poses minimal to no risk to the individuals interviewed. All of the questions we plan to ask relate to participants' daily work at their respective clinics. Further, the data will not contain identifying information.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[X] Yes [ ] No [ ] NA

If yes, explain:

The RTI interviewer and note taker will have access to participants' names and affiliations in order to schedule the interviews. However, this information will not be linked to the interview data in any way, shared outside of the RTI project team, or presented in summary reports.

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

[ ] Yes [X] No [ ] NA

If yes, explain:_____

_____

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

[ ] Yes [ ] No [X] NA

If no, explain:_____

_____

2. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[ ] Yes [ ] No [X] NA

If yes, explain:_____

_____

D. Describe other categories of exempt research[1] here:

_____

[1] Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

----------Space below this line for IRB use only.----------

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: Jamia Bachrach, JD

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

__(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

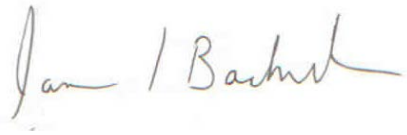
X (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

__(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

__5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

__(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



02-27-2013

Signature of IRB Coordinator or Chair named above | Date

Version 11-30-00