12291

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: 1/06/08 **RTI Project/Proposal No.: 0211776**

Project Title: Evaluating the Title XX Adolescent Family Life (AFL) Program

Project Manager: Olivia Ashley **Sponsor: Office of Population Affairs (OPA), Department of Health and Human Services (DHHS)**

Date Participation of Human Subjects Scheduled to Begin: 1/13/08

A. Brief Description of Study Procedures and Participant Population:

This Office of Population Affairs (OPA) funded project involves an outcome evaluation and process evaluation. This project included a pilot study to test outcome evaluation data collection instruments; the IRB reviewed and approved the pilot study on May 4, 2007. IRB approval for the outcome evaluation data collection procedures and instruments was received on July 22, 2008. This project will also involve collecting data about program implementation for the Title XX Adolescent Family Life (AFL) Program. The AFL Program is administered by the Office of Adolescent Pregnancy Programs (OAPP) within OPA to support Prevention demonstration projects providing abstinence education to adolescents and Care demonstration projects providing services to pregnant and parenting adolescents. The process evaluation will collect data on the implementation of the AFL Program through self-administered instruments completed by AFL grantee staff. The purpose of this IRB protocol is to review the process evaluation procedures and instruments for the pilot study.

To gather data about program implementation for the pilot study, AFL Prevention and Care demonstration project directors will complete a self-administered instrument, which for the main process evaluation will be attached as an enclosure to the end-of-year reporting template submitted to OPA (a copy of the instruments is attached). OPA will solicit volunteer project directors to participate in the pilot study and supplement the list of volunteers with project directors selected to reflect diversity in program implementation (e.g., home visiting, case management, peer leadership, mentoring, etc.). A pre-notification memorandum will be e-mailed from OPA informing selected project directors that OPA is conducting a process evaluation to describe the activities of Prevention and Care demonstration projects, that a pilot study will be conducted to test the process evaluation instruments, and to alert them to the timeline for the pilot test (a copy of the memorandum is attached.) A second memorandum will be e-mailed from OPA to selected project directors attaching the instrument and asking them to complete it and send it to OPA within 3 weeks (a copy of the memorandum is attached). The sample of selected Prevention demonstration project directors (n=9) and Care demonstration project directors (n=9) will complete the instruments electronically using Microsoft Word or paper and pencil, whichever is easiest. Forms can be returned by project directors to OPA electronically, by facsimile transmission, or by Federal Express. The project directors will be asked detailed questions about the implementation of AFL demonstration projects, including the program delivery, content, theoretical orientation, empirical basis, use of best practices, organizational context, innovation, fidelity, and dosage. Process evaluation pilot data will be collected from January 20, 2009, to February 11, 2009. This pilot test will also elicit comments on the availability, usefulness, and likely accuracy of the data requested; the burden associated with providing the data; the overall instrument; and specific instrument questions. No identifying information about adolescents or sensitive information about sexual behavior will be collected from AFL Prevention and Care demonstration project directors for the process evaluation pilot test.

B. Description of Physical, Psychological, Social or Legal Risks to Participants:
There are no anticipated physical, psychological, social, or legal risks for participants. There are no sensitive questions associated with this data collection. Process evaluation data collection forms completed by Prevention and Care demonstration project directors will address the implementation of AFL demonstration projects including the extent to which project activities are theoretically based, whether project activities are evidence-based, the

extent to which grantees are utilizing best practices, the organizational contexts in which project activities are conducted, and characteristics of projects.

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 instruments will include a field identifying the grantee and the person completing the instrument.

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: **Juesta Caddell, Ph.D.**

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.

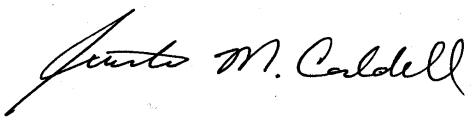
_X(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers 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.



Signature of IRB Coordinator or Chair named above

January 8, 2009
Date

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