IRB ID Number: 12612

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: 4/19/10 **RTI Project/Proposal No.:** 0210700.001.005.001.001

Project Title: Coordinating Center for the Evaluation of the Grants for the Benefit of Homeless Individuals (GBHI)

Project Manager: Nahama Broner, PhD

Sponsor: Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (CSAT)

Date Participation of Human Subjects Scheduled to Begin: 6/1/10

A. Brief Description of Study Procedures and Participant Population:

RTI is conducting an evaluation of **the Grants for the Benefit of Homeless Individuals (GBHI) program.** The Center for Substance Abuse Treatment (CSAT) at the Substance Abuse and Mental Health Services Administration (SAMHSA) was funded by Congress to establish the Grants for the Benefit of Homeless Individuals (GBHI) program, sometimes also referred to as the Treatment for Homeless program, one of the grant programs in the Co-Occurring and Homeless Activities Branch (CHAB).

Between 2001 and 2008, GBHI awarded 169 grants to provide services to the target population. Additionally, 25 new grantees were funded in 2009 (FY2010 cohort). The evaluation that RTI will be conducting will focus primarily on this FY 2010 cohort. Additionally, to provide sufficient sample size to answer the CSAT evaluation objectives and address the primary goal of the evaluation, the evaluation plan includes limited data collection from prior grantee cohorts funded between 2004 and 2009.

We have already received approval from RTI's Office of Human Research Protection to exempt the client level GPRA data we will be receiving. In addition to the GPRA questions that will be administered to respondents regardless of study participation, we have added cross-site study specific questions onto the standard GPRA interview that will be asked only of study participants by grantee staff interviewers. Both the GPRA and supplemental GPRA questions will be administered by the grantee program staff interviewers as is the standard practice for the programs and a condition of their grant award. These data are de-identified and are secondary data as they are administered by grantee staff interviewers and no data will be directly collected by RTI. These questions ask about the client's experiences with the program, communication between program staff and the client, overall program satisfaction, background and attitudes about drugs and alcohol. The portion of questions focused on background (e.g., criminal justice involvement, education, employment and housing) are the standard SAMHSA GPRA OMB approved questions, but with an extended time frame (e.g., 6 months rather than 30 days). The portion of these questions addressing communication and satisfaction will be self-administered. For this subset of questions, the grantee staff administering the questionnaire will ask respondents to complete the survey themselves in paper and pencil format, seal their responses in tamper-proof envelopes, and return the envelopes to the grantee staff interviewers. These data also are de-identified. The envelops along with the questionnaires administered by grantee staff will be mailed to RTI for processing. The consent form and the study-specific questions are attached to this application for your review and will be administered by grantee staff. As a reminder, all GPRA data (standard and the add-on) is secondary data, administered by the grantees, and will come to us in de-identified form. The

interviews will be labeled with unique identifiers that will allow us to match the results to future GPRA interviews as they occur but we will never be in possession of any identifying information.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: Participation in the evaluation will create minimal risks for participants. The add-on questions are not overly sensitive and in fact the majority are standard SAMHSA GPRA OMB approved questions with extended time frame; new questions focus on client satisfaction and program/client communication. As discussed above, procedures are in place to help promote and protect the confidentiality of survey responses; no data will be collected from clients by RTI. These data are secondary data collected by the program, de-identified and sent to RTI for processing.

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?*

   [ ] Yes [ ] No [X] NA

   If yes, explain:_____

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 [ ] No [X] 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:

Exemption Category 5(i):
This is an evaluation that is funded by and subject to the approval of the Center for Substance Abuse Treatment (CSAT) at the Substance Abuse and Mental Health Services Administration (SAMHSA). It is designed to evaluate the Grants for the Benefit of Homeless Individuals (GBHI) program. The respondents are program clients and the questionnaire administers are program staff and not RTI or affiliated RTI evaluation staff.. The add-on questions pose minimal risk and no identifying data will be collected or sent to RTI.

[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:_____

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.

__(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.

_X_ 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.

Ira H Wallace

April 29, 2010

Signature of IRB Coordinator or Chair named above **Date**

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