

**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: 4/06/10

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 will use several methods to collect primary data including conference calls; site visit interviews and tours of facilities and observation of the interventions; a Web survey of non-client partner/stakeholders, individual telephone interviews with 2004 through 2009 grantees; web in-person focus groups of the same types of participants; interviews with GPOs; and interviews and with TA Contractors. Below (at the end of this document) is a table that provides an overview with regard to the purpose of each type of primary data collection, the mode of consent, the burden, the type of respondents, the participating sites (e.g., grantee cohorts), and the schedule for data collection for the base year (e.g., Year 1) and each of the 4 option years (Years 2–5). Also attached are the related consent forms and interview/focus group guides.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: Participation in the evaluation will create minimal risks for participants. The questions are solely focused on aspects of their daily work or the overall topic of needs and services for the homeless. To encourage respondents to offer candid responses, they will be assured of the confidentiality of their responses and information gathered in the interviews will be reported only in aggregate or synthesized form.

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 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 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 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 NA

If yes, explain: _____

D. Describe other categories of exempt research¹ 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 government (federal, state, county, or city) employees, local grantee evaluators, contractors, and grantee staff and partners.

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.

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Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: Ina Wallace

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.



Signature of IRB Coordinator or Chair named above

Version 11-30-00

April 19, 2010

Date

Primary Data Collection: 0210700.001.005.001.001

	Purpose	Respondents	Mode of Consent	Burden	Sites	Schedule*
Site Visit Related Conference Calls	<ul style="list-style-type: none"> Prepare for site visit: logistics, agenda and documents needed 	Project Directors Local Evaluators Others designated by Grantee	<ul style="list-style-type: none"> Telephone call-logistics: consent N/A— 	<ul style="list-style-type: none"> 30 minutes 	<ul style="list-style-type: none"> 25 FY10 sites 	--Years 1–4 preceding and as needed after 1 st and 2 nd site visits
Site Visits	<ul style="list-style-type: none"> Intervention Fidelity, adaptation and innovation Topics include cost, project organization, services, grantee & target population characteristics, TA, partners, sustainability 	Project Directors Financial staff Project staff Stakeholders Local Evaluators	<ul style="list-style-type: none"> In person 	<ul style="list-style-type: none"> 2 days 	<ul style="list-style-type: none"> 25 FY10 sites 	--Summer 2010 Year 1–2 first site visits; --Year 4 second site visits
Web Survey	<ul style="list-style-type: none"> Grantee characteristics Population served Service environment Implementation Fidelity, adaptation, and innovation Sustainability TA Local evaluation 	Stakeholders	<ul style="list-style-type: none"> Web consent 	<ul style="list-style-type: none"> 17 minutes 	<ul style="list-style-type: none"> 25 FY10 sites 2005–2009 sites on voluntary basis 	--Year 2 and Year 4 pending OMB approval
Focus Groups	<ul style="list-style-type: none"> Implementation Service adaptation Lessons learned (barriers & facilitators) 	Project Directors Local Evaluators	<ul style="list-style-type: none"> Web and in-person script for consent 	<ul style="list-style-type: none"> 1.5 hours 	<ul style="list-style-type: none"> 25 FY10 Sites Selected grantee 2006 to present 	--Periodic in Year 1 and 2 and in Year 5
Telephone Interviews Follow-up to Document Exaction	<ul style="list-style-type: none"> Verify or update information from document extraction Sustainability Lessons learned 	2004 to present Project Directors grantees	<ul style="list-style-type: none"> Telephone, Verbal consent 	<ul style="list-style-type: none"> 45 minutes 	<ul style="list-style-type: none"> 2005–2009 sites on voluntary basis 	--One time beginning Spring 2010
GPO Interviews	<ul style="list-style-type: none"> TA & Grantee Support Monitoring Lessons for improvement 	Current GPOs	<ul style="list-style-type: none"> In person verbal consent 	<ul style="list-style-type: none"> 45 minutes 	<ul style="list-style-type: none"> CHAB GPOs 	--Annual beginning summer 2010

TA Contractor Interviews	<ul style="list-style-type: none"> • TA • Grantee and GPOS support needs • Lesson learned 	Current Contractors: SAIS: RTI; CHAB: JBS, AHP, & RTI	<ul style="list-style-type: none"> • In person and via telephone verbal consent 	<ul style="list-style-type: none"> • 45 minutes 	<ul style="list-style-type: none"> • Current SAIS and CHAB TA staff 	--Annual beginning summer 2010
Cost Data	<ul style="list-style-type: none"> • Program cost and cost-effectiveness 	Grantees	<ul style="list-style-type: none"> • Part of site visit and calls described above 	<ul style="list-style-type: none"> • 3 hours 	<ul style="list-style-type: none"> • 25 FY10 sites 	--Years 1 and Year 4

Note: Years refer to years in the GBHI Cross-site Evaluation begun September 15, 2009.