Evaluation of the SAMHSA Primary and Behavioral Health Care Integration Grant Program 2010-0762

RAND HSPC Information Online (RHINO)

Date: Tuesday, January 11, 2011 2:09:19 PM

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1.0 Study Introduction

1.0 * **Title:**
Evaluation of the SAMHSA Primary and Behavioral Health Care Integration Grant Program

2.0 * **Briefly describe the purposes, populations, procedures, data sources, and methods of this project or provide an abstract. (2,000 character limit)**
Primary and Behavioral Health Care Integration (PBHCI) is a SAMHSA service grant program designed to improve the overall wellness and physical health of people with Serious Mental Illness (SMI) and/or co-occurring substance use disorders by integrating primary care services into in community mental health settings. RAND will conduct a program-wide (n=56 clinic) evaluation of the impact of these integrated services on consumers' physical and mental health. This project includes a base year and two optional years. Activities in the Base Year and Optional Year 1 will include secondary data collection from clinical staff (quarterly reports of process activities; infrastructure data from a SAMHSA on-line data repository, TRAC, collected for SAMHSA's ongoing QA activities) and patients (clinical registry data abstraction; survey and physical health data from a SAMHSA on-line data repository, TRAC, also for SAMHSA's ongoing QI activities). It also includes primary data collection from patients (physical health assessments and surveys). Optional year 2 activities will include secondary data collection (clinical staffs' quarterly reports; patient-level clinical registry data) and primary data collection (clinical staff interviews and surveys). This application includes only the activites in the Base Year and Optional Year 1 of the study because the funding available for Optional Year 2 activities is still uncertain.

3.0 **Research Unit(s):**

- ☐ Arroyo Center
- ☐ Child Policy
- ☐ Education
- ☑ Health
- ☐ Infrastructure, Safety, and Environment
- ☐ Institute for Civil Justice
- ☐ Labor and Population
- ☐ National Security Research Division
- ☐ Project AIR FORCE
- ☐ Pardee RAND Graduate School
- ☐ Other
- ☐ N/A

4.0 * **Principal Investigator.** (You can have only one PI. The PI has edit rights to the study in Rhino, but only the PI, and the proxy they designate, can submit the study to the HSPC.)
Click Select to **add** or **change** the Principal Investigator
Deborah Scharf

5.0 **Co-Principal Investigators**. (Co-Investigators can be added under item 7.0. Co-PIs can edit the study in Rhino, but must be designated by the PI as a proxy to submit the study to the HSPC.)

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Last Name	First Name	Organization
Burnam	Audrey	Behavioral Sciences

6.0 **Primary HSPC Contact.** (If the primary contact is either the PI or a Co-PI and there is one or more Co-PIs, then please select the name of the PI or Co-PI that should be the primary contact for the HSPC. If the Primary HSPC Contact is not listed as a PI or Co-PI above, they will have edit rights to the study in Rhino, but must be designated by the PI as a proxy to submit the study to the HSPC.)
Deborah Scharf

7.0 **Other Study Staff involved in the research.** Other study staff added below can view the study but not modify it. They will also receive certain correspondence related to HSPC status.

Last Name	First Name	Organization	Role
[View] Lovejoy	Susan	Policy Sciences	Key Researcher
[View] Perlman	Judy	Survey Research Group	Survey Director

8.0 **Do you wish to check to see if your study would be "No Human Subjects" or "Exempt"?** Choosing 'Yes' will present you with questions that will assist the HSPC in determining if your study is "No Human Subjects" or "Exempt from HSPC Review". If a determination is made that your study does not qualify for one of these two outcomes, then you will need to fill out sections 4 - 8 of the study form.

○ Yes ◉ **No**

1.1 Study Funding

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 2 of a possible 26 screens.

1.0 * **Funding Status:**

- ○ Proposed
- ○ Sponsor requires review before funding (Just in Time Review)
- ◉ Funded
- ○ Initiated, but not yet funded

2.0 * **Funding Sources - Click Add to list a funding source. To edit, click on the link. To delete, check the checkbox and click Delete.**

Funding Institution Type	Name	Project Task Number	Proposal Number	Last Modified
[View] Federal Govt	SAMHSA	HD140-1000		12/5/10

4.0 Research Overview - Dates

1.0 * **Project Start Date (mm/dd/yyyy): (Grant and non-FFRDC research should use the award date as the project start date. FFRDC research should use the date the Project/Task Number was opened.)**
10/4/2010

2.0 * **Anticipated Project End Date (mm/dd/yyyy):**
9/27/2013

3.0 * **Anticipated Data Acquisition Start Date (mm/dd/yyyy):**
2/1/2011

4.0 * **Anticipated Data Acquisition End Date (mm/dd/yyyy):**
6/28/2013

4.1 Research Overview - RAND's Role in the Research

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 12 of a possible 26 screens.

1.0 * **Which institution is the prime contractor or grantee?**

(•)	A.	RAND
( )	B.	Other, Specify:

2.0 **What is the role of RAND (including subcontractors to RAND) in the research study? (Check all that apply)**

☑	A.	Be involved in obtaining informed consent.
☑	B.	Be involved in data collection
☑	C.	Receive identifiable individual-level data
☑	D.	Research design
☑	E.	Data analysis, and/or interpreting and reporting results
☑	F.	Other (e.g., training, technical assistance, consulting)

2.1 * **If Other, please specify the other role(s) of RAND or it's subcontractors in the research study.**
Training, technical assistance, consulting

4.2 External Organizations Collaborating in the Research

1.0 **External Organizations Collaborating in the Research - Click Add to list an external organization. To edit, click on the link. To delete, check the checkbox and click Delete.**

Organization	Last Modified
National Council for Community Behavioral Health Care	12/23/10
OnSite Health Diagnostics	12/23/10

4.5 Research Overview - Populations and Procedures

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 16 of a possible 26 screens.

1.0 Population Procedures:

Population: Consumers

Procedure	Will Perform
TRAC - Infrastructure Data	No
Patient Physical Health Exam	Yes
Clinical Registry Data Abstraction	Yes
Quarterly Reports	No
Patient Survey	Yes
TRAC - Physical Health Exam and Lifestyle Survey	Yes

Population: Clinic Staff

Procedure	Will Perform
TRAC - Infrastructure Data	Yes
Patient Physical Health Exam	No
Clinical Registry Data Abstraction	No
Quarterly Reports	Yes
Patient Survey	No
TRAC - Physical Health Exam and Lifestyle Survey	No

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4.2 External Organizations Collaborating in the Research

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 13 of a possible 26 screens.

1.0 * Name of organization.
National Council for Community Behavioral Health Care

2.0 Organization staff will:

- [ ] A. Give RAND names and contact information to assist in subject recruitment without their prior written consent
- [ ] B. Be involved in obtaining informed consent.
- [ ] C. Be involved in data collection
- [ ] D. Receive identifiable individual-level data
- [ ] E. Share responsibility for research design, data analysis, and/or interpreting and reporting results.
- [x] F. Other. Please describe the other activities that the organization staff will perform.
- [ ] G. None of the above

2.1 If Other, please describe the other activities that the organization staff will perform.
Training and technical assistance center. Collaborate with RAND on training and technical assistance activities.

IRB Review

3.1 **Will the organization be carrying out its own IRB review?**

- ○ Yes
- ○ No
- ◉ Don't know

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4.2 External Organizations Collaborating in the Research

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 13 of a possible 26 screens.

1.0 * **Name of organization.**
OnSite Health Diagnostics

2.0 **Organization staff will:**

- ☐ A. Give RAND names and contact information to assist in subject recruitment without their prior written consent
- ☑ B. Be involved in obtaining informed consent.
- ☑ C. Be involved in data collection
- ☑ D. Receive identifiable individual-level data
- ☐ E. Share responsibility for research design, data analysis, and/or interpreting and reporting results.
- ☐ F. Other. Please describe the other activities that the organization staff will perform.
- ☐ G. None of the above

If you check options A - E, it may be necessary for this external organization to obtain an IRB review because the activities this organization will be performing could be considered to be human subjects research

IRB Review

3.1 **Will the organization be carrying out its own IRB review?**

- ○ Yes
- ◉ No
- ○ Don't know

3.2 **Will the organization be deferring to RAND's IRB/HSPC review?**

- ◉ Yes
- ○ No

- Don't know

5.0 Population Detail for: Consumers

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 17 of a possible 26 screens.

1.0 * **Will you be piloting or pre-testing procedures or instruments for this population?**
no

2.0 * **Please give the inclusion or selection criteria for participation in the research.**
Inclusion criteria:
-Adults (ages 18 years or older)
-Primary psychiatric diagnosis is a Serious Mental Illness (as per SAMHSA's definition)
-Current clients of a community behavioral health center participating in the PBHCI grant program OR of a community behavioral health center serving as a matched control for a PBHCI program clinic
NOTE: The total number of consumers represented in secondary data collection activities is expected to range between 33,600 - 140,000 (56 clinics x 600 to 2500 consumers)
NOTE: The total number of consumers participating in primary data collection is expected to range between 1,500 - 1,800.

3.0 **What are the criteria for excluding individuals from the population described?**
For Primary Data Collection Only
-Failure or inability to provide written informed consent.

4.0 * **Are you going to intentionally exclude anyone because of gender, racial/ethnic groups, or language fluency?**
yes

4.1 * **If 'Yes', please explain why you are going to intentionally exclude someone on the basis of gender, racial/ethnic groups, or language fluency:**
For primary data collection participants must be able to provide written informed consent in English

5.0 * **Please indicate which, if any, of the following vulnerable populations will be knowingly and intentionally *included*.**

- [ ] A. Children/minors
- [ ] B. Prisoners, incarcerated individuals, detainees, parolees, probationers
- [ ] C. Cognitively impaired persons
- [ ] D. Physically incapacitated
- [ ] E. Seriously or terminally ill
- [ ] F. Illegal immigrants
- [ ] G. Economically or educationally disadvantaged
- [x] H. Other
- [ ] I. None of the above

5.1 * **If 'H.', please describe the other vulnerable population(s) that you are including.**
Adults with serious mental illness

6.0 * **Are any of the participants in a situation where they could be coerced to participate (e.g., employer/employee, doctor/patient)?**
yes

7.0 * **Will individuals in this subject population be asked or recruited to participate in the research?**
yes

7.1 **What is the earliest date at which you expect any recruitment activities to begin? (mm/dd/yyyy)**
2/1/2011

7.2 **How many potential participants do you expect to contact regarding participation? (e.g., your starting sample size)**
1650

7.3 **How many participants do you expect to have? (e.g., number of respondents or participants)**
1500

7.4 *** Please describe the recruitment procedure. Include who, what, where, when, and how.**
Recruitment procedures are only for primary data collection activities.

Prospective participants will be asked by a staff person at their behavioral health center if they would like to be contacted in order to learn about a research study. Staff at the behavioral health clinic will compile a list of persons who agree to be contacted and they will send this list with names and contact information to RAND over a HIPAA-compliant secure SharePoint site. RAND will securely transmit this list to our subcontractor, OnSite Health Diagnostics, who will send a letter (attached) to prospective participants describing the stuyd. Letters will go out 1-2 weeks prior to the data collection date with information about the study and an invitation for consumers to come to their behavior health clinic on a specific date to participate. OnSite Health Diagnostics will also call prospective participants 1-2 days prior to the data collection date to provide additional information about the study and to further invite consumers to participate in the study.
Participants who do not show-up on the day of data collection but who had indicated that they would like to participate will be called by OnSite Health once more and invited to participate in the study on a second date shortly thereafter.

7.5 **Add Recruitment Material (e.g., advertisements, flyers, letters of introduction) - To add document: Click Add, click Browse, select desired document, click Open, title attachmnet, and then click OK. To edit, click on the link. To delete, check the checkbox and click Delete.**

**** If prompted with a Security Warning Named: _ClusterUploadApplet_, Publisher: CLICK WEBRIDGE INCORPORATED, then click "Run" to continue. This will enable you to add attachments properly. If you need assistance, please contact the Rhino Helpdesk at x4772.**

Name	Description	Version
Patient Recruitment Letter		0.01

7.6 *** After the project ends, is there a possibility the participants will be contacted to participate in future research?**
No

7.8 *** Please explain how you plan to obtain informed consent (and/or assent from youth) from this population. Describe the processes and methods (e.g., written, oral, implicit, passive) involved. For additional explanation of these methods, refer to http://intranet.rand.org/groups/hspc/consent.html .**
Consumers taking part in secondary data collection will come from clinics whose IRBs or Privacy Boards will have waived patient authorization for release of HIPAA-protected data to RAND for research purposes.

Consumers taking part in primary data collection (Patient Physical Health Exam and Patient Survey) will provide written, informed consent on the day of data collection. An OnSite Health staff member with experience working with psychiatric populations will completely review the informed consent form with consumers and answer their questions. Only consumers who provide written informed consent will participate in any study procedures. Participants in the study will be given a copy of the informed consent form to keep.
A copy of the consent form is appended to this application.

5.0 Population Detail for: Clinic Staff

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 17 of a possible 26 screens.

2.0 * **Please give the inclusion or selection criteria for participation in the research.**

Secondary Data Collection
-Quarterly reports: Will be collected from all PBHCI grantees. Grantees are required to provide these reports to SAMHSA as part of their PBHCI contracts.
-Clinical registry data abstraction: Will be collected from all PBHCI clinics who have obtained, and can demonstrate approval to release patient information to RAND.
NOTE: All n=56 PBHCI grantee clinics will participate in secondary data collection.

Primary Data Collection
Intervention clinics: Must be community behavioral health clinics participating in the PBHCI grantee program.
Control clinics: Must be community behavioral health clinics that are similar to PBHCI clinics on the following criteria:
-Geographic proximity to the intervention site
-Similar consumer population (age, primary diagnosis)
-Provision of similar behavioral health services
-Adequate program capacity and data infrastructure to support an evaluation
-Willingness and ability to serve as a control site
NOTE: n=3 intervention clinics and n=3 control clinics will participate in primary data collection

3.0 **What are the criteria for excluding individuals from the population described?**

Secondary Data Collection
-Clinical registry data abstraction: Failulre to demonstrate approval to release patient informaiton to RAND

Primary Data Collection:
-Intervention clinics: None
-Control clinics
-Provision of integrated primary care
-Different from the matched intervention site as follows: Physical distance of more than 75 miles from the intervention site, different consumer populations (age, primary dianosis), provision of different behavioral health services, inadquate program capacity and/or data infrastructure to support evaluation
-Unwilling or inability to serve as a control site

4.0 * **Are you going to intentionally exclude anyone because of gender, racial/ethnic groups, or language fluency?**

no

5.0 * **Please indicate which, if any, of the following vulnerable populations will be knowingly and intentionally *included*.**

- ☐ A. Children/minors
- ☐ B. Prisoners, incarcerated individuals, detainees, parolees, probationers
- ☐ C. Cognitively impaired persons
- ☐ D. Physically incapacitated
- ☐ E. Seriously or terminally ill
- ☐ F. Illegal immigrants
- ☐ G. Economically or educationally disadvantaged
- ☐ H. Other
- ☑ I. None of the above

Procedure: TRAC - Infrastructure Data

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- [ ] A. Interview/Survey (oral or written)
- [ ] B. Focus Group
- [ ] C. Observation of individual
- [ ] D. Socio-behavioral intervention
- [ ] E. Educational tests
- [ ] F. Psychological test, measurement, or assessment
- [ ] G. Physical exam, test, measurement, assessment (w/o specimen collection)
- [ ] H. Specimen collection/testing
- [ ] I. Clinical treatment
- [x] J. Previously collected individual level data or records
- [ ] K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- ( ) A. Primary Data
- (•) B. Secondary Data

Secondary Data Follow-Up Questions

We will ask a few secondary data questions at this point to determine if some of the population and procedure questions on the later screens can be skipped.

4.1 * **Can the data received by this RAND project (including RAND subcontractors) identify a specific individual by one of the following methods? (Check all that apply)**

- [ ] A. Direct identifiers included in the data file
- [x] B. Codes that can be linked with identities by someone
- [x] C. Inference

- [ ] D. Data cannot be identified by one of the above methods

4.2 * **Please check which institutions will be able to link the data with individual identities. (Check all that apply)**

- [ ] A. RAND
- [ ] B. RAND Subcontractor
- [ ] C. Primary Contractor (RAND is the subcontractor)
- [ ] D. Adjunct Staff/Collaborator
- [ ] E. Data Provider
- [x] F. Collaborator or Cooperating Institution

4.3 * **Is there any agreement involved in obtaining the data (e.g. web based agreement, data use agreement, other conditions on use)?**

- (•) A. Yes – Data Use Agreement
- ( ) B. Yes – Other paperwork
- ( ) C. No

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

- [ ] A. In Person
- [ ] B. Phone
- [ ] C. Mail
- [x] D. Web
- [ ] E. Audio/Video
- [ ] F. Other

2.0 * **Provide a step-by-step overview of the procedure(s).**
TRAC is SAMHSA's Transformation and Accountability System, a web-based repository for data intended to help SAMHSA monitor the quality and improvement of its grantees activities. PBHCI grantees are required, as specified in their contractual agreements with SAMHSA, to enter clinic-level infrastructure data into TRAC bi-annually. All PBHCI grantees will enter infrastructure data in TRAC.
A list of TRAC infrastructure items is appended to this application.

3.0 **Please describe the training procedures for the data collectors.**
All grantees attend several webinars teaching them how to use the TRAC system.

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

- (•) Yes
- ( ) No
- ( ) Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**
Grantees enter infrastructure data into TRAC bi-annually for the life of their 5-year grants.
RAND will only obtain and analyze TRAC data from Feb, 2011 - June, 2013.

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** no

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- ☐ A. Physical consequences (e.g., pain or discomfort)
- ☐ B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- ☐ C. Financial/economic harm
- ☐ D. Social harm (e.g., stigma of participation)
- ☐ E. Other
- ☑ F. No risk for this procedure

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- ☑ A. Substance use (e.g., alcohol, drug, tobacco)
- ☐ B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- ☐ C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- ☐ D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- ☐ E. Illegal activity
- ☐ F. Immigration status
- ☐ G. Sexual behavior
- ☐ H. Abuse/neglect (e.g., child, elder, domestic)
- ☐ I. Educational Records
- ☐ J. Employment History
- ☐ K. Financial information including employment/income
- ☐ L. Other
- ☐ M. None of the above

Secondary Data

3.0 * **Which secondary data set(s) will you acquire? If unsure, please list what you are considering.**
SAMHSA's TRAC infrastructure data for PBHCI grantees only.

4.0 * **Do you have the Data Use Agreement?**
yes

4.1 * **Upload the Data Use Agreement or other paperwork - Click Add to list data use agreement. To edit, click on the link. To delete, check the checkbox and click Delete.**
TRAC Data Use Agreement(0.01)

5.0 * **Do you plan to combine individual level data from two or more different data sources?**
yes

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- ○ Yes
- ◉ No
- ○ Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- ☑ A. Research team members who are RAND associates
- ☐ B. Research team members who are not RAND associates
- ☑ C. Data collection subcontractors, vendors, or other service providers
- ☐ D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- ◉ Yes
- ○ No
- ○ Don't know

8.1 * **If yes, when do you estimate the data identifiers or link files be destroyed? (mm/dd/yyyy)**
9/30/2013

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**
no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**
yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

Procedure: Patient Physical Health Exam

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- [ ] A. Interview/Survey (oral or written)
- [ ] B. Focus Group
- [ ] C. Observation of individual
- [ ] D. Socio-behavioral intervention
- [ ] E. Educational tests
- [ ] F. Psychological test, measurement, or assessment
- [x] G. Physical exam, test, measurement, assessment (w/o specimen collection)
- [x] H. Specimen collection/testing
- [ ] I. Clinical treatment
- [ ] J. Previously collected individual level data or records
- [ ] K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- (•) A. Primary Data
- ( ) B. Secondary Data

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

[x]	A.	In Person
[ ]	B.	Phone
[ ]	C.	Mail
[ ]	D.	Web
[ ]	E.	Audio/Video
[ ]	F.	Other

2.0 * **Provide a step-by-step overview of the procedure(s).**

Individuals who have provided written informed consent for primary data collection will participate in a physical health exam. The physical health exam will be conducted by trained and experienced staff from OnSite Health Diagnostics -- a national biometric and diagnostic health screening company (HIPAA compliant).
OnSite Health will perform the following patient assessments during the physical health exam:
Height, weight, body mass index (calculated from height and weight), blood pressure, waist circumference,

breath carbon monoxide (an indicator of tobacco smoke exposure; participant blows into a tube).
OnSite Health Diagnostics licensed and trained phlebotomists will also collect a blood sample (approximately 3 tablespoons) for the following tests: blood sugar and HgBA1C (diabetes indicators), cholesterol (total, HDL and LDL), and triglycerides.
OnSite staff will also ask participants if they succesfully fasted for 8 hours prior to the health exam; an 8 hour fast is necessary prior to the blood tests for diabetes indicators

3.0 **Please describe the training procedures for the data collectors.**
OnSite Health staff who are coordinating the data collection will undergo a half-day training session at their headquarters which will be attended and supplemented with material provided by RAND staff (Perlman). RAND materials will focus on strategies for working effectively with seriously mentally ill adults.

Each OnSite Health team will include a nurse or similar staff with extensive experience working with psychiatric populations.

OnSite staff doing the primary data collection are experienced physical health assessors. They will also receive an additional debriefing about the each site the morning of data collection.

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

- (•) Yes
- ( ) No
- ( ) Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**
Participants at Control Sites:
Participants at control sites will participate in two physical health exams, conducted one year apart. These two exams will represent a baseline assessment and 1-year follow-up assessment of participants' physical health.

Participants at Intervention Sites:
Participants at PBHCI intervention clinics will only take part in one physical health exam. This will occur in the second year of the study (Optional Year 1) because RAND will extract comparable baseline data for participants at intervention clinics from TRAC Physical Health data (see TRAC Physical Health procedures section; TRAC data do not exist for participants at control sites).

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** yes

5.1 * **If yes, what tests or measurements are you collecting?**
Height, weight, body mass index (calculated from height and weight), blood pressure, waist circumference, breath carbon monoxide (an indicator of tobacco smoke exposure; participant blow into a tube).
OnSite Health Diagnostics licensed and trained phlebotomists will also collect a blood sample (approximately 3 tablespoons) for the following tests: blood sugar and HgBA1C (indicators of diabetes), cholesterol (total, HDL and LDL), and triglycerides.

5.2 * **If yes, what are the plans to inform the respondents?**
OnSite Health Diagnostics will provide participants with the results of the mechanical assessment (Height, weight, body mass index, blood pressure, waist circumference, breath carbon monoxide) at the time of the assessment.
Copies of the results of blood tests will be mailed to participants when they are available from the lab (typically within 2 weeks of the assessment).
OnSite will also send copies of the results of the mechanical assessment and lab results to participants' primary care providers (at intervention sites) and to the medical directors at the participants' control clinics, respectively.
Note that there are no primary care providers at the control clinics.

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

7.0 * **Will biological sample(s) be collected solely for research purposes as part of this study? (e.g., sample(s) weren't collected for medical purposes)**

- (•) Yes

- ○ No
- ○ Don't Know

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.2 Biological Samples Questions

1.0 **Please indicate which biological sample types will be collected. (Check all that apply)**

- ☐ A. Urine
- ☑ B. Blood
- ☐ C. Saliva
- ☐ D. Hair
- ☐ E. Cell Sample
- ☑ F. Other, specify:

1.1 * **What other sample types will be collected?**
Breath carbon monoxide (indicator of tobacco smoke exposure)

2.0 **To what types of testing might the specimens be subjected?**

- ☑ A. Analysis for disease
- ☑ B. Analysis for drug(s)
- ☐ C. Genetic
- ☐ D. Other

3.0 * **Please provide the details of how and where the samples will be collected. Include the method (e.g., blood draw, saliva swab), person who will collect the specimen, volume and intervals between specimen collections, qualifications and supervision of the persons who will collect the specimens.**
OnSite Health Diagnostics will collect blood samples through venipuncture.
A licensed phlebotomist (or nurse) will collect the blood samples. Samples wil be approximately 3 tablespoods of blood. Sampling procedures will be supervised by a licensed, OnSite nurse.
Blood samples will test only for glucose and A1C, cholesterol and tryglycerides.
Breath samples for carbon monoxide are not stored (they dissepate immedately) and will only be used to indicate tobacco smoke exposure. Physical exams will be conducted in private rooms to protect participant confidentiality.

4.0 * **Will participants or others (e.g., doctors, teachers, parents) be notified of assessments or tests with individual clinical significance?** yes

4.1 * **If yes, please provide a detailed explanation of how and why participants or others will be notified of results. (e.g., out of range values, reportable diseases, only physicians will be notified)**
Results of breath carbon monoxide tests will be given to patients at the time of the screen.
For participants at PBHCI clinics, results of blood tests and breath tests will be given to the participant's PBHCI primary care provider.
For participants at control clinics, results of blood tests and breath tests will be given to the clinic's medical director. Control clinics do not employ primary care providers.

5.0 * **What will the be the ultimate disposition of the sample(s) collected during this study?**

- ◉ A. Destroyed at the end of this study
- ○ B. Anonymous sample(s) banked for future research

- ○ C. Identifiable sample(s) banked for future research

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- ☑ A. Physical consequences (e.g., pain or discomfort)
- ☑ B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- ☐ C. Financial/economic harm
- ☑ D. Social harm (e.g., stigma of participation)
- ☐ E. Other
- ☐ F. No risk for this procedure

Physical Pain/Discomfort

2.1 * **Might the *amount* of physical pain or discomfort be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
no

2.2 * **Might the *likelihood* of physical pain or discomfort be greater than ordinarily encountered in daily life by healthy individuals in the U.S?** no

2.3 * **Please explain the nature of the physical pain, what might cause it, and steps that would be taken to mitigate it.**
Participants may experience some physical discomfort during the venipuncture. Blood sampling will be done by licensed professionals.

Psychological Discomfort/Distress

3.1 * **Might the *amount* of pyschological discomfort or distress be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
yes

3.2 * **Might the *likelihood* of psychological discomfort or distress be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
yes

3.3 * **Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.**
Some participants might find it embarassing or uncomfortable to be touched by a healthcare provider whom they do not know very well. OnSite Health staff conducting the physical health exams will have undergone training to work effectively with seriously mentally ill adults and will have learned how to minimize any emotional discomfort associated with the procedures. Opposite sex providers and patients may request a staff person of the same sex as the participant to remain in the room during the physical assessment.

Social Harm

5.1 * **Might the *amount* of social harm be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
no

5.2 * **Might the *likelihood* of social harm be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
no

5.3 * **Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.**
Risks of social harm are associated with potential breaches of confidentiality. OnSite Health is experienced at preserving patient confidentiality and maintaining strict HIPAA compliance, as are the staff of this RAND team. Data will not bne stored with participant names and all linking information will be kept in a locked cabinet in the co-PI's (Scharf's) office.

6.5 Benefits, Confidentiality, Incentives, and Costs Questions

1.0 * **Please describe any specific benefits that might come to individuals from participating in this procedure.**
Participants will receive a free physical health exam, the results of the physical health exam, and $20 compensation in the form of a gift card after completing the physical health exam and accompanying survey.

2.0 * **Is confidentiality being promised to subjects?**
yes

3.0 * **Are comments or other information going to be attributed to individually identifiable participants in published reports, including by name or inference (e.g. other information that identifies individuals)?**
no

4.0 * **Will the participants receive an incentive?**
yes

4.1 * **If Yes, what will the participants receive as an incentive (e.g. cash, voucher, etc.)?**
Participants will receive a $20 gift card to a local major chain store (Target, Walmart) chosen by the local community behavioral healthcare center.

4.2 * **If Yes, how and when will the incentives be distributed to participants?**
Participants will receive the study incentive after they complete the informed consent form, the patient physical health exam and associated survey.

5.0 * **Might the subjects incur any additional costs by participating in the study that they would not otherwise incur and will not be reimbursed by the study?**
yes

5.1 * **If Yes, please explain.**
Participants will be responsible for the cost of transportation to the study site.

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- [x] A. Substance use (e.g., alcohol, drug, tobacco)
- [x] B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- [ ] C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- [ ] D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- [ ] E. Illegal activity
- [ ] F. Immigration status
- [ ] G. Sexual behavior
- [ ] H. Abuse/neglect (e.g., child, elder, domestic)
- [ ] I. Educational Records
- [ ] J. Employment History
- [ ] K. Financial information including employment/income
- [ ] L. Other
- [ ] M. None of the above

Primary Data

2.0 * **Check all types of identifying information that your research will acquire about these participants.**

- [x] A. Names (including names appearing on consent forms, payment receipts, or emergency contact on a medical record)
- [x] B. Location identifiers smaller than a state, some restrictions apply (click here for more details)
- [x] C. Dates directly related to the individual (e.g. birthdate), some restrictions apply (click here for more details).
- [x] D. Telephone numbers
- [x] E. Fax numbers
- [x] F. E-mail address
- [ ] G. Social security number
- [x] H. Medical record number
- [ ] I. Health plan beneficiary number
- [ ] J. Account numbers (including but not limited to student id's)
- [ ] K. Certificate/license number (e.g., driver's license, professional certificate, etc.)
- [ ] L. Vehicle identifiers and serial numbers, including license plate numbers
- [ ] M. Device identifiers and serial numbers (if associated with individual users)
- [ ] N. Web Universal Resource Locators (URLs) (if associated with individual users)
- [ ] O. Internet Protocol (IP) address numbers (if associated with individual users)
- [ ] P. Biometric indicators (e.g., finger prints, voice prints)
- [ ] Q. Full Face Photographic Images and any Comparable Images
- [ ] R. OTHER: Any other unique identifying number, characteristic, or code that could be used alone or in combination with any other available information to identify an individual
- [ ] S. OTHER: Any remaining information that could be used alone or in combination with any other available information to identify an individual who is subject of the information
- [ ] T. None of the above

2.2 * **Do you plan to apply for a Certificate of Confidentiality after you have an approved consent form?**

- ( ) Yes
- (•) No
- ( ) TBD

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- (•) Yes
- ( ) No
- ( ) Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- [x] A. Research team members who are RAND associates
- [ ] B. Research team members who are not RAND associates
- [x] C. Data collection subcontractors, vendors, or other service providers
- [ ] D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- (•) Yes
- ( ) No
- ( ) Don't know

8.1 * **If yes, when do you estimate the data identifiers or link files be destroyed? (mm/dd/yyyy)**
9/30/2013

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**
no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**
yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

Procedure: Clinical Registry Data Abstraction

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- ☐ A. Interview/Survey (oral or written)
- ☐ B. Focus Group
- ☐ C. Observation of individual
- ☐ D. Socio-behavioral intervention
- ☐ E. Educational tests
- ☐ F. Psychological test, measurement, or assessment
- ☐ G. Physical exam, test, measurement, assessment (w/o specimen collection)
- ☐ H. Specimen collection/testing
- ☐ I. Clinical treatment
- ☑ J. Previously collected individual level data or records
- ☐ K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- ○ A. Primary Data
- ◉ B. Secondary Data

Secondary Data Follow-Up Questions

We will ask a few secondary data questions at this point to determine if some of the population and procedure questions on the later screens can be skipped.

4.1 * **Can the data received by this RAND project (including RAND subcontractors) identify a specific individual by one of the following methods? (Check all that apply)**

- ☐ A. Direct identifiers included in the data file
- ☑ B. Codes that can be linked with identities by someone
- ☐ C. Inference
- ☐ D. Data cannot be identified by one of the above methods

4.2 * **Please check which institutions will be able to link the data with individual identities. (Check all that apply)**

- ☑ A. RAND
- ☐ B. RAND Subcontractor
- ☐ C. Primary Contractor (RAND is the subcontractor)
- ☐ D. Adjunct Staff/Collaborator
- ☑ E. Data Provider
- ☐ F. Collaborator or Cooperating Institution

4.3 * **Is there any agreement involved in obtaining the data (e.g. web based agreement, data use agreement, other conditions on use)?**

- ○ A. Yes – Data Use Agreement
- ◉ B. Yes – Other paperwork
- ○ C. No

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

- ☐ A. In Person
- ☐ B. Phone
- ☐ C. Mail
- ☑ D. Web
- ☐ E. Audio/Video
- ☐ F. Other

2.0 * **Provide a step-by-step overview of the procedure(s).**
Only PBHCI grantees will participate in clinical registry data abstraction.
Every 3 months, grantees will upload clinical registry data to RAND's secure PBHCI SharePoint site. Each grantee's data is only available to site administrators and not to other grantees.

3.0 **Please describe the training procedures for the data collectors.**
PBHCI grantees will have already attended a webinar teaching them about which data to abstract from their records and how to transmit this data securely to RAND through the secure PBHCI secure SharePoint site. SAMHSA has also funded a large Training and Technical Assistance Center which grantees can use to help them with registry set-up, maintenance, data abstraction, and data transfer to RAND.

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

- ◉ Yes
- ○ No
- ○ Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**
Data will be submitted quarterly for the life of the evaluation (Feb 2011 - June 2013).

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** no

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- [ ] A. Physical consequences (e.g., pain or discomfort)
- [ ] B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- [ ] C. Financial/economic harm
- [ ] D. Social harm (e.g., stigma of participation)
- [ ] E. Other
- [x] F. No risk for this procedure

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- [x] A. Substance use (e.g., alcohol, drug, tobacco)
- [x] B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- [x] C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- [ ] D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- [ ] E. Illegal activity
- [ ] F. Immigration status
- [ ] G. Sexual behavior
- [ ] H. Abuse/neglect (e.g., child, elder, domestic)
- [ ] I. Educational Records
- [ ] J. Employment History
- [ ] K. Financial information including employment/income
- [ ] L. Other
- [ ] M. None of the above

Secondary Data

3.0 * **Which secondary data set(s) will you acquire? If unsure, please list what you are considering.**
Data will be extracted from PBHCI grantees' clinical registries. We will not extract all registry data. Data fields will be limited to a unique patient identifier, the date of the encounter, and physical health, mental health, substance use, and wellness services received, as well as the providers seen associated with these services. A spreadsheet detailing the data to be collected is appended to this application.

4.0 * **Do you have the Data Use Agreement?**
no

5.0 * **Do you plan to combine individual level data from two or more different data sources?**
yes

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- (●) Yes
- ( ) No
- ( ) Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- [x] A. Research team members who are RAND associates
- [ ] B. Research team members who are not RAND associates
- [x] C. Data collection subcontractors, vendors, or other service providers
- [ ] D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- (●) Yes
- ( ) No
- ( ) Don't know

8.1 * **If yes, when do you estimate the data identifiers or link files be destroyed? (mm/dd/yyyy)**
9/30/2013

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**
no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**
yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

Procedure: Quarterly Reports

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- [ ] A. Interview/Survey (oral or written)

- [ ] B. Focus Group
- [ ] C. Observation of individual
- [ ] D. Socio-behavioral intervention
- [ ] E. Educational tests
- [ ] F. Psychological test, measurement, or assessment
- [ ] G. Physical exam, test, measurement, assessment (w/o specimen collection)
- [ ] H. Specimen collection/testing
- [ ] I. Clinical treatment
- [x] J. Previously collected individual level data or records
- [ ] K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- ( ) A. Primary Data
- (•) B. Secondary Data

Secondary Data Follow-Up Questions

We will ask a few secondary data questions at this point to determine if some of the population and procedure questions on the later screens can be skipped.

4.1 * **Can the data received by this RAND project (including RAND subcontractors) identify a specific individual by one of the following methods? (Check all that apply)**

- [x] A. Direct identifiers included in the data file
- [ ] B. Codes that can be linked with identities by someone
- [ ] C. Inference
- [ ] D. Data cannot be identified by one of the above methods

4.2 * **Please check which institutions will be able to link the data with individual identities. (Check all that apply)**

- [x] A. RAND
- [ ] B. RAND Subcontractor
- [ ] C. Primary Contractor (RAND is the subcontractor)
- [ ] D. Adjunct Staff/Collaborator
- [ ] E. Data Provider
- [ ] F. Collaborator or Cooperating Institution

4.3 * **Is there any agreement involved in obtaining the data (e.g. web based agreement, data use agreement, other conditions on use)?**

- ( ) A. Yes – Data Use Agreement
- (•) B. Yes – Other paperwork
- ( ) C. No

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

☐	A.	In Person
☐	B.	Phone
☐	C.	Mail
☑	D.	Web
☐	E.	Audio/Video
☐	F.	Other

2.0 * **Provide a step-by-step overview of the procedure(s).**
PBHCI grantee clinics will upload their quarterly reports to the RAND secure PBHCI SharePoint site every 3 months.Quarterly reports are collected by SAMHSA for ongoing quality improvement efforts. RAND is using these reports as a secondary data source to help support the national-level evaluation.

3.0 **Please describe the training procedures for the data collectors.**
PBHCI grantees will have already attended a webinar teaching them how to complete the quarterly reports and how to upload them to the secure PBHCI SharePoint site.

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

- ◉ Yes
- ○ No
- ○ Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**
PBHCI grantees will upload quarterly reports to the secure SharePoint site every three months throughout the life of the evaluation (Feb, 2011 - June, 2013).

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** no

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- ☐ A. Physical consequences (e.g., pain or discomfort)
- ☐ B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- ☐ C. Financial/economic harm
- ☐ D. Social harm (e.g., stigma of participation)

- ☐ E. Other
- ☑ F. No risk for this procedure

3.1 * **If yes, please explain why and under what conditions comments may be associated with participants in published reports.**
The population of grantees is small. Given the unique features of several programs (e.g., mobile treatment unit; specialty dental clinic) some programs could be identified by inference. No programs will be identified by name.

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- ☐ A. Substance use (e.g., alcohol, drug, tobacco)
- ☐ B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- ☐ C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- ☐ D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- ☐ E. Illegal activity
- ☐ F. Immigration status
- ☐ G. Sexual behavior
- ☐ H. Abuse/neglect (e.g., child, elder, domestic)
- ☐ I. Educational Records
- ☐ J. Employment History
- ☐ K. Financial information including employment/income
- ☐ L. Other
- ☑ M. None of the above

Secondary Data

3.0 * **Which secondary data set(s) will you acquire? If unsure, please list what you are considering.**
Quarterly reports are collected by SAMHSA for ongoing quality improvement. Our RAND team plans to use these reports secondarily to support the national-level evaluation. We plan to collect these reports directly from grantees through the PBHCI secure SharePoint site.

4.0 * **Do you have the Data Use Agreement?**
no

5.0 * **Do you plan to combine individual level data from two or more different data sources?**
yes

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- ○ Yes
- ◉ No
- ○ Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- ☑ A. Research team members who are RAND associates
- ☐ B. Research team members who are not RAND associates
- ☐ C. Data collection subcontractors, vendors, or other service providers
- ☐ D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- ○ Yes
- ◉ No
- ○ Don't know

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**

no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**

yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

Procedure: Patient Survey

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- ☑ A. Interview/Survey (oral or written)
- ☐ B. Focus Group
- ☐ C. Observation of individual
- ☐ D. Socio-behavioral intervention

- ☐ E. Educational tests
- ☐ F. Psychological test, measurement, or assessment
- ☐ G. Physical exam, test, measurement, assessment (w/o specimen collection)
- ☐ H. Specimen collection/testing
- ☐ I. Clinical treatment
- ☐ J. Previously collected individual level data or records
- ☐ K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- ◉ A. Primary Data
- ○ B. Secondary Data

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

☑	A.	In Person
☐	B.	Phone
☐	C.	Mail
☐	D.	Web
☐	E.	Audio/Video
☐	F.	Other

2.0 * **Provide a step-by-step overview of the procedure(s).**

After providing informed consent, participants will be asked to complete a brief (20 minute) survey including questions about demographics, daily role functioning, tobacco, drug and alcohol use, housing status, education, employment and recent arrests, client perceptions of care, social connectedness, health service utilization, diet and nutrition, physical activity and physical fitness, physical health and healthcare, and their medications and associated side effects. The survey is designed to be self-administered, however OnSite Health Diagnostics staff will be available to assist participants read and complete the survey if they so choose. Surveys will be completed in private booths to maintain confidentiality of participants' responses.

3.0 **Please describe the training procedures for the data collectors.**

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

- ◉ Yes
- ○ No
- ○ Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**

Participants at matched control sites will complete the survey once at baseline and once at a 1-year follow-up session.

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** no

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- ☐ A. Physical consequences (e.g., pain or discomfort)
- ☑ B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- ☐ C. Financial/economic harm
- ☑ D. Social harm (e.g., stigma of participation)
- ☐ E. Other
- ☐ F. No risk for this procedure

Psychological Discomfort/Distress

3.1 * **Might the *amount* of pyschological discomfort or distress be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
yes

3.2 * **Might the *likelihood* of psychological discomfort or distress be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
yes

3.3 * **Please explain the nature of the discomfort or distress, what might cause it, and steps that would be taken to mitigate it.**
Some participants may find it embarassing to answer questions about their physical, mental, or behavioral health. Some participants may also feel pressured to exaggerate their satisfaction with the care they receive at their community behavioral healthcare center because data collection is taking place at that location.
We have taken steps to mitigate these risks:
1. Participants will complete surveys in private booths or rooms.
2. Independent data collectors (OnSite Health staff) will be adminstering questions about their perceptions of care.
3. Participants will be reminded that all survey data will be kept strictly confidential and will not be shared with their care team (unlike the results of the physical health exam).

Social Harm

5.1 * **Might the *amount* of social harm be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
no

5.2 * **Might the *likelihood* of social harm be greater than ordinarily encountered in daily life by healthy individuals in the U.S.?**
no

5.3 * **Please explain the nature of the social harm, what might cause it, and steps that would be taken to mitigate it.**
Risks of social harm are associated with potential breaches of confidentiality. OnSite Health is experienced at preserving patient confidentiality and maintaining strict HIPAA compliance, as is this RAND team. Data will not be stored with participant names and all linking information will be kept in a locked cabinet in the co-PIs (Scharf's) office.

6.5 Benefits, Confidentiality, Incentives, and Costs Questions

1.0 * **Please describe any specific benefits that might come to individuals from participating in this procedure.**
There are no direct benefits to participants for completing the Patient Survey except for the study incentive (a $20 giftcard).

2.0 * **Is confidentiality being promised to subjects?**
yes

3.0 * **Are comments or other information going to be attributed to individually identifiable participants in published reports, including by name or inference (e.g. other information that identifies individuals)?**
no

4.0 * **Will the participants receive an incentive?**
yes

4.1 * **If Yes, what will the participants receive as an incentive (e.g. cash, voucher, etc.)?**
Participants who complete the informed consent form, patient survey AND physical health exam will receive a $20 gift card to a large, local chain store (e.g., Walmart, Target) selected by the community behavioral healthcare center.

4.2 * **If Yes, how and when will the incentives be distributed to participants?**
Incentives will be given to participants as soon as they complete the informed consent form, the physical health exam and the patient survey.

5.0 * **Might the subjects incur any additional costs by participating in the study that they would not otherwise incur and will not be reimbursed by the study?**
yes

5.1 * **If Yes, please explain.**
Participants will incur the costs associated with their travel to the study site.

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- [x] A. Substance use (e.g., alcohol, drug, tobacco)
- [x] B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- [x] C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- [ ] D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- [x] E. Illegal activity
- [ ] F. Immigration status
- [ ] G. Sexual behavior
- [ ] H. Abuse/neglect (e.g., child, elder, domestic)
- [ ] I. Educational Records
- [ ] J. Employment History
- [ ] K. Financial information including employment/income
- [ ] L. Other
- [ ] M. None of the above

Primary Data

2.0 * **Check all types of identifying information that your research will acquire about these participants.**

- [x] A. Names (including names appearing on consent forms, payment receipts, or emergency contact on a medical record)
- [x] B. Location identifiers smaller than a state, some restrictions apply (click here for more details)
- [x] C. Dates directly related to the individual (e.g. birthdate), some restrictions apply (click here for more details).
- [x] D. Telephone numbers
- [ ] E. Fax numbers
- [x] F. E-mail address
- [ ] G. Social security number
- [x] H. Medical record number
- [ ] I. Health plan beneficiary number
- [ ] J. Account numbers (including but not limited to student id's)
- [ ] K. Certificate/license number (e.g., driver's license, professional certificate, etc.)
- [ ] L. Vehicle identifiers and serial numbers, including license plate numbers
- [ ] M. Device identifiers and serial numbers (if associated with individual users)
- [ ] N. Web Universal Resource Locators (URLs) (if associated with individual users)
- [ ] O. Internet Protocol (IP) address numbers (if associated with individual users)
- [ ] P. Biometric indicators (e.g., finger prints, voice prints)
- [ ] Q. Full Face Photographic Images and any Comparable Images
- [ ] R. OTHER: Any other unique identifying number, characteristic, or code that could be used alone or in combination with any other available information to identify an individual
- [ ] S. OTHER: Any remaining information that could be used alone or in combination with any other available information to identify an individual who is subject of the information
- [ ] T. None of the above

2.2 * **Do you plan to apply for a Certificate of Confidentiality after you have an approved consent form?**

- ( ) Yes
- (•) No
- ( ) TBD

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- (•) Yes
- ( ) No
- ( ) Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- [x] A. Research team members who are RAND associates
- [ ] B. Research team members who are not RAND associates
- [x] C. Data collection subcontractors, vendors, or other service providers
- [ ] D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- (•) Yes
- ( ) No
- ( ) Don't know

8.1 * **If yes, when do you estimate the data identifiers or link files be destroyed? (mm/dd/yyyy)**
9/30/2013

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**
no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**
yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

Procedure: TRAC - Physical Health Exam and Lifestyle Survey

6.0 Procedure Overview - Part A

2.0 * **Which of the following describes this procedure? (Check all that apply)**

- [ ] A. Interview/Survey (oral or written)
- [ ] B. Focus Group
- [ ] C. Observation of individual
- [ ] D. Socio-behavioral intervention

- ☐ E. Educational tests
- ☐ F. Psychological test, measurement, or assessment
- ☐ G. Physical exam, test, measurement, assessment (w/o specimen collection)
- ☐ H. Specimen collection/testing
- ☐ I. Clinical treatment
- ☑ J. Previously collected individual level data or records
- ☐ K. Other research procedures:

3.0 **Please indicate the type of data that will be associated with this procedure.**

- **Primary data**: New data you will create. Includes data that is created by abstracting information from existing records into a new dataset.
- **Secondary data**: Acquisition of existing datasets that contain individual level data (i.e. not aggregate data).

- ○ A. Primary Data
- ◉ B. Secondary Data

Secondary Data Follow-Up Questions

We will ask a few secondary data questions at this point to determine if some of the population and procedure questions on the later screens can be skipped.

4.1 * **Can the data received by this RAND project (including RAND subcontractors) identify a specific individual by one of the following methods? (Check all that apply)**

- ☐ A. Direct identifiers included in the data file
- ☑ B. Codes that can be linked with identities by someone
- ☐ C. Inference
- ☐ D. Data cannot be identified by one of the above methods

4.2 * **Please check which institutions will be able to link the data with individual identities. (Check all that apply)**

- ☑ A. RAND
- ☐ B. RAND Subcontractor
- ☐ C. Primary Contractor (RAND is the subcontractor)
- ☐ D. Adjunct Staff/Collaborator
- ☐ E. Data Provider
- ☑ F. Collaborator or Cooperating Institution

4.3 * **Is there any agreement involved in obtaining the data (e.g. web based agreement, data use agreement, other conditions on use)?**

- ◉ A. Yes – Data Use Agreement
- ○ B. Yes – Other paperwork
- ○ C. No

6.0 Procedure Overview - Part B

1.0 * **What are the mode(s) of data collection used in this procedure? (Check all that apply)**

- ☑ A. In Person

☐	B.	Phone
☐	C.	Mail
☐	D.	Web
☐	E.	Audio/Video
☐	F.	Other

2.0 * **Provide a step-by-step overview of the procedure(s).**

Each consumer enrolled in the PBHCI program is required to complete a physical health exam and lifestyle survey at entry into PBHCI services, every six months, and at discharge from the program.

The lifestyle survey is SAMHSA's National Outcomes Measures tool, which is built into TRAC, SAMHSA's Transformation Accountability system. The TRAC system is a web-based system through which all SAMHSA CMHS grants report performance measurement data. The NOMs tool (attached) includes questions about: demographics, functioning, stability in housing, education and employment, crime and criminal justice, perception of care, social connectedness, reassessment status, clinical status at discharge, and clinical services received.

The NOMs lifestyle survey is administered by a trained grantee staff person and entered directly into the TRAC system.

Participants in the PBHCI program also undergo regular screenings for physical health conditions. PBHCI grantee medical staff (or staff at a partnering medical organization) are required to check blood pressure, height, weight, body mass index on a quarterly basis, and enter the information to TRAC every 6 months. They may optionally check for and report waist circumference and breath carbon monoxide during these assessments. Participants also undergo an annual blood test for either blood glucose or HgBA1C, as well as tryglycerides, and cholesterol (total, HLD, LDL). PBHCI grantee clinic staff enter these data into the TRAC system once per year, coinciding with a NOMs survey

3.0 **Please describe the training procedures for the data collectors.**

Staff participate in several webinars to learn how to administer the lifestyle survey and to upload survey and physical health data to the TRAC system. Staff who complete the physical health exam are licensed medical personnel funded by the PBHCI grant.

4.0 * **Will individuals participate in this procedure more than once? (e.g., a longitudinal study)**

◉	Yes
○	No
○	Possibly

4.1 * **If yes or possibly, at what intervals and how many intervals?**

Consumers enrolled in PBHCI services will complete the survey and physical health assessment at intake into integrated care, every six months, and at discharge from the PBHCI program. Physical health indicators from blood tests (as above) are collected annually.

5.0 * **Are you collecting any tests or measurements where the individual's well-being might be affected by not knowing the results?** yes

5.1 * **If yes, what tests or measurements are you collecting?**

Mechanical measures: Height, weight, body mass index, blood pressure, waist circumference, and breath carbon monoxide (indicator of tobacco smoke exposure).
Blood test: blood glucose or HgBA1C (markers of diabetes), triglycerides, and cholesterol (total, HDL and LDL)

5.2 * **If yes, what are the plans to inform the respondents?**

Data are being collected by participants' regular primary care team who are responsible for informing patients of any results requiring follow-up or treatment.

6.0 * **Will participants be assigned to experimental and control/comparison conditions at the individual or group level?** no

8.0 * **Will any drug, substances, nutrients, or supplements be administered as part of this procedure?** no

6.4 Risk Questions

1.0 * **Which of the following might be encountered during participation? (Check all that apply)**

- ☐ A. Physical consequences (e.g., pain or discomfort)
- ☐ B. Psychological consequences (e.g., distress, embarrassment, or pressure to participate)
- ☐ C. Financial/economic harm
- ☐ D. Social harm (e.g., stigma of participation)
- ☐ E. Other
- ☑ F. No risk for this procedure

6.6 Data Collection Questions

1.0 * **Will any of the following sensitive information be acquired about an individual? (Check all that apply)**

- ☑ A. Substance use (e.g., alcohol, drug, tobacco)
- ☑ B. Physical health (e.g., diagnosis, treatment, reportable diseases, sexually transmitted diseases)
- ☑ C. Mental Health (e.g., diagnosis, treatment, institutionalization, suicidality, assessment)
- ☐ D. Traumatic events (e.g. victimization, bereavement, accident, etc.)
- ☑ E. Illegal activity
- ☐ F. Immigration status
- ☐ G. Sexual behavior
- ☐ H. Abuse/neglect (e.g., child, elder, domestic)
- ☐ I. Educational Records
- ☑ J. Employment History
- ☐ K. Financial information including employment/income
- ☐ L. Other
- ☐ M. None of the above

Secondary Data

3.0 * **Which secondary data set(s) will you acquire? If unsure, please list what you are considering.**
We will get TRAC physical health and lifestyle survey (NOMs survey) from the TRAC contractor for PBHCI grantees only.

4.0 * **Do you have the Data Use Agreement?**
yes

4.1 * **Upload the Data Use Agreement or other paperwork - Click Add to list data use agreement. To edit, click on the link. To delete, check the checkbox and click Delete.**
TRAC Data Use Agreement(0.01)

5.0 * **Do you plan to combine individual level data from two or more different data sources?**
yes

Data Identifiability

6.0 * **Will private health information (e.g., medical records, administrative data, health insurance claims, pharmaceutical data) be acquired from a doctor or other health care provider, hospital, insurance company, managed care company, or other covered entity under HIPAA?**

- ○ Yes
- ◉ No
- ○ Not Sure

7.0 * **Will any of the following people have access to the identifiable data? (Check all that apply)**

- ☑ A. Research team members who are RAND associates
- ☐ B. Research team members who are not RAND associates
- ☑ C. Data collection subcontractors, vendors, or other service providers
- ☐ D. Anyone who is not on the research team

8.0 * **Will the data identifiers or link file be destroyed?**

- ◉ Yes
- ○ No
- ○ Don't know

8.1 * **If yes, when do you estimate the data identifiers or link files be destroyed? (mm/dd/yyyy)**
9/30/2013

9.0 **Will any information that you collect go into non-research records (e.g. medical, educational, or employment records) that is not maintained and controlled solely by the project?**
no

10.0 **Do you have a Data Safeguarding Plan (DSP)?**
yes

10.1 **Please upload the Data Safeguarding Plan (DSP).**

name	version
Data Safeguarding Plan	0.01

7.0 Informed Consent

Required fields are indicated with a red asterisk (*) to the left of the question.
You are on screen 25 of a possible 26 screens.

1.0 *** Will informed consent be administered in languages other than English?**
no

2.0 *** Individuals must be given enough information to make an informed participation decision. Which elements of informed consent, if any, do you wish to omit or alter? (Check all that apply)**

- ☐ A. That the project is a research study
- ☐ B. Purpose of the research, what organizations are conducting and sponsoring it
- ☐ C. That participation is voluntary
- ☐ D. Procedures (nature, duration, etc.)
- ☐ E. Risks from participation, if any
- ☐ F. Benefits to the individual from participation, if any
- ☐ G. How the project will treat confidential data
- ☐ H. Point of contact for questions or problems
- ☑ I. None of the above

3.0 **Please upload all informed consent documents (e.g., written consent form, oral scripts) - To add document: Click Add, click Browse, select desired document, click Open, title attachment, and then click OK. To edit, click edit. To delete, check the checkbox and click Delete.**

**** If prompted with a Security Warning Named: _ClusterUploadApplet_, Publisher: CLICK WEBRIDGE INCORPORATED, then please click "Run" to continue. This will enable you to add attachments properly. If you need assistance, please contact the Rhino Helpdesk at x4772.**

Name	Description	Version
Informed consent document for primary data collection		0.01

5.0 *** Making the assumption there would be a signed consent document, would it be the only record linking the participant and the research?**
yes

5.1 *** If yes to 5.0 above, would the principal risk to participants be potential harm resulting from a breach of confidentiality?**
no

8.0 Conclusion

1.0 * **What are the potential benefits of the research to society?**

This evaluation of SAMHSA's PBHCI program will provide the first rigorous evaluation of a nation-wide effort to integrate primary care services into community behavioral healthcare centers. Data from this evaluation will be used to determine if integrating primary care into community behavioral healthcare centers improves the physical and mental health of persons with serious mental illness who receive care at community behavioral health care centers. It will also be used to describe the structural and clinical approaches to integration being implemented at community behavioral health care centers, as well as which models and respective model features have the greatest impact on seriously mentally ill consumers' physical and mental health.

2.0 * **Does the proposed research activity involve any ethical issues not already discussed in the study application?**

no

2.1 * **If yes, please explain:**

3.0 **Attach other miscellaneous documents.** **To add document: Click Add, click Browse, select desired document, click Open, title attachment, and then click OK. To edit, click Edit. To delete, click Reset.**

If prompted to download or run a program while trying to attach a document, please follow the directions to do so. To learn more click here.

Name	Description	Version
Clinical Registry Abstraction Data Template		0.01
Patient Survey		0.01
Quarterly Report Template		0.01
TRAC Infrastructure Data Fields		0.01
TRAC Patient Lifestyle Survey (NOMs)		0.01