



Office for Human Research Protections
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October 15, 2007

Gary R. Butchen
Executive Director
Bridge Back Recovery Homes, Inc.
6823 5th Avenue
Brooklyn, NY 11220

RE: Human Research Subject Protections Under SAMHSA Grant
Research Project: Project New Life Path
Principal Investigator: Gary Butchen, CSW-R, CASAC and Richard Juman, Ph.D.
Project Number: NOFA #TI 04-001

Dear Mr. Butchen:

The Office for Human Research Protections (OHRP) has reviewed the responses of Bridge Back Recovery Homes (BBRH) to OHRP's August 21, 2006 and June 25, 2007 letters regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR part 46) involving Project New Life Path (PNLP), a service program for previously incarcerated homeless women with substance abuse disorders, funded by the HHS Substance Abuse and Mental Health Services Administration (SAMHSA).

Based on the description of PNLP in BBRH's grant proposal to SAMHSA in response to NOFA #TI 04-001, and BBRH's letters to OHRP on or around September 23, 2006 and July 31, 2007, OHRP makes the following determinations regarding PNLP:

(1) HHS regulations at 45 CFR 46.102(d) define *research* as follows:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The PNLN grant proposal submitted to SAMHSA describes the Project as follows:

Bridge Back Recovery Homes Inc's Project New Life Path will establish an enhanced, specially trained Assertive Community Treatment ("ACT") team that will offer outreach, engagement, in vivo treatment, and wraparound case management services to 450 women of color who are homeless or will be homeless upon their release from prison, and are forced by their lack of fiscal resources and/or inability to organize existing supports, to accept referral to a shelter or live on the streets of New York City (NYC). The target population is comprised of formerly incarcerated women of color, all of whom have been diagnosed with a substance use disorder and most of whom have histories of trauma, serious and persistent mental illness, approximately 18% of whom have HIV/AIDS, and 78% of whom have children from whom prison has forced separation....The proposed ACT team will work with NYC shelters and the New York State Division of Parole to link clients to transitional or permanent housing, with continuing and intensive, but flexible supports.... Project staff will employ the "best practice" ACT team model and will be trained in additional skills that will enhance the basic ACT model with services specifically required by the target population: the Seeking Safety trauma treatment model; Motivational Enhancement Therapy; a derivative Functional Family Therapy; and HIV/AIDS prevention and treatment. (BBRH Proposal for Project New Life Path responding to NOFA #TI 04-001 ("BBRH's Proposal for PNLN"), Application Abstract, Page 1).

PNLN also includes an evaluation component which collects data to assess service effectiveness. The evaluation study quantifies client participation in an array of services including housing placement, substance abuse treatment, psychiatric evaluation and treatment, entitlements and legal advocacy, HIV testing and counseling, primary health care, vocational counseling, and family counseling. Client outcomes are collected using a pre/post research design which includes a baseline and two follow-up interviews, at 6 months and program discharge.

In addition, a detailed and comprehensive computerized record is created for each client over the course of treatment which documents the frequency, time, staffing, site, content and other features of each ACT program activity. Using this database, participation statistics may be analyzed on a per client, per staff member, or per type of service basis. The clinical record includes: (1) an intake evaluation (including psychiatric characteristics, symptoms, and current/past treatment, sexual abuse, drug use, HIV status and risk category), (2) treatment plan (primary health care, vocational training, HIV counseling, housing placement), (3) progress notes (toxicology findings, clinical impressions, physical exam results) and (4) referral tracking (contacts with clients, collaterals or agencies to implement the treatment plan). Program implementation is evaluated for fidelity to key ACT standards adapted from Teague, Drake and Ackerson (1995). Analyses consist of calculating descriptive statistics (such as frequencies and averages) for service use and referral, outcome indicators, and client characteristics. Comparisons between types of services,

client subgroups, client participation (i.e., completers vs. drop-outs), and status subgroups are also conducted. BBRH's Proposal for PNLP, Pages 30-34).

The grant includes a Participant Informed Consent document which states:

Purpose of Research: The goal of this evaluation is to assess the effectiveness of the PNLP Project and general knowledge about how to improve services for women released from prison who are homeless and who reside in the shelter or on the street. The knowledge that is gained from this evaluation is expected to be useful in improving treatment services for women released from the state correctional system.

OHRP finds that PNLP's evaluation study as described in BBRH's Proposal for PNLP submitted in response to NOFA #TI 04-001 constitutes *research* as defined in HHS regulations at 45 CFR 46.102(d). The evaluation study is a systematic investigation designed to develop or contribute to generalizable knowledge. The grant describes the evaluation plan as a concerted effort to collect and analyze data in order to determine whether PNLP's enhanced ACT service model will benefit women released from prison with substance abuse disorders by promoting their transition to permanent housing and family reunification. OHRP notes that a former investigator for the evaluation study stated the following in a letter appended to the PNLP grant application: "I believe that this proposed study, albeit challenging, will address and potentially answer several serious questions regarding services for this population".

(2) OHRP finds that BBRH conducted HHS-supported and non-exempt human subjects research without an active assurance of compliance with OHRP. Specifically, OHRP finds that a federalwide assurance for the PNLP evaluation study was filed on May 10, 2005 but expired on August 14, 2006. OHRP notes that the research does not fall within the exemption at 45 CFR 46.101(b)(3) for survey and interview research because individual-level client clinical records containing identifiable private information, in addition to interview and survey results, are included in the evaluation database.

(3) In accordance with HHS regulations at 45 CFR 46.108(b) and 46.110, all non-exempt human subjects research must be reviewed by a convened institutional review board (IRB) unless expedited review is permissible. HHS regulations at 45 CFR 46.110(b)(1) limit the use of expedited review procedures to minimal risk research meeting specific categories published in the Federal Register at 63 FR 60364--60367 (see <http://www.dhhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).

It appears from documentation BBRH provided to OHRP that the PNLP evaluation study was reviewed by a two person subcommittee of the National Development and Research Institutes, Inc. (NDRI) IRB on March 15, 2005, and that the convened IRB subsequently confirmed the "expedited approval" at a meeting on May 10, 2005. (See March 23, 2005 letter from Paul Jayne, IRB secretary, to Dr. Nancy Jainchill). OHRP finds that the IRB inappropriately applied

expedited review to research that involves greater than minimal risk, and that does not appear in the categories of research published in the Federal Register.

(4) OHRP finds that BBRH failed to conduct continuing review of the PNLP evaluation study at least once per year, as required by HHS regulations at 45 CFR 46.109(e). Specifically, OHRP finds that no IRB has reviewed the ongoing PNLP evaluation study since May 10, 2005.

(5) With respect to the allegation that that the IRB failed to make required findings in accordance with 45 CFR 46.305-306 when reviewing research involving prisoners as subjects, OHRP finds that BBRH did not enroll prisoners as subjects in PNLP. OHRP notes BBRH's statement in its July 31, 2007 letter to OHRP:

At the request of the Correctional Programs, PHLP and many other grant-funded programs will routinely travel up to the prisons and describe for the inmates the services offered. It is ultimately the inmate's decision to select (or not) a program they are interested in attending. A brief non-clinical screening and pre-interview are conducted. The prisons release their inmates to the NYC shelter system. PNLP is notified of the inmate's release date and shelter location. PNLP then engages the woman at the shelter, conducts the GPRA (Government Performance and Results Act of 1993) [survey instrument for collecting data on mental illness and substance abuse required by SAMHSA], and enrolls her in the program.

Required Actions: By November 19, 2007, please provide OHRP with corrective action plans to address findings (1) – (4) above.

OHRP has the following additional concerns about PNLP:

[Redacted]

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Gary R. Butchen, Executive Director – Bridge Back Recovery Homes, Inc.
October 15, 2007

Please submit your response to the above concerns so that OHRP receives it no later than November 19, 2007.

OHRP appreciates the commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Carol J. Weil, J.D.
Division of Compliance Oversight

cc: Terry Cline, Ph.D., Administrator, SAMHSA
Mr. John Randall, IRB Chair, NDRI
Dr. Ivor Pritchard, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Kristina Borrer, OHRP
Ms. Shirley Hicks, OHRP
Dr. Irene Stith-Coleman, OHRP
Ms. Pat El-Hinnawy, OHRP
Ms. Kelley Booher, OHRP
Mr. Barry Bowman, OHRP