DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration
Center for Mental Health Services
Center for Substance Abuse Treatment

Guidance for Applicants (GFA) No. SM 01- 013
Part I - Programmatic Guidance

Cooperative Agreements for CMHS/CSAT Collaborative Program on Homeless Families: Women with Psychiatric, Substance Use, or Co-Occurring Disorders and their Dependent Children – Phase 2

Short Title: Homeless Families Program – Phase 2

Application Due Date: April 18, 2001

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Authority: Sections 501(d)(5), 520(A) and 509 of the Public Health Service Act, as amended,

and subject to the availability of funds

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Agency

The Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services and Center for Substance Abuse Treatment.

Action and Purpose

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) and Center for Substance Abuse Treatment (CSAT), invite currently funded grantees under the "Cooperative Agreements for CMHS/CSAT Collaborative Program on Homeless Families: Women with Psychiatric, Substance Use, or Co-Occurring Disorders and Their Dependent Children," GFA No. 99-011, to submit applications for Phase 2 cooperative agreements.

The overall goal of the Homeless Families program is to evaluate time-limited, multi-faceted interventions targeted to homeless mothers with psychiatric, substance use, or co-occurring disorders who are caring for their dependent children.

The Homeless Families program is being conducted in two phases. In Phase 1 of this initiative, study sites were required to identify and describe interventions designed to foster movement out of homelessness, increase stability in housing placement, increase family preservation or reunification, decrease alcohol and drug use, foster trauma recovery, and improve mental health and social functioning. Sites could request funds to augment services as needed to support the subsequent cross-site evaluation with the proviso that they secure alternate sources of funding to continue these services through Phase 2. In Phase 2 (the focus of this GFA), study sites will conduct evaluations of their interventions using the cross-site protocol developed by the Steering Committee in Phase 1 (see Appendices A & B). Study sites will compare their documented intervention with an alternative treatment condition using experimental or quasi-experimental designs. Projects may use additional measures to conduct a site-specific study.

It is estimated that $3.4 million will be available to support 6 to 8 awards under this GFA in FY 2001. The average award is expected to be in the range of $425,000 to $567,000 in total costs (direct plus indirect). Actual funding levels will depend upon the availability of appropriated funds and the number of applicants funded.

Support should be requested for a period of 3 years (in three budget periods of one year each). Annual awards will depend on the availability of funds and progress achieved.

Note: Funding for services and/or augmentation allowed in Phase 1 will no longer be provided in Phase 2. Applicants are expected to demonstrate that alternate sources of funding have been secured to continue supporting the enhanced services developed in Phase 1.

Program Goals

The primary goals of Phase 2 of the program are to answer the following questions:

- Are intensive, time-limited (< 9 months), multi-faceted interventions for homeless families more effective than alternative treatments in fostering:
  - improvement in mental health functioning;
  - reduced drug and alcohol use;
  - trauma recovery;
  - participation in treatment, support, and training programs;
  - employment;
  - movement to safer and more stable housing;
  - improved parental functioning;
  - family preservation; and
  - improved child outcomes?

- Are there consistent key dimensions of intensive, time-limited (<9 months), multi-faceted interventions for homeless families across the study sites that appear to be positively associated with the above outcomes?

Note: In order to achieve the program goals stated above, each grantee must conduct a rigorous test of the effectiveness of the intervention documented in Phase 1, using either an experimental design or a non-equivalent control group quasi-experimental design. See Appendix A for a summary of the cross-site evaluation design approved by the Steering Committee.

Who Can Apply?

As stipulated in the Phase 1 GFA, eligibility to apply for Phase 2 awards will be limited to Phase 1 grantees. Continuation into Phase 2 is competitive and will be limited to those sites who have satisfied the requirements of Phase 1 and who can demonstrate the capacity to participate fully in the cross-site study. Not all Phase 1 grantees will necessarily continue into Phase 2.

Application Kit

Application kits have several parts. This document is Part I. Part I is different for each GFA. Part II has general policies and procedures that apply to **all** SAMHSA grants and cooperative agreements. You will need to use both Parts I and II for your application. Part II is enclosed.

Complete application kits for this program will be mailed to each Phase 1 grantee.

To obtain additional application kits, including Parts I and II, you may:

Call the Knowledge Exchange Network (KEN), phone number: 800-789-2647. The address for KEN is provided in Part II.

Application kits may also be downloaded from the SAMHSA site at www.SAMHSA.gov. Go to the “grants” link.

Where to Send the Application

Send the **original and 2 copies** of your grant application to:

SAMHSA Programs
Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC-7710
Bethesda, MD 20892-7710*

*Change the zip code to 20817 if you use express mail or courier service.

Please note:

- Use application form PHS 5161-1
- Be sure to type:
  "SM 01– 013 Homeless Families Program: Phase 2" in Item Number 10 on the face page of the application form.
- Please use the exact address listed above.

Application Date

Your application must be received by *April 18, 2001*. Applications received after this date will be accepted only if they have a proof-of-mailing date from the carrier no later than 1 week before the deadline date.

Private metered postmarks are not acceptable as proof of timely mailing. Late applications will be returned without review.

Contacts for Further Information

For questions on program issues, contact:

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G.T. (Gigi) Belanger, or
Pamela J. Fischer, Ph.D.
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Substance Abuse and Mental Health Services Administration
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Rockville, MD 20857
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E-Mail: lrickard@samhsa.gov
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Cheryl Gallagher, M.A., or
James M. Herrell, Ph.D.
Clinical Intervention and Organizational Models Branch
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockwall II, 7th Floor
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Rockville, MD 20857
(301) 443-7259 (CG)
(301) 443-2376 (JH)
E-Mail: cgallagh@samhsa.gov
jherrell@samhsa.gov

For questions on grants management issues, contact:

Gwendolyn Simpson
Grants Management Specialist
Division of Grants Management, OPS
Substance Abuse and Mental Health
Services Administration
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Cooperative Agreements

These awards are being made as cooperative agreements because the complexity of the program requires substantial involvement of Federal staff.

Role of Federal Staff

The Cooperative Agreement mechanism includes appreciable post-award Federal programmatic participation by CMHS and CSAT staff in the conduct of the project. Federal staff will:

- Provide the Federal interpretation on the provisions of the GFA and protect Federal interests.
- Monitor the overall progress of the program and study sites.
- Conduct periodic site visits to each project to monitor the implementation of the family intervention and evaluation activities.
- Consult on the modification of project designs to accommodate cross-site data collection and analysis.
- Provide technical assistance to sites on the implementation of site-specific and cross-site evaluations, client tracking, data collection, and data analysis.
- Provide training for site staff on such topics as diagnostic issues, trauma recovery, and parenting skills.
- Participate on the Steering Committee and subcommittees.
- Convene Steering Committee meetings.
- Collaborate on the analysis of data, preparation of publications, and conference presentations to disseminate program findings.

Role of the Study Site

By accepting the cooperative agreement award, the grantee agrees to:

- Comply with all aspects of the Terms and Conditions of the cooperative agreement.
- Participate and cooperate fully with CMHS and CSAT staff, the Steering Committee, and the Coordinating Center in the implementation of the cross-site evaluation.
- Cooperate with CMHS and CSAT staff in accepting guidance and responding to requests for information relevant to the Homeless Families Program.
- Implement the cross-site common

protocol, cross-site study design, and cross-site quality control mechanisms (e.g., tracking programs and data entry programs) approved by the Steering Committee.

Note: Data collection for the cross-site protocol requires approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This data collection may not begin until OMB approval (currently being sought by CMHS) is received.

- Implement site-specific fidelity and outcome evaluations.
- Participate on the Steering Committee (up to three 2-day meetings per year).
- Abide by decisions of the Steering Committee.
- Abide by the publication policy recommendations developed by the Steering Committee.
- Co-author publications to disseminate cross-site study findings.
- Take advantage of the technical assistance that will be provided by CMHS and CSAT staff and the Coordinating Center in post award activities.
- Appoint a consumer representative and alternate to the Consumer Panel and facilitate their participation in the project (see Appendix C). Sites should:
  - provide logistical support and assume the costs for transportation, hotel, *per diem*, and incidental expenses for consumer representatives attending Steering Committee meetings (up to three 3-day meetings per year); and
  - budget for consumer participation in grant-related activities (for consumers who are not agency staff). Phase 2 budget requests may include up to 24 days remuneration and compensation for additional work related expenses like transportation, childcare, telephone calls, and Internet access.

Role of the Coordinating Center

A five-year cooperative agreement was awarded in FY 99 for a Coordinating Center to work with study sites throughout the Homeless Families Program. In Phase 2, the Coordinating Center will:

- Coordinate the overall study.
- Develop and maintain a common cross-site data repository, manage data, and monitor data quality.
- Analyze cross-site data.
- Participate on the Steering Committee and subcommittees.
- Facilitate the activities of the Steering Committee, using a consensus building process.
- Provide training and technical assistance to study sites regarding the cross-site study.
- Convene and provide logistical support

for up to three 2-day Steering Committee meetings and three 3-day Consumer Panel meetings per year in

the Washington, D.C. area and arrange for conference calls:

- Assign two consumers from the Coordinating Center to serve on the Consumer Panel, consult with consumers on issues as they arise, and help coordinate the Consumer Panel.

- Submit an annual report that summarizes progress, interim findings, and lessons learned.

- Develop a comprehensive final report that summarizes the findings of the cross-site studies.

- Coordinate the dissemination activities including identification of core papers and conference presentations.

- Author or co-author publications to disseminate program findings.

Role of the Consumer Panel

The Consumer Panel will be composed of the consumer representatives from each of the study sites and the Coordinating Center. The Chair and Co-Chair of the Consumer Panel will be elected by the members of the Consumer Panel annually. The Consumer Panel will:

- Advise the Steering Committee, Coordinating Center, and Federal GPOs on the implementation of the cross-site evaluation from the consumer perspective. Of particular interest are the issues of:

  - interview and data collection procedures,
  - issues related to obtaining informed consent,
  - participant protection,
  - confidentiality,
  - the interpretation and implications of study results, and
  - input on the final reports.

- Participate in Steering Committee meetings, Subcommittee activities (including organizing presentations on key consumer issues), and conference calls.

Role of the Steering Committee

The Steering Committee will be composed of the Project Directors from each of the study sites, consumer representatives from each of the study sites, the Coordinating Center, and CMHS and CSAT Government Project Officers. The roles of the Steering Committee components are as follows:

- CMHS and CSAT staff, the Coordinating Center, and the Consumer Panel will:

  - participate in all activities and deliberations of the Steering Committee,
  - not chair the Steering Committee,
  - have only a single vote each.

- The Project Directors will:

  - participate in all activities and deliberations of the Steering

Committee, and
- have one vote per site.

- The chair of the Steering Committee will be appointed by CMHS/CSAT Directors.

The Steering Committee will have the responsibility of working with the Coordinating Center in conducting the following cross-site activities:

- Design the cross-site study and analysis plan.

- Develop policies on:

  - data sharing,
  - access to data and materials, and
  - publications, conference, and presentations.

- Develop consensus on decisions (majority vote will determine decisions where consensus cannot be reached).

- Form subcommittees of the Steering Committee, as needed, to consider topics relevant to the cross-site study.

- Convene up to three times a year in the Washington, D.C., area (additional meetings may be called to address issues relevant to the cross-site study).

- Develop procedures for deciding authorship and writing publications.

Note: Publications on which SAMHSA staff are included as authors or co-authors may require agency clearance.

Funding Criteria

Decisions to fund a cooperative agreement under this announcement will be based upon:

- The overall technical merit of the application as determined by the Peer Review Committee, and with concurrence by the CMHS and CSAT Advisory Councils.

- Geographical distribution of study sites.

- Balance in intervention approaches across projects.

- Availability of funds.

Post-Award Requirements

Phase 2 grantees will be required to:

- Comply with the GFA requirements and the Terms and Conditions of Awards.

- Submit an annual report that includes:

  - project progress,
  - changes in key personnel,
  - problems incurred and how they were addressed,
  - alterations in approaches utilized,
  - actual expenditures for the year,
  - proposed plans for the next budget period, and
  - a proposed budget and budget justification for the next budget year.

- Submit a final report at end of project that includes:

- < project findings,
- < lessons learned, and
- < implications for services.

- C Submit other reports as requested by CMHS and CSAT staff.

- C Provide data so that SAMHSA can comply with the Government Performance Results Act (GPRA) reporting requirements.

Note: Instructions regarding the format and contents of the reports will be provided to each grantee by the GPO.

Target Population

The target of the intervention will be homeless mothers with psychiatric and/or substance use disorders who are caring for their dependent children. However, the underlying assumption of this initiative is that as mothers advance in their recovery and improve their functioning and skills, their children will also demonstrate improvement on behavioral and functional indicators. Thus, although child focused interventions are beyond the scope of this GFA, it is crucial that measures of child response be part of the study design.

- C In order to be included in the cross-site study population, mothers must meet the following criteria (as defined in Appendix D):

  - < be new entrants into the programs,
  - < be aged 18 years and older;
  - < meet criteria for being homeless or doubled-up;
  - < have psychiatric, substance use, or co-occurring disorders;
  - < be the current head of the household (women living with partners at program entry may be included provided the women have major financial and custodial responsibility for the children); and
  - < be the custodial parent of at least one minor child (women pregnant with their first child at program entry are **not** eligible for inclusion into the cross-site study).

Detailed Information on What to Include in Your Application

In order for your application to be **complete and eligible**, it must include the following in the order listed. Check off areas as you complete them for your application.

‘ ***1. FACE PAGE***

Use Standard Form 424. See Appendix A in Part II for instructions. In signing the face page of the application, you are agreeing that the information is accurate and complete.

‘ ***2. ABSTRACT***

Your total abstract may not be longer than 35 lines.

In the first 5 lines or fewer of your abstract, write a summary of your project that can be used in publications, reporting to

Congress, or press releases, if funded.

‘ ***3. TABLE OF CONTENTS***

Include page numbers for each of the major sections of your application and for each appendix.

‘ ***4. BUDGET FORM***

Standard Form 424A. See Appendix B in Part II for instructions.

‘ ***5. PROJECT NARRATIVE AND SUPPORT DOCUMENTATION***

These sections describe your project. The Project Narrative is made up of Sections A through E. More detailed information of A-E follows #10 of this checklist. Sections A-E may not be longer than 35 pages.

G **Section A -** Description of the Target Population, Intervention, and Completion of Phase 1 Requirements

G **Section B -** Evaluation Design - Cross-Site Study

G **Section C -** Evaluation Design - Site-Specific Study

G **Section D -** Data Collection and Analysis

G **Section E -** Project Management and Staffing Plan

The support documentation for your application is made up of sections F through I.

There are no page limits for the following sections, except for Section H, the Biographical Sketches/Job Descriptions.

G **Section F-** Literature Citations
This section must contain complete citations, including titles and all authors, for any literature you cite in your application.

G **Section G -** Budget Justification, Existing Resources, Other Support

Fill out sections B, C, and E of the Standard Form 424A. Follow instructions in Appendix B, Part II.

NOTE: Although the budget for the proposed project is not a review criterion, the Review Group will be asked to comment on the budget after the merits of the application have been considered.

G **Section H -** Biographical Sketches and Job Descriptions

-- Include a biographical sketch for the Project Director/principal Investigator, Evaluator, Project Coordinator, Data Coordinator, Interviewers and other key positions. Each sketch should not be longer than **2 pages**. If the person has not been hired, include a letter of commitment with the sketch.

-- Include job descriptions for key personnel. They should not be longer than **1 page**.

-- ***Sample sketches and job***

descriptions are listed in Item 6 in the Project Narrative section of the PHS 5161-1.

G Section I- Confidentiality and SAMHSA Participant Protection (SPP)

The seven areas you need to address in this section are outlined after the *Project Narrative Sections A - E Highlighted* section of this document.

‘ ***6. APPENDICES 1 THROUGH 4***
--Use only the appendices listed below.
--**Don't** use appendices to extend or replace any of the sections of the Project Narrative (reviewers will not consider them if you do).
--**Don't** use more than **30 pages** (plus all instruments) for the appendices.

Appendix 1: Site Specific Data Collection Instruments

Appendix 2: Sample Consent Forms

Appendix 3: Letters of Commitment - Organizations

Appendix 4: Letters of Commitment - Consultants

‘ ***7. ASSURANCES***
Non- Construction Programs. Use Standard form 424B found in PHS 5161-1.

‘ ***8. CERTIFICATIONS***

‘ ***9. DISCLOSURE OF LOBBYING ACTIVITIES***
Please see Part II for lobbying prohibitions.

‘ ***10. CHECKLIST***
See Appendix C in Part II for instructions.

Project Narrative– Sections A Through E Highlighted

Your application consists of responding to sections A through I. **Sections A through E, the project narrative parts of your application, describe what you intend to do with your project.** Below you will find detailed information on how to respond to sections A through E.

- **T** Sections A though E may not be longer than **35** pages.

- **T** A peer review committee will assign a point value to your application based on how well you address these sections.

- **T** The number of points after each main heading shows the maximum points a review committee may assign to that category.

- **T** Reviewers will also be looking for plans to address cultural competence. Points will be awarded to applications that adequately address the cultural aspects of the review criterion (see Appendix D, Part II).

- **T** Reviewers will assign points to each of the sections on the basis of the adequacy, thoroughness, quality, and appropriateness of the descriptions, information, and examples provided; the scientific and technical merit of evaluation plans; and demonstrated capacity to participate in and conduct rigorous cross-site and site-specific evaluations that are consistent with the goals of the GFA.

Section A: Description of the Target Population, Intervention, and Completion of Phase 1 Requirements (30 Points)

General Instructions: In order to be successful in Phase 2 applicants must have completed Phase 1 requirements. In this section applicants must provide sufficient detail to demonstrate completion of Phase 1 requirements. In addressing this section, pay particular attention to:

- **P** The adequacy, thoroughness, quality, and appropriateness of descriptions, information, and examples provided.

- **P** Demonstrating the scientific and technical merit of the process evaluation conducted in Phase 1.

- **P** The inclusion in the interventions of key minimum program components required by the GFA (i.e., mental health and/or substance abuse treatment, trauma recovery services, housing services, parenting, and goal setting).

Applicants must provide information on Phase I activities, as follows

- **C** Provide a profile of the target population of homeless mothers and children. Include descriptors such as:

  - < demographic characteristics of mothers and children (including racial and ethnic composition and language assistance needs),
  - < family size and composition,
  - < education and work history,

- < income,
- < housing history,
- < history of homelessness,
- < legal/criminal history,
- < assessment of skill development needs,
- < health status of mothers and children,
- < mental health and substance abuse status and treatment history,
- < trauma history, and
- < treatment and support needs.

C Describe methods used to collect information on the target population.

C Describe the patterns in treatment and service use for your study site.

C Summarize the pathways by which homelessness occurred.

C Describe the process evaluation of the identified treatment and comparison interventions that was conducted in Phase 1.

C Document the **current existence** of the time-limited, multi-faceted, and intensive treatment intervention (including any enhancements) that is being provided to the target population. Include information on the length of time the intervention has been in existence.

C Describe any changes to the intervention that were undertaken in Phase 1 to support the cross-site or site-specific evaluations to be conducted in Phase 2. Specifically:

- < describe what changes, enhancements, or capacity expansion were made;
- < describe why they were made;
- < indicate when they were implemented;
- < describe who received the modified intervention and service enhancements; and
- < identify funding sources to maintain the enhancements and/or capacity expansion through Phase 2.

C Discuss the appropriateness and applicability of the intervention to the target population.

C Describe methods used to assure that the intervention described is being implemented as designed. If multiple treatment and control sites are proposed, provide evidence of consistency in implementation at each site.

C Document the potential effectiveness of the intervention through case studies, focus groups, or other qualitative methods.

C Describe how the intervention has been implemented (i.e., qualifications, number and role of staff, timing/stages of the intervention, and where the intervention is delivered).

C Describe how consumers contributed to the design of the cross-site and site-specific evaluation designs and how they will be involved in the implementation of the intervention and the cross-site evaluation in Phase 2.

C Provide a logic model of the intervention that depicts the

relationships among the conceptual framework of the intervention; theory and methods; target population; environmental context, intervention components; and the goals, objectives, and anticipated outcomes. Compare and contrast with the cross-site logic model (Appendix B).

- Describe the **environmental context** in which the **intervention** is implemented, including:
  - comprehensiveness of the agency,
  - service linkages,
  - housing availability,
  - availability and accessibility of services, and
  - the impact or anticipated impact of TANF regulations on homeless mothers.

- Identify and describe the **components** of the **intervention**, including:
  - eligibility criteria, recruitment procedures, and retention strategies;
  - screening methods;
  - length of the intervention;
  - assessment of psychiatric, substance use, or co-occurring disorders, trauma and homelessness;
  - provision of health, mental health, and substance abuse treatment and other services;
  - provision of trauma recovery services;
  - procurement of housing that is safe, affordable, and stable; and
  - provision of parenting, household management, vocational training, and other skills assessment and training.

- For mental health, substance abuse and trauma recovery components, describe where and how the services are being provided, educational background of staff providing the services, and any specialized or advanced training they have received relevant to the components.

- Describe the **components** of the **comparison** program as above, but also include:
  - problems and issues it is designed to address,
  - key contrasts between the intervention and the alternate treatment condition,
  - where and by whom the comparison program will be offered, and
  - what "services as usual" constitute (if that will be the comparison).

- Describe the **key ingredients** of the **intervention** program, including:
  - the anticipated effect of each component,
  - contrasts and similarities to key ingredients in the comparison program, and
  - how the relative effects will be determined if the proposed intervention has more than one component or more than one homeless families intervention is proposed.

- Describe the program structure for both the intervention and comparison sites,

including:

- < administrative and service staff,
- < budget,
- < facilities, and
- < other elements essential to the intervention.

Section B: Evaluation Design - Cross-Site Study (30 Points)

General Instructions: The applicants must provide an evaluation plan, using either an experimental or quasi-experimental design, for participation in the systematic cross-site outcome evaluation that will compare the effectiveness of the intervention program with an alternative treatment condition during Phase 2 of the program. In addressing this section, pay particular attention to:

- P Demonstrating the capacity to participate in and conduct a rigorous evaluation that is consistent with the cross-site design.
- P The adequacy, thoroughness, quality, and appropriateness of descriptions, information, and examples provided.
- P The scientific and technical merit of the cross-site evaluation plan.
- P The extent to which the Phase 1 findings were used to inform the evaluation design.

The evaluation plan should describe the applicant's approach for carrying out key tasks during the 3-year Phase 2 project period as follows:

- C Summarize the plan for the Phase 2 cross-site evaluation of the documented intervention.
- C Describe how the site will address the cross-site questions and hypotheses.
- C Discuss the threats to internal and external validity and how they will be addressed.
- C Describe selection procedures for the intervention and the comparison groups, including eligibility criteria, recruitment and retention strategies, and sources for study participants.
- C Provide the rationale for choosing either an experimental or quasi-experimental design for the evaluation and describe how the selection contributes to the cross-site approach.
- C If an experimental design is proposed, describe:
  - < the process for how random assignment will be achieved and implemented,
  - < the number of potential participants in the eligible pool,
  - < safeguards against corruption of the randomization, and
  - < contingency plans for the break-down of the random assignment process.
- C If a quasi-experimental design is proposed, describe the strategies for assignment into the study and comparison conditions, the number of participants anticipated for each condition, and the similarities and differences of each population on key

demographic, history and experiential variables.

- Provide a power analysis on the study mothers that describes:
  - anticipated sample size,
  - alpha level,
  - anticipated statistical tests (including controls for sampling error),
  - justification for the projected effect size, and
  - how the evaluation design affects the power.

- Provide a power analysis on the children (ages 2 to 16) to be included in the study that describes:

  - anticipated sample size and its adequacy for the analysis of the child measures,
  - alpha level,
  - anticipated statistical tests (including controls for sampling error), and
  - justification for the projected effect size.

- Provide data that demonstrate the ability of the grantee to recruit and retain adequate numbers of participants into each group, including:

  - agency capacity on a daily/yearly basis,
  - average tenure and client flow in the program,
  - recruitment time frame,
  - projected attrition rates,
  - treatment of drop-outs, and
  - alternative strategies for increasing numbers in cases of shortfalls.

- Describe strategies for client tracking and follow-up for each group.

- Provide evidence of commitment from other relevant organizations and

  proposed collaborators in support of the proposed evaluation.

- Provide evidence that the site's study population is diverse in terms of age, gender, racial/ethnic and cultural characteristics, and reflects the community in need of services.

- Document commitment to participate with the Coordinating Center in implementing the cross-site study and adhering to the common data collection protocol.

- Describe the capacity to contribute to the goals of the GFA and expanding the knowledge base regarding interventions directed to the target population.

Section C: Evaluation Design – Site-Specific Study (10 points)

General Instructions: In addition to participating in the cross-site study, each grantee must conduct a site-specific study that fits within the scope of the Program Goals. This site-specific study may be one that is entirely independent from the cross-site study, or it may be an extension of the cross-site study in that it uses the same participants but asks additional questions and/or adds additional target populations that fit within the guidelines of this GFA. In addressing this section, pay particular

attention to:

- The adequacy, thoroughness, quality, and appropriateness of descriptions, information, and examples provided.

- The scientific and technical merit of the site-specific study.

The site-specific evaluation plan should:

- Discuss the goals and purpose of the site-specific evaluation.

- Provide the specific evaluation questions to be examined by the site-specific study and hypotheses to be tested.

- Discuss the compatibility of the site-specific study with the goals of the cross-site study.

- If a different study and/or comparison group will be used, describe:

  - eligibility criteria,
  - recruitment strategies and sources for study participants, and
  - strategies for assignment into study and comparison conditions.

- If the intervention and/or comparison group is altered, provide a power analysis that describes:

  - anticipated sample size,
  - alpha level,
  - anticipated statistical tests (including controls for sampling error), and
  - justification for the projected effect size.

- Describe the use of any qualitative data collection approaches.

- List any other information to be collected and the sources of data.

- Provide evidence of commitment from other relevant organizations and proposed collaborators in support of the proposed evaluation.

- If more than two comparison models will be evaluated during Phase 2, describe the rationale for selecting the additional comparison models.

- Provide evidence that the proposed evaluation plan is sensitive to age, gender, racial/ethnic and cultural characteristics of the target population.

- Demonstrate the capacity to contribute to the goals of the GFA and expand the knowledge base regarding interventions directed to the target population.

Section D: Data Collection and Analysis (20 Points)

General Instructions: The applicant must describe plans for collecting, managing, and analyzing cross-site and site-specific data and reporting results of the evaluation studies. In addressing this section, pay particular attention to:

- Demonstrating the capacity to participate in and conduct a rigorous evaluation that is consistent with the cross-site design.

- The adequacy, thoroughness, quality,

and appropriateness of descriptions, information, and examples provided.

Describe plans for collecting, managing, and analyzing cross-site and site-specific data and reporting results of the evaluation studies:

- Describe the recruitment, qualifications, training, and supervision of interviewers who reflect the cultural composition of the target population.

- Describe the data collection plan including methods of quality assurance.

C Describe the protocol developed for providing assistance to women who exhibit potential problems during the baseline or follow-up interviews, including decompensation, suicidal ideation, traumatic flashbacks, child abuse, or threat of imminent danger from a domestic partner. Describe how interviewers will be trained in clinical and cultural competency issues to better understand and recognize when an interview participant may need assistance.

C Describe the data management plan including storage of site-specific data and provision of cross-site data to the Coordinating Center.

C Describe the responsibilities of the Data Coordinator and how regular and frequent contact will maintained with the Coordinating Center throughout the various phases of the evaluation.

C Describe plans to monitor and ensure the integrity of the implementation of the intervention (i.e., fidelity or process evaluation).

C Describe the analytic methods and techniques to be used.

C Discuss any limitations on the generalizability of the findings.

C Discuss how consumers will participate and contribute to the data collection efforts and interpretation and dissemination of the findings.

C Discuss plans for preparing interim and final reports, conference presentations, publications, and other means of disseminating the evaluation findings.

Section E: Project Management and Staffing Plan (10 Points)

General Instructions: Applicants must demonstrate their ability to carry out the proposed Phase 2 activities in terms of staffing and management plans. In addressing this section, pay particular attention to:

P Demonstrating the capacity to participate in and conduct a rigorous evaluation that is consistent with the cross-site design.

P The adequacy, thoroughness, quality, and appropriateness of descriptions, information, and examples provided.

Applicants must demonstrate their ability to carry out the proposed Phase 2 activities by providing

information on the following staffing and management plans:

- Describe the qualifications and experience of the key personnel, including:
  - project director,
  - evaluator,
  - analytic and data management staff,
  - interviewers,
  - consumer representative/alternate, and
  - other key personnel.
- Document the capability and experience of the applicant organization with similar projects and populations.
- Provide evidence of the capability, experience, and commitment of proposed consultants and subcontractors, including letters of commitment (attach as Appendices 3 & 4).
- Assign responsibility for specific tasks described in the evaluation plan to named staff.
- Demonstrate the feasibility of accomplishing the project in terms of:
  - management plan
  - time frames,
  - complementarity of skills in project staff,
  - adequacy and availability of resources (e.g., staffing, facilities, equipment, cooperating agencies).
- Describe the extent to which the staffing and management plans, project organization, and other resources are appropriate to carrying out all aspects of the proposed project.
- Demonstrate that the staff is reflective of or sensitive to the diversity of the target population; sensitive to age, gender, race/ethnicity, and other cultural factors related to the target population and, as appropriate, to the community to be served.
- Describe your plans for conducting cultural competence training specific to the target population, including the components of the training curriculum, credentials of trainer(s), target staff, incorporation into programs, and use as criteria for retention and/or promotion.
- Describe any need for interpreters on staff and discuss plans to assure availability and training of interpreters in mental health and substance abuse issues.

Confidentiality and SAMHSA Participant Protection (SPP)

You must address 7 areas regarding confidentiality and SAMHSA participant protection in your supporting documentation. However, no points will be assigned to this section.

This information will:

- reveal if the protection of participants is adequate or if more protection is needed.

/ be considered when making funding decisions.

Some projects may expose people to risks in many different ways. In Section I of your application, you will need to:

- Report any possible risks for people in your project,
- State how you plan to protect them from those risks, and
- Discuss how each type of risk will be dealt with, or why it does not apply to the project.

The following 7 issues must be discussed:

Ø Protect Clients and Staff from Potential Risks:

- Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse effects.
- Discuss risks which are due either to participation in the project itself, or to the evaluation activities.
- Describe the procedures that will be followed to minimize or protect participants against potential health or confidentiality risks. Make sure to list potential risks in addition to any confidentiality issues.
- Give plans to provide help if there are adverse effects to participants, if needed in the project.
- Where appropriate, describe alternative treatments and procedures that might be beneficial to the subjects.
- Offer reasons if you do not decide to use other beneficial treatments.

Ù Fair Selection of Participants:

- Describe the target population(s) for the proposed project. Include age, gender, racial/ethnic background. Address other important factors such as homeless youth, foster children, children of substance abusers, pregnant women, or other special population groups.
- Explain the reasons for using special types of participants, such as pregnant women, children, institutionalized or mentally disabled persons, prisoners, or others who are likely to be vulnerable to HIV/AIDS.
- Explain the reasons for including or excluding participants.
- Explain how you will recruit and select participants. Identify who will select participants.

Ú Absence of Coercion:

- Explain if participation in the project is voluntary or required. Identify possible reasons why it is required. For example, court orders requiring people to participate in a program.
- If you plan to pay participants, state how participants will be awarded money or gifts, and the anticipated amount or value of such payments.
- State how volunteer participants will be told that they may receive services and incentives even if they do not complete

the study.

Û Data Collection:

- Identify from whom you will collect data. For example, participants themselves, family members, teachers, others. Explain how you will collect data and list the site. For example, will you use school records, interviews, psychological assessments, observation, questionnaires, or other sources?

- Identify what type of specimens (e.g., urine, blood) will be used, if any. State if the material will be used just for evaluation and research or if other use will be made. Also, if needed, describe how the material will be monitored to ensure the safety of participants.

- Provide in Appendix No. 3, "Site-specific Data Collection Instruments/Interview Protocols," copies of all available data collection instruments and interview protocols that you plan to use.

Ü Privacy and Confidentiality:

- Describe how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.
- Describe:
  -How you will use data collection instruments.
  - Where data will be stored.
  - Who will or will not have access to information.
  - How the identity of participants will be kept private. For example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data.

NOTE: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

Ý Adequate Consent Procedures:

- List what information will be given to people who participate in the project. Include the type and purpose of their participation. Include how the data will be used and how you will keep the data private.

- State:
  - If their participation is voluntary.
  - Their right to leave the project at any time without problems.
  - Risks from the project.

  - Plans to protect clients from these risks.

- Explain how you will get consent for youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

  Note: If the project poses potential physical, medical, psychological, legal, social, or other risks, you should get written informed consent.

- Indicate if you will get informed consent from participants or from their parents or legal guardians. Describe how the consent will be documented. For example: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give

them copies of what they sign?

- Include sample consent forms in your Appendix 4, titled "Sample Consent Forms." If needed, give English translations.

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or releases your project or its agents from liability for negligence.

- Describe if separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both the treatment intervention and for the collection of data. Will individuals who do not consent to having individually identifiable data collected for evaluation purposes be allowed to participate in the project?

- Risk/Benefit Discussion:

- Discuss why the risks are reasonable compared to expected benefits and importance of the knowledge from the project.

Appendix A: Summary of the Cross-Site Evaluation Design

Overview

The Homeless Families Program – Phase 2 cross-site study provides an unprecedented opportunity to identify, describe, and systematically examine time-limited, multi-faceted interventions for a population of homeless women with psychiatric, substance use, or co-occurring disorders who are caring for their dependent children. The cross-site study is designed to answer the following questions:

- Are intensive, time-limited interventions (< 9-months) for homeless women with psychiatric and/or substance use disorders and histories of trauma associated with more positive outcomes than alternative treatments for both the women and their dependent children?

- Are there consistent key dimensions in these interventions across the sites that are associated with positive outcomes?

During Phase 1, the Steering Committee (comprised of the Principle Investigators from each of fourteen individual study sites, the Consumer Panel, the Coordinating Center, and the Federal Government) designed the cross-site study, including the underlying conceptual framework, the study participant data collection protocol, and the parameters and logistics guiding the cross-site data collection.

Conceptual Framework

A cross-site logic model was developed by the Steering Committee in Phase I that outlines the cross-site conceptual framework for the study (see Appendix B). In addition to the assumptions underlying the program, the logic model details the outcomes for the mothers and children that are expected if the interventions are effective and the key ingredients in the interventions that are believed to be critical to achieving effective outcomes. Also detailed in the logic model are the individual and contextual factors that are believed to moderate the achievement of outcomes, and factors that serve as mediators to the achievement of long-term outcomes.

This logic model served as a tool for developing a common cross-site data collection instrument and will serve as a basis for developing the cross-site analysis plan.

Study Participant Data Collection

Study Eligibility

Families eligible for the study are those who are new entrants to the treatment and comparison programs under study and who meet the following criteria:

- are literally homeless — lacking a fixed, regular, and adequate nighttime residence, including a primary nighttime residence is:

  - a supervised public or private shelter designed to provide temporary living accommodations; or
  - an institution that provides a temporary residence for individuals intended to be institutionalized; or
  - a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings; or
  - time-limited/non-permanent transitional housing arrangements for individuals

engaged in mental health and/or substance abuse treatment.

- are living doubled-up — in a temporary living situation where their name is not on the lease and they are subject to the hospitality and whims of the host.

- are female-head of a households with at least one minor child, where the mother:

  - is over 18 years of age and is primary custodian of minor children;
  - is caring for her dependent children, or temporarily separated from her children for while receiving treatment; and
  - has experienced DSM-IV Axis I mental health or substance use problem within the past year.

Note: Because of Child Behavioral Check List constraints, only children between the ages of 2 to 16 years will be included in the cross-site study for measurement purposes.

Study Recruitment

Families who are new entrants to the targeted treatment and comparison interventions and who meet the above eligibility criteria will be recruited for the study prior to or upon entry into the program. Consent procedures will be handled on an individual site basis with each needing IRB approval.

An "intent to treat" protocol will be followed, provided the participant completes the baseline interview. Therefore, no specified amount of treatment is required for enrollment in the study.

- Interviewers will be individually trained in administration of the interviews and as often as possible will share the characteristics of the study population.

- Interviews will be conducted in a centralized location that is private and safe for both the study participant and staff.

- Arrangements will be made so children will not be present during interviews.

Domains and Measures

To measure the individual-level outcomes, moderators, and mediators, the following domains and instruments were agreed-upon for inclusion in the cross-site data collection interview:

Domains	Measures
Demographics	Various modified items from other cross-site studies

Residential History	Revised Residential Follow-Back
Maternal Health	SF-8 Health Survey
Substance Abuse	Addiction Severity Index (ASI)
Mental Health	Brief Symptom Inventory
Legal	Various modified items from other cross-site studies
Trauma history	Various modified items from other instruments
Trauma recovery	Post-Traumatic Stress Diagnostic Scale
Social Support	Modified items from the CMHS Housing Initiative
Family Resources	Family Resource Scale
Children's Mental Health	Child Behavior Checklist (CBCL; for children 2+ years)
School Attendance	CBCL and additional items
Parenting	Parenting Practices Questionnaire
Service Use	Items on service need and use developed for this study

Intervals

The baseline interview is expected to be conducted before the intervention begins and no more than 2 weeks after program enrollment.

Follow-up interviews will be conducted at 3, 9, and 15 months following the baseline interview.

Translation

The Coordinating Center will create a generic Spanish translation of each instrument with site-specific adaptations for particular populations.

Training

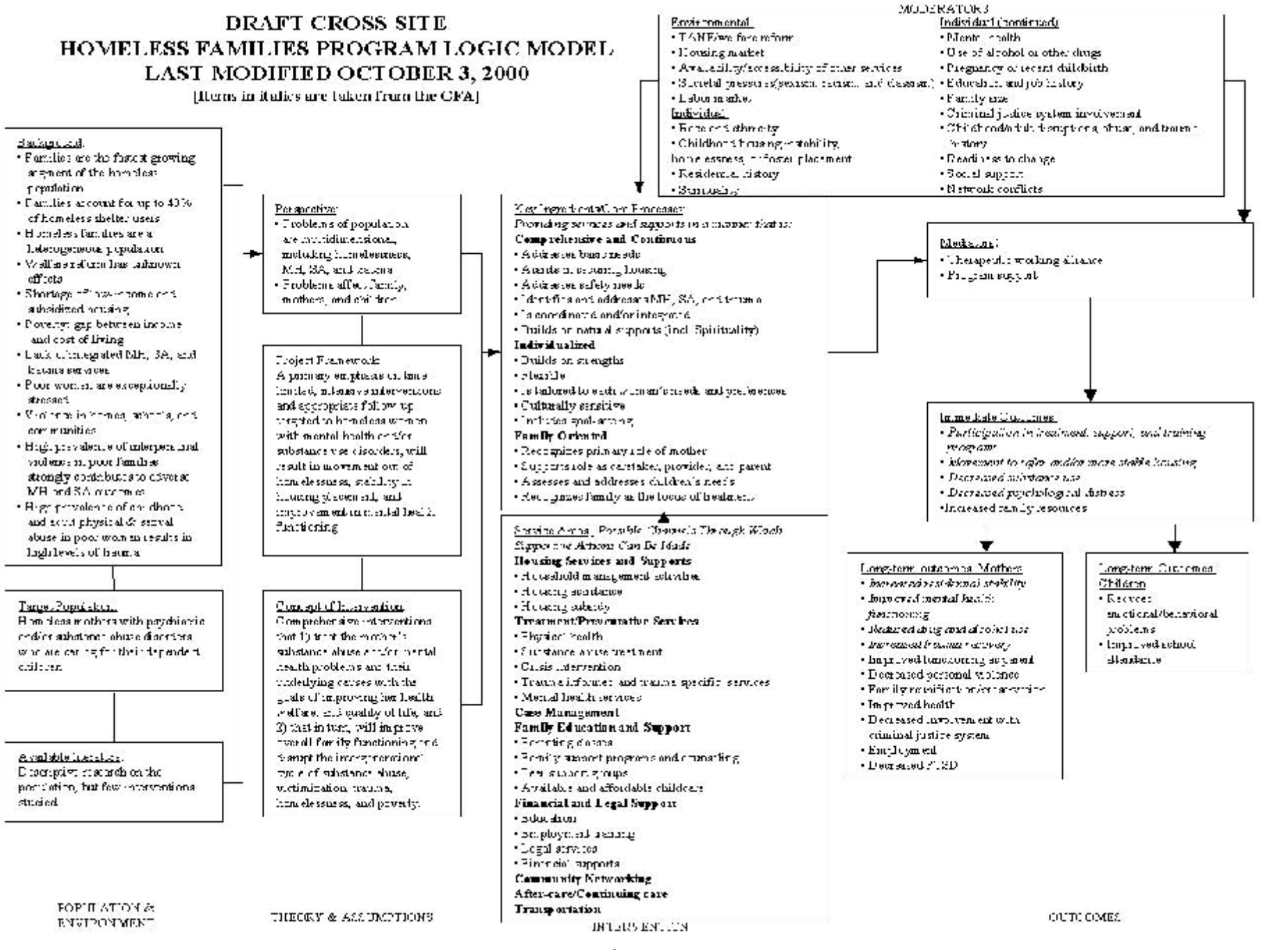
Interviewers will be individually trained in the administration of the interviews. The Coordinating Center will conduct a training session with each site's interviewer trainer. The training sessions will be videotaped for broader and continuing use at the sites. Training will cover both the administration and coding of the instrument.

Data Quality Control

The Coordinating Center will implement procedures to ensure the validity of data received from each of the individual study sites. The Coordinating Center will:

- Work with the Data Coordinator in each site to implement common coding decisions.
- Develop a common tracking computer program that can be used by all sites and will allow for the development of a Coordinating Center cross-site database for tracking study participants.
- Develop a common data-entry program to facilitate uniform procedures in computerization of the data.
- Maintain a common repository of the data and conduct the cross-site analyses.
- Develop systems for quality control and cleaning of the data that will ensure a uniform manner of reviewing data elements.
- Develop procedures and a schedule for data submission.
- Develop common procedures for developing a participant Study ID.
- Develop a strategy for assessing the reliability of the administration of the cross-site study.

Appendix B: Cross-site Logic Model



Appendix C: Guidance for Consumer Participation

There is a growing body of evidence from both practice and literature that supports the benefit of consumer involvement at the programmatic, policy, and administrative levels for service provider organization and in conducting research. Many of the Phase 1 study sites, following instructions in the original GFA, involved consumers in programmatic and research issues for the first time. Much was learned from this experience and from the valuable contributions of the Consumer Panel on how consumers can be effectively utilized by sites. The following are recommendations to study sites on the selection, preparation, and compensation of consumers.

Consumer Selection

- Choose a consumer representative and alternate who are mothers who have experience with homelessness and the mental health and/or substance abuse treatment systems.

    < The women selected need not be currently homeless;
    < The women selected should be willing and able to share their experiences and perspective as consumers with other members of the research team, Consumer Panel, and the Steering Committee;
    < The women selected should be at a stage of recovery that will allow them to participate fully in meeting and conference call discussions, deliberations, negotiations, voting, and review of study materials;
    < Completing or graduating from a program should not necessarily remove the representative or alternate from their position; and
    < Consider ethnic and cultural diversity in the selection of consumer representatives.

Preparation of Consumers for their Roles

- Prepare the consumer representative and alternate for their role on the Consumer Panel and Steering Committee and at the study site.

    < Appoint a member of the research team to be a liaison/mentor to the Consumer Panel representative and alternate;
    < Engage consumers in a manner that conveys acceptance and respect;
    < Provide an orientation to the intervention program, training for their role, and support for their continuation as the Consumer Representative;
    < Clearly define and outline the responsibilities, expectations, travel, and compensation to women offered these positions;
    < Ensure that both the representative and alternate are kept up-to-date on both cross-site and site-specific information and materials;
    < Brief the consumer representative and alternate prior to Steering Committee and site meetings, and debrief them following these events; and
    < Review materials to ensure that the consumers understand the information, have the opportunity to ask questions and gain clarification, and share their perspective with the other members of the site team.
    < Ensure continuity and consistency in representation by making no unnecessary changes in the consumer representative or alternate. Frequent changes in consumer representation disrupts the

Consumer Panel with the loss of experienced representatives and may inhibit consumer input due to fear of reprisals for voicing their opinions.

- < Work to overcome barriers to consumer participation, make reasonable accommodations for consumers dealing with changing life or work situations, and coordinate site meetings that will accommodate the consumers' schedules and transportation difficulties.

Compensation of Consumers

- Compensate consumers for time spent at Consumer Panel and Steering Committee meetings, site team meetings, site visits, and on conference calls.

- Pay for consumer expenses for their participation at Consumer Panel and Steering Committee meetings, site team meetings, site visits, and on conference calls. Examples of consumer expenses include, but is not limited to:

  - < Travel, transportation, per diem, and incidentals for steering committee meetings;
  - < Transportation for local meetings and site-related activities;
  - < Child care;
  - < Telephone calls;
  - < Supplies.

Appendix D: Definitions

For the purposes of this GFA, the following definitions are used:

The term "**homeless**" includes persons who lack a fixed, regular, and adequate nighttime residence. It also includes persons whose primary nighttime residence is either a supervised public or private shelter designed to provide temporary living accommodations, time-limited/ nonpermanent transitional housing arrangements for individuals engaged in mental health and/or substance abuse treatment, an institution that provides a temporary residence for individuals not intended to be institutionalized, a public or private facility not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.

"**Doubled-up**" refers to residential status that places individuals at imminent risk for becoming homeless, and is defined as sharing another person's dwelling on a temporary basis where continued tenancy is contingent upon the hospitality of the primary leaseholder or owner and can be rescinded at any time without notice.

"**Alternative treatment/services**" refers to the comparison program(s) where participants receive treatment and/or services (e.g., "treatment as usual" or a different treatment/service model or strategy) that are different from the intervention provided at the study site and allow for contrast between the programs for evaluation purposes.

The term "**psychiatric disorder**" refers to the condition of currently having, or at any time during the past year having had, a diagnosable mental, behavioral, or emotional disorder of sufficient duration to meet diagnostic criteria specified within DSM-IV (Axis I) that has resulted in functional impairment that interferes with or limits one or more major life activities.

These disorders include any mental disorders listed in Axis I of the DSM-IV or their ICD-9-CM equivalent (and subsequent revisions), with the exception of DSM-IV "V" codes, substance use disorders, mental retardation, and developmental disorders, which are excluded unless they co-occur with another diagnosable psychiatric disorder meeting the above criteria. All of these disorders may have episodic, recurrent, or persistent features, and may vary in terms of severity and disabling effects. For the purposes of this GFA, it is **not** required that the study participants be diagnosed with serious mental illnesses.

Diagnosable "**substance use disorders**" include both DSM-IV abuse and dependence categories. Substances may include alcohol and/or drugs, but excludes nicotine use or abuse. For the purposes of this GFA, substance use disorders may include substance use, dependence, or addiction.

"**Time-limited, multi-faceted intervention**" is defined as the effort to produce positive consumer/client outcomes by using an intervention with an active or intense period of services/ treatment of generally nine months or less in duration. This definition does not include follow-up to the intervention (e.g., support activity, case management, brief augmenting of skills), which may extend beyond the intervention period. The intervention must be fully implemented by March 1, 2001, and able to be evaluated within the three-year Phase 2 grant period.

Time-limited, multi-faceted interventions - whether provided by a single integrated treatment program or as brokered, coordinated services provided by multiple service organizations - must minimally include all of the following:

- mental health treatment;
- substance abuse treatment;
- trauma recovery;
- securing and maintaining appropriate and affordable housing;
- parenting skills;
- household, time, and money management; and
- goal setting (particularly vocational goals).

Custodial parent refers to the circumstance where the mother is the primary provider and current care giver to her child(ren) and the child(ren) have not been removed from the mother's care. If separation has occurred other than on a voluntary basis, it is with an agreement with the court that the child(ren) will be returned to the mother's care at the end of her participation in the time-limited intervention.