



REQUEST FOR PROPOSAL NO.: AMENDMENT NO. 01  
RFP NO. NIMH-01-OC-0014

TITLE: "NIMH Communications Support Program"

OMB No.: 0990-0115

ISSUED BY: Patricia L. Gibbons, Contracting Officer  
National Institute of Mental Health  
Contracts Management Branch, ORM  
6001 Executive Blvd., Rm. 6107 MSC 9603  
Bethesda, Maryland 20802-9603

DATE ISSUED: Monday, June 18, 2001

PURCHASE AUTHORITY: Public Law 95-218 as amended

SMALL BUSINESS SET-ASIDE: No

JUST IN TIME: Yes

OFFER EXPIRATION DATE: Offers will be valid for 120 days unless a  
different period is specified by the Offeror

To all Offerors: The purpose of this amendment is to extend the receipt date for submission of Proposals from Friday, June 22, 2001 to Tuesday, July 10, 2001, and respond to offerors' questions as follows:

**Q1.** As noted in the RFP, page 12, Task V, Focus Groups (10 – 15 per year), please provide copies of full reports regarding NIMH focus group studies.

**A1.** Due to the length and complexity of these reports, it is not feasible to post them in full on our web site for this RFP. The key findings of one report and an executive summary of another are attached for your information. The successful offeror will be given full copies of all of the reports for review upon the award of this contract. Any future focus groups will be developed in communication with the GPO around very specific projects.

**Q2.** Please clarify: regarding sample materials (that are limited to fit into one 18" x 12" x 10" box), how many copies of each sample material are to be provided? 1 copy of each? 5? 10?

**A2.** 3 copies will be sufficient.

**Q3.** The current website is hosted on the NIH web server(s).

- a. Is it necessary to continue to host it there or is the NIMH open to exploring alternative hosting scenarios?
- b. What web server software is currently used on the host server?
- c. What databases currently exist that are tied to the content of the current site and in what formats do they exist?
- d. What is the current methodology for altering/updating content on the site? (i.e. are suggestions for new content sent to a web designer/developer to be formatted and uploaded or are there automated site administrative tools in place that allow non-technical personnel to update content and links on the site?)
- e. What standards exist for software used in the development of a web site or in the expansion of the current site for NIMH?

**A3.** In response to questions 3a-b, web hosting and management are not part of this contract. OCPL will need materials to be formatted for the web site in the most current and user-friendly formats. Currently, we are using PDF and HTML, but this may change over the course of the contract. In reference to the design and recommendations to the web, those will be channeled through the GPO; the successful offeror will work directly with the GPO and the NIMH web team on all new materials to be posted to ensure that designs and formats are consistent with what is currently being used on the NIMH web site.

**Q4.** How frequently is content updated currently? -Daily -Weekly -Monthly – Quarterly.

**A4.** The NIMH web site is updated daily.

**Q5.** Is there a policy in place for linking to partners and/or supporting information?

**A5.** In general, the NIMH web site currently limits links to other governmental agencies. There are exceptions made under certain circumstances; and the NIMH does link to *MedlinePlus*, which links to many vetted outside organizations and associations.

**Q6.** What is the current method for tracking traffic to the site? Do we know the average # of unique visitors per day/week/month?

**A6.** Tracking of the web site is done in house. NIMH counts the number of hits, user sessions, and visitors per day to each individual page on the web site.

**Q7.** How many people subscribe to the NIMH Listserv?

- A7.** There are approximately 8,000 current subscribers to the NIMH Listserv.
- Q8.** Does NIMH own or use any other URLs besides <http://www.nimh.nih.gov>?
- A8.** Yes, the NIMH also has <http://www.mentalhealth.gov/>
- Q9.** What, if any, graphical standards exist in relation to NIMH's logo or other materials which might impact web design?
- A9.** Please review our web site to see how we use the NIMH logo throughout our materials. The successful offeror will work with our web team to ensure that all new materials and designs are consistent with our guidelines.
- Q10.** Where can we obtain a copy of the current communications plan?
- A10.** Current communication plans and strategies will be relayed to the successful offeror for review and comment.
- Q11.** In addition to preparing publications for printing by GPO, will we be responsible for providing duplication services for some or all of the publications prepared under the contract? If so, what quantities are normally produced by NIMH contractors?
- A11.** Very rarely, and only in times of emergency, will the contractor be required to provide copies of NIMH publications. In these cases, the quantities will be very small and will likely not exceed 1,000 copies.
- Q12.** The RFP contains no specific information on the level of effort. Please provide guidance on the number of labor hours or full-time equivalents and on the other direct costs you expect to be required for this procurement?
- A12.** The current RFP outlines this information in the kinds of activities required and their frequency.
- Q13.** Is NIMH currently receiving the same or largely similar communications services under any existing support contract? If so, please identify the contractor or contractors that are providing those services and the value of the existing contracts.
- A13.** The incumbent for this requirement is Porter Novelli. The value of the existing contract is approximately 3.3 million over 4 years.
- Q14.**
- a. Do you want to see specific creative work developed for an education campaign?
  - b. If so, when developing this creative, should we simply choose a topic (page 11 lists six subject areas) and target audience to focus on or is there one in particular you would like us to address?
  - c. Where do you suggest would be the best place to go for research that would provide us with the background information pertinent to developing a strategy for the educational campaign?

- d. Should the educational campaign specific creative consist include television, radio, print, web, and coordinating collateral materials? Should it be something else?
- e. Are you looking for specific media recommendations (e.g., TV PSAs vs print PSAs) for the above mentioned campaign?
- f. Is there a specific response we would like the target audience to have - i.e., call a number, look on web, order brochure...what is the call to action?

**A14.** In response to questions 14a-f, there is quite a bit of information regarding future educational campaigns in the current RFP, including examples. This is also an area where we would like the successful offeror to have prior experience, and therefore part of the review will be looking for evidence of that experience (see Evaluation Factors, #2), which would include developing the campaign, creativity in creating campaign materials, knowing where to go to find the pertinent information, and how best to market the campaign. We would be interested in seeing any samples of previous work and strategies, particularly in the field of mental health. Proposed ideas for future campaigns would also be considered in the review, if deemed necessary.

**Q15.** Would you consider receiving a separate proposal for the recruitment of participants in clinical studies and clinical trials?

**A15.** No, the NIMH is currently exploring the feasibility of competing a contract for Clinical Trial Recruitment Services.

**Q16.** Please clarify the total points for the evaluation criteria.

**A16.** The total number of points assigned for evaluation of proposals is 117.5.

## **National Institute of Mental Health Focus Groups of Teens With & Without Depression**

### **KEY FINDINGS**

Three focus groups were conducted in New York City on May 10, 2000. Two of these were with boys and girls ages 12-17 who had been diagnosed with depression; the third was with adolescents of the same age who were not diagnosed with depression. The groups explored adolescents' perception of depression, treatment approaches, and the idea of participating in a clinical trial.

### **PERSPECTIVES OF ADOLESCENTS**

- **Psychotherapy.** All the adolescents with depression had received psychotherapy following their diagnosis, and most were satisfied with this treatment, found it highly personal, confidential and non-judgmental. Many said they would be loathe to change therapists or give up psychotherapy.
- **Medications.** In general, teens thought that depression was something that had to be “worked through” and thought medications would provide only temporary relief and/or create a blank, unreal mood. Side effects were also a concern. (Only two of the participants had been on antidepressant medication.) The teens without depression, however, did not express unfavorable opinions about the use of medications to treat depression.
- **Medical Research.** Only a few participants knew about medical research. Once explained, many thought there were risks involved in medical research and no guarantee that trial participation would actually help a person. Most didn't understand why someone would want to participate unless they had exhausted all other treatment options, were desperate or terminally ill. Critical issues included:
  - Safety. Some expressed the fear of being tested on; others feared side effects of medication; a few indicated a fear of dying. Possible parental concerns were mentioned.
  - Choice. In general, the teens did not want to be denied the choice of treatment. Most couldn't understand the meaning of and reason for randomization, and felt that depression should be treated on an individual basis, in consultation with the patient.
  - Medications. Because of their aversion to medications, most teens said they wouldn't participate in a trial where medication was given. Placebo use was also a source of aversion and confusion.
  - Payment. Many teens indicated that payment would influence them to participate, provided the trials were completely safe; some weren't positive it would be worth the risk.
  - NIMH Sponsorship did lend some credibility, as compared to a pharmaceutical company.

## **ROLE OF PARENTS (AND OTHER FAMILY MEMBERS)**

While no parents were interviewed, it appears that parents play a very important role in treatment decisions for their children, although they may not be actively involved in the psychotherapeutic process. In many cases, it was the parents who had initiated diagnosis and treatment. Most of the teens said that their parents would be concerned about their safety in a clinical trial and would need detailed information about the trial before they would consider participation. Several teens thought their parents would object to their participation.

***-EXECUTIVE SUMMARY-***

The Systematic Treatment Enhancement Program  
**for Bipolar Disorder (STEP-BD):**

**Focus Group Report**

**Findings from Focus Groups Involving Adults with Bipolar Disorder and  
Family Members of Adults with Bipolar Disorder**

**February 1 and 7, 2000  
Veterans Administration Hospital  
Baltimore, MD**

**Prepared for:**

**National Institute of Mental Health  
Office of Communications and Public Liaison  
6001 Executive Blvd.,  
Room 8184, MSC 9663  
Bethesda, MD 20892-9663**

**Prepared by:**

**Porter Novelli  
Washington, DC**

**May 2000**

## **EXECUTIVE SUMMARY**

### **Introduction and Methodology**

To improve the treatment of bipolar disorder, the National Institute of Mental Health (NIMH) is sponsoring a clinical trial entitled the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD). STEP-BD will evaluate participants' responses to different treatments and treatment combinations over time, with the primary aim of determining the most effective strategies for treating acute episodes of depression and mania and for preventing recurrent episodes.

STEP-BD is one of a new generation of treatment effectiveness trials designed to examine how well existing pharmacological and psychosocial treatments for mental disorders work for patients in “real-world” clinical practice settings. *Effectiveness* research seeks not only to determine how well particular treatments work to reduce symptoms, but also to evaluate their effects on outcomes such as quality of life, ability to work, social functioning, treatment adherence, and treatment cost-effectiveness. Effectiveness studies have few exclusionary criteria and enroll very large numbers of participants—several hundred to thousands—so that the findings will be representative of and broadly applicable to an entire population group.

Recognizing that recruitment of participants is a challenging aspect in the execution of clinical trials, the NIMH Office of Communications and Public Liaison (OCPL) initiated a series of activities to inform the development of effective recruitment strategies for NIMH clinical trials in general, and for the large-scale effectiveness trials in particular. These activities have included a set of focus groups held in Chicago, IL involving adults with bipolar disorder and family members, and a meeting between mental health advocacy group representatives and NIMH researchers in Washington, DC.

Most recently, on February 1 and 7, 2000, OCPL held four additional focus groups involving adults with bipolar disorder and family members at the Veterans Administration hospital in Baltimore, MD (one of the study sites for STEP-BD). The main objective of this research was to learn what factors might motivate or prevent individuals with bipolar disorder from participating in STEP-BD. Separate groups were conducted with Caucasian and African American participants, and each group discussion was facilitated by a specially trained, male moderator of the same race/ethnicity. Overall, a total of 33 people participated: 20 were female and 13 were male.

This report presents the detailed findings from the focus groups. Its content is based on notes taken by the observers during the groups, subsequent discussions with the moderator and among the observers, and transcripts of the group proceedings. Differences between adults with bipolar disorder and family members, and between Caucasian and African American participants are noted where appropriate. Differences by age and gender cannot be identified because the groups were not stratified on these variables.

It should also be noted that focus groups are qualitative in nature. They are useful for obtaining a range of responses and for identifying larger issues to be considered in further depth; however, the findings cannot be extrapolated to the population of adults with bipolar disorder and their family members.

## **Key Findings**

### ***Experience of Living with Bipolar Disorder***

- Adults with bipolar disorder uniformly described the illness as both physically and emotionally painful, affecting every aspect of their lives. Several described a range of problems, from an inability to carry out simple, routine tasks such as bathing and dressing to issues such as financial difficulties, substance abuse, and suicide attempts.
- All of the family members agreed that having a loved one with bipolar disorder causes them to feel much stress, frustration, anger, and guilt. They explained that it is painful to watch their loved ones struggle with the disorder.
- Several family members, particularly those who were primary caregivers, also expressed a lack of control over the actions of their loved ones. Some family members wondered how much or for how long they should try to help their loved one cope with the disorder. Moreover, family members (particularly the older ones) often worried about who will look after their loved ones after they die.
- Many adults with bipolar disorder indicated that they are currently undergoing some form of treatment. Similarly, many family members indicated that their loved ones are involved in treatment. A few participants indicated that they, or their relatives with bipolar disorder, were not currently in treatment.
- The treatment most commonly mentioned by adults with bipolar disorder and family members was multiple drug therapy. Psychiatrists were mentioned far more often than any other type of health care professional, because they are the ones primarily responsible for prescribing the medications. In addition, some adults with bipolar disorder and family members mentioned psychotherapy provided by a variety of mental health professionals including psychologists, social workers, group therapists, and family therapists.
- The quality of the relationship with the treating physician was very important to adults with bipolar disorder and family members.
- Both adults with bipolar disorder and family members said that, to gain their trust, a doctor would have to be caring, empathetic, and a good communicator. They unanimously prioritized these qualities above medical training/credentials and over racial or cultural similarity.

- Some African American adults with bipolar disorder and family members said they prioritize empathy and communication skills above race/ethnicity.

### ***Openness to Participating in STEP-BD***

- The Bipolar Disorder Management Program and the Randomized Treatment Arms were presented and described separately to adults with bipolar disorder and family members to elicit their response to each of these programs. In general, adults with bipolar disorder and family members were more open to participating in the Bipolar Disorder Management Program than in the Randomized Treatment Arms. In fact, most of the reasons given *for* participation pertained to the Bipolar Disorder Management Program, and many of the *barriers* mentioned arose from the features of the Randomized Treatment Arms.
- Openness to participation was not affected by race/ethnicity; African American adults with bipolar disorder and family members were no more likely to express distrust in medical research studies than were the Caucasian participants. A few African American adults with bipolar disorder and family members recounted the Tuskegee Syphilis Study, but not without extensive probing by the moderator. In fact, many did not seem to be aware of the study and its consequences.

### ***Motivators for Participation***

The primary motivation for adults with bipolar disorder and family members to participate in the study was the hope for a more stable life for the person with the disorder. This was true of both Caucasian and African American participants. Other benefits, such as the opportunity to help reduce the difficulties of other people with bipolar disorder or to learn more about managing the disorder, were also mentioned.

- At some point in the discussions, most adults with bipolar disorder and family members expressed hope that the research would uncover a more effective treatment that would bring them closer to regaining a routine life. It was for this reason primarily that they were receptive to the Bipolar Disorder Management Program and medical research in general. However, a few participants noted that they supported medical research as long as they or people close to them did not have to be involved.
- The wish for better treatment was connected to past experiences with treatments that brought little or limited stability and/or had severe side effects.
- A few adults with bipolar disorder and family members said they liked the “holistic” approach of the Bipolar Disorder Management Program, in contrast to the narrow focus of most current treatment plans. They noted that comprehensive programs are preferable, but are not widely available.
- Regardless of race/ethnicity, other aspects of the Bipolar Disorder Management Program identified by adults with bipolar disorder and family members as being

positive include:

- Individualizing each patient’s treatment plan
- Long-term monitoring
- Treatment by specially-trained experts in bipolar disorder

### *Barriers to Participation*

- The reasons expressed for not wanting to participate in the Bipolar Disorder Management Program and Randomized Treatment Arms were ultimately based on the perception that the interests of the patient are not the primary focus of the research.
- Several adults with bipolar disorder and family members were hesitant to change the current course of treatment and therefore were not interested in the Randomized Treatment Arms. They explained that doing so might result in a loss of any gains in stability that were so painstakingly acquired over the years, or a decline in the person’s condition due to the inadequacy or side effects of the randomly assigned treatment.
  - In particular, family members said they have no desire to cope with the negative consequences that might result from a change in treatment.
  - Adults with bipolar disorder and family members noted that only those who are dissatisfied with their current treatment might be interested in changing treatments, or that those who currently are not undergoing any treatment might consider participating. Such persons, it was suggested, “have nothing to lose.”
- Regardless of race/ethnicity, many adults with bipolar disorder and family members expressed concerns about being unable to continue treatment with their current physician. Continuity of treatment and maintenance of a good patient-physician relationship are particularly important to adults with bipolar disorder and family members, many of who have long histories with unsuccessful or inadequate treatments or less-than-satisfactory physician relationships. Adults with bipolar disorder did not want to lose their current doctor if he or she was regarded as trustworthy and knowledgeable.
- In addition, family members noted that their loved ones would be unable to adhere to their treatment plans and complete their forms without help from their family members or others.
  - Some African American adults with bipolar disorder were not able to complete their focus group consent forms without assistance.
  - The moderator of the African American groups noticed that some participants were not reading, or appeared to have difficulty reading, the handouts describing the study. Hence, he read the handouts aloud, which helped to engage the

participants in each group. This observation suggests that limited literacy may be a significant barrier to participation in STEP-BD.

- Many adults with bipolar disorder and family members were frightened by the concept of receiving a randomized treatment. Several negative consequences of randomization were mentioned:
  - Being assigned a placebo.
  - Receiving a medication that has already been found to be ineffective for the person with bipolar disorder.
  - Receiving a medication that has not been tried beforehand but is nevertheless ineffective for the person with bipolar disorder.
  - Receiving medications that have not been tested on enough people and thus have not been proven efficacious.<sup>1</sup>
- Adults with bipolar disorder and family members also mentioned that denial of the illness and resistance to treatment on the part of the person with bipolar disorder might be significant barriers to recruitment. They explained that many people with bipolar disorder are simply not in places where they would see messages about the study, or are not predisposed to respond to messages they see. Individuals with bipolar disorder who are more seriously ill—those who might be the best candidates for the Randomized Treatment Arms—were thought to be the least open to promotional messages about these programs. For this reason, family members said they do not feel they have enough control over their loved ones to guarantee they would enroll or remain in a clinical trial.
- Other barriers mentioned were concern about having to pay for therapy, and other general exams, transportation, and child care.

### ***Family Members' Participation and Involvement***

- There was a clear disconnect between the adults with bipolar disorder and the family members about the level of family involvement in the treatment and management of the disorder.<sup>2</sup> While few of the adults described their family members as being involved in their lives, many family members who participated in the focus groups described themselves as being deeply involved in the treatment and care of loved ones with bipolar disorder. However, there were a few family members whose loved ones were not currently in treatment.

---

<sup>1</sup> Although it was explained to the focus group participants that experimental treatments would not be part of the study, some still had the perception that they would receive unproven treatments.

<sup>2</sup> This apparent contradiction may be explained, in part, by the likelihood that the family members who were willing to participate in the focus groups are those who are actively involved and interested in caring for their relative with bipolar disorder. Thus, the findings from these groups may reflect only the views of such actively involved and interested family members.

- Few of the adults described their family members as being involved in their lives. Some considered their family members to be unsupportive of their current course of treatment and uninterested in participating in the Bipolar Disorder Management Program and/or the Randomized Treatment Arms.
- Many family members described themselves as being deeply involved in the lives of their loved ones in ways that ranged from providing daily care such as bathing and feeding to helping them out of unfortunate situations such as financial difficulties. Furthermore, many said they actively try to stay involved in their loved one’s treatment and play a necessary role in treatment.
- In addition, some family members expressed a deep sense of frustration because they are often excluded by doctors from treatment discussions and decisions.
- Almost all family members said they would participate in the Bipolar Disorder Management Program and the Randomized Treatment Arms if their loved one were enrolled. They saw family participation as a clear benefit of these programs.
  - Family members listed two key benefits they would experience by participating: (1) they would have access to more information about how to cope with their loved one’s illness; and (2) they would gain a sense of relief that would come with knowing that they would not have to shoulder the burden of caring for their loved one alone, a feeling they have often experienced. Closely connected to the second benefit was the idea of having experts available to help manage the disorder.

***Promotion of STEP-BD***

- Most adults with bipolar disorder indicated that they would need more information about the Bipolar Disorder Management Program and Randomized Treatment Arms before deciding to participate; and similarly, most family members agreed they would need more information before talking to their loved one about possibly enrolling. Specifically, they said they would need detailed information about:
  - The sponsor of the study
  - Who is conducting the study
  - The purpose of the study
  - Who is being recruited
  - Where the study sites are located
  - How the confidentiality of participants will be respected
- Throughout the discussions, it became clear that certain terms such as “randomization” and “individualized treatment” were not clearly understood by participants (despite repeated explanations by the moderator).

- Some adults with bipolar disorder and family members advised against using the word “disease,” including in the program title or campaign messages. They explained that such a word might perpetuate the myth that people with bipolar disorder are contagious and therefore should be avoided.
- Regardless of race/ethnicity, adults with bipolar disorder and family members said that, because of the stigma, they only tell close family members and friends about the disorder. Some family members also said their bosses and co-workers know because of time away from work.
- It should be noted that, at the end of their discussion, a few African American family members suggested using the word “study” instead of “research,” because the latter term connotes human experimentation and guinea pigs. They said that “study” would be a better term for implying honesty.
- Toward the end of the focus groups, adults with bipolar disorder and family members were shown three draft messages designed to promote the Bipolar Disorder Management Program and the Randomized Treatment Arms. The adults and family members indicated being most open to messages stressing better treatment options, partnering with physicians, and management for bipolar disorder.
- A few adults with bipolar disorder and a number of family members said they have received information about bipolar disorder from advocacy organizations. They specified the National Alliance for the Mentally Ill (NAMI), regional organizations like the Maryland Alliance for Mental Health, Depression Related Anxiety Disorders Association (DRADA), the Stanley Bipolar Foundation, and a variety of other local and national groups. Most of the references were made by Caucasian participants.
- As for reaching those open to messages, adults with bipolar disorder and family members believed that a combination of mass media, possibly involving a celebrity spokesperson, and highly targeted communications would work for this program.
- Some participants said they were familiar with the National Institute of Mental Health (NIMH); however, few were able to accurately describe the Institute. Most of those who said they were familiar provided vague yet positive responses.
- Some participants said the affiliation with NIMH would enhance the credibility of the Bipolar Disorder Management Program and Randomized Treatment Arms.
- Those who felt compelled to get another opinion about participating in the program were most likely to want to talk to the program’s sponsors or, more often, principal investigators about details of the program before making a final decision. The adults with bipolar disorder also mentioned that they would talk to their doctor or a family member.