OMB No. 0990-0115

AWARD / CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES
		1 44

CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST PROJECT NO.
N01MH90003	See Block 16c	

5. ISSUED BY CODE
National Institute of Mental Health
Contracts Management Branch, ORM
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesds, MD 20892-9603

6. ADMINISTERED BY (If other than item 5) CODE

7. NAME AND ADDRESS OF CONTRACTOR (No. street, city, county, State and ZIP Code)
University of Texas, Southwestern
Medical Center at Dallas
5323 Harry Hines Boulevard
Dallas, TX 75235-9086

8. DELIVERY
☐ FOB ORIGIN ☐ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) To THE ADDRESS SHOWN IN: ITEM

CODE FACILITY CODE

11. SHIP TO/MARK FOR CODE

12. PAYMENT WILL BE MADE BY CODE
See Section G

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c) ( ) ☐ 41 U.S.C. 253(c) ( )

14. ACCOUNTING AND APPROPRIATION DATA
EIN# [redacted]

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Treatment Resistant Depression (TRD)			Funded Amount	3,633,266.00

15G. TOTAL AMOUNT OF CONTRACT $26,936,110

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return three (3) copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by teh following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. [ ] AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)

20A. NAME OF CONTRACTING OFFICER
Patricia L. Gibbons, Contracting Officer

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY [signature] (Signature of person authorized to sign)	9/28/99	BY [signature] (Signature of Contracting Officer)	9/29/99

NSN 7540 - 01 - 152 - 8069
PREVIOUS EDITION UNUSABLE

STANDARD FORM 26 (REV. 4 - 85)
Prescribed GSA
FAR (48 CFR) 53.214(a)

SECTION B

SUPPLIES OR SERVICES

B.1 Brief Description of Supplies or Services

Title: Treatment Resistant Depression (TRD)

B.2 Estimated Cost and Fixed Fee

a. The estimated cost of this contract is $[redacted]

Year 1	$[redacted]
Year 2	$[redacted]
Year 3	$[redacted]
Year 4	$[redacted]
Year 5	$[redacted]
Total	$[redacted]

estimated Costs redacted per guidance

b. Option to Extend Term for 5 years:

Option 01 $[redacted]

c. Options for Additional Services: The costs for Options 02-06, if exercised, shall be negotiated prior to executing any of these options.

Option 02 - An option to expand the work of the project by adding new antidepressant drugs as they are approved by the FDA or adding other comparison treatments as scientifically indicated

Option 03 - An option to expand the work of a Trial to include screening, recruitment, and sample collection from subjects and family members for pharmacogenetic or genetic linkage studies sponsored by NIMH or other organizations

Option 04 - An option to expand the work of the Trial to include a trial of early intervention during the risk or symptomatic phases of illness

Option 05 - An option to expand the work of the Trial to include studies of pathophysiology and treatment mechanism

Option 06 - A combination of one or more of the above options

d Total funds currently available for payment and allotted to this contract are $3,633,266.00. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Section I "Contract Clauses."

e. It is estimated that the amount currently allotted will cover performance of the contract through 9/30/2000.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

g. Payments to the contractor will Direct Billing procedures and are payable upon acceptance by the Government for the services specified in Section C, "Statement of Work" and upon submission by the contractor of a proper invoice (Section G, Contract Administration Data).

B.3 Provisions Applicable to Direct Costs

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the contract clauses titled: "Allowable Cost and Payment" (July 1991) and Subcontracts Under Cost-Reimbursement and Letter Contracts" (July 1985), unless otherwise expressly provided elsewhere in this contract, prior authorization in writing by the Contracting Officer or his/her authorized representative is required for the following costs. Their incurrence with the intent of claiming reimbursement as direct costs shall therefore be at the Contractor's own risk, if without such prior authorization:

(1) Acquisition, by purchase or lease, of any interest in real property;
(2) Special rearrangement or alteration of facilities;
(3) Purchase or lease of <u>any</u> item of general-purpose office furniture or office equipment regardless of dollar value. (General-purpose equipment is defined as any items of personal property, which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
(4) Travel to attend general scientific meetings;
(5) Any subcontract, or any purchase order in accordance with FAR 52.244-2;
(6) Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the <u>Contractor's Guide for Control of Government Property</u>), 1990, regardless of acquisition value.
(7) Any costs incurred prior to the contract's effective date.
(8) Costs of clinical care, such as patient bed costs, outpatient visit fees and clinical laboratory determinations shall not be reimbursable. This includes: tests and procedures that are clinically required for standard treatment of the patient and are routinely performed for a fee in institutional laboratories.

b. Indirect Costs

The Contractor shall be reimbursed in accordance with the Department of Health and Human Services rate Agreement dated July 1, 1994.

TYPE	BILLING RATE	CEILING RATE	BASE
Fringe Benefits			(A)
Indirect Costs	56%	◯%	(B)

indirect cost rate

Rate application base:

(A) Fringe Benefits are specifically identified to each employee and are charged individually as direct costs.

(B) Toal direct costs excluding captial expenditures (buildings, individual items of equipment; alterations and renovations), that protion of each subaward in excess of $25,000; hosptialization and other fees associated with patient care whether the services are obrained from an owned, related or third patrty hosptial or other medical facility; renta/maintenance of off-site activities; student tuition remission and student support costs (e,g., student aid, stipends, dependency allowances, scholarships, fellowships).

The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates. In the event that the final indirect cost rates are less then these negotiated ceiling rates; the final negotiated ceiling rates shall be reduced to conform to the lower rates.

Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant or cooperative agreement.

Notwithstanding the foregoing provisions of this article, the Contractor shall, in the case of an upward adjustment of the provisional rate, comply with the requirements of the contract clause FAR 52.232-22, "Limitation of Funds" (April 1984) and provide timely notification to the Contracting Officer where such increase in costs causes operation of that clause.

B.4 Advance Understandings

A. Subcontracts with University of Pittsburgh; Massachusetts General Hospital; Columbia University and; To Be Named Regional Sites:

To negotiate fixed fee type subcontracts with above referenced subcontractors to assist the prime contractor in the performance of the Statement of Work for the period of performance. Award of any subcontracts shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer).

SECTION C

STATEMENT OF WORK

I. BACKGROUND

Major depression is one of the most common disorders treated by mental health practitioners. There are many pharmacologic, psychotherapeutic, and combination treatment options available to the clinician for initiating treatment of depression. However, many persons with depression do not respond optimally to initial treatments, even when the appropriate treatment is provided in an adequate manner by the clinician.

When initial treatment includes antidepressant medications, approximately 20-30% of depressed patients do not respond to treatment. In addition, it has been estimated that as many as 60-70% of depressed patients achieve only a partial resolution of their symptoms in response to initial antidepressant treatment. The definition of treatment response is complicated by the question of what constitutes an acceptable outcome. This is often defined in terms of specific symptom reduction however, less is known about broader functional outcome measures.
Because of the substantial mortality and morbidity associated with prolonged or ineffective trials of initial approaches to the treatment of depression, treatment resistant depression is a major public health problem. The scope of this problem is vast both in terms of numbers of affected individuals and resources involved. The management of treatment resistant depression clearly represents a substantial portion of the cost of depression accounting for a disproportionate amount of clinician time, patient disability, and associated complications.

However, despite the enormous public health significance of the problem of treatment resistant depression, systematic research on this topic has been very difficult. In particular, the timely and accurate identification of treatment resistant patients has been very problematic. It is generally accepted that there is a biologically determined latency period that limits the onset of response to antidepressant treatment. This latency period is believed to reflect time required to reach therapeutic drug levels or to achieve adequate intensity of psychotherapy coupled with time needed for biochemical and electrophysiological adaptations required for clinically significant change.

Major sources of patient heterogeneity also contribute to treatment response. In those patients treated with pharmacological approaches, there are major differences among patients and among drugs with respect to pharmacokinetics, pharmacodynamics, and mechanisms of action. In those patients treated with psychotherapeutic approaches, or where psychotherapy is included in initial combined treatment, time needed to achieve an optimal therapeutic alliance becomes a factor in treatment response. To encompass this heterogeneity, pharmacologic studies of treatment resistance have often employed lengthy trials of initial agents used at doses that ensure optimal blood levels. In psychotherapeutic studies, investigators have been similarly conservative in establishing treatment resistance.

In actual practice, a lengthy trial of a potentially ineffective initial treatment may delay access to effective treatment and may lead to prolonged suffering or to dropout from treatment. Therefore,

a major goal of the proposed studies will be the refinement of our definition of what constitutes an optimal trial of initial treatment. In addition, the identification of promising early predictors of treatment response (REM latency, EEG changes, etc.) should be considered for inclusion in the protocol.

The appropriate identification of treatment resistant depression is problematic. Treatment response is usually defined in terms of changes in depressive symptoms as measured by conventional depression rating scales. However, we know relatively little about changes in disability, functional impairment, and other broad measures of outcome associated with treatment of depression. Therefore, the assessment of treatment resistance is often based on measures that have limited external validity and that may seriously underestimate the incidence and magnitude of treatment resistance. In addition, treatment response is greatly complicated by the presence of comorbid conditions, heterogeneity of patients, diversity of treatment settings, and many other factors that restrict the generalizability of study findings. To address these problems, the proposed contract should be performed using a public health model with the broadest possible outcome measures and the least restrictive inclusion criteria in order to maximize the external validity of the results.

Underlying this contract is the dilemma that confronts the field concerning the practical limitations of designing a trial of treatment approaches to treatment resistant depression. A large number of treatment options are currently in use as secondary therapy including numerous augmentation and drug switching strategies. Comparisons of these treatment modalities having adequate statistical power would require large numbers of people. This problem is compounded by the fact that using stringent criteria for the definition of treatment resistance, subject recruitment is a limiting factor. Selecting the key questions to be addressed and designing a trial with sufficient external validity and statistical power will likely require a major consensus development effort to identify critical treatment options.

II. OBJECTIVES

The clinical trial should focus on understanding what interventions (pharmacologic and psychosocial) provide the best outcomes (both clinical and functional) for people who fail to respond to initial treatment of depression. In addition, it should address the impact of other factors on the delivery of and compliance with treatment interventions. Data from the study should be able to inform the provision of care in broad categories of people with treatment resistant depression in the community and provide an estimate of the cost-effectiveness of such treatment. Ancillary studies should contribute to the primary focus but they could also consider additional research issues in treatment resistant depression.

The major research questions to be addressed in this study include the following:

- For a person with depression who has not responded adequately, at what point should a diagnosis of treatment resistance be made, and when should treatment be changed in order to optimize outcome?
- How should the magnitude of response (partial or complete) influence the optimal point at which treatment is changed?

- How should the type of depression (melancholic, atypical, minor) influence the optimal point at which treatment is changed?
- How does the type of the initial treatment determine the optimal point at which treatment is changed?
- Does the optimal point at which treatment is changed vary among various populations (age, gender, race, and ethnicity)?
- How does the presence of medical comorbidity influence the optimal point at which treatment is changed?
- How does the presence of psychiatric comorbidity (substance abuse, Axis II, other diagnoses) influence the optimal point at which treatment is changed?
- How do side effects associated with initial treatment influence the optimal point at which treatment is changed?
- What is the optimal treatment strategy for management of treatment resistant depression?
- Among the many treatment options (augmentation, switching, intensification of psychotherapy), are any clearly superior?
- How does the magnitude of response to the initial treatment or the type of depression influence the choice of secondary treatment?
- How does the type of initial treatment influence the choice of secondary treatment?
- What are the relative burdens of side effects associated with different treatment strategies?
- What are the other relevant outcome factors associated with different treatment approaches?
- How do different strategies impact on compliance with treatment?
- How does the choice of a treatment influence an individual's expectations or therapeutic alliance?
- How do different strategies impact on function and quality of life?
- Are particular treatment strategies better suited to specific treatment settings? (inpatient, outpatient, primary care, rural, urban)
- How do the various treatment strategies differ in terms of direct and indirect costs?
- What are the optimal approaches to diagnosis and management of treatment refractory (poor response to adequate secondary treatment) depression?
- Can we identify biological (genetic and other biopsychosocial) markers for treatment resistance?

The contractor shall use a research protocol that addresses the Research Objectives of this initiative and should include a process for revising and refining the protocol. The contract shall have two major phases: protocol development and clinical trial coordination and administration. A third phase may consist of extension studies that are contingent upon results obtained from the earlier phases. Preliminary protocols should be presented with the understanding that a period of refinement will be incorporated for the finalization of the protocols.

III. SPECIFIC REQUIREMENTS

The contract shall include the following activities:

Protocol Development

The contractor shall formulate a work plan to develop and refine an intervention model that addresses the general and specific Objectives and Approach of the contract. NIMH anticipates that this will generally proceed in two phases: protocol development and protocol implementation. A development phase shall be used to finalize the protocol and could include meta-analyses of existing data, expert consensus workshops and symposia, review of ongoing clinical trial protocols supported by the pharmaceutical industry, foundations, or government agencies, and any necessary pilot studies. At a minimum, the contractor will meet three major goals of the development phase.

1) Developing methods for establishing a practical definition of treatment resistance that accounts for:

- True biological latency to response
- Subtypes of depression
- Differences among pharmacologic treatment approaches
- Differences among psychotherapeutic approaches
- Differences among subject populations
- Differences in compliance and adherence to treatment
- Interpersonal and other factors influencing the patient-clinician dyad
- Co-morbid conditions
- Likelihood of eventual response
- Socioeconomic constraints
- Clinical significance of partial responses

2) Identification of the most promising secondary treatment strategies

- Switching within treatment approaches
- Switching between treatment approaches
- Pharmacological augmentation
- Psychotherapeutic augmentation
- Other psychosocial and educational approaches
- Somatic treatments

This phase shall also serve as an opportunity to begin recruitment of clinical sites. NIMH anticipates that the basic administrative structure, relationships with coordinating centers, choice of computer platform and database management system shall have been finalized prior to the protocol development phase. There can be opportunity to test and finalize data collection, management, and reporting procedures.

3) Design of the Trial

The result of the protocol development phase shall be intervention protocols combining pharmacologic and psychosocial interventions organized in such a way that they can be applied in both specialty mental health and in general health care settings. The protocols shall incorporate acute and long-term rehabilitative intervention strategies directed toward enhancement of social functioning, reduction or elimination of side effects, and management or control of residual symptoms. The protocols shall include provisions to retain and adequately treat people that become suicidal during the study. The treatment outcomes to be assessed shall include at least: completeness or degree of recovery, speed of symptom stabilization, all adverse effects, suicidal behavior, treatment adherence, patient satisfaction, functional capacity, disability, rates of recurrence or relapse and long-term follow-up. Other criteria considered essential for the intervention strategy shall be: assessment of cost-effectiveness and transportability to a variety of health care settings within the community. It would be advantageous to include the involvement of large integrated health care systems and managed care organizations. The protocols should address factors that impact on the delivery of and adherence with the treatment interventions.

In order to accomplish the goals of optimal power, sensitivity, internal and external validity, it is anticipated that investigators will consider more than one study design. An approach that appears to be highly desirable would be a hybrid that includes both experimental and observational components.

Protocol Implementation

In the implementation phase, the PI(s) shall initiate, manage and coordinate a large, multi-site intervention trial with adequate statistical power to address the general and specific research objectives. Activities shall include site selection, development of study policies and procedures, clinical monitoring, development of data collection and management procedures, training of clinical and research staff, interim and final data analysis, and preparation of draft reports. A public use database with appropriate documentation shall be prepared by the end of the contract period.

During the implementation phase of a protocol, subjects shall be randomized after any necessary stratification, to active treatment conditions.

Generalizability/Transportability of Results

Generalizability and transportability of results is crucial to the success of this initiative. Trial participants must be representative of community clinical populations, and the treatments studied must be transferable to community practice settings. The goal is to improve treatment and optimize outcomes for people with treatment resistant depression. This is expected to be randomized clinical trials but alternative or hybrid approaches may be appropriate. The study designs and the final protocols should recognize the trade-off (and discuss the appropriate balance) between what is ideal methodologically or clinically, and what is achievable in the real world.

Subject entry criteria should be broad and comorbid psychiatric and medical disorders (including substance abuse and suicidality) should not be excluded beyond what is necessary for safety. Indeed, if study results are to be useful in the community, a significant proportion of subjects with comorbid disorders is a necessity. Subject stratification (during randomization and during data analysis) shall be used to deal with comorbid disorders. Demographic and geographic diversity will be important. When a trial extends beyond acute treatment to examine outcome and effectiveness, subjects will have to be followed for extended periods of time (one to two years). Subject retention will be crucial, and protocol mechanisms must be in place to deal with hospitalizations and exacerbations to minimize drop outs. Similarly, a mechanism should be provided to handle treatment failures whether due to lack of efficacy or side effects (e.g., re-randomization).

One particularly problematic issue will be treatment setting. Because psychopharmacological treatment trials have been, to this point, the province of the pharmaceutical industry, previous studies have been confined to academic centers and a small number of private hospitals and outpatient centers. Subject recruitment in these settings is unlikely to be fully representative of community populations, and the providers involved differ in many ways from those practicing in the community. One of the goals of this initiative is to broaden the spectrum of treatment settings able and interested in participating in clinical trials. The contractor should provide an outreach plan for recruiting practitioners and sites that have not been involved in previous treatment trials, particularly ones in managed care or public mental health settings.

Inclusion of more representative trial sites will also facilitate translation of study results into clinical practice. It will be important for the contractor to develop methods for disseminating and implementing findings. While publication of results and changes in treatment guidelines must await the completion of these studies, the need for translation and application in community settings must guide experimental design, and dissemination of results should be planned from the beginning.

Ancillary Studies, and Coordination with Other Projects

The pool of subjects screened and recruited in these trials will be a unique resource for other clinical research studies. There should be a process for considering investigator-initiated ancillary studies. Ancillary studies can be proposed by any investigator (not limited to investigators participating in the Trial) as an opportunity to enhance the value of the overall initiative. Funding for ancillary studies will not be provided in this contract and must be submitted as separate research project grants (R01, etc.). An ancillary study must be judged scientifically meritorious and operationally feasible. An ancillary study shall not be considered if it is judged to have the potential for interfering with the completion of the main objectives of a trial or the project, if it adversely affects subject availability or cooperation, if it diverts resources from the main objectives, or if it compromises the public image of the initiative. The External Advisory Committee should be involved in reviewing the scientific value and appropriateness of the ancillary study. An ancillary study will not be considered for peer review at NIH without a letter from the contract PI (or designee) stating that it meets the above criteria, and which has the concurrence of the GPO.

There are ongoing treatment studies sponsored by NIMH and other entities, and it is likely that new studies will be supported in the future, independent of this initiative. If NIMH requests, the

contractor shall cooperate with these other projects, coordinating methodology and protocol design so that meaningful comparisons can be drawn.

These studies may be funded either through the contract or through any investigator initiated mechanism (R01 etc). The mechanism will depend on the nature and scope of the questions involved and their relationship to the primary project.

In addition, investigators are strongly encouraged to propose methods of disseminating and implementing the findings of these studies in clinical practice. Proposals to test treatment algorithms developed from these studies in other clinical settings may be funded through extension of this contract. Development of methods for distributing information derived from these studies to practitioners through publications, practice guidelines, and novel training materials (video, computer-based training, etc) is strongly encouraged. Communicating findings derived from these studies to consumers, families, employers, and other concerned parties is also a major objective.

Organization/Responsibilities

The contractor for this initiative shall be responsible for central coordination of the trial including protocol development, recruiting clinical sites, finalizing the study design, preparing informed consent documents, providing data forms, training, centralized communication, data entry and management and quality control, as well as statistical analysis, report writing and other related activities. The main organizational components shall be:

A) **Study Chairperson.** The Study Chairperson, or Principal Investigator (PI), is responsible for the overall conduct of the clinical trial and for providing scientific, technical, and administrative leadership to the study. He/She will have lead responsibility for supervising and directing all parts of the study and for oversight of the study's resources. The PI may also have direct leadership responsibility for the coordinating center(s) and/or a major clinical site. In carrying out these responsibilities, the Study Chairperson will actively seek advice from all study components. The Study Chairperson will be the primary interface with NIMH staff concerning routine operations and reporting on progress of the project.

B) **Coordinating Center.** The Coordinating Center will manage sites participating in the project and will centralize database management. More than one Coordinating Center may be proposed. For example, it may be desirable to locate clinical coordination and site management in one center and information systems, database management, and statistical analysis in another. Coordinating Center director(s) will play an important role in the design, implementation, and execution of the clinical trial. Under the leadership of the Executive Committee, the directors shall be responsible for all aspects of the operations of his/her center and for the local implementation of the study protocol. The center(s) are involved in performing specified support functions such as training and certification of clinical center staff, designing and maintaining quality assurance programs, data management, data analysis, and preparing publications.

C) **Study Sites.** Each participating clinical site will have a local lead investigator or site director who has the primary responsibility of identifying and recruiting eligible patients at his/her site. He/She will be responsible for the follow up, as specified in the study protocol, of each patient enrolled in the clinical trial at that site and for submitting required data to the Coordinating Center. The site director is also responsible for ensuring that clinic personnel at that site are trained and certified to carry out study procedures. A single "site" might encompass multiple locations if, for example, it was a managed care system or other network of providers. Site directors are expected to remain masked with respect to treatment assignment for the duration of the trial; any deviation from this should be described and explained.

D) **Executive Committee:** Composed of the Study Chairperson, who serves as Chair, the Coordinating Center director(s), the National Institute of Mental Health GPO (*ex officio*), and a small group of clinical site investigators who are elected by the full group of participating clinical site directors for a set term. If appropriate, the committee may include senior researchers from the contractor or Coordinating center(s). This committee acts as the administrative and executive arm of the clinical trial. It makes decisions on day-to-day operational issues; considers and adopts changes in study procedures as necessary; reviews and implements recommendations from the NIMH Data and Safety Monitoring Board; reviews progress of the trial in achieving its main goal and takes steps required to enhance likelihood of success; and, reviews data collection practices and procedures as summarized in performance monitoring reports for clinical centers to identify and correct remediable deficiencies.

E) **External Advisory Committee.** This group consists of scientific advisors who will provide methodologic consultation and guidance to the contractor, particularly during the protocol design phases. The Advisory Committee may also play a role in the design and approval of ancillary studies. The Advisory Committee will be made up of well recognized experts in the field. Nominations for Chair and members of the Advisory Committee will be proposed by the Study Chairperson and submitted for approval to the GPO.

F) **Data and Safety Monitoring Board** (DSMB) This standing NIMH-appointed committee consists of independent experts in clinical trials who are charged with reviewing the safety of protocols and advising the Director, NIMH on the progress of the study. The DSMB plans to meet the third week every January, April, July and October for protocol review. Protocols shall be submitted at least one month prior to the DSMB meeting at which it is to be discussed. Actions of the DSMB include approval or deferral. Approval by the DSMB is required prior to the enrollment of any patients in the trial.

G) **Editorial/Communication Committee:** This committee has the responsibility for reviewing manuscripts produced by the study investigators and for assisting in the preparation of the main trial results. This committee will also play an active role in coordinating the dissemination of results to the scientific and lay community. This will include not only printed material, but also may include the development of a website for

wide distribution of information related to this study. This committee will take responsibility for development of practice guidelines and other materials generated by this study. Its members are the Study Chairperson, coordinating center directors, the NIMH Project Officer, and several clinical center investigators elected by the full group of clinical site directors.

Masking

Ordinarily, the Study Chairperson, Coordinating Center director(s), Site directors, Executive Committee members, External Advisory Committee members, and Editorial/Communication Committee members would be expected to remain masked with respect to treatment for the duration of the trial. Any deviation in masking should be described and justified in the work plan and final protocol.

Number of Subjects

A Request for Information (RFI) was issued during the development of this requirement. Respondents estimated that a sample size of approximately 2,000 subjects would be necessary for adequate statistical power to achieve the objectives of this trial. This estimate is based on a number of assumptions about the design of the trial. The actual power analysis for any proposed trial will depend on the exact design and goals of that trial and may result in a larger or smaller number of subjects.

IV. Services to be Performed

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to conduct intervention trials in treatment resistant depression. All work under the contract shall be conducted under the general guidance of the Government Project Officer (GPO).

Protocol Development and Finalization

NIMH anticipates that there will be 1 trial and 1 protocol. It is estimated that the preliminary activities prior to initiating the trial will require at least 6 but not more than 9 months for completion. This estimate includes approximately 3 to 6 months from the effective date of the contract to finalize the protocol; and up to 3 months for selection of the Clinical Sites. Other preparatory activities listed below shall also be completed within this nine month period after contract award.

The Contractor shall complete the development of a final protocol using whatever mechanisms deemed to be appropriate.

At a minimum, the final protocol shall include the following aspects:

1. A review of the study objectives, public health significance, specific aims, and endpoints
2. A review of general and specific issues as discussed in Objectives and Approach of the Statement of Work

3. Trial design and administrative structure
4. Treatment specifications (with attachment of treatment manuals, as needed) and length of treatment
5. Patient selection criteria with rationale for limited exclusions
6. Randomization and stratification/blocking methods
7. Outcome measures to examine symptomatology
8. Outcome measures (where appropriate) to examine issues such as compliance, disability, vocational function, social function, and quality of life
9. Outcome measures (where appropriate) to evaluate how external factors (setting, psychosocial support, economic factors, etc) impact treatment delivery, and outcome
10. Outcome measures (where appropriate) to evaluate cost-effectiveness and pharmaco-economic issues
11. Sample size and power estimates
12. Clinical and laboratory monitoring procedures
13. Reporting of adverse events
14. Plans for subject retention and minimization of dropouts
15. Rules for dealing with exacerbations, hospitalizations, and treatment failures
16. Plans for dealing with clinical emergencies and breaking of masked treatment (if applicable)
17. Stopping rules and possible rerandomization rules
18. Rules for possible dosage adjustments
19. Rules for adjunctive pharmacologic, psychotherapeutic, or other treatment
20. Plans for preventing, identifying, and handling protocol violations
21. Plans for addition of new antidepressants if and when they are released
22. Procedures for addition and/or removal of clinical sites
23. Outreach plans (if needed) for additional recruitment of practitioners and clinical sites from a variety of settings (particularly the public sector and managed care) and plans (as needed) for training and developing a clinical research infrastructure at these sites
24. Plans (where appropriate) for evaluating the impact of changes in external factors (e.g. health care settings or reimbursement policies, psychosocial support systems, economic factors etc.) on treatment delivery, compliance, and outcome
25. Rules for interim analysis and early termination of a treatment arm if appropriate
26. Plans for study staff training
27. Plans for monitoring and coordination of each site
28. Data collection and monitoring
29. Human subjects considerations
30. Periodic data safety review
31. Plans for biostatistical input and data analysis
32. Plans for disseminating and implementing findings from the trial
33. A timeline with milestones and evaluation criteria against which progress of the trial will be judged

The GPO shall organize a scientific review of each final protocol to be carried out by experts not otherwise associated with the trial. This review will be carried out within two weeks of submission of the final protocol by the contractor, and will result in recommendations to proceed with submission to the NIMH Data and Safety Monitoring Board (DSMB) or to revise and

address specific issues.

Selection of the Clinical Sites

Recruitment of clinical sites, particularly managed care system and public sector sites not previously involved in clinical trials will be ongoing. Selection of sites for a trial and awarding of subcontracts will take place after the protocol is finalized. Each site will provide a proposal, an agreement to comply with the protocol, fixed cost per patient, and will meet the criteria listed below. The contractor should propose a process for selecting, awarding and managing clinical site subcontracts that conforms to the requirements of the contract. The review process should judge sites as acceptable or not acceptable as well as ranking them according to criteria that include the following:

1. Access to a sufficient number of potential study participants to ensure prompt enrollment of study subjects and timely completion of the study
2. Diversity of subjects including a range of ages, sexes, ethnic diversity, and geographical dispersion (including a balance between urban and rural). A variety of treatment settings are needed, including university settings, private practice, managed care systems, and public mental health systems
3. Investigators experienced in conducting clinical trials involving the psychopathology and treatment modalities of the protocol
4. Availability of adequate experienced professional and technical staff to provide scientific and administrative coordination and support to the clinical trial, including site management and quality control expertise, appropriate clinical expertise, and capacity for patient recruitment and followup
5. Adequate facilities, equipment, and support staff to conduct clinical trials (unless it is a unique setting not previously involved in research)
6. Adequate computing resources and support staff, including internet access, and electronic communication capabilities,
7. Any needed capabilities and staff for data collection, entry, editing, electronic transfer, quality control, database management (maintaining security and accessibility), and data backup (on site and off site).
8. Access to a standing Institutional Review Board (IRB) with a multiple project assurance from the NIH Office of Protection from Research Risks (OPRR), or commitment to acquire a single project assurance from the OPRR
9. Agreement to participate as a site for this trial
10. Agreement to comply with all the required Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition regulation (HHSAR) clauses that apply to a fixed price Research and Development contract with an educational institution or profit making concern, as appropriate
11. Acceptance of the proposed fixed site cost falling within the amounts included in the contract proposal and negotiated in the Coordinating Center contract; the site cost shall be inclusive of all costs associated with the completion of the protocol at the site and reimbursement shall be made on a per patient fixed price basis

The contractor will provide a list of acceptable sites and their rankings, along with all information submitted by prospective Sites to the GPO. The GPO shall review the proposed list and attached relevant information, consult with the scientific advisors, as appropriate, and notify the Contractor of the decision of approval/disapproval within 2 weeks from receipt of the list.

Within two weeks from receiving the GPO's concurrence, the contractor shall execute subcontracts to the approved Sites. Unless some compelling reason is provided, NIMH expects the primary contractor will issue subcontracts to the Clinical Sites rather than a Center or Administrative Core subcontractor (thus avoiding multiple overhead charges from having subcontracts to subcontracts).

Sample Terms & Conditions for Clinical Site Subcontracts

a. At the time of award, the clinical site shall have an established source of research subjects appropriate for the protocol design
b. All research activities conducted at the study site shall follow the state-of-the-art of good clinical trial practice criteria, in order to generate data that can be published in peer-reviewed scientific journals
c. All institutional, NIMH, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent forms shall be approved by the appropriate IRB
d. All materials/data collected from the specific study funded under this contract shall be property of the NIMH and shall be made available to the NIMH both electronically and in hard copy using standard procedures that safeguard the confidentiality of the research records. It is anticipated that the GPO and other Government officials involved in the activities conducted under this contract will publish study data jointly with the PIs and study Site staff. Publication will be in accordance with the Terms and Conditions of the Contract Statement of Work
e. NIMH or its designees shall have the right to audit patient records and research data at any time during the study
f. The clinical site leader shall be responsible for all aspects of the performance of this contract, including the performance of any subcontracts. All subcontracts require prior review and approval of the GPO and Contracting Officer (CO) before award
g. All work under this contract shall be monitored by the GPO, PI, and the Executive Committee
h. The Clinical Site leader shall be considered Key Personnel and shall not be replaced without prior approval of the CO, the GPO, and the PI.

Clinical Trial Preparation

The following tasks shall also be completed within 6 to 9 months from the award of the contract to ensure that patient enrollment begins on schedule:

1. Develop the text of the study consent and assent forms for use by the clinical sites, provide the sites with such documents, and ensure that, after appropriate modifications to meet local standards, these forms are submitted and approved by the IRB at each Site
2. Submit to the GPO all materials necessary to obtain approval of a clinical exemption from the NIH Clinical Exemption Review Committee before the start of patient enrollment into the protocol and all materials necessary to obtain approval of the Office of Management and Budget (OMB) if required
3. Develop and test procedures for collecting all data needed on study subjects, using either standardized clinical research forms or an electronic equivalent
4. Prepare manuals of study policies and procedures
5. Pilot test all forms and procedures before their finalization and distribution to the Sites
6. Arrange and coordinate training of the clinical staff, in order to ensure reliability of evaluation, treatment and assessment procedures
7. Develop and implement a system for random treatment assignment of eligible patients and appropriate stratification
8. Obtain study medications and prepare them for proper use in the study
9. Develop and implement a plan for closely monitoring adverse effects of study medications to maximize patient safety, including plans for prompt reporting of the more severe adverse events
10. Develop and implement a plan for subject retention and a system for dealing with clinical emergencies, both acute and subacute (hospitalization, adjunctive medications, etc.)
11. Develop a plan for overall quality control and for monitoring patient recruitment and for early identification of Sites with recruitment problems and for addressing recruitment difficulties
12. Develop a plan for dropping a Site should the Site not be able to maintain minimal recruitment goals and for adding new Sites as necessary or appropriate

Computer System

The contractor shall develop a data collection and management system suitable for the study. This should be a commercially available, relational database management system (DBMS) that is fully ANSI SQL compliant, and that runs on a UNIX or Microsoft NT platform. Data entry/verification procedures should minimize opportunities for human error and mis-entry. If feasible, and if it does not delay study onset, NIMH encourages the use of electronic forms for initial entry of individual subject data by on site staff (with a paper printout). In this case, the contractor may choose to provide a standardized data management system to each Clinical Site, or work with existing compatible systems at each Site. Alternatively, if initial entry of subject data is done using paper based forms, keypunching may be done at the different Centers, the Administrative Core, or at each Clinical Site. At a minimum, the system shall provide for the following:

1. Internet access and capacity for electronic communications. NIMH anticipates that the contractor will develop a secure Intranet to facilitate interactions between Clinical Sites, Centers, Administrative Core, and NIMH

2. A method must be provided to ensure security and confidentiality of all clinical records. In particular, the investigators shall be prohibited from collecting or maintaining information about any patient enrolled in the research study which would allow that individual to be personally and directly identified
3. On-site and off-site backup of electronic data is necessary, as well as procedures to avoid data loss and down-time in case of equipment failure (e.g., hard disk crashes computer breakdowns, power outages, etc.)
4. While NIMH does not plan to do so, at the request of the GPO and CO, the contractor shall close out data entry and transfer the entire database, DBMS, and all associated programs, source code, codebooks, indices, data tables, documentation, etc., within 30 calendar days of such notification, in a readily usable form to NIMH and/or to its designee. The computer system, DBMS, and any software used to enter, store, manipulate and report study data must be transferable and reproducible. Site specific and legacy systems are to be avoided, and any programs written by DBMS staff must be executable on systems available to NIMH and/or third parties.

Data Management Activities

The Contractor (Coordinating Center) shall have all the necessary procedures operational to perform the following activities to be conducted at different times during the duration of the contract:

1. A standardized method of data entry and data verification
2. A method and schedule for transferring data (electronic and/or paper) from the Clinical Sites to the Center,
3. The DBMS must be able to receive, process, edit, correct, update, store, track, retrieve, and analyze all study data.
4. Data entry, verification, and transfer procedures, and the DBMS as a whole, shall be tested prior to patient recruitment to ensure reliable performance.
5. The contractor will monitor Clinical Site data collection, subject tracking, and transfer of data to the Center. The Contractor shall train staff at the Clinical Sites in proper procedures and standards to ensure prompt accumulation, completeness, entry, and editing of study data. Procedures for entering and verifying data shall be specified
6. The contractor shall monitor how accurate, complete and up to date the database is. There will be a plan for resolving problems identified in the monitoring process
7. As data are received from the Clinical Sites, the contractor shall, as needed, check, keypunch (if received as hard copy), verify, process, monitor, correct, update, file, store, and inventory the data using the DBMS. Data received from the Clinical Sites shall be reviewed within one week from receipt for completeness, accuracy, consistency, out-of-range values, and overall quality. Sites shall be informed promptly, and in any case within 2 weeks from receipt of any missing, incomplete, or erroneous data
8. The contractor shall develop appropriate methods for analyzing and presenting study data using standard statistical software capable of univariate and multivariate analyses

9. The contractor shall develop procedures to be used by the PIs and the GPO to obtain (through DBMS staff) data from the database in either raw or summary form, for reports and analysis. The information will be provided electronically and/or as hard copy depending on the request. The PIs and GPO shall specify standard (recurrent) database queries which should be immediately answerable (less than 24 hours) by the data managers. Other, non-standard database queries shall be answered within 7 calendar days.
10. The contractor shall prepare and provide periodic study data and reports as requested by the GPO, the PIs, and the NIMH DSMB
11. On or before the final date of the contract, the contractor shall provide the GPO with the DBMS, a final, cleaned, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc, in a format that is readily usable by NIMH or its designee.
12. On or before the final date of the contract, the contractor shall provide the GPO with final statistical reports of the study outcomes

Protocol Implementation

After finalization of a protocol, the Contractor shall provide a timeline with mileposts to judge progress. Enrollment into the study protocol shall start at approximately 9 months from contract award and shall be completed during the following 4 years. During this period, the Contractor shall perform all the activities necessary for a proper conduct of the study, including, among others:

1. Monitor Sites for rate of recruitment, protocol adherence, data collection, data entry and ensure quality performance at each Site
2. Ensure that adequate supply of study medication is available at each Site
3. Ensure adequate monitoring and prompt reporting of adverse medical events
4. Ensure data transfer from the Sites to the Coordinating Center
5. Assess the quality of the data received from the Sites and verify (if needed) the database against any source documentation
6. Prepare and send monthly reports on the state of the study to the GPO. After starting recruitment, the monthly reports shall include, at a minimum the following information, both by individual Site and cumulative: number of subjects enrolled and their demographic characteristics, number of subjects screened but not enrolled with reason for non enrollment, number of subjects who dropped out of the protocol and reasons, number of subjects who have completed the study, anticipated subject enrollment and completion schedules
7. Prepare and distribute reports for the NIMH DSMB (on average every 3 months during the conduct of the study), the GPO, the PIs and Executive Committee, as requested

Meetings/Communications

The following tasks will be performed at different times during the duration of the contract, as specified below:

1. Schedule and coordinate periodic telephone conference calls with the GPO, other NIMH staff, advisors, and other staff involved in the study, in order to discuss the progress of the study and other project related activities. The frequency of these calls shall be scheduled at least monthly but could be more frequent depending upon the phase of the study, complexity of issues, actual progress, and problems encountered. The Contractor shall prepare minutes of these calls and send them to the GPO and other relevant parties within 4 working days after each call.
2. Schedule, coordinate, arrange, participate in, and provide any information necessary for the Executive Committee meetings. These meetings will be as frequent as required by the phases and progress of the study. It is anticipated that in year 1, at a minimum, a two-day meeting will need to be organized before starting recruitment, in order to finalize the protocol and plan training. The Contractor shall prepare minutes of these meetings and distribute them to the GPO and other relevant parties within 7 working days after each meeting.
3. Attend and participate in the meetings of the External Advisory Committee. It is estimated that advisors will meet once or twice per year, based on the phase and progress of the study
4. Schedule, arrange, and coordinate meetings with Clinical Site staff with the purpose of training staff in all the relevant activities of the study. NIMH anticipates that at least one training meeting will be required within 6-9 months after the contract award.
5. Arrange for a Site visit at least once a year at each participating Site, with the purpose of monitoring adherence to protocol, ensuring consistency across Sites, and quality controlling the data collected and entered in the database. A schedule for these visits shall be established annually, and provided to the GPO who may choose to attend any or all visits. The Study Chairperson, the Coordinating Center director(s), site monitors, or other personnel as appropriate may perform these visits. Only personnel necessary to accomplish the review of that site for that stage of performance shall perform visits. Audits shall be designed to minimize contract expenditures to the maximum extent feasible. The Contractor shall prepare a written report for the GPO on the results of each visit, which will be sent to the Site and the GPO within 15 working days after completion of the visit. Reports shall indicate number of clinical files and procedures audited, number and type of protocol violations or deviations encountered, and number and type of data discrepancies. Reports shall include recommendations and plans aimed at correcting any problems encountered at the Clinical Sites.

Terms and Conditions

1. A single contract shall be issued for the project as a whole. The contractor shall issue all subcontracts. The Terms and Conditions and Statement of Work for the primary contract shall apply to these subcontracts

2. All tasks described in this statement of work shall be coordinated and implemented by the Contractor in conjunction with and under the guidance of the GPO
3. All research activities conducted under the contract shall follow the state-of-the-art of good clinical trial practice criteria, in order to generate data that can be published in peer-reviewed leading scientific journals
4. All institutional, NIMH, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent forms shall be approved by the appropriate IRB
5. All materials/data collected by the PI from the specific study funded under this contract shall be property of NIMH and shall be made available to NIMH electronically and/or as hard copy prior to the end of the contract period or within 30 calendar days of a written request by the GPO or CO. The contractor shall use standard procedures to safeguard confidentiality of research records.
6. NIMH or its designees shall have the right to audit patient records and research data, as well as independently access and analyze study data, at any time during the study
7. The Study Chairperson, Coordinating Center director(s) and clinical site directors shall be responsible for all aspects of the performance of this contract, including the performance of any subcontracts. All subcontracts require prior review and approval of the GPO and CO before award
8. The Editorial/Communication Committee and GPO shall expeditiously prepare reports on study results for publication in peer-reviewed scientific journals.
9. The GPO and other NIMH staff actively involved in the scientific aspects of the study shall publish results jointly with the Study Chairperson and others as determined by the Editorial/Communication Committee.
10. No data from studies funded under this contract shall be released, presented at meetings or published without prior review and approval by the Editorial/Communication Committee and GPO, until the primary reports of the results of the trial are published. Once the primary report is published (or within 3 years of the end of the contract, whichever is sooner), a copy of the database shall be made available directly to all PIs involved in the study, and other reports for publication may be produced without the approval of the GPO, but with appropriate acknowledgment of the contract as the source of the data
11. A copy of the database will be made available for public use upon publication of the primary papers, or within 3 years of the end of the contract, or at the discretion of the GPO
12. The GPO or CO may require that the entire database, and all associated programs, source code, codebooks, indices, data tables, documentation, etc, be transferred within 30 calendar days, in a readily usable form to NIMH or its designee
13. At the end of the Contract period, or when the trial is completed, or at the discretion of the GPO and CO, the Contractor shall be prepared to transfer to NIMH or its designee all trial material including training material, data collection procedures, all data, and any other information, equipment, or procedures necessary to implement and conduct the trial
14. The Contractor shall establish procedures to safeguard the confidentiality of any proprietary information provided by the GPO or the Sites

15. The GPO reserves the right to interact directly with the Clinical Sites and appoint consultants to ensure contract-related activities meet all the requirements agreed in the contract and are performed in accordance with the standards and requirements of NIMH
16. A statement must be included in the protocol that the PI and each center director, and site leader agrees and is committed to share, in a timely manner, materials, expertise, and/or data generated in performance of work under any resultant contract with other project participants (including investigators conducting ancillary studies)
17. The study chairperson and key coinvestigators shall be considered Key Personnel and shall not be replaced without prior approval of the GPO and the CO
18. The Contractor shall not enter into any subcontract that has not received the scientific and technical review of the GPO and has not been approved in writing by the Contracting Officer

Reporting Requirements and Deliverables

In addition to any ad hoc reports requested by the GPO, the Contractor shall submit Technical Progress Reports covering the work accomplished during each reporting period (as outlined below).

Monthly Study Reports: The Contractor shall submit one copy to the GPO and one copy to the Contracting Officer (CO) of the monthly report within ten days following the end of the month. At a minimum this report shall include a description of the study progress, quality of data, Clinical Site performance/compliance (the number of subjects enrolled in the study and their demographic characteristics, subjects screened but not enrolled and reasons why not enrolled, subjects that have completed the study, and anticipated subject enrollment and completion schedules for the remainder of the study), listing of adverse reactions, complications and problems encountered and their resolution. The report shall present overall study information as well as data for each Clinical Site. Problems in recruiting and plans for correcting recruiting problems must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution should be included.

Quarterly Report to NIMH DSMB: The Contractor shall submit one copy to the GPO, one copy to the CO, and one copy to the staff coordinator of the NIMH DSMB of a quarterly report detailing study progress, subjects screened, subjects enrolled, adverse reactions, complications, and any other problems encountered and their resolution. The report shall present overall study information as well as data for each Clinical Site.

Annual Report for Gender/Minority/Child and Adolescent Tracking: Annually, the Contractor will submit one copy to the GPO of a recruiting report with the following information: report date, date enrollment/recruitment was initiated, date enrollment/recruitment was completed, whether a minority sub-population has been identified, and a count of subjects targeted by gender, ethnic group (American Indian or Alaskan Natives; Asian or Pacific Islanders; Black,

Not of Hispanic Origin; White, Not of Hispanic Origin; Hispanic; and Other or Unknown), and age group. A similar count of subjects recruited by gender, ethnic group, and age group must be included.

Study Final Report: The Contractor shall submit to the GPO two hard copies and one electronic copy of the Final Report on or before the contract completion date. The CO shall also receive one hard copy of this report. This report shall include a summation of the work performed and results obtained. This report shall be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data and statistical analyses performed in text, tabular and graphical form.

Final Data Set(s) and Other Materials: On or before the final date of the contract, the contractor shall provide the GPO with the DBMS, a final, cleaned, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc, in a format that is readily usable by NIMH or a third party.

Other Reimbursable and Non-Reimbursable Contract Costs

The Contractor will establish a policy for insurance or other third-party reimbursement of the costs of clinical care that normally would have been provided to patients in the trial. The Contractor will establish a contingency fund for reimbursement of Trial related expenses not covered by insurance or other third-party carriers. Costs of care for conditions not part of a Trial (such as costs that would be incurred during routine clinical care) will not be reimbursable under this contract. Costs of care (including inpatient hospitalization) for conditions studied in a Trial will be reimbursable only if they are directly attributable to participation in the Trial and only if they would not have been incurred had the subject not participated in the Trial.

V. OPTION TO EXTEND TERM AND OPTIONS FOR ADDITIONAL SERVICES

As the project and Trial matures, questions may emerge that could best be answered by extending or enlarging the Trial or the project. Similarly, advances in clinical or scientific knowledge may raise issues that could be addressed through an expansion of the Trial or the project. NIMH reserves the option to extend the Trial or the project as a whole in time and/or in scope. The PIs involved in the project may also propose expansions that could be funded through extension of the contract or through another investigator initiated mechanism (R01, etc). The mechanism will depend on the nature and scope of the questions and relationship to the primary project.

Option to Extend Term

If NIMH exercises its option to expand the time or scope of the contract, the contractor should be prepared to carry out any required work, or, if NIMH chooses, to cooperate with another NIH contractor or grantee to carry out this work. NIMH does not commit to

the following, but is considering an option to extend a Trial or the project for up to 5 years beyond the end of the initial contract.

Option for Additional Services

Option 02 - An option to expand the work of the project by adding new antidepressant drugs as they are approved by the FDA or adding other comparison treatments as scientifically indicated

Option 03 - An option to expand the work of a Trial to include screening, recruitment, and sample collection from subjects and family members for pharmacogenetic or genetic linkage studies sponsored by NIMH or other organizations

Option 04 - An option to expand the work of the Trial to include a trial of early intervention during the risk or symptomatic phases of illness

Option 05 - An option to expand the work of the Trial to include studies of pathophysiology and treatment mechanism

Option 06 - A combination of one or more of the above options

SECTION D

PACKAGING AND MARKING REQUIREMENTS

Specific Requirements, if any, for packaging, marking, and shipping of deliverables will be inserted here. If specific requirements exist, they will be incorporated by modification to the contract.

SECTION E

INSPECTION AND ACCEPTANCE

1. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

2. For the purpose of this Article, the Project Officer is the authorized representative of the Contracting Officer.

3. Inspection and acceptance will be performed as determined by the Project Officer.

4. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

5. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at the Website address: http://www.arnet.gov/FAR.

   FAR Clause No. 52.246-8, INSPECTION OF RESERCH AND DEVELOPMENT-COST REIMBURSEMENT (APRIL 1984).

SECTION F

DELIVERIES OR PERFORMANCE

F.1 Period Of Performance

Performance of this contract shall begin with the effective date of the contract and shall extend to September 30, 2004, unless the contract is extended by written modification to the contract.

F.2 Delivery Schedule - After the contract award date, the contractor shall deliver the following items to the GPO in accordance with the stated delivery schedule:

ITEM/DESCRIPTION	QUANTITY (each due date)	DUE DATE
Work Plan	2	Thirty days after contract award date
Subcontracts	2	Prior to subcontract award
Monthly Study Reports	2	Within 10 days following the end of the month
Periodic Phone Conference Reports	2	Within 10 days following the conference
Site Visit Reports	2	Within 15 working days following the Site visit
Draft Protocol for Clinical Trial	2	Within 4 months of contract award
Final Protocol for Clinical Trial	2	Within 7 months of contract award
Advisory Committee Minutes	2	Within 10 days following meeting
Draft Final Report	2	One month prior to contract expiration date
Final Report	2	By contract expiration date (2 hard copies & 1 electronic copy)
Study Data & Other Materials	2	By project completion
Publication Draft	2	Before submitting for publication

F.3 The items/reports identified shall be addressed and delivered to the GPO. In addition, one (1) copy of each monthly progress reports, the subcontracts report and the final report shall be delivered to the Contracting Officer by the specified delivery date.

F.4 Clauses Incorporated by Reference, FAR 52.252-2 (February 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. The full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/. FAR Clause 52.242-15, Stop Work Order (August 1989) with Alternate I (April 1984)

SECTION G

CONTRACT ADMINISTRATION DATA

G.1 Government Project Officer

The following Government Project Officer (GPO) and Alternate Government Project Officer (AGPO) will represent the Government for the purpose of this contract:

Name	Title
Herbert Harris, M.D.	Government Project Officer, NIMH
Barry Lebowitz, Ph.D.	Alternate Government Project Officer, NIMH

The GPO and AGPO are responsible for: (l) monitoring the Contractor's performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with the authority to act as an agent of the Government under this contract. Only the Contracting Officer has authority to: (l) direct or negotiate any changes in Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

G.2 Key Personnel

Pursuant to the Key Personnel clause incorporated in this contract HHSAR 352.270-5, the following individual is considered to be essential to the work being performed hereunder:

Name	Title
A. John Rush, M.D.	Principal Investigator
Madhukar Trivedi, M.D.	C0-Principal Investigator
Maurizio Fava, M.D.	Director, MGH Regional Site
Fredrick Quitkin, M.D.	Director, Columbia U. Regional Site
Michael Thase, M.D.	Director, U. Pitts Regional Site
Stephen Wisniewski	Prinicpal Invesitgator, U. Pitts. Data Center
Sheryl Kelsey	Co-Investigator, U. Pitts. Data Center

The clause cited above contains a requirement for review and approval by the Contracting Officer of written requests for a change of Key Personnel reasonable in advance of diverting and of these individuals from this contract. Requests for Key Personnel changes shall include the amount of time committed for presently active contracts, cooperative agreements, and grants, as well as commercial agreements, proposed time commitments under proposals under

consideration for award; and the individual's effort proposed for this contract. Receipt of written requests shall be at least 30 days prior to a proposed change considerable reasonable.

G.3 Invoice Submissions

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, and attached and made part of this contract (Section J) The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated office:

National Institute of Mental Health
Contracts Management Branch, ORM
6001 Executive Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603

Inquiries regarding payment of invoices should be directed to the Contracting Officer by telephone on (301) 443-2696.

b. At a minimum, the Contractor agrees to include the following information on each invoice:

1. Contractor's name and invoice date,
2. NIMH's Contract number, or other authorization for delivery of property and/or services
3. Description, cost or price, and quantity of property and/or services actually delivered or rendered,
4. Shipping and payment terms,
5. Other substantiating documentation or information as required by the contract,
6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide a detailed breakdown per task on invoices of the following cost categories:

(a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) Fringe Benefits - Cite rate and amount
(c) Overhead - Cite rate and amount
(d) Materials & Supplies - Include detailed breakdown.
(e) Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.

(f) Consultant Fees - Identify individuals and amounts.
(g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
(h) Equipment - Cite authorization and amount.
(i) G&A - Cite rate and amount.
(j) Total Cost
(k) Fixed Fee
(l) Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

2. The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

G.4 Method Of Payment (APRIL 1984)

a. Payments under this contract shall be made either by check or by wire transfer through the Treasury Financial Communications System at the option of the Government. The Contractor shall forward the following information in writing to:

Chief, Contracts Section, FAAB
Division of Financial Management
National Institutes of Health
Building 31, Rm. B1B58
Bethesda, MD 20892

No later than seven (7) days after receipt of notice of award, including:

1. Full name (where practicable), title, phone number, and mailing address of responsible official(s) to whom check payments are to be sent, and who may be contacted concerning the bank account information requested below.

2. The following bank account information is required to accomplish wire transfers:

   a. Name, address, and telegraphic abbreviation of the receiving financial institution
   b. Receiving financial institution's nine digit American Bankers Association (ABA) identifying numbers for routing transfer of funds. (Provide this number only if the receiving financial institution has access to the Federal Communications System.)

c. Recipient's name and account number at the receiving financial institution to be credited with the funds.
d. If the receiving financial institution does not have access to the Federal Reserve Communications Systems, provide the name of the correspondent financial institution through which the receiving financial institution receives electronic funds transfer messages. If a correspondent financial institution is specified, also provide the address and telegraphic abbreviation of the correspondent financial institution, and the correspondent financial institution's nine digit ABA identifying number for routing transfer of funds.

3. Any changes to the information furnished under paragraph (2) of this clause shall be furnished to:

Chief, Contracts Section, FAAB
Division of Financial Management
National Institutes of Health
Building 31, Rm. B1B58
Bethesda, MD 20892

in writing at least thirty (30) days before the effective date of the change. It is the Contractor's responsibility to furnish these changes promptly to avoid payments to erroneous addresses or bank accounts.

4. The document furnishing the information required in paragraph 2 and 3 must be dated and contain the signature, title, and telephone number of the Contractor's official authorized to provide it, as well as the Contractor's name and contract number.

G.5 Late Payment to the Government

Late payment of debts owed the Government by the Contractor, arising from whatever cause, under this contract/order shall bear interest at a rate or rates to be established in accordance with the Treasury Fiscal Requirements Manual. For purposes of this provision, late payments are defined as payments received by the Government more than thirty (30) days after the Contractor has been notified in writing by the Contracting Officer of:

1. The basis of the indebtedness,
2. The amount due,
3. The fact that interest will be applied if payment is not received within thirty (30) days from the date of mailing of the notice,
4. The approximate interest rate that will be charged.

G.6 Mandatory Information for Electronic Funds Transfer Payment

The information required by FAR Clause 52.232-33 - Mandatory Information for Electronic Funds Transfer Payment (August 1996) shall be submitted to the following address:

Chief, Contracts Section, FAAB
Division of Financial Management
National Institutes of Health
Building 31, Rm B1B58
Bethesda, MD 20892

G.7 Contract Financial Report

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "PREPARATION INSTRUCTIONS," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within the Financial Report of Individual Project/Contract, NIH 2706, Section J, attached hereto and made a part of this contract.

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

G.8 Indirect Cost Rates

a. In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d) (2), Allowable Cost and Payment incorporated by reference in this contract, the cognizant organization responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Cost Allocation
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201 Ph. (202) 401-2808

h. The allowable indirect costs under this contract shall be established in accordance with the procedure set forth in Clause No. 52.216-7 of the General Provisions titled: "Allowable Cost and Payment."

G.9 Government Property

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in Section I of this contract, the Contractor shall comply with the provisions of DHHS Publication, Contractor's Guide for Control of Government Property, (1990), which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contract Property Administrator.

Contracts Property Administrator
Research Contracts Property Administration, NIH
6011 Executive Blvd., Room 641E
Rockville MD 20852-7670 Ph. (301) 496-6466

G.10 Post Award Evaluation of Past Performance

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

SECTION H

SPECIAL CONTRACT REQUIREMENTS

H.1 Inclusion Of Minority Group And Gender Representation (NIH 185)

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

H.2 Human Subjects

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract until the protocol developed has been approved by written notice provided by the Contracting Officer and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

H.3 Notice to Offerors of Requirement for Adequate Assurance of Protection of Human Subjects (PHS253.280-1)

Prospective contractors being considered for award will be required to give acceptable assurance that the project described herein will be subject to initial and continuing review by an appropriate institutional committee. This review shall assure that the rights and welfare of the individuals involved are adequately protected, that the risks to an individual are out-weighed by the potential benefits to him/her or by the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate.

H.4 Human Material

It is understood that the acquisition and supply of any and all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

H.5 Continued Ban on Funding of Human Embryo Research

Section 513 of the Fiscal Year 1998 Appropriations Act (P.L. 105-78) prohibits NIH form using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation o a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.6 Needle Exchange

Pursuant to Section 505 of Public Law 105-78, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

H.7 Privacy Act

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract in Section J.

H.8 Anti -Lobbying

Pursuant to Section 503(a) of Public Law 105-78, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

Pursuant to Section 503(b) of Public Law 105-78, contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

H.9 Reimbursement Of Costs For Independent Research And Development Projects

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

H.10 Publication and Publicity

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Institute of Mental Health, National Institutes of Health, under Contract N01MH90003."

H.11 Press Releases

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents

describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

H.12 Subcontracting Provisions

The contractor will negotiate a fixed-price and cost-reimbursement type subcontracts. Award of the subcontracts shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

a. Subcontracting Reports

(1) The Contractor shall submit the original and 1 copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract: April 30th, October 30 th

The Report shall be sent to the following address:

National Institute of Mental Health
Contracts Management Branch, ORM
6001 Executive Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603

(2) The Contractor shall submit 1 copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the October 30 for the entire life of this contract.

The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This Report shall be mailed to the following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 205-6475 for the correct address if unknown.

H.13 Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www1.od.nih.gov/oma/oma.htm)

H.14 EPA Energy Star Requirements

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf-software both before and after recovery from its energy conservation mode.

H.15 Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE-SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and Year 2000 and leap year calculations.

H. 16 Option Provision

a. Option to Extend Term of Contract (FAR 52.217-9)

Until such time that the Government elects to exercise the Option 01 for this contract, the contract period of performance shall be sixty (60) months. The Government may, by unilateral contract modification, require the contractor to perform the Option 01, of the Statement of Work of this contract. If the Government wishes to exercise Option 01, the notice must be given 30 days before the beginning of the option period. The preliminary notice to exercise Option 01 does not commit the Government to actually exercise this option. When any option is exercised, the estimated cost of the contract will be increased as set forth in Section B of this contract.

If the Government exercises this option, the extended contract shall be considered to include this option provision.

The total duration of this contract, including the exercises of any options under this clause, shall not exceed 10 years.

b. Option for Additional Services

The Government may require the delivery of the services identified below as option items to the contract. The Contracting Officer may unilaterally exercise these Options by providing the Contractor with at least 90 days written notification. If the Government exercises these options, the estimated cost/price of the contract will be increased as negotiated and established under the basic award.

Option 02 - An option to expand the work of the project by adding new antidepressant drugs as they are approved by the FDA or adding other comparison treatments as scientifically indicated

Option 03 - An option to expand the work of a Trial to include screening, recruitment, and sample collection from subjects and family members for pharmacogenetic or genetic linkage studies sponsored by NIMH or other organizations

Option 04 - An option to expand the work of the Trial to include a trial of early intervention during the risk or symptomatic phases of illness

Option 05 - An option to expand the work of the Trial to include studies of pathophysiology and treatment mechanism

Option 06 - A combination of one or more of the above options

The total duration of this contract, including the exercises of any options under this clause, shall not exceed 10 years.

H.17 Salary Rate Limitation Legislation Provisions

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds for the applicable fiscal year(s) and periods cited in paragraph b., below may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year and period covered. Direct salary is exclusive of overhead, fringe benefits and general and administrative expenses. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

b. Public Law No.	Fiscal Year	Salary Limitation
P.L. 105-277	1999	$125,900

SECTION I

CONTRACT CLAUSES

GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT WITH AN EDUCATIONAL INSTITUTION - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FAR CLAUSE	TITLE/DATE
52.202-1	Definitions Oct 1995
52.203-3	Gratuities (Over $100,000) Apr 1984
52.203-5	Covenant Against Contingent Fees (Over $100,000) Apr 1984
52.203-6	Restrictions on Subcontractor Sales to the Government (Over $100,000) Jul 1995
52.203-7	Anti-Kickback Procedures(Over $100,000) Jul 1995
52.203-8	Cancellation, Recission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000) Jan 1997
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000) Jan 1997
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000) Jun 1997
52.204-4	Printing/Copying Double-Sided on Recycled Paper (Over $100,000) Jun 1996
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) Jul 1995
52.215-2	Audit and Records - Negotiation (Over $100,000), Jun 1999 Alternate II (Apr 1998)
52.215-8	Order of Precedence - Uniform Contract Format Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data Oct 199752.215-12 Subcontractor Cost or Pricing Data (Over $500,000) Oct 1997
52.215-14	Integrity of Unit Prices (Over $100,000) Oct 1997
52.215-15	Pension Adjustments and Asset Reversions Dec 1998
52.215-18	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions Oct 1997
52.215-19	Notification of Ownership Changes Oct 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications Oct 1997
52.216-7	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3") Apr 1998

FAR CLAUSE	TITLE/DATE
52.216-11	Cost Contract - No Fee Apr 1984
52.219-8	Utilization of Small Business Concerns (Over $100,000) Jun 1999
52.219-9	Small Business Subcontracting Plan (Over $500,000) Jan 1999
52.219-16	Liquidated Damages - Subcontracting Plan (Over $500,000) Jan 1999
52.222-2	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.) Jul 1990
52.222-3	Convict Labor Aug 1996
52.222-26	Equal Opportunity Feb 1999
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era Apr 1998
52.222-36	Affirmative Action for Workers with Disabilities Jun 1998
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era Jan 1999
52.223-2	Clean Air and Water (Over $100,000) Apr 1984
52.223-6	Drug-Free Workplace Jan 1997
52.223-14	Toxic Chemical Release Reporting Oct 1996
52.225-3	Buy American Act - Supplies Jan 1994
52.225-11	Restrictions on Certain Foreign Purchases Aug 1998
52.227-1	Authorization and Consent, Alternate I (Apr 1984) Jul 1995
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000) Aug 1996
52.227-11	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual. Jun 1997
52.227-14	Rights in Data - General, Alternate IV (Jun 1987)
52.232-9	Limitation on Withholding of Payments Apr 1984
52.232-20	Limitation of Cost Apr 1984
52.232-23	Assignment of Claims Jan 1986
52.232-25	Prompt Payment Jun 1997
52.232-34	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration May1999
52.233-1	Disputes Dec 1998
52.233-3	Protest After Award, Alternate I (Jun 1985) Aug 1996
52.242-1	Notice of Intent to Disallow Costs Apr 1984
52.242-4	Certification of Final Indirect Costs Jan 1997
52.242-13	Bankruptcy (Over $100,000) Jul 1995
52.243-2	Changes-Cost Reimbursement Aug 1987
52.244-2	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings. Aug 1998
52.244-5	Competition in Subcontracting (Over $100,000) Dec 1996

FAR CLAUSE	TITLE/DATE
52.245-5	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Jan 1986 Alternate I (Jul 1985)
52.246-23	Limitation of Liability (Over $100,000) Feb 1997
52.249-5	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions) Sep 1996
52.253-1	Computer Generated Forms Jan 1991

HHSAR CLAUSE	TITLE/CLAUSE
352.202-1	Definitions - Alternate I (Apr 1984)
352.228-7	Insurance - Liability to Third Persons Dec 1991
352.232-9	Withholding of Contract Payments Apr 1984
352.233-70	Litigation and Claims Apr 1984
352.242-71	Final Decisions on Audit Findings Apr 1984
352.249-14	Excusable Delays Apr 1984
352.270-5	Key Personnel Apr 1984
352.270-6	Publication and Publicity Jul 1991
352.270-7	Paperwork Reduction Act Apr 1984

Updated: 08/10/99

Attachment 1

INVOICE INSTRUCTIONS FOR NIH FIXED-PRICE CONTRACTS

General The contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form 1035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, or the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies As indicated in the Invoice Submission Clause in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer.

Preparation and Itemization of the Invoice The invoice shall be prepared in ink or typewriter as follows:

(a) Designated Billing Office and address
(b) Invoice Number
(c) Date of Invoice
(d) Contract number and date
(e) Payee's name and address. Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.
(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.
(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)
(h) Equipment If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency All NIH contracts are expressed in United States dollars. Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contactor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

General: The Contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal; and Standard Form 1035, Public Voucher for Purchases and Services Other Than Personal--Continuation Sheet, or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement.. In lieu of SF-1034 and SF-1035, claims may be submitted on Form NIH 2706, Financial Report of Individual Project/Contract, or on the payee's letterhead or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission/Contract Financing Request clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the payment clause shall be submitted monthly unless otherwise authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) Costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval which are not set forth in an advance understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) number.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) Interim Invoice/Contract Financing Request: These are interim payment requests submitted during the contract performance period.

(b) Completion/Final Invoice: The completion invoice is a final invoice which is submitted promptly upon completion of the work, but no later than one year from the contract completion date. The completion invoice should be submitted when all costs (except for finalization of indirect cost rates) have been assigned to the contract and all performance provisions have been completed.

(c) Final Invoice: A revised final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., final indirect cost rates and resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries of the sample invoice/financing request.

(a) Payor's Name and Address : The paying office and address, identified in the Invoice Submission clause of the contract, shall be entered on all copies of the invoice/financing request.

(b) Invoice/Financing Request Number : Insert the appropriate serial number of the invoice/financing request.

(c) Date Invoice/Financing Request Prepared : Insert the date the invoice/financing request is prepared.

(d) Contract Number and Date : Insert the contract number and the date of the contract.

(e) Payee's Name and Address : Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Total Estimated Cost of Contract : Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) Total Fixed-Fee : Insert the total fixed-fee (where applicable).

(h) Billing Period : Insert the beginning and ending dates (day, month, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) Amount Billed for Current Period : Insert the amount billed for the major cost elements, adjustment and adjusted amounts for the period.

(j) Cumulative Amount from Inception to Date of this Billing : Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) Direct Costs : Insert the major cost elements. For each element, consider the application of the paragraph entitled Costs Requiring Prior Approval on page 1 of these instructions.

(1) Direct Labor : This consists of salaries and wages paid (or accrued) for direct performance of the contract.

(2) Fringe Benefits : This represents fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) Accountable Personal Property : This category of cost includes permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS Contractor's Guide for Control of Government Property.) Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS 565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

(A) The item number for the specific piece of equipment listed in the Property Schedule;

(B) The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule, or;

(C) Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) Materials and Supplies: This category includes equipment with unit costs of less than $500 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) Premium Pay: This is remuneration in excess of the basic hourly rate.

(6) Consultant Fee: Fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) Travel: Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel should be billed separately from domestic travel.

(8) Subcontract Costs: List subcontractor(s) by name and amount billed.

(9) Other: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amount separately. If the contract contains restrictions on any cost element, that cost element should be listed separately.

(l) Cost of Money (COM): Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) Indirect Costs--Overhead: Cite the formula (rate and base) in effect during the time the cost was incurred and for which reimbursement is claimed. If special rate is being used; e.g., off-site, then so specify.

(n) Fixed-Fee: If the contract provides for a fixed-fee, it must be claimed as provided for by the contract. Cite the formula or method of computation.

(o) Total Amounts Claimed: Insert the total amounts claimed for the current and cumulative periods.

(p) Adjustments: This includes amounts conceded by the Contractor, outstanding suspensions and disapprovals subject to appeal.

(q) Grand Totals

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Payor's Name and Address NATIONAL INSTITUTES OF HEALTH Office of Financial Management Contracts Section Building 31, Room B1B58 31 CENTER DR MSC 2045 BETHESDA MD 20892-2045	(b) Invoice/Financing Request No. (c) Date Voucher Prepared (d) MAO No. and Date
(e) Payee's Name and Address ABC CORPORATION 100 Main Street Anywhere, U.S.A. Zip Code Attention: Name, Title and Phone Number of Official to Whom Payment is Sent	(f) Total Estimated Cost of MAO (g) Total Fixed Fee

(h) This invoice/financing request represents reimbursable costs from August 1, 1992 through August 31, 1992.

	(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception to Date of this Billing
(k) Direct Costs		
(1) Direct Labor	$ 3,400	$ 6,800
(2) Fringe Benefits	600	1,200
(3) Accountable Personal Property (Attach HHS 565)		
Permanent Research	3,000	8,000
General Purpose	2,000	2,000
(4) Materials and Supplies	2,000	4,000
(5) Premium Pay	100	150
(6) Consultant Fee	100	100
Dr. Jones/1 day @ 100-COA #3		
(7) Travel - Domestic	200	200
Foreign	200	200
(8) Subcontract Cost	0	0
(9) Other	$ 0	0
Total Direct Costs	$ 11,600	$20,650
(l) Cost of Money (Factor) or (Appropriate Base)	2,400 4,000	3,600 6,000
(m) Indirect Costs - Overhead _% of Direct Labor or Other Base (Formula)	700	1,400
(n) Fixed-Fee Earned (Formula)	$ 18,700	$31,650
(o) Total Amount Claimed		
(p) Adjustments Outstanding Suspensions	____	____
(q) Grand Totals	$ 18,700	$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

(Name of Official) (Title)

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference with the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions

52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.219-8	Oct 1999	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.229-3	Jan 1991	Federal, State and Local Taxes (Over $100,000)
52.229-5	Apr 1984	Taxes - Contracts Performed in U.S. Possessions or Puerto Rico
52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration

52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-1	Aug 1987	Changes - Fixed Price, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-2	Sep 1996	Termination for the Convenience of the Government (Fixed-Price)
52.249-9	Apr 1984	Default (Fixed-Price Research and Development)(Over $100,000)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Apr 1984	Definitions
352.232-9	Apr 1984	Withholding of Contract Payments
352.270-4	Apr 1984	Pricing of Adjustments
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT - Rev. 10/2000].

Attachment 2

INSTRUCTIONS FOR COMPLETING FORM NIH 2706 "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by be NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract,

but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

NIH 2706, Instructions
(May 1997)

National Institutes of Health FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT, NIH FORM 2706 *Note: Complete this Form in Accordance with Accompanying Instructions.*	Project Task:	Contract No.:	Date of Report:	0990-0134 0990-0131
	Reporting Period:	Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-- Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Funded Contract Amount	Variance (Over or Under) (I - H)
	Funded	Actual							
A	B	C	D	E	F	G	H	I	J

Attachment 3

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting officer.

67 - Photographic Equipment

69 - Training Aids and Devices

70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)

71 - Furniture

72 - Household and Commercial Furnishings and Appliances

74 - Office Machines and Visible Record Equipment

77 - Musical Instruments, Phonographs, and Hometype Radios

78 - Recreational and Athletic Equipment

When Equipment in these Federal Supply Groups is requested by the contractor and determined essential by the contracting officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

NIH(RC)-7

OMB Bulletin 81-16, 4/1/84

Attachment 4

NATIONAL INSTITUTE OF MENTAL HEALTH
NATIONAL INSTITUTES OF HEALTH

Date: March 2, 1994

Management Issuance No. 15

Relevant NIH Issuance: Chapter 1183 and I&I OER 90-08 (12/7/90)

Subject: NIMH Publication By-Lines

This policy and procedure is issued to ensure that conflict of interest regulations and acquisition procedures are adhered to and that credit is appropriately given for by-lines for NIMH publications.

To ensure conformance with conflict of interest policies, and to avoid even the appearance of conflict of interest, Institute Directors are required to establish and maintain strong and effective controls over the process by which decisions are made about staff collaboration on publications resulting from Institute-funded projects. Materials developed by staff or with support from a contract, grant, or cooperative agreement are included.

Only those individuals who have had substantial involvement in developing and writing a publication may be cited. Such involvement may include, for example, a substantial role either in originating specific ideas which led to the development of the program activity or in actually conducting the activity, and a substantial personal contribution to the preparation of the material for publication.

Before initiating any funding activity which might entitle the employee to appropriate credit, he or she should request and receive written approval of the Director, NIMH. An NIMH employee may not function or be cited as a coauthor or coeditor of material produced under a grant, contract, or cooperative agreement, whether such material is to be published by NIMH, or by a recipient of Institute funds (or any employee of the recipient) without such approval. Requests are to be routed through the Chairperson, Publication and Audiovisual Plan (PAP) Advisory Board. (See NIMH Issuance No. I-2B) for review and sign off by the Board before being sent to the Director, NIMH.)

Employees should work closely with the Grants Management or Contracts Management Officer to be certain that by-line credit is a planned part of the work scope or purchase order description.

A by-line may be given to the author of a monograph, report, chapter, or article which presents his or her original work. In this instance, an author's name usually appears on the title page or at the head of the text of an article or chapter, in a modest size. It may not appear on the cover of a publication, but NIMH author(s)' names may appear on the spine along with the Institute's initials.

The name of a person who writes material based on others' original work may be placed on the title page or other appropriate location so long as it is clear that the material is based on others' original scientific work. (Examples: On the title page, clarify through use of a subtitle or explanation such as "NIMH-supported research," or "A review of current research literature.") A contract, grant, or cooperative agreement writer's name may be handled in the same way. The person(s) responsible for the

original work about which the author is writing may be cited on the inside cover or back of title page. (Example: Include contract, grant, or cooperative agreement number, name(s) of investigator(s), and affiliation(s).)

The organizational affiliations of NIMH staff who have by-lines may appear on the title page. For contract, grant, and cooperative agreement authorship, the name of the individual author may be placed on the title page, but the affiliation, including city and State, will appear elsewhere, normally with the contract, grant, or cooperative agreement citation on the back of the title page.

The name of a contractor may be excluded at the discretion of the Institute's clearance officer when the purpose of the contract was to develop materials for NIMH publication.

If an NIMH official is associated in a significant way with the publication content and the employee's name and title would bestow special interest or credence to the material, the official's name would appear as the author, and it would be at the same official's discretion whether or not the staff writer is cited. (Example: At the end of the article, "Prepared with the assistance of Mary K. Jones, NIMH Staff Writer.")

If an individual is assigned responsibility for all or part of a publication, such as a health professional who serves as editor of a collection of scientific reports or the proceedings of a conference on a subject in which he or she is knowledgeable and experienced, a credit would read as follows: "Edited by Raymond Brown, Ph.D."

Example of responsibility for part: "By Mary C. Kent, Ph.D., Division of Services and Applied Research, NIMH, and, in the Study of Juvenile Problems (Chapter V), George Smith, Ph.D., Division of Clinical Research, NIMH."

If an individual selects citations for a bibliography and/or writes annotations for a bibliography, a credit would read as follows: "Compiled (or developed) by Jane Smith."

William T. Fitzsimmons
Executive Officer, NIMH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; New System of Records

Agency: National Institutes of Health, HHS.

Action: Notification of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09-25-0200, ''Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.'' This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

DATES: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH receives comments on the routine uses which would result in a contrary determination.

ADDRESS: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832. The numbers listed above are not toll free.

SUPPLEMENTARY INFORMATION: The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0200, ''Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.'' This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative

efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic-type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study participation.

The system will comprise records about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, ``Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf:45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

DATED: October 30, 1996. Anthony L. Itteilag, Deputy Director for Management, National Institutes of Health. 09-25-0200

SYSTEM NAME: Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION: None.

SYSTEM LOCATION: Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government

agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored,is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM: Adults and/or children who are the subjects of clinical, epidemiologic, and biometric research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: Normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM: The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: Name, study identification number, address, relevant telephone numbers, Social Security Number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curriculum vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM: ``Research and Investigation,'' ``Appointment and Authority of the Directors of the National Research Institutes,'' ``National Cancer Institute,'' ``National Eye Institute,'' ``National Heart, Lung and Blood Institute,'' ``National Institute on Aging,'' ``National Institute on Alcohol Abuse and Alcoholism,'' ``National Institute on Allergy and Infectious Diseases,'' ``National Institute of Arthritis and Musculoskeletal and Skin Diseases,'' ``National Institute of Child Health and Human Development,'' ``National Institute on Deafness and Other Communication Disorders,'' ``National Institute of Dental Research,'' ``National Institute of Diabetes, and Digestive and Kidney Diseases,'' ``National Institute of Drug Abuse,'' ``National Institute of Environmental Health Sciences,'' ``National Institute of Mental Health,'' ``National Institute of Neurological Disorders and Stroke,'' and the ``National Center for Human Genome Research,'' of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S): To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was

provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless therecord is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a property identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security

Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE: Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY: During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, Social Security Number, medical record or study identification number, etc.).

During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the HHS General Administration Manual and Part 6, ``ADP System Security'' of the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL: Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1--``Keeping and Destroying Records'' (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30

years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS: See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following systems have been subsumed under this umbrella system notice.

09-25-0001 Clinical Research: Patient Records, HHS/NIH/NHLBI
09-25-0010 Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI
09-25-0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS
09-25-0016 Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS
09-25-0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS
09-25-0028 Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS
09-25-0037 Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA
09-25-0038 Clinical Research: Patient Data, HHS/NIH/NIDDK
09-25-0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK
09-25-0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK
09-25-0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR
09-25-0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR
09-25-0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID
09-25-0053 Clinical Research: Vision Studies, HHS/NIH/NEI
09-25-0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/NIH/NCI
09-25-0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI
09-25-0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI
09-25-0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI
09-25-0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI
09-25-0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI
09-25-0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI
09-25-0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS
09-25-0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD
09-25-0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI
09-25-0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS

09-25-0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA
09-25-0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID
09-25-0145 Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI
09-25-0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR
09-25-0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD
09-25-0154 Biomedical Research: Records of Subjects: 1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and 2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD
09-25-0170 Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK
09-25-0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR
09-25-0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH
09-25-0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH
09-25-0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

NOTIFICATION PROCEDURE: To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the

medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075.

NIH Privacy Act Coordinators

Office of the Director, (OD), NIH
Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive
Bethesda, MD 20892

National Cancer Institute (NCI)
Privacy Act Coordinator, NCI, NIH
Building 31, Room 10A34
31 Center Drive
Bethesda, MD 20892

National Eye Institute (NEI)
Privacy Act Coordinator, NEI, NIH
Building 31, Room 6A-19
31 Center Drive
Bethesda, MD 20892

National Heart, Lung and Blood Institute (NHLBI)
Privacy Act Coordinator, NHLBI, NIH
Building 31, Room 5A08
31 Center Drive
Bethesda, MD 20892

National Institute on Aging (NIA)
Privacy Act Coordinator, NIA, NIH
Building 31, Room 2C12
31 Center Drive
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Privacy Act Coordinator, NIAAA, NIH
Wilco Building, Suite

6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases (NIAID)
Privacy Act Coordinator, NIAID, NIH
Solar Building, Room 3C-23
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Privacy Act Coordinator, NIAMS, NIH
Natcher Building, Room 5QS49
45 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD)
Privacy Act Coordinator, NICHD, NIH
6100 Executive Blvd., Room 5D01
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders (NIDCD)
Privacy Act Coordinator, NIDCD, NIH
Building 31, Room 3C02
9000 Rockville Pike
Bethesda, MD 20892

National Institute of Dental Research (NIDR)
Privacy Act Coordinator, NIDR, NIH
Building 31, Room 2C-35
31 Center Drive, MSC 2290
Bethesda, MD 20892-2290

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK)
Privacy Act Coordinator, NIDDK, NIH
Building 31, Room 9A47
31 Center Drive
Bethesda, MD 20892

National Institute on Drug Abuse (NIDA)
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences (NIEHS)
Chief, Epidemiology Branch, NIEHS, NIH

P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health (NIMH)
Privacy Act Coordinator, NIMH, NIH
6001 Executive Blvd., Rm 6107, MSC 9603
Bethesda , Maryland 20892-9603

National Institute of Neurological Disorders and Stroke (NINDS)
Privacy Act Coordinator, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research (NCHGR)
Chief, Office of Human Genome Communications, NGHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE: Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE: Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES: The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: None.

Appendix I: System Managers and Addresses

Office of the Director, NIH
Associate Director for Disease Prevention, OD, NIH
Building 1, Room 260
1 Center Drive

Bethesda, MD 20892

National Cancer Institute
Computer Systems Analyst, DCBD, NCI, NIH
Executive Plaza North, Room 344
Bethesda, MD 20892

American Burkitt's Lymphoma Registry
Division of Cancer Etiology, NCI, NIH
Executive Plaza North, Suite 434
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH
Executive Plaza North, Suite 439
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Clinical Genetics Section
Clinical Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Suite 400
6130 Executive Blvd.
Bethesda, MD 20892

Program Director, Research Resources
Biological Carcinogenesis Branch, DCE, NCI, NIH
Executive Plaza North, Room 540
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Environmental Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Room 443
6130 Executive Blvd.
Bethesda, MD 20892

Associate Director, Surveillance Program, DCPC, NCI, NIH
Executive Plaza North, Room 343K
6130 Executive Blvd.
Bethesda, MD 20892

Head, Biostatistics and Data Management Section, DCT, NCI, NIH
8601 Old Georgetown Road
Bethesda, MD 20892

Chief, Clinical Research Branch
Biological Response Modifiers Program

Frederick Cancer Research and Development Center, DCT, NCI, NIH
501 W. 7th Street, Suite #3
Frederick, MD 21701

Deputy Branch Chief, Navy Hospital
NCI--Naval Medical Oncology Branch, DCT, NCI, NIH
Building 8, Room 5101
Bethesda, MD 20814

Chief, Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCT, NCI, NIH
Executive Plaza North, Suite 804
Bethesda, MD 20892

Director, Extramural Clinical Studies, BRB, BRMP, DCT, NCI, NIH
Frederick Cancer Research and Development Center
Fort Detrick
Frederick, MD 21701

National Eye Institute
Clinical Director, NEI, NIH
Building 10, Room 10N-202
10 Center Drive
Bethesda, MD 20892

Director, Division of Biometry and Epidemiology, NEI, NIH
Building 31, Room 6A-52
31 Center Drive
Bethesda, MD 20892

National Heart Lung and Blood Institute
Administrative Officer, Division of Intramural Research, NHLBI, NIH
Building 10 Room 7N220
10 Center Drive, MSC 1670
Bethesda, MD 20892-1670

Senior Scientific Advisor, OD
Division of Epidemiology and Clinical Applications, NHLBI, NIH
Federal Building, 220
7550 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Aging
Computer Scientist, Longitudinal Studies Branch, IRP, NIH
Gerontology Research Center, GRC
4940 Eastern Avenue

Baltimore, MD 21224

Associate Director, Epidemiology,
Demography and Biometry Program, NIA, NIH
Gateway Building, Suite 3C309
7201 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism
Deputy Director, Division of Biometry and Epidemiology, NIAAA, NIH
Willco Building, Suite 514
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

Deputy Director, Div. of Clinical and Prevention Res., NIAAA, NIH
Willco Building, Suite 505
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases
Chief, Respiratory Viruses Section, LID, NIAID, NIH
Building 7, Room 106
9000 Rockville Pike
Bethesda, MD 20892

Chief, Hepatitis Virus Section, LID, NIAID, NIH
Building 7, Room 202
9000 Rockville Pike
Bethesda, MD 20892

Chief, Epidemology and Biometry Branch, DMID, NIAID, NIH
Solar Building, Room 3A24
Bethesda, Maryland 20892

Special Assistant, Clinical Research Program, DAIDS, NIAID, NIH
Solar Building, Room 2C-20
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Clinical Director, NIAMS, NIH
Building 10, Room 9S205
10 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development

Chief, Contracts Management Branch, NICHD, NIH
Executive Plaza North, Room 7A07
6100 Executive Blvd.
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders
Acting Director of Intramural Research, NIDCD, NIH
Building 31, Room 3C02
31 Center Drive
Bethesda, MD 20892

Director, Division of Human Communication, NIDCD, NIH
Executive Plaza South, Room 400B
6120 Executive Boulevard
Rockville, MD 20852

National Institute of Dental Research
Deputy Clinical Director, NIDR, NIH
Building 10, Room 1N-113
10 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Research Psychologist, Clinical Invsetigations, NIDR, NIH
Building 10, Room 1N114
10 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Chief, Contract Management Section
Extramural Program, NIDR, NIH
Natcher Building, Room 4AN-44B
45 Center Drive, MSC 6402
Bethesda, MD 20892-6402

National Institute of Diabetes and Digestive and Kidney Diseases
Chief, Clinical Investigations, NIDDK, NIH
Building 10, Room 9N222
10 Center Drive
Bethesda, MD 20892

Chief, Phoenix Clinical Research Section, NIDDK, NIH
Phoenix Area Indian Hospital, Room 541
4212 North 16th Street
Phoenix, Arizona 85016

Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH
Natcher Building, Room 5AN-18G

45 Center Drive, MSC 6600
Bethesda, MD 20892

National Institute on Drug Abuse
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health
Director, Intramural Research Program, NIMH, NIH
Building 10, Room 4N-224
9000 Rockville Pike
Bethesda, MD 20205

Privacy Act Coordinator, NIMH, NIH
6001 Executive Blvd., Rm. 6107, MSC 9603
Bethesda, Maryland 20892-9603

National Institute of Neurological Disorders and Stroke
Chief, Epilepsy Branch, NINDS, NIH
Federal Building, Room 114
7750 Wisconsin Avenue
Bethesda, MD 20892

Chief, Development Neurology Branch, NINDS, NIH
Federal Building, NIH
7550 Wisconsin Avenue
Bethesda, MD 20892

Assistant Director, CNP, DIR, NINDS, NIH
Building 10, Room 5N226
10 Center Drive
Bethesda, MD 20892

Deputy Chief, Laboratory of Central Nervous Systems Studies
Intramural Research Program, NINDS, NIH
Building 36, Room 5B21,
9000 Rockville Pike
Bethesda, MD 20892

Director, Division of Fundamental Neurosciences, NINDS, NIH
Federal Building, Room 916
7550 Wisconsin Ave
Bethesda, MD 20892

Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH
Federal Building, Room 810
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Stroke and Trauma, NINDS, NIH
Federal Building, Room 8A08
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research
Chief, Office of Human Genome Communications, NCHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, MD 20892

[FR Doc. 97-8592 Filed 4-4-97; 8:45 am]

Attachment 6

ANNUAL TECHNICAL PROGRESS REPORT FORMAT FOR EACH STUDY

Study Title:

Date:

Provide the number of subject enrolled in the study to date according to the following categories:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
TOTAL							

Subpopulations of the minority groups should also be reported, using a similar format.