TOPICS FOR DISCUSSION

Program Announcement (PA)

- Identifies areas of increased priority and/or emphasis on particular funding mechanisms for a specific area of science
- Usually accepted on standard receipt (postmarked) dates on an on-going basis
- Remains active for three years from date of release unless the announcement indicates a specific expiration date or the NIH Institute/Center (I/C) inactivates sooner (see January 13, 2005 NIH Guide Notice for more information on Expiration Dates)
- Special Types
  - PAR: A PA with special receipt, referral and/or review considerations, as described in the PAR announcements
  - PAS: A PA that includes specific set-aside funds as described in the PAS announcement

Request for Application (RFA)

- Identifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants
- Usually has a single receipt (received on or before) date specified in the RFA announcement
- Usually reviewed by a Scientific Review Group convened by the issuing awarding component

Request for Proposal (RFP)

- Solicits contract proposals. An RFP usually has one receipt date, as specified in RFP solicitation
Research Project Grant - Parent R01 (PA-07-070)

Parent R01 Website: http://grants.nih.gov/grants/guide/pa-files/PA-07-070.html

Definition of an R01
The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

Parent R01 (PA-07-070) Characteristics

- Limited to $500,000 direct cost per year. See NOT-OD-02-004, October 16, 2001 for special instructions for applications requesting $500,000 (direct costs) or more per year.

- Requires Detailed Budget if more than $250,000 in annual direct costs in any year. If less than $250,000 per year, must use modular budget which has a limit of $250,000 per year.

- Generally awarded for 1-5 budget periods, each normally 12 months in duration.

- Page Limits - Items 2-5 of the PHS398 Research Plan component of the R01 application may not exceed 25 pages, including tables, graphs, figures, diagrams, and charts. The Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods components of the Research Plan must not exceed 25 pages.

- **Appendix:** New, resubmission, renewal, and revision applications may include the following materials in the Appendix:

  - Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications:
    - Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
    - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
    - Patents directly relevant to the project: The entire document should be submitted as a PDF attachment. (Do not include unpublished theses, or abstracts/manuscripts submitted but not yet accepted) for publication.
    - Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.
    - For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVD, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

  - **Items that must not be included in the appendix:**
    - Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.
    - Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.
REQUEST FOR APPLICATIONS (RFA) CHARACTERISTICS:

1. Specific Key Dates (i.e. letter of intent deadline, earliest anticipated award date) *does not follow NIH standard receipt dates

2. Pay attention to "Additional Overview Content" as this may stipulate "each applicant organization may submit only one application" If so, follow specific instructions from OVPR (insert)

3. Read the RFA carefully, as there will be specific budgetary information imbedded as to budgeting for Steering Committee meetings, Data Safety Monitoring Board (DSMB) meetings, conference calls specific, etc.

4. Will state specifically, the amount of funding dollars available and number of years to be requested Under Section II. Award Information 2. Funds Available

5. Mailing instructions are very specific – typically, the Original (including checklist) and three copies are submitted directly to the CSR (Center for Scientific Review) and two copies and ALL copies of the appendix materials are usually sent to the participating institute (i.e. NHLBI). These detailed instructions are found under Section IV. Application and Submission Information 3.B. Sending an Application to the NIH.

6. Review the RFA carefully, as it may involve 6. Other Submission Requirements particular information is Budget and Related Issues.

RFAs that are issued as and R series mechanism have started to migrate to the Grants.gov process. Specific funding mechanisms (such as U series or P series) have not yet been transferred to the grants.gov process. These types of award mechanism are still being completed on the PHS398 application forms.

Funding Opportunities & Notices Search (All Active Requests for Applications (RFAs)):

http://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=rfa
Section II. Award Information

1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the DP1 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project. Applications proposing multiple PIs are not allowed.

2. Funds Available

This is a Roadmap initiative. The NIH Common Fund has set aside sufficient funds in FY2008 to provide at least 5-10 awards, contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Awards will be for $500,000 in direct costs each year for five years, plus applicable Facilities and Administrative costs to be determined at the time of award.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

For this FOA, Facilities and Administrative (F&A) costs requested by consortium participants must be included in the total direct costs requested. The F&A costs for the primary grantee institution will be added at the time of award, and will be based on the grantee institution's current negotiated rate.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application(s) if your institution/organization is a domestic institution that has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State Government
- Institutions in U.S. Territory or Possession
- Indian/Native American Tribal Government (Federally Recognized)
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Indian/Native American Tribally Designated Organization
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native- and Native Hawaiian-serving Institution
- Regional Organization
- Eligible agency of the Federal Government
- Faith-based or community-based organization

Non-domestic (non-U.S.) entities (Foreign Organizations) are not eligible to apply.

1.B. Eligible Individuals
Investigators at all career levels who meet the eligibility criteria and are currently engaged in research are eligible to apply. The research proposed need not be in a conventional biomedical or behavioral discipline; if the applicant's experience is in non-biological areas, however, he/she must demonstrate a commitment to exploring topics of biomedical or behavioral relevance. If selected for an award, applicants must show evidence of institutional infrastructure support.

This initiative is to support investigators who intend to pursue new research directions—research that is distinct from that currently or previously conducted by the investigator. Applications for projects that are extensions of ongoing research should not be submitted and will not be funded. Awardees are required to commit the major portion (at least 51%) of their research effort to activities supported by the Pioneer Award program. Applicants who were not selected for an award in prior years may submit applications this year. Investigators at all career levels are eligible.

Those at early to middle stages of their careers, and women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply.

There are no citizenship or residency requirements.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current NIH Grants Policy Statement.

3. Other-Special Eligibility Criteria

Applicants may submit only one application as a PD/PI in response to this FOA. There is no limit to the number of applications that institutions may submit. All applications will be considered "new" applications, regardless of any previous applications to the Pioneer Award Program. Competing renewal (formerly "competing continuation") applications will not be accepted.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site. See the detailed instructions below regarding choosing an application package (Section 1 – Request Application Information).

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/GetStarted) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Started

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to: Grants.gov Customer Support
of scientific research. The selection of scientific area by applicants is solely to aid in selection of the most appropriate group of peer reviewers and does not in itself affect an application's funding potential. All ten scientific areas are considered as a single competition, are reviewed in the same time period, and compete for a single source of funds.

**Areas of Science:**

01 Behavioral and Social Sciences
02 Chemical Biology
03 Clinical and Translational Research
04 Epidemiology
05 Immunology
06 Instrumentation and Engineering
07 Molecular and Cellular Biology
08 Neuroscience
09 Physiology and Integrative Systems
10 Quantitative and Computational Biology

- **Effort Commitment:** Awardees are required to commit at least 51% of their research effort to the project supported by the Pioneer Award. In their list of current and pending support, applicants must include a statement that, if chosen to receive an award, the applicant will commit a minimum of 51% of his/her research effort to the project supported by the Pioneer Award.

- **An abstract** of no more than 300 words (not to exceed one page) describing the goals of the project.

- **An essay** of 3-5 pages that addresses the investigator's innovative vision for, and the significance of, the biomedical or behavioral problem to be addressed, and his/her qualifications to engage in groundbreaking research. The essay should describe the individual's view of the major challenges in biomedical or behavioral research to which he/she can make seminal contributions. No detailed scientific plan should be provided since the research plan is expected to evolve during the tenure of the grant. The essay should include the following sections within the 3-5 page limit:

  - **Project description:** What is the scientific problem that will be addressed, and why is this important? What are the pioneering, and possibly high-risk, approaches that, if successful, might lead to groundbreaking or paradigm-shifting results?

  - **Evidence of innovativeness:** What concrete evidence can you provide for your claim of innovativeness? For example, qualities common to many highly innovative people include an interest in, and the ability to integrate, diverse sources of information; an inclination to challenge paradigms and take intellectual risks; persistence in the face of failure; an ability to attract the right collaborators; and the energy and concentration necessary to plan and execute effective strategies for accomplishing goals.

  - **How the planned research differs from your past or current work:** Describe how the project represents a new and distinct direction for your research.

  - **Suitability for Pioneer Award program:** Why is the planned research uniquely suited to the stated goal of the Pioneer Award program, rather than a traditional grant mechanism?
• References are not required but if included must fit within the five-page limit. Figures and illustrations may be included but must also fit within the five-page limit. The essay is uploaded on the Research & Related Other Project Information Component form, Item 7.

• A two-page biographical sketch for the PD/PI only. (Use the sample format shown in the URL in Section 4.5.2 of the Application Guide, omitting Section C, Research Support.) The biographical sketch is uploaded on the Research & Related Senior/Key Person Component form. No other biographical sketches are to be submitted.

• A list of current and pending research support from all sources, including current year direct costs and percent effort devoted to each project. (Use the format shown in Section 3.1.1.8 of the Application Guide.) Applicants must include a statement that, if chosen to receive an award, the applicant will commit a minimum of 51% of his/her research effort to the project supported by the Pioneer Award. Applicants must also include in this section a brief statement of the facilities to be used for the conduct of the research. This document is uploaded on the Research & Related Senior/Key Person Component form.

Special requirements for completing the SF424 (R&R) application are specified in Section IV.6, below. In addition:

• The Budget request is entered only on Line 16a and b, as described in Section IV.6, below. Awards are for $2.5 million in direct costs for the five-year budget/project period. Funds may be requested for personnel (including co-investigators and collaborators), supplies, equipment, sub-contracts, and other allowable costs. Only the five-year total – $2.5 million -- should be entered on Line 16a and b. A detailed budget is not requested and will not be accepted.

• No other documentation, such as letters of collaboration or biographical sketches of other personnel will be accepted. Information about personnel other than the PD/PI is not required, but may be included within the 3-5-page essay.


3. Submission Dates and Times

See Section IV.3.A for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: December 16, 2007 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): Not applicable
Application Submission/Receipt Date: January 16, 2008
Peer Review Date(s): April 2008
Advisory Council to the Director Review Date(s): August 2008
Earliest Anticipated Start Date: September 30, 2008

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity and will not be accepted.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/Apply and follow steps 1-4. Also see “Special Instructions” in Section IV.2 of this FOA. Note: Applications must only be submitted electronically. PAPER APPLICATIONS WILL NOT BE ACCEPTED.
PD/PI Credential (e.g., Agency Login)

The NIH requires the PD/PI to fill in his/her Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

All application instructions outlined in the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf) are to be followed, incorporating “Just-in-Time” information concepts, with the following exceptions, which are specific requirements for Pioneer Award applications. Applications that do not conform to the specific instructions detailed below will not be reviewed.

1. SF424 (R&R) COVER COMPONENT

<table>
<thead>
<tr>
<th>Item Number and Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Type of Application</td>
<td>Must be “New”</td>
</tr>
<tr>
<td>13. Proposed Project</td>
<td>Enter start date: 09/30/2008; Enter end date: 07/31/2013</td>
</tr>
<tr>
<td>16 Estimated Project Funding</td>
<td>Enter $2,500,000</td>
</tr>
<tr>
<td>16 a. Total Estimated Project Funding</td>
<td></td>
</tr>
<tr>
<td>16 b. Total Federal &amp; Non-Federal Funds</td>
<td>Enter $2,500,000</td>
</tr>
</tbody>
</table>

2. RESEARCH & RELATED OTHER PROJECT INFORMATION COMPONENT:

<table>
<thead>
<tr>
<th>Item Number and Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are Human Subjects Involved?</td>
<td>Follow the Application Guide instructions for all fields in Section 1.a. Check “Yes” or “No” as appropriate. If “Yes”, enter “None,” or the IRB Approval Date, Exemption Number, and Human Subject Assurance Numbers may be entered but are not required at the time of submission. Detailed plans regarding protection of human subjects, inclusion of women and minorities, targeted/planned enrollment, and inclusion of children are not required at the time of submission. This information will be requested on a just-in-time basis at the time of award.</td>
</tr>
<tr>
<td>2. Are Vertebrate Animals Used?</td>
<td>Follow the Application Guide instructions for all fields in 2.a. Check “Yes” or “No” as appropriate. Enter “None.” Detailed plans regarding the use of vertebrate animals are not required at the time of submission. The IACUC Approval Date and Animal Welfare Assurance Numbers may be entered but are not required at the time of submission. This information will be requested on a just-in-time basis at the time of award.</td>
</tr>
<tr>
<td>6. Project Summary/Abstract</td>
<td>Attach abstract. (Maximum of 300 words [not to exceed one page]; PDF format)</td>
</tr>
<tr>
<td>7. Project Narrative</td>
<td>Attach essay (Maximum of 5 pages; PDF format)</td>
</tr>
<tr>
<td>8. Bibliography &amp; References Cited</td>
<td>Do not use. If you choose to include figures or reference citations, they must be included in the essay, subject to the 5-page limit.</td>
</tr>
<tr>
<td>9. Facilities &amp; Other Resources</td>
<td>Do not use.</td>
</tr>
<tr>
<td>10. Equipment</td>
<td>Do not use.</td>
</tr>
<tr>
<td>11. Other Attachments</td>
<td>Attach description of your most significant research accomplishment (one page maximum; PDF format.)</td>
</tr>
</tbody>
</table>

Note: Applications found not to comply with the page limit requirements or that contain attachments other than those specified will be rejected during the agency validation process.
3. SF424 (R & R) SENIOR/KEY PERSON PROFILE COMPONENT:

Complete items only for Project Director/Principal Investigator. Do not submit profiles for other senior/key personnel.

<table>
<thead>
<tr>
<th>Item Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile- PD/PI - Attach Biographical Sketch</td>
<td>Attach biographical sketch here (two-page maximum, PDF format). Use the form shown in the URL in Section 4.5.2 of the Application Guide, omitting Section C, Research Support (see below).</td>
</tr>
<tr>
<td>Profile- PD/PI - Attach Current &amp; Pending Support</td>
<td>Attach a list of Current and Pending Support here (PDF format). Use the form shown in Section 3.1.1.8 of the Application Guide. Be sure to include statement affirming that you will devote at least 51% of research effort to Pioneer Award project. Also, include a brief statement of the facilities to be used for the conduct of the research.</td>
</tr>
<tr>
<td>Profile – Senior Key Person 1</td>
<td>Do not use. Submit information only for PD/PI. Information on collaborators may be included in the essay.</td>
</tr>
</tbody>
</table>

Note: Applications found not to comply with the page limit requirements will be rejected during the agency validation process.

4. PHS 398 Cover Letter File (Optional):

Cover letters should be included only when submitting late applications or Changed/Corrected applications after the submission deadline. Do not submit cover letters for initial submissions or for changed/corrected applications submitted before the submission deadline. The cover letter should contain only the following information:

1. PD/PI name.

2. Funding Opportunity Title: 2008 NIH Director's Pioneer Award Program (DP2).

3. For Changed/Corrected Applications submitted after the submission deadline, include an explanation of the reason for the Changed/Corrected Application.

(See full instructions for submitting the Cover Letter Component in Section 5.2 of the Application Guide. Note: Items 3 – 6 of the Guide do not apply to Pioneer Award applications.)

Letters of Reference:

Letters of reference are an important component of the Pioneer Award application. Applicants must arrange to have three (and no more than three) letters of reference submitted on their behalf. Applications that are missing letters of reference may be considered non-responsive and may not be reviewed. Late letters will not be accepted. Applicants are responsible for monitoring the submission of their letters to ensure that three letters have been submitted prior to the submission deadline. Applicants can check the status of their letters in their Commons accounts.

Letters may be submitted beginning December 18, 2007, and must be submitted no later than 5:00 p.m. (EST) January 16, 2008.

Applicants must provide the following to their referees (Note: referees will not be able to submit letters without this information):

- Funding Opportunity Number (FOA) for this announcement RFA-RM-08-013;

  The applicant's Commons User Name (Note: Referees do not have to be registered in the Commons and do not need their own Commons User Name – only the Commons User Name of the applicant is required);

  The applicant’s first and last name (note – the name must match exactly the applicant’s name in the Commons);
REQUEST FOR PROPOSALS (RFP) CHARACTERISTICS:

Office of Acquisition Management and Policy at the National Institutes of Health


This will be where you will locate the RFPs Available by Institute.

Main points:

1. A Proposal Intent Response Sheet is typically required to be sent to the NIH. This form requires SPA signature and endorsement.

2. Separation of the Technical Proposal from the Business Proposal

3. Specific packaging and delivery of proposal (i.e. # of copies of technical and # of copies of business (usually includes submission of one copy of each on a CD.) # of appendices are specifically mentioned and may also need a CD.

4. Statement of Work is clearly and specifically defined

5. Budget to be completed on the NIH contract forms Excel spreadsheet located at http://oamp.od.nih.gov/ContractOpportunity/rfps/BUSCOST.HTM

6. A Technical Proposal Cost Summary need to be completed as well based on the FINAL Business Proposal Budget. Format is located at: http://www4.od.nih.gov/ocm/contracts/rfps/techcst5.htm

7. SPA offices need to complete Institutional forms to be submitted with the Business Proposal such as the Representations and Certifications (REPS and CERTS) and the Small Business Subcontracting Plan.

Information on the Small Business Subcontracting Plan can be found at http://www.ospa.umn.edu/policiesandprocedures/smallbusinessplans/index.html


## RFP TABLE OF CONTENTS

PART I - THE SCHEDULE ................................................................. 4

   SECTION A - SOLICITATION/CONTRACT FORM ................................. 1

   SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS ..................... 4

   SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT ............... 5

   SECTION D - PACKAGING, MARKING AND SHIPPING ........................... 6

   SECTION E - INSPECTION AND ACCEPTANCE ................................... 7

   SECTION F - DELIVERIES OR PERFORMANCE .................................. 7

   SECTION G - CONTRACT ADMINISTRATION DATA ............................... 8

   SECTION H - SPECIAL CONTRACT REQUIREMENTS ................................ 14

PART II - CONTRACT CLAUSES ....................................................... 24

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS ....... 29

   SECTION J - LIST OF ATTACHMENTS .......................................... 29

      SOLICITATION ATTACHMENTS .............................................. 29

      TECHNICAL PROPOSAL ATTACHMENTS .................................. 29

      BUSINESS PROPOSAL ATTACHMENTS .................................... 29

      INFORMATIONAL ATTACHMENTS ............................................ 29

PART IV - REPRESENTATIONS AND INSTRUCTIONS ................................ 30

   SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS .................................................. 30

   SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS .... 30

1. GENERAL INFORMATION .......................................................... 30

   a. INSTRUCTIONS TO OFFERORS—COMPETITIVE ACQUISITION .................. 30

   b. NAICS CODE AND SIZE STANDARD .......................................... 35

   c. TYPE OF CONTRACT AND NUMBER OF AWARDS ................................ 35

   d. LEVEL OF EFFORT ............................................................. 35

   e. COMMITMENT OF PUBLIC FUNDS ............................................ 35

   f. COMMUNICATIONS PRIOR TO CONTRACT AWARD ............................... 35

   g. RELEASE OF INFORMATION .................................................. 35

   h. COMPARATIVE IMPORTANCE OF PROPOSALS ................................ 36

   i. PREPARATION COSTS .......................................................... 37

   j. SERVICE OF PROTEST ....................................................... 37

   k. LATE PROPOSALS AND REVISIONS ......................................... 37

2. INSTRUCTIONS TO OFFERORS .................................................. 37

   a. GENERAL INSTRUCTIONS .................................................... 37

      1. Contract Type and General Clauses .................................... 37

      2. Authorized Official and Submission of Proposal ....................... 37

      3. Proposal Summary and Data Record (NIH-2043) ........................ 38

      4. Separation of Technical and Business Proposals ....................... 38

      5. Alternate Proposals ....................................................... 38

      6. Evaluation of Proposals ................................................ 38

      7. Potential Award Without Discussions ................................... 38

      8. Use of the Metric System of Measurement ................................ 39

      9. Standards for Privacy of Individually Identifiable Health Information . 39

- 2 -
11. Selection of Offerors .................................................................................. 41
12. Institutional Responsibility Regarding Conflicting Interests of Investigators .......... 42
13. ROTC Access and Federal Military Recruiting on Campus .......................... 43
14. Solicitation Provisions Incorporated by Reference .................................... 43
b. TECHNICAL PROPOSAL INSTRUCTIONS ................................................. 44
   1. Technical Discussions ........................................................................... 44
   2. Technical Evaluation .......................................................................... 46
   3. Additional Technical Proposal Information ....................................... 46
   4. Other Considerations ......................................................................... 46
   5. Human Subjects .................................................................................. 46
   6. Instructions to Offerors Regarding Protection of Human Subjects ............ 47
   7. Required Education in the Protection of Human Research Participants .... 49
   8. Research Involving Human Fetal Tissue .............................................. 50
   9. Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research) ................................................................. 50
   10. Human Embryonic Germ Cell (HEGC) Research .............................. 51
   11. Human Embryonic Stem Cell (HESC) Research ............................... 51
   12. Data and Safety Monitoring in Clinical Trials .................................... 51
   13. Obtaining and Disseminating Biomedical Research Resources .......... 53
c. BUSINESS PROPOSAL INSTRUCTIONS ...................................................... 59
   1. Basic Cost/Price Information ................................................................ 59
   2. Cost and Pricing Data .......................................................................... 59
   3. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data ............................................................. 62
   4. Salary Rate Limitation in Fiscal Year 2007 .......................................... 63
   5. Small Business Subcontracting Plan ................................................... 64
   6. Qualifications of the Offeror ................................................................ 66
   7. Other Administrative Data .................................................................. 68
   8. Subcontractors ................................................................................... 70
   9. Proposer's Annual Financial Report .................................................... 70
  10. Representations and Certifications - SECTION K ................................. 70
  11. Travel Costs/Travel Policy ................................................................... 70

SECTION M - EVALUATION FACTORS FOR AWARD ....................................... 70
   1. GENERAL ......................................................................................... 70
   2. EVALUATION OF DATA SHARING PLAN ..................................... 71
   3. TECHNICAL EVALUATION CRITERIA ........................................... 71
   4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION .. 71
TOPICS FOR DISCUSSION

Program Announcement (PA)

- Identifies areas of increased priority and/or emphasis on particular funding mechanisms for a specific area of science
- Usually accepted on standard receipt (postmarked) dates on an on-going basis
- Remains active for three years from date of release unless the announcement indicates a specific expiration date or the NIH Institute/Center (I/C) inactivates sooner (see January 13, 2005 NIH Guide Notice for more information on Expiration Dates)
- Special Types
  - PAR: A PA with special receipt, referral and/or review considerations, as described in the PAR announcements
  - PAS: A PA that includes specific set-aside funds as described in the PAS announcement

Request for Application (RFA)

- Identifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants
- Usually has a single receipt (received on or before) date specified in the RFA announcement
- Usually reviewed by a Scientific Review Group convened by the issuing awarding component

Request for Proposal (RFP)

- Solicits contract proposals. An RFP usually has one receipt date, as specified in RFP solicitation
Research Project Grant - Parent R01 (PA-07-070)

Parent R01 Website:  http://grants.nih.gov/grants/guide/pa-files/PA-07-070.html

Definition of an R01
The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

Parent R01 (PA-07-070) Characteristics
- Limited to $500,000 direct cost per year See NOT-OD-02-004, October 16, 2001 for special instructions for applications requesting $500,000 (direct costs) or more per year.

- Requires Detailed Budget if more than $250,000 in annual direct costs in any year. If less than $250,000 per year, must use modular budget which has a limit of $250,000 per year.

- Generally awarded for 1-5 budget periods, each normally 12 months in duration.

- Page Limits - Items 2-5 of the PHS398 Research Plan component of the R01 application may not exceed 25 pages, including tables, graphs, figures, diagrams, and charts. The Specific Aims, Background and Significance, Preliminary Studies, and Research Design and Methods components of the Research Plan must not exceed 25 pages.

- Appendix: New, resubmission, renewal, and revision applications may include the following materials in the Appendix:
  - Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications:
    - Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
    - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
    - Patents directly relevant to the project: The entire document should be submitted as a PDF attachment. (Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)
    - Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.
    - For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Items that must not be included in the appendix:
- Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.
- Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.
REQUEST FOR APPLICATIONS (RFA) CHARACTERISTICS:

1. Specific Key Dates (i.e. letter of intent deadline, earliest anticipated award date) *does not follow NIH standard receipt dates

2. Pay attention to “Additional Overview Content” as this may stipulate “each applicant organization may submit only one application” If so, follow specific instructions from OVPR (insert)

3. Read the RFA carefully, as there will be specific budgetary information imbedded as to budgeting for Steering Committee meetings, Data Safety Monitoring Board (DSMB) meetings, conference calls specific, etc.

4. Will state specifically, the amount of funding dollars available and number of years to be requested Under Section II. Award Information 2. Funds Available

5. Mailing instructions are very specific – typically, the Original (including checklist) and three copies are submitted directly to the CSR (Center for Scientific Review) and two copies and ALL copies of the appendix materials are usually sent to the participating institute (i.e. NHLBI). These detailed instructions are found under Section IV. Application and Submission Information 3.B. Sending an Application to the NIH.

6. Review the RFA carefully, as it may involve 6. Other Submission Requirements particular information is Budget and Related Issues.

RFAs that are issued as and R series mechanism have started to migrate to the Grants.gov process. Specific funding mechanisms (such as U series or P series) have not yet been transferred to the grants.gov process. These types of award mechanism are still being completed on the PHS398 application forms.

Funding Opportunities & Notices Search (All Active Requests for Applications (RFAs)):

http://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=rga
Section II. Award Information

1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the DP1 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project. Applications proposing multiple PIs are not allowed.

2. Funds Available

This is a Roadmap initiative. The NIH Common Fund has set aside sufficient funds in FY2008 to provide at least 5-10 awards, contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Awards will be for $500,000 in direct costs each year for five years, plus applicable Facilities and Administrative costs to be determined at the time of award.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

For this FOA, Facilities and Administrative (F&A) costs requested by consortium participants must be included in the total direct costs requested. The F&A costs for the primary grantee institution will be added at the time of award, and will be based on the grantee institution’s current negotiated rate.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application(s) if your institution/organization is a domestic institution that has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State Government
- Institutions in U.S. Territory or Possession
- Indian/Native American Tribal Government (Federally Recognized)
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Indian/Native American Tribally Designated Organization
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native- and Native Hawaiian-serving Institution
- Regional Organization
- Eligible agency of the Federal Government
- Faith-based or community-based organization

Non-domestic (non-U.S.) entities (Foreign Organizations) are not eligible to apply.

1.B. Eligible Individuals
Investigators at all career levels who meet the eligibility criteria and are currently engaged in research are eligible to apply. The research proposed need not be in a conventional biomedical or behavioral discipline; if the applicant's experience is in non-biological areas, however, he/she must demonstrate a commitment to exploring topics of biomedical or behavioral relevance. If selected for an award, applicants must show evidence of institutional infrastructure support.

This initiative is to support investigators who intend to pursue new research directions – research that is distinct from that currently or previously conducted by the investigator. Applications for projects that are extensions of ongoing research should not be submitted and will not be funded. Awardees are required to commit the major portion (at least 51%) of their research effort to activities supported by the Pioneer Award program. Applicants who were not selected for an award in prior years may submit applications this year. Investigators at all career levels are eligible.

Those at early to middle stages of their careers, and women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply.

There are no citizenship or residency requirements.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current NIH Grants Policy Statement.

3. Other-Special Eligibility Criteria

Applicants may submit only one application as a PD/PI in response to this FOA. There is no limit to the number of applications that institutions may submit. All applications will be considered “new” applications, regardless of any previous applications to the Pioneer Award Program. Competing renewal (formerly “competing continuation”) applications will not be accepted.

Section IV. Application and Submission Information

To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, link to http://www.grants.gov/Apply/ and follow the directions provided on that Web site. See the detailed instructions below regarding choosing an application package (Section 1 – Request Application Information).

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/GetStarted) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Started

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to: Grants.gov Customer Support
of scientific research. The selection of scientific area by applicants is solely to aid in selection of the most appropriate group of peer reviewers and does not in itself affect an application's funding potential. All ten scientific areas are considered as a single competition, are reviewed in the same time period, and compete for a single source of funds.

**Areas of Science:**

- 01 Behavioral and Social Sciences
- 02 Chemical Biology
- 03 Clinical and Translational Research
- 04 Epidemiology
- 05 Immunology
- 06 Instrumentation and Engineering
- 07 Molecular and Cellular Biology
- 08 Neuroscience
- 09 Physiology and Integrative Systems
- 10 Quantitative and Computational Biology

- **Effort Commitment:** Awardees are required to commit at least 51% of their research effort to the project supported by the Pioneer Award. In their list of current and pending support, applicants must include a statement that, if chosen to receive an award, the applicant will commit a minimum of 51% of his/her research effort to the project supported by the Pioneer Award.

- **An abstract** of no more than 300 words (not to exceed one page) describing the goals of the project.

- **An essay** of 3-5 pages that addresses the investigator's innovative vision for, and the significance of, the biomedical or behavioral problem to be addressed, and his/her qualifications to engage in groundbreaking research. The essay should describe the individual's view of the major challenges in biomedical or behavioral research to which he/she can make seminal contributions. No detailed scientific plan should be provided since the research plan is expected to evolve during the tenure of the grant. The essay should include the following sections within the 3-5 page limit:

  - **Project description:** What is the scientific problem that will be addressed, and why is this important? What are the pioneering, and possibly high-risk, approaches that, if successful, might lead to groundbreaking or paradigm-shifting results?

  - **Evidence of innovativeness:** What concrete evidence can you provide for your claim of innovativeness? For example, qualities common to many highly innovative people include an interest in, and the ability to integrate, diverse sources of information; an inclination to challenge paradigms and take intellectual risks; persistence in the face of failure; an ability to attract the right collaborators; and the energy and concentration necessary to plan and execute effective strategies for accomplishing goals.

  - **How the planned research differs from your past or current work:** Describe how the project represents a new and distinct direction for your research.

  - **Suitability for Pioneer Award program:** Why is the planned research uniquely suited to the stated goal of the Pioneer Award program, rather than a traditional grant mechanism?
References are not required but if included must fit within the five-page limit. Figures and illustrations may be included but must also fit within the five-page limit. The essay is uploaded on the Research & Related Other Project Information Component form, Item 7.

- A two-page biographical sketch for the PD/PI only. (Use the sample format shown in the URL in Section 4.5.2 of the Application Guide, omitting Section C, Research Support.) The biographical sketch is uploaded on the Research & Related Senior/Key Person Component form. No other biographical sketches are to be submitted.

- A list of current and pending research support from all sources, including current year direct costs and percent effort devoted to each project. (Use the format shown in Section 3.1.1.8 of the Application Guide.) Applicants must include a statement that, if chosen to receive an award, the applicant will commit a minimum of 51% of his/her research effort to the project supported by the Pioneer Award. Applicants must also include in this section a brief statement of the facilities to be used for the conduct of the research. This document is uploaded on the Research & Related Senior/Key Person Component form.

Special requirements for completing the SF424 (R&R) application are specified in Section IV.6, below. In addition:

- The Budget request is entered only on Line 16a and b, as described in Section IV.6, below. Awards are for $2.5 million in direct costs for the five-year budget/project period. Funds may be requested for personnel (including co-investigators and collaborators), supplies, equipment, sub-contracts, and other allowable costs. Only the five-year total — $2.5 million — should be entered on Line 16a and b. A detailed budget is not requested and will not be accepted.

- No other documentation, such as letters of collaboration or biographical sketches of other personnel will be accepted. Information about personnel other than the PD/PI is not required, but may be included within the 3-5-page essay.


3. Submission Dates and Times

See Section IV.3.A for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: December 16, 2007 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): Not applicable
Application Submission/Receipt Date: January 16, 2008
Peer Review Date(s): April 2008
Advisory Council to the Director Review Date(s): August 2008
Earliest Anticipated Start Date: September 30, 2008

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity and will not be accepted.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/Apply and follow steps 1-4. Also see “Special Instructions” in Section IV.2 of this FOA. Note: Applications must only be submitted electronically. PAPER APPLICATIONS WILL NOT BE ACCEPTED.
PD/PI Credential (e.g., Agency Login)

The NIH requires the PD/PI to fill in his/her Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

All application instructions outlined in the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf) are to be followed, incorporating “Just-in-Time” information concepts, with the following exceptions, which are specific requirements for Pioneer Award applications. Applications that do not conform to the specific instructions detailed below will not be reviewed.

1. SF424 (R&R) COVER COMPONENT

<table>
<thead>
<tr>
<th>Item Number and Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Type of Application</td>
<td>Must be “New”</td>
</tr>
<tr>
<td>13. Proposed Project</td>
<td>Enter start date: 09/30/2008; Enter end date: 07/31/2013</td>
</tr>
<tr>
<td>16 Estimated Project Funding</td>
<td>Enter $2,500,000</td>
</tr>
<tr>
<td>16 a. Total Estimated Project Funding</td>
<td></td>
</tr>
<tr>
<td>16 b. Total Federal &amp; Non-Federal Funds</td>
<td>Enter $2,500,000</td>
</tr>
</tbody>
</table>

2. RESEARCH & RELATED OTHER PROJECT INFORMATION COMPONENT:

<table>
<thead>
<tr>
<th>Item Number and Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are Human Subjects Involved?</td>
<td>Follow the Application Guide instructions for all fields in Section 1.a. Check “Yes” or “No” as appropriate. If “Yes”, enter “None,” or the IRB Approval Date, Exemption Number, and Human Subject Assurance Numbers may be entered but are not required at the time of submission. Detailed plans regarding protection of human subjects, inclusion of women and minorities, targeted/planned enrollment, and inclusion of children are not required at the time of submission. This information will be requested on a just-in-time basis at the time of award.</td>
</tr>
<tr>
<td>2. Are Vertebrate Animals Used?</td>
<td>Follow the Application Guide instructions for all fields in 2.a. Check “Yes” or “No” as appropriate. Enter “None.” Detailed plans regarding the use of vertebrate animals are not required at the time of submission. The IACUC Approval Date and Animal Welfare Assurance Numbers may be entered but are not required at the time of submission. This information will be requested on a just-in-time basis at the time of award.</td>
</tr>
<tr>
<td>5. Project Summary/Abstract</td>
<td>Attach abstract. (Maximum of 300 words [not to exceed one page]; PDF format)</td>
</tr>
<tr>
<td>7. Project Narrative</td>
<td>Attach essay (Maximum of 5 pages; PDF format)</td>
</tr>
<tr>
<td>8. Bibliography &amp; References Cited</td>
<td>Do not use. If you choose to include figures or reference citations, they must be included in the essay, subject to the 5-page limit.</td>
</tr>
<tr>
<td>9. Facilities &amp; Other Resources</td>
<td>Do not use.</td>
</tr>
<tr>
<td>10. Equipment</td>
<td>Do not use.</td>
</tr>
<tr>
<td>11. Other Attachments</td>
<td>Attach description of your most significant research accomplishment (one page maximum; PDF format.)</td>
</tr>
</tbody>
</table>

Note: Applications found not to comply with the page limit requirements or that contain attachments other than those specified will be rejected during the agency validation process.
3. SF424 (R & R) SENIOR/KEY PERSON PROFILE COMPONENT:

Complete items only for Project Director/Principal Investigator. Do not submit profiles for other senior/key personnel.

<table>
<thead>
<tr>
<th>Item Title</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile- PD/PI - Attach Biographical Sketch</td>
<td>Attach biographical sketch here (two-page maximum, PDF format). Use the form</td>
</tr>
<tr>
<td></td>
<td>shown in the URL in Section 4.5.2 of the Application Guide, omitting Section</td>
</tr>
<tr>
<td></td>
<td>C, Research Support (see below).</td>
</tr>
<tr>
<td>Profile- PD/PI - Attach Current &amp; Pending</td>
<td>Attach a list of Current and Pending Support here (PDF format). Use the form</td>
</tr>
<tr>
<td>Support</td>
<td>shown in Section 3.1.1.8 of the Application Guide. Be sure to include</td>
</tr>
<tr>
<td></td>
<td>statement affirming that you will devote at least 51% of research effort to</td>
</tr>
<tr>
<td></td>
<td>Pioneer Award project. Also, include a brief statement of the facilities to</td>
</tr>
<tr>
<td></td>
<td>be used for the conduct of the research.</td>
</tr>
<tr>
<td>Profile – Senior Key Person 1</td>
<td>Do not use. Submit information only for PD/PI. Information on collaborators</td>
</tr>
<tr>
<td></td>
<td>may be included in the essay.</td>
</tr>
</tbody>
</table>

Note: Applications found not to comply with the page limit requirements will be rejected during the agency validation process.

4. PHS 398 Cover Letter File (Optional):

Cover letters should be included only when submitting late applications or Changed/Corrected applications after the submission deadline. Do not submit cover letters for initial submissions or for changed/corrected applications submitted before the submission deadline. The cover letter should contain only the following information:

1. PD/PI name.

2. Funding Opportunity Title: 2008 NIH Director’s Pioneer Award Program (DP2).

3. For Changed/Corrected Applications submitted after the submission deadline, include an explanation of the reason for the Changed/Corrected Application.

(See full instructions for submitting the Cover Letter Component in Section 5.2 of the Application Guide. Note: Items 3 – 6 of the Guide do not apply to Pioneer Award applications.)

Letters of Reference:

Letters of reference are an important component of the Pioneer Award application. Applicants must arrange to have three (and no more than three) letters of reference submitted on their behalf. Applications that are missing letters of reference may be considered non-responsive and may not be reviewed. Late letters will not be accepted. Applicants are responsible for monitoring the submission of their letters to ensure that three letters have been submitted prior to the submission deadline. Applicants can check the status of their letters in their Commons accounts.

Letters may be submitted beginning December 18, 2007, and must be submitted no later than 5:00 p.m. (EST) January 16, 2008.

Applicants must provide the following to their referees (Note: referees will not be able to submit letters without this information):

- Funding Opportunity Number (FOA) for this announcement RFA-RM-08-013;

  The applicant's Commons User Name (Note: Referees do not have to be registered in the Commons and do not need their own Commons User Name – only the Commons User Name of the applicant is required);

  The applicant’s first and last name (note – the name must match exactly the applicant’s name in the Commons);
REQUEST FOR PROPOSALS (RFP) CHARACTERISTICS:

Office of Acquisition Management and Policy at the National Institutes of Health


This will be where you will locate the RFPs Available by Institute.

Main points:

1. A Proposal Intent Response Sheet is typically required to be sent to the NIH. This form requires SPA signature and endorsement.

2. Separation of the Technical Proposal from the Business Proposal

3. Specific packaging and delivery of proposal (i.e. # of copies of technical and # of copies of business (usually includes submission of one copy of each on a CD.) # of appendices are specifically mentioned and may also need a CD.

4. Statement of Work is clearly and specifically defined

5. Budget to be completed on the NIH contract forms Excel spreadsheet located at http://oamp.od.nih.gov/ContractOpportunity/rfps/BUSCOST.HTM

6. A Technical Proposal Cost Summary need to be completed as well based on the FINAL Business Proposal Budget. Format is located at: http://www4.od.nih.gov/ocm/contracts/rfps/techcst5.htm

7. SPA offices need to complete Institutional forms to be submitted with the Business Proposal such as the Representations and Certifications (REPS and CERTS) and the Small Business Subcontracting Plan.
   
   Information on the Small Business Subcontracting Plan can be found at http://www.ospa.umn.edu/policiesandprocedures/smallbusinessplans/index.html


RFP TABLE OF CONTENTS

PART I - THE SCHEDULE. .......................................................... 4
SECTION A - SOLICITATION/CONTRACT FORM. ......................... 1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS. .......... 4
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT. . 5
SECTION D - PACKAGING, MARKING AND SHIPPING. ................. 6
SECTION E - INSPECTION AND ACCEPTANCE. ......................... 7
SECTION F - DELIVERIES OR PERFORMANCE. ....................... 7
SECTION G - CONTRACT ADMINISTRATION DATA. .................... 8
SECTION H - SPECIAL CONTRACT REQUIREMENTS. .................... 14

PART II - CONTRACT CLAUSES. ............................................... 24

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS. 29
SECTION J - LIST OF ATTACHMENTS. .................................. 29
SOLICITATION ATTACHMENTS. ........................................... 29
TECHNICAL PROPOSAL ATTACHMENTS. .............................. 29
BUSINESS PROPOSAL ATTACHMENTS. .................................. 29
INFORMATIONAL ATTACHMENTS. ....................................... 29

PART IV - REPRESENTATIONS AND INSTRUCTIONS. .................... 30
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS. 30
SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS. 30

1. GENERAL INFORMATION. ............................................... 30
   a. INSTRUCTIONS TO OFFERORS—COMPETITIVE ACQUISITION. . 30
   b. NAICS CODE AND SIZE STANDARD. ................................ 35
   c. TYPE OF CONTRACT AND NUMBER OF AWARDS. .................. 35
   d. LEVEL OF EFFORT. .................................................. 35
   e. COMMITMENT OF PUBLIC FUNDS. .................................. 35
   f. COMMUNICATIONS PRIOR TO CONTRACT AWARD. ................ 35
   g. RELEASE OF INFORMATION. ........................................ 35
   h. COMPARATIVE IMPORTANCE OF PROPOSALS. ..................... 36
   i. PREPARATION COSTS. .............................................. 37
   j. SERVICE OF PROTEST. ............................................. 37
   k. LATE PROPOSALS AND REVISIONS. ............................... 37

2. INSTRUCTIONS TO OFFERORS. ...................................... 37
   a. GENERAL INSTRUCTIONS. ......................................... 37
      1. Contract Type and General Clauses. ......................... 37
      2. Authorized Official and Submission of Proposal. ........... 37
      3. Proposal Summary and Data Record (NIH-2043). .............. 38
      5. Alternate Proposals. .......................................... 38
      6. Evaluation of Proposals. ..................................... 38
      7. Potential Award Without Discussions. ....................... 38
      8. Use of the Metric System of Measurement. .................. 39
      9. Standards for Privacy of Individually Identifiable Health Information. 39
11. Selection of Offerors ......................................................................................... 41
12. Institutional Responsibility Regarding Conflicting Interests of Investigators .......... 42
13. ROTC Access and Federal Military Recruiting on Campus .................................. 43

b. TECHNICAL PROPOSAL INSTRUCTIONS ......................................................... 44
   1. Technical Discussions ..................................................................................... 44
   2. Technical Evaluation ..................................................................................... 46
   3. Additional Technical Proposal Information ................................................ 46
   4. Other Considerations .................................................................................... 46
   5. Human Subjects ........................................................................................... 46
   6. Instructions to Offerors Regarding Protection of Human Subjects .................. 47
   7. Required Education in the Protection of Human Research Participants .......... 49
   8. Research Involving Human Fetal Tissue ......................................................... 50
   9. Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research) ................................................. 50
10. Human Embryonic Germ Cell (HEGC) Research ............................................ 51
11. Human Embryonic Stem Cell (HESC) Research ............................................ 51
12. Data and Safety Monitoring in Clinical Trials .................................................. 51
13. Obtaining and Disseminating Biomedical Research Resources ......................... 53
14. Information Security ....................................................................................... 54

c. BUSINESS PROPOSAL INSTRUCTIONS ......................................................... 59
   1. Basic Cost/Price Information ..................................................................... 59
   2. Cost and Pricing Data ................................................................................. 59
   3. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data ................................................................. 62
   4. Salary Rate Limitation in Fiscal Year 2007 ................................................... 63
   5. Small Business Subcontracting Plan ............................................................ 64
   6. Qualifications of the Offeror ....................................................................... 66
   7. Other Administrative Data ......................................................................... 68
   8. Subcontractors ............................................................................................ 70
10. Representations and Certifications - SECTION K ............................................... 70
11. Travel Costs/Travel Policy ............................................................................. 70

SECTION M - EVALUATION FACTORS FOR AWARD ............................................. 70
   1. GENERAL .................................................................................................. 70
   2. EVALUATION OF DATA SHARING PLAN ............................................. 71
   3. TECHNICAL EVALUATION CRITERIA ..................................................... 71
   4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION ....... 71