

Challenge Area:
Challenge Topic:
Project Title:

The Challenge and Potential Impact (~1 p)

RFA Instructions:

- What is the research opportunity, scientific knowledge gap or technology that will be addressed?
- How broad is the potential impact in science and/or health?
- Which community(ies) will be affected?
- What is (are) the size(s) of the community(ies)?
- Will the potential impact be major?

{*Advice* – Remember that your project will be described and tracked on recovery.gov in a manner that is accessible to Congress and to the public (including animal rights activists, for those of you working with animal models, so be careful of how you word your methods and any reference to animal experiments). These bullets could well reflect how HHS envisions reporting individual projects and hence the “bureaucratic review criteria”. “Communities” generally refers to taxpayer/patient constituencies (disease, geographic, racial/ethnic, etc.) but can include scientific and professional communities as well as policy makers and other stakeholders. Just be sure you can identify direct beneficiaries.

To make it easy for reviewers (peer & program), you might well highlight these phrases in the sentences/paragraphs in which they are addressed or create helpful subheads (e.g., Need Addressed, Overall Impact, Communities Affected). As I mentioned in the PPT, this section will need to cover the impact to the local (Burgh, Western PA), regional (emphasize UPMC’s reach into OH and WV especially) and US economy and toward making US health care more efficient/cost-effective/clinically efficacious. Any available estimates of the current cost of care, estimated cost of unnecessary care, lost wages/productivity, and so forth could go here and/or in the background-rationale portion of **The Approach**.)

NIH Review Criteria – Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the 5 core review criteria [significance, innovation, approach, investigators, environment].

{*Advice* – The Impact Score replaces the traditional priority score and will have a range of 10-90 in whole numbers, with 10 being, indeed, a perfect 10. The Impact Score is not calculated from the scores a reviewer assigns to the 5 individual criteria. Note that above I suggested using the subhead Overall Impact, which would help reviewers both with the NIH review process and the responsiveness to the RFA instructions and stimulus evaluation needs.}

NIH Review Criteria – Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technological advances, technical capability, clinical practice, and/or health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

NIH Review Criteria – Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, technological developments, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

{*Advice* – again, to help peer reviewers with this new scoring procedure, you could make their lives easier by including subheadings for Significance and Innovation. If the work itself not necessarily innovative, the

application of established methods to a new question could be highlighted as innovative, or the data to be obtained could be considered innovative.}

{*Advice* – NCMHD – minority health & health disparities – includes their criteria for ARRA funding, which gets to the spirit of the stimulus funding and is applicable to most challenge topics. Certainly anyone pursuing a health disparities topic will want to take the areas of emphasis into consideration as well.}

NCMHD will provide 2 years of funding only to support proposals that are consistent with the purpose of the ARRA to:

1. Preserve and create jobs and promote economic recovery
2. Assist those most impacted by the recession
3. Provide investments to increase economic efficiency by spurring technological advances in science and health

AREAS OF EMPHASIS

Applications related to health disparities will be considered from new and existing grantees with emphasis on:

- Community participation and mobilization
- Training and utilization of community health workers
- Collaboration/Partnership with non-traditional groups, settings, or across geographic boundaries
- Multidisciplinary approaches to intervention strategies
- At-risk communities
- Innovative outreach strategies
- Application of innovative technological advances
- Capacity Building/Infrastructure development in health disparity communities or underserved institutions
- Biological and non-Biological determinants of health disparities
- Establishment of regional networks/consortia for health disparities research
- Training the health workforce pipeline
- Telehealth/Telemedicine
- Rural health
- Prison health

The Approach (~9-10 p)

RFA Instructions:

- How will you attempt to explore or solve the stated research problem?
- How will your rationale and/or approach overcome existing challenges or barriers in the field?
- If you propose to improve existing technologies or to develop new technologies, which needs are being addressed and what is unconventional and exceptionally innovative about your approach?
- Provide enough information for reviewers to determine what you are proposing to do, but do not include a detailed experimental plan.

{*Advice* – Since thousands of applications will flood in from every conceivable discipline, I think you should assume your reviewers will not necessarily be peers intimately familiar with your work. I would recommend writing **The Approach** at the level of a general scientific expert audience and would suggest having research friends outside your area of expertise read through this section to see if it makes sense or is too jargony or difficult to follow. You cannot include animations anywhere in the narrative.

Your Specific Aims will lay out the broad rationale, aims, hypotheses (if any), overall project design/plan, and a brief note regarding the impact on public health and economy. Here you can restate the specific aims in terms of the milestones you will use to measure progress (both scientific & economic stimulus/community impact).

You want to cover a bit more background and rationale (see 2nd & 3rd bullets above), including any preliminary data you have to support the feasibility-early promise of your work. This would also be a good place to place your work in the context of your target IC's current strategic plan (you may recall when stimulus funding was first announced, it was described as being used to help ICs achieve some of their highest priorities).

Finally, you'll want to provide the project/study design and work flow (diagram, if appropriate), including your approach to data analysis and evaluating progress toward achieving milestones. I know this is where you are accustomed to including the most detail, so take your usual research plan and keep distilling the experimental details into fewer and fewer sentences to get the Cliffs Notes or Reader's Digest Condensed version.}

NIH Review Criteria – Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

NIH Review Criteria – Investigators. Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

NIH Review Criteria – Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

{*Advice* – Since you'll have a truncated biosketch and reviewers probably won't have/take the time to slog through lengthy Facilities & Other Resources or Equipment files, you would do well to include subheads for these latter two criteria with a few laudatory sentences hitting all the highlights. People and environment are integral to the approach, so it is not out of place.}

Timeline and Milestones (~1 p)

RFA Instructions:

- Provide a timeline for the proposed research indicating points where intermediate objectives will be assessed and decisions will be made regarding the course and direction of the continuing research effort.
- Possible alternative paths that may be followed at critical junctures in the project plan should be described and indicated on the timeline.

{*Advice* – Here you need to incorporate awareness of the reporting requirements, which I think will be critical when program starts selecting applications. Program will be looking for PIs who are shovel ready to shovel the ... you know what ... exactly the way OMB wants to receive it.

Remember that you will need to track spending from this account on a quarterly basis. The faster you can spend it, the better, so big equipment purchases in October or November 2009 would be great for economic stimulus, as would saving jobs/hiring new personnel. A quarterly timeline will need to reflect preparation of the upcoming report in advance of its receipt date (Jan 10, April 10, July 10, Oct 10). Funding will start September 30, 2009, so your first report would be due Jan 10, 2010.

Remember too that you will draw down ARRA funds on an award-specific basis, and pooling of ARRA award funds with other funds is not permitted. These are grants but should be thought of more like contracts. You will need to spend the money pretty much as you said you would in your timeline milestones – not to do interesting non-ARRA work on the side or cover an emergency in another project or carry over for a rainy day.

Again, I suspect program will reward people who reflect their grasp of this unfortunate reality in their narrative since program does not want to be chasing after hundreds of negligent PIs for these data. The NIH will want to show Congress that its \$10B in stimulus investment paid off in terms of increasing the tax base/GNP to the point that the NIH budget deserves to be permanently upped from ~\$30B to \$40+ billion in 2011 and beyond, and these reporting data will help the NIH make this case.

Methods to track & document all this progress should be mentioned in **The Approach** and could include formative (needs assessment, recruitment/enrollment monitoring, expenditures, etc.) and summative (aims achieved, jobs saved/created, investment in local economy, IP generated, generation of data for future research, cost savings in care/productivity, outcomes analysis, etc.) evaluation measures.

Just be sure to show you know what to track/report and have a method at the ready to do so. I've included the why and what of ARRA reporting requirements to help guide your presentation of milestones in a manner appropriate to your project/study that also satisfies what NIH needs its awardees to do.}

Why do we have these reporting requirements?

From OMB: “These requirements are intended to meet crucial accountability objectives:

- Funds are awarded and distributed in a prompt, fair, and reasonable manner;
- The recipients and uses of all funds are transparent to the public, and the public benefits of these funds are reported clearly, accurately, and in a timely manner;
- Funds are used for authorized purposes and instances of fraud, waste, error, and abuse are mitigated;
- Projects funded under this Act avoid unnecessary delays and cost overruns; and
- Program goals are achieved, including specific program outcomes and improved results on broader economic indicators.”

What are the reporting requirements?

From OMB: “As required by Section 1512 of the Recovery Act and this guidance, each recipient, as described above, is required to report the following information to the Federal agency providing the award 10 days after the end of each calendar quarter, starting on July 10th. These reports will include the following data elements, as prescribed by the Recovery Act:

- (1) The total amount of recovery funds received from that agency;
- (2) The amount of recovery funds received that were obligated and expended to projects or activities. This reporting will also include unobligated Allotment balances to facilitate reconciliations.
- (3) A detailed list of all projects or activities for which recovery funds were obligated and expended, including--
 - (A) The name of the project or activity;
 - (B) A description of the project or activity;
 - (C) An evaluation of the completion status of the project or activity;
 - (D) An estimate of the number of jobs created and the number of jobs retained by the project or activity; and
 - (E) For infrastructure investments made by State and local governments, the purpose, total cost, and rationale of the agency for funding the infrastructure investment with funds made available under this Act, and name of the person to contact at the agency if there are concerns with the infrastructure investment.
- (4) Detailed information on any subcontracts or subgrants awarded by the recipient to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 (P.L. 109-282), allowing aggregate reporting on awards below \$25,000 or to individuals, as prescribed by the Director of OMB.”

(Tip – if you will have sub-awards, just indicate your awareness of this need for extra detail and that you have mechanisms – and personnel – in place to track these data from each participating sub-awardee)

Other RFA Points of Consideration

- Multiple PIs allowed (need multiple PI plan & to identify a contact PI)
- All biosketches are limited to **TWO PAGES** and **TEN PUBLICATIONS**
- Bibliography and Literature Cited is limited to **ONE PAGE**
- Specific Aims are limited to **ONE PAGE**
- Project Summary/Abstract is **ONE PAGE** (usually 30 lines).

When writing your project summary, think of how you would explain to your mom how things will be better at the end of these 2 years – what you'll have accomplished, what that accomplishment means for the community you are seeking to help, and, of course, how you've contributed to economic recovery and growth.

- Other typically uploaded items (Protection of Human Subjects, Vertebrate Animals, Letters of Support, Resource Sharing Plans, etc.) are all handled as usual
- CSR has not given a hint about how they will distribute these for review other than to say they won't run 2,000 study sections. I'd suggest you use the cover letter to indicate the specific type of expertise that would be appropriate as well as, for reference purposes, the study section that would be appropriate if these applications were going to chartered study sections. No names, as usual. Dr. Kitt (deputy director of CSR) said they might start with the 15 broad Challenge Areas as the initial layer of sorting applications, so it could be your challenge area number will determine your initial review assignment.
- As an aside, remember again that not only will CSR be receiving thousands of applications on every imaginable topic to be rapidly distributed for rapid review and even faster funding decisions, they will be applying the new 1-9 scoring procedure (to be premiered in the upcoming round of reviews) and new review criteria to this very new application mechanism. Jiminy Cricket. Never before have you wanted to make life as easy as possible for the reviewers (and many of you will likely be called upon) and the program officers as they make their scoring and funding decisions.
- New and Early Stage Investigators will lose their special status if they receive an NIH Challenge Grant award. That is, they lose the percentile break on their first R01 and consideration of the ESI quota to be met when program selects applications for awards. The Challenge Grants are only 2 year awards and cannot be renewed. Although the NIH budget will likely get some relief in the coming years, NIAID is counseling applicants to brace themselves for very low – perhaps historically low – paylines in 2011:

"The Institute does not expect the growth in our base funding level to be sufficient for establishing a payline to continue funding all those grants. Neither will NIAID have R56-Bridge award money to extend them. As a result, we expect the payline to drop precipitously. So FY 2011 will be a very difficult year for people to secure funding, whether they are funded from the stimulus funds or the regular appropriation."

NIAID recommends that you start writing your next grant now in time for FY2010 funding, complete your research on time to strongly justify your renewal (if it needs to be submitted in 2011), and keep your timing options open. I'd say the NIAID advice applies across all the ICs. Given the tremendous competition for these stimulus awards, I think a New/ESI applicant who succeeds here probably could succeed with a traditional R01 without the payline break and will have the advantage of \$1 million in start-up funds for his/her independent research program. But, think carefully about whether you want to be the PI on one of these or a well-funded co-investigator, preserving your major award PI virginity.