

SUMMARY STATEMENT

PROGRAM CONTACT:

(Privileged Communication)

Release Date: 10/23/2019

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Application Number: 1 G11 AI152214-01

Principal Investigator

JARAMILLO ZULUAGA, ANDRES

Applicant Organization: CENTRO INTERNACIONAL (CIDEIM)

Review Group: ZAI1 AMC-D (J1)
National Institute of Allergy and Infectious Diseases Special Emphasis Panel
Global Infectious Disease Research Administration Development Award for Low-
and Middle-Income Country Institutions (G11)

Meeting Date: 10/16/2019 *RFA/PA:* PAR18-335
Council: JAN 2020 *PCC:* X84 D
Requested Start: 05/01/2020

Project Title: Implementing strategies for Building Capacity in Research Administration at CIDEIM, and subsequent dissemination within Colombia and the Latin American region

SRG Action: Impact Score [REDACTED]

Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm

Human Subjects: 10-No human subjects involved

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
1	[REDACTED]	[REDACTED]
2	[REDACTED]	[REDACTED]
TOTAL	[REDACTED]	[REDACTED]

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

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1G11AI152214-01 Jaramillo Zuluaga, A**FOREIGN INSTITUTION**

RESUME AND SUMMARY OF DISCUSSION: This outstanding new Extramural Associate Research Development Award application entitled “Implementing strategies for Building Capacity in Research Administration at CIDEIM, and subsequent dissemination within Colombia and the Latin American region” was submitted in response to PAR18-335: Global Infectious Disease Research Administration Development Award For Low-and Middle-income Country Institutions (G11-Clinical Trial Not Allowed) by the Centro Internacional de Entrenamiento e Investigaciones Medicas (CIDEIM), Cali, Colombia with Dr. Andres Jaramillo Zuluaga as Principal Investigator (PI). The application aims to (1) institutionalize at CIDEIM grants management best practices for NIH grants and (2) disseminate grant management best practices for NIH grants in the region.

This application presents a well-articulated strategy and objectives, with the goal to strengthen the institution and develop grants administration capacity both at CIDEIM and at other institutions in the region. The application provides a clear picture of the current scientific and administrative infrastructure, and the proposed program is appropriately focused on addressing gaps that have been identified in the grants administration process. The training plan properly outlines the proposed work, including specific plans of how to improve grants management, and proposed methodologies are very clear. The institutional environment both in Colombia and at Yale University is strong, with a positive culture of compliance. Staff are well trained and experienced, with excellent experience at managing NIH awards, as well as expertise in training and mentoring others. The training program includes multiple innovative elements. Key personnel at CIDEIM will be enrolled in Yale leadership courses to enhance their training experience. The inclusion of administrative and support staff in the training process is seen as a strength. The application also includes the innovative proposal for the lead trainer from Yale to travel to CIDEIM, the trip coinciding with preparation of the RPPR and planning for year two. Sustainability plans are adequate, including sharing of best practices and paradigms for procedures. The investigators also propose to leverage existing resources to enhance their program. CIDEIM will utilize platforms put in place by other programs to develop Spanish language online training for grants administration. Building on platforms that are already in place and functional demonstrates the investigators’ ability to execute similar programs effectively and increases the potential for rapid success. Enthusiasm for the application is tempered by a few minor weaknesses. Training is focused on post-award topics with little training based on pre-award concerns, though this is likely due to the fact that post-award topics were identified as gaps in the needs assessment. The application proposes to mentor other institutions in the region, but very little information is provided regarding how many institutions will be mentored and how the mentorship will impact them. The focus on leveraging of existing materials both at CIDEIM and Yale will likely increase the probability of program success, but there may be a need to customize materials for the needs of CIDEIM trainers and staff. Finally, alternative plans for online training in the event of power outages or internet connectivity issues are not adequately discussed and should be planned for, though the investigators do have experience with other academic courses.

Overall, this is an outstanding application, with only a few minor weaknesses reducing the enthusiasm of the panel. Based upon the evaluation of scientific and technical merit, this application received an Impact/Priority score of ■.

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DESCRIPTION (provided by applicant): The Centro Internacional de Entrenamiento e Investigaciones Medicas, CIDEIM, is recognized by COLCIENCIAS as a research center within the National System of Science, Technology and Innovation of Colombia. CIDEIM originated in Colombia in 1961 as an International Center for Medical Research and Training awarded to Tulane University by the United States National Institutes of Health and hosted by Colombia as a bilateral Technical Assistance Mission. Successive renewals of this program were followed by funding through the US NIAID ICIDR program until 1989. In 1990 at the initiative of COLCIENCIAS, CIDEIM was established as a Colombian non-profit foundation and in 1991, successfully competed for a Tropical Medicine Research Center TMRC award from the US NIAID. Since then, CIDEIM investigators have developed collaborative research and training programs with U.S. universities through subawards within projects supported by NIAID and the Fogarty International Center, as well as receiving direct awards from the US NIAID. Our current NIAID funding includes a TMRC U19 award and sub-award within a U19 award to the University of Connecticut, which have increased our institutional role in, and responsibility for the management of USNIAID grants. The overall goal of this project is to strengthen the capacity of CIDEIM to develop and implement institutional policies and practices for grants management that are compliant with NIH guidelines and requirements for administration of NIH grants, and to share this capacity with other institutions in the region. To achieve this goal, we will first address critical gaps in CIDEIM grants administration for current and future grants funded by the USNIH, by training CIDEIM management leaders at Yale University. Senior administrators trained in the U.S. will then transfer and implement these policies and practices including oversight of updated NIH guidelines, in CIDEIM. Second, we will design, implement and evaluate an internal training plan, curriculum and materials that will provide the bases for institutionalization of sustainable grants management and administration capacity through continuing education and updating of training in accordance with changes in NIH guidelines. This training curriculum and corresponding materials will be adapted for external training and transfer of capacity to other institutions in Colombia and the region. Our management leaders and their teams will review and adjust Institutional policies, procedures and standard operating procedures (SOPs) to meet good management practices in compliance with NIH requirements throughout the pre-award, award and post award phases of the natural history of programs and projects. Adaptation of training to internal and external online access and development of an in-house grant tracking system will promote sustainability of these practices.

PUBLIC HEALTH RELEVANCE: The mission of CIDEIM is to reduce the impact of infectious diseases and thereby improve the quality of life of those affected. In pursuing this mission, NIAID support has been fundamental to our research and training for prevention and control of transmissible diseases. Training of CIDEIM management leaders in the administration of US NIH grants will be sustainably implemented in CIDEIM and shared with other national and regional institutions, thereby benefitting current and future NIAID supported projects and research priorities, and optimizing the investment of NIH.

CRITIQUE: The comments in the CRITIQUE section were prepared by the reviewers assigned to this application and are provided without significant modification or editing by staff. They are included to indicate the range of comments made during the discussion, and may not reflect the final outcome. The RESUME AND SUMMARY OF DISCUSSION section summarizes the final opinion of the committee after the discussion and is the basis for the assigned Overall Impact/Priority score.

CRITIQUE 1

Significance:	2
Investigator(s):	2

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Innovation: 3
Approach: 1
Environment: 2

Overall Impact: The applicant is proposing a well thought out methodology with each stage systematically and logically fitting into the next stage: Beginning with the US institution attachment of the two officials; followed by designing, implementation and evaluation of an internal training plan and development of curriculum that will provide the basis for institutionalization of sustainable capacity; through continuing education and updating in accordance with changes in NIH guidelines; and adapt and pilot the training materials and curriculum for other Institutions external training with clear courses and module descriptions.

This is because the applicant clearly knows what gaps in research administration exist and what exactly needs to be done to close those gaps and what the new improved situation will look like and how it will be sustained and maintained through building an interinstitutional community of managers of NIH grants in the region.

1. Significance:

Strengths

- The significance of this application is that Mrs. Kathleen Fisher, Director Research Administration at Yale School of Public Health will oversee all the training related to this opportunity and bring over twenty-five years of experience in research administration at both central and departmental levels to the program.
- In order to achieve the training and business practices goals of the program, the administrators from CIDEIM will have monthly meetings with Ms. Fisher to review and follow up training activities and management/business plans. At the end of month 10, it's expected that Mrs. Fisher would visit CIDEIM to review the progress in situ and together with the two senior administrators set up a strategy for improving grants management oversight and business practices at CIDEIM, this document would be signed and sent to NIH following the report instructions.

Weaknesses

- Applicant does not indicate the projected number of Research administrators and Research institutions in the region who will benefit from the internal and external trainings
- Does not indicate what indicators they will use in order to measure and verify that learning has taken place and the identified gaps have been closed

2. Investigators:

Strengths

- The PI is the Coordinator Research Promotion and Development Unit and has got the relevant experience and mandate to implement changes which will ensure Grants management policies and procedures for the NIH compliance and requirements. The PI in this position serves as Administrative Official with the responsibility of grants administration and is able to interact at national and international levels with researchers and trainees, University faculty, administrators, and funding agencies.
- The PI is a member of the Society of Research Administrators International and has attended several annual meetings of the Society of Research Administration (SRA) and other trainings

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organized by NIAID. He has got access to NIH grants management resources which will enable him in designing the content for the outlined training plan.

- The PI has promoted and participated in the organization of web-based courses and seminars offered through the research training program that CIDEIM and Yale University. He will use this same experience to implement the proposed on-line Web based training courses in NIH research administration and compliance and has collaboratively developed national and regional training programs.
- The PI is currently, coordinating the dissemination of trainings by CIDEIM as the Latin American Regional Training Centre supported by the WHO TDR program in collaboration with the WHO and will leverage on this network platform and collaboration to reach the potential beneficiaries of the proposed training plan internally and externally.
- The Administrative Coordinator proposed as the second Senior Administrator on this project is currently responsible for the design and support of a wide range of organizational processes including the development and implementation of policies and procedures, as well as compliance, In accordance with her role in quality assurance of all administrative processes. She is strategically positioned to add the NIH specific policies and compliance requirements arising from the proposed in this project strategy.
- Vanessa has also trained in the Train-the-Trainer methodology course for Good Clinical laboratory Practice, which she will apply to the content of the proposed training project.
- Mrs. Kathleen Fisher, Director Research Administration at Yale School of Public Health who has been proposed to oversee all the training related to this opportunity will bring over twenty-five years of experience in research administration at both central and departmental levels to the program.

Weaknesses

- Although Mrs. Kathleen Fisher Director Research Administration at Yale School of Public Health has provided a letter of support for the PI, she has not provided her Bio sketch and also not listed in the Key Personnel Profile sheets

3. Innovation:

Strengths

- The project will leverage on the already existing Library documentation center with an online database, which has been developed by the CIDEIM library, which through partnership with ICESI University, has access to the university library, which is part of a larger Services and Resources Unit. This is already good infrastructure which will support the PI to build on this training project. This will guarantee quick wins, because there will be no need for facility startup, testing and capacity building resources.
- The proposal has made sustainability innovations like translation of Grants management materials into Spanish, development of Online components for the grants management training program and development of an in-house Grant Tracking System; webinar training and videoconferencing which will last for many years after the project period.
- This Spanish language curriculum will deliver the information and corresponding sources for what research administrators and staff in CIDEIM need to know about NIH requirements for foreign institutions. This curriculum will be pertinent and applicable to other institutions in the region

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- These CIDEIM senior administrators will also take two elective courses from Yale leadership Development training: InsideOut Coaching and Leading with Influence.

Weaknesses

- It is not clear that the other targeted institutions in the region have got a Robust IT and Internet connectivity to enable Online learning and Teleconferencing
- No record of the number of the expected potential external institutions and beneficiaries of the training project and also in the post project sustainability strategy
- Preparation of the Senior administrators as Train of Trainers (TOT) is not evident in the methodology and at Yale

4. Approach:

Strengths

- Document Management: CIDEIM has implemented Sharepoint online, this tool is a collaborative platform web based that allows sharing news, SOPs and procedures registered in the Quality System Management, communication of internal orders and requirements to the Administrative Unit and log in to Institutional Databases. In addition, CIDEIM has implemented OneDrive for all users, this tool is a file hosting service that allows users to create, edit, share, and sync files in their computers and to access them from a web browser or mobile device. This tool strengthens the collaborative work.
- Videoconferencing Resources: Videoconferencing facilities are available on site within CIDEIM, with three appropriately furnished conference rooms. The larger conference room is equipped with video projector, an audio system (amplifier, speakers and microphones), and a dedicated desktop computer with Microsoft software.
- The other two conference rooms, meant to be used for videoconferences with small groups of local participants, are equipped with 42" Sharp LCD flat screen television with appropriate video and audio connections to laptop. For web-based courses, connecting international collaborators and the members of the Colombian Postgraduate Training Network is achieved through ZOOM platform. CIDEIM employs a dedicated laptop for video conferencing needs, including archiving session recordings.
- In addition, the recordings are loaded in the YouTube private channel of CIDEIM. In addition to its internal resources, CIDEIM has access to the conferencing and other facilities of ICESI University.

Weaknesses

- None

5. Environment:

Strengths

- CIDEIM has established external and internal advisory committees, as well as institutional review boards (IRBs), which define policies, instruments and mechanisms to ensure compliance with national and international standards and regulations for biomedical research offering a conducive environment for implementing of revised Research administration policies changes resulting from this proposed project strategy.
- CIDEIM has got proven Institutional Research Compliance and Oversight with Diverse research support units like the biostatistics and data management unit, clinical research unit, research

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ethics office and administrative unit, all these units will support and compliment the efforts of successfully implementing the proposed project.

- The administrative unit under the authority of the Director; with their functions and expertise in Finance management, human resources, purchasing, quality assurance and IT processes, has got the mandate to ensure regulatory, legal and financial requirements. This support will be instrumental in implementing the closing of the capacity gaps as a result of the training intervention proposed in this project
- Institutionalization of compliance procedures and good research practices is promoted and monitored in collaboration with the Training Unit already mandated to follow-up and have oversight of all the institutional training programs. The same training unit will continue monitoring the proposed training in this proposal.
- CIDEIM's Information and Communication infrastructure has got Library and Documentation Center, 180 node network controlled by a Windows server 2016 Standard controlling computer access to internet and internal ftp, and can allow sharing of resources such as desks and printers located at different sites of the institution with Research administrators the project is targeting to train.

Weaknesses

- It is not clear that the targeted beneficiaries of the e-learning modules and video conferencing will have unlimited and robust internet connectivity with power backup; also no alternative measures have been considered in the design

CRITIQUE 2

Significance:	1
Investigator(s):	1
Innovation:	2
Approach:	2
Environment:	1

Overall Impact:

This is a very well-written application. An excellent discussion on the current administrative infrastructure of the host institution is provided. The PI does an outstanding job in highlighting current existing gaps in its grant management system and how this application will assist in addressing those gaps. Outstanding needs assessment analysis. The significance of the project is high, and the specific aims of the project are well-conceived. The PI and his collaborators are quite experienced, competent, and committed. The application uses innovative approaches. The approach is discussed in great details and is very sound. Tentative timeline proposed is credible. Plans for sustainability are sound. The environment is also quite appropriate. The only weakness, according to this reviewer, is the lack of plans to assess the impact of the training plan on other institutions in the region.

1. Significance:

Strengths

- The foreign institution seems to be committed in strengthening its administrative structure to manage grants and contracts awarded by NIH
- Specific Aims are very well-articulated

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- If aims are achieved, the administrative infrastructure at the host institution, to effectively implement policies and practices to manage federal grants and contracts, will be improved significantly
- The training plan has been designed based on existing gaps in the current grant management system at the host institution
- An adequate needs assessment was conducted

Weaknesses

- None were noted.

2. Investigators:

Strengths

- The PI as well as other key personnel have the necessary experience and expertise to carry out the plan
- The PI seems to have the required authority to carry out the proposed activities
- The USA consultant has the appropriate skills and experience in managing NIH awards to train a foreign senior administrator.
- Communication and coordination with the USA partner appears to be excellent

Weaknesses

- None were noted.

3. Innovation:

Strengths

- The approach of the application seems innovative and very well-articulated

Weaknesses

- None were noted.

4. Approach:

Strengths

- The proposed approach is discussed in detail and it appears to be logical and doable.
- A tentative timetable is presented is very reasonable
- An excellent discussion of existing gaps in the current administrative structure is provided
- A rigorous needs assessment was conducted by an expert reviewer
- Plans for sustainability are sound

Weaknesses

- Plans for assessing the impact of the training plan on other institutions in the region are not compelling

5. Environment:

Strengths

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- The environment at the applicant institution seems to be appropriate for the implementation of proposed activities
- The PI and the application seem to be supported by the upper administration at the applicant institution and by their collaborating institutions
- The USA institution has the appropriate grants management staff and adequately train a foreign senior grants manager
- The site for training in the USA is appropriate
- Institutional commitment towards the PI and the application is high

Weaknesses

- None were noted.

CRITIQUE 3

Significance:	5
Investigator(s):	4
Innovation:	4
Approach:	6
Environment:	5

Overall Impact: This proposal contemplates a partnership between Corporation Centro Internacional de Entrenamiento e Investigaciones Medicas (CIDIEM) and Yale University to create a training program leading to improved knowledge, policies and procedures for grants administration both locally and regionally. The proposal contemplates translation of key training materials into Spanish for generalizable use in the region, as well as development of on-line courses and in-person training, plus updated SOPs, policies and procedures to ensure compliance with NIH requirements. An on-line system for certain administrative requirements will also be created. Yale will be an excellent partner for CIDIEM given their international strength and their vast experience. The scope of the training and activities to be undertaken seems to strongly favor the post-award experience. The impact to others (both within CIDIEM and regionally) during the grant period and beyond needs more detail to properly understand the potential impact.

1. Significance:

Strengths

- Great idea to include the two Yale leadership courses (Leading with Influence and InsideOut Coaching) to the curriculum for the PI and Co-I.
- The competency model for the PI and Co-PI's jobs that was developed after a Yale site visit is to be commended.

Weaknesses

- While some gaps or weaknesses are identified, the training plan appears to be primarily general, and primarily focused on post-award topics. There appear to be no training courses related to finding funding opportunities, budget preparation, or proposal preparation and submission, or award negotiation and acceptance.

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- I would have liked to have understood more about the Administrative Tracking system that is being proposed (and see that of significantly more importance than a training tracking system) and to understand how it would be implemented and rolled out to CIDIEM staff and researchers.

2. Investigators:

Strengths

- I was pleased to see that this proposal extends an already-existing collaboration.
- The PI already has good background (MBA, Strategic Management, 7 years of related experience, and a recent promotion). He has participated in previous NIH research administrator training as well as worked with other grants, including with the director of CIDEIM. There is support for him to implement change and he is likely in the correct role to be able to achieve this.
- The Co-I has a master's degree, 4 years of experience, and has specialized training in training and evaluation.

Weaknesses

- I did not get a broad picture of the size/complexity of the grantee's environment and how the training would be "flowed" to the rest of the organization.

3. Innovation:

Strengths

- While the idea to have the US lead visit the PI and Co-PI's site is not new, I thought it was innovative to time that visit in such a way as to allow the US lead to help with the grantee's first RPPR, and to help plan Year 2.
- Kudos for creating the job competency model for the PI's job and the Co-I's job in advance of the application!

Weaknesses

- This application is not innovative, but it does not need to be to provide the needed capability expansion.

4. Approach:

Strengths

- I was pleased to see that the NIH fundamentals class will be required for all administrative and support staff at CIDIEM and for all NIH-funded instructors, postdocs, and project managers.
- While the plan to translate materials into Spanish is clearly desirable, there does not appear to have been any effort to understand whether such materials already exist elsewhere or if any pilot work has already been undertaken based on courses previously taken by the PI.

Weaknesses

- The training courses at Yale seem primarily focused on the PI/Co-I taking existing Yale sponsored research courses – while undoubtedly excellent training, this may not closely match the needs of the CIDIEM participants. For example, the course on Principal Investigator eligibility may be unnecessary. While there is mention of other training being provided by in-house Yale experts but the topics on these also appear to be limited.

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- The timing of the in-house NIAID training is all slated for Year 2; which may be fine but it is not clear how the timing for this is being synced with the adjustment of institutional policies and SOPs and development of the grant tracking system.
- The plan for training administrators outside of CIDIEM is only covered minimally, and appears to include invitations after identifying other potential local or regional participants via RePORT. Inadequate homework on this appears to have been done, though a statement is made that these individuals will be invited to participate in teaching as well as participating as students. Because inadequate work on this appears to have been done, it is not clear what other local talent already exists that can be harnessed. Training of other institutions is planned both in person and on-line. No sufficient long-range plan is identified or cost model proposed.

5. Environment:

Strengths

- Clear statement by Dr. Saravia, Director of CIDEIM that the PI and Co-I have the authority to implement process and practices, and to create policies in conjunction with the Board of Directors, and that she will support institutionalization of guidelines and practices in compliance with rules and regulations for both investigators and admin personnel.
- CIDEIM appears to have access to good videoconferencing and shared document storage.
- The site in the US for training is excellent – highly experienced and knowledgeable.

Weaknesses

- Only a general statement about “access to conferencing and other facilities of ICESI University” is provided with a general statement about one large and two smaller videoconferencing rooms; no details are provided or commitment of resources to the training needs outlined in the proposal.
- No funding for support maintenance and enhancement of the Grants management system over time has been identified.
- The funded time commitment for the senior three personnel is actually 1.5 months in Year 2 (calculated as such) but listed as 3.0 months for each.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: NOT APPLICABLE

INCLUSION OF WOMEN PLAN: NOT APPLICABLE

INCLUSION OF MINORITIES PLAN: NOT APPLICABLE

INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN: NOT APPLICABLE

VERTEBRATE ANIMAL: NOT APPLICABLE

RESOURCE SHARING PLANS

DATA SHARING PLAN: NOT APPLICABLE

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MODEL ORGANISM SHARING PLAN: NOT APPLICABLE**GENOMIC DATA SHARING PLAN: NOT APPLICABLE****FOREIGN INSTITUTION: JUSTIFIED**

Comments: Colombia

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES: NOT APPLICABLE**BUDGETARY OVERLAP: NOT APPLICABLE****COMMITTEE BUDGET RECOMMENDATIONS:**

The budget is recommended as requested in all years.

Footnotes for 1 G11 AI152214-01; PI Name: Jaramillo Zuluaga, Andres

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.