Stanford Child Health Research Institute

Mobilize Stanford discoveries and expertise to launch healthier lives

Grant and Postdoctoral Support
Application Instructions
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1. General Instructions

1.1. Introduction

These instructions pertain to applications for the Stanford Child Health Research Institute (CHRI) Grant and Postdoctoral program. For detailed program policy, please refer to the CHRI Grant and Postdoctoral Support Policy.

1.2. Format Specifications

Font and margin specifications must be followed; if not, application processing may be delayed or the application may not be reviewed. Page limits must be followed or the application may not be reviewed.

Font
- Use only Arial, a black font color, and a font size of 10 points or larger. A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.
- Use black ink that can be clearly copied.
- Print must be clear and legible.

PageMargins
- Use at least one-half (0.5) inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, except for the PI's name and page numbers.

Page Formatting
- Use only a standard, single-column format for the text.
- Put applicant's last name in the footer on every page (except the face page).
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).
- Do not include unnumbered pages. Number all pages.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes
- A smaller type size here is acceptable, but it must be in black ink, readily legible, and follow the font typeface requirement.

Grantsmanship
- Use English and avoid jargon.
- If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Photographs and Images
- Do not include photographs or other materials that are not printed directly on an application page in the body of the application.
You may include black-and-white or color images in the application provided such images are printed directly on the application page and are critical to the content of the application.

**Page Limits**

Observe the page number limits provided in the table below.

<table>
<thead>
<tr>
<th>SECTION OF APPLICATION</th>
<th>PAGE LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face Page</td>
<td>1 page</td>
</tr>
<tr>
<td>Budget and Budget Justification</td>
<td>2 pages</td>
</tr>
<tr>
<td>Introduction (Resubmissions only)</td>
<td>2 pages</td>
</tr>
<tr>
<td>Research Plan</td>
<td>3 pages</td>
</tr>
<tr>
<td>Appendix ** (figures and references)</td>
<td>3 pages</td>
</tr>
<tr>
<td>NIH Biographical Sketch (per person)</td>
<td>5 pages</td>
</tr>
<tr>
<td>Mentoring Plan</td>
<td>2 pages</td>
</tr>
</tbody>
</table>

** Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies.

**1.3. Resubmission Applications**

**Opportunity for Resubmission**

For all applications originally submitted (i.e. for the first time) in 2007 or later, CHRI will accept a maximum of two resubmissions per project (amendments to the original application). Any third resubmission will be administratively withdrawn and not accepted for review.

There are 3 requirements for a Resubmission application:

- The Applicant must make significant changes to the application;
- An Introduction (max 2 pages) must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Reviewer Comments. Use the Introduction to Application of the Research Plan to provide this information. All format requirements apply.
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing typography. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Research Plan should incorporate work completed since the prior version of the application was submitted.
- Research Plan should incorporate work completed since the prior version of the application was submitted.

Investigators who have submitted multiple versions of an application and have not been successful often ask what constitutes a “new application.” It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests. However, a new application following multiple reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a Resubmission application.

Simply rewording the title and Specific Aims or incorporating minor changes in response to the Reviewer Comments does not constitute a substantial change in scope or content. Changes to the Research Plan...
should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims.

Applicants are encouraged to meet with a CHRI reviewer to discuss revisions and suggestions for improvement prior to resubmission. Contact CHRI Administration (chri_admin@stanford.edu) to request a resubmission consultation with a reviewer.

1.4.  Post-Submission of Application Materials

Grant application materials will only be accepted after submission of the application but before the initial peer review if they result from unforeseen administrative issues (e.g., see below). The materials should be emailed as a PDF attachment to spectrumchildhealth@stanford.edu.

The original application is kept intact; any application material sent post-submission is sent separately to reviewers. Updated or supplemental grant application materials used in the peer review process will be retained as part of the official grant file and remain part of the permanent record for that application.

Acceptable post-submission materials include:

- Revised budget (e.g., change in total budget request due to new funding)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- News of an article accepted for publication

Unacceptable post-submission materials include:

- Updated Specific Aims or Research Plan pages
- Late-breaking research findings
- Supplemental pages - information not contained in the existing application
- New letters of support or collaboration that do not result from a change in senior/key personnel due to the loss of an investigator

Page limits for post-submission materials:

- All post-submission materials must conform to the CHRI Grant and Postdoctoral Support Application Instructions on font size, margins, and paper size
- Additional pages such as budget, biographical sketches, and other required forms must follow CHRI page limit requirements

The deadline for receipt of additional materials is one month (30 calendar days) prior to the peer review meeting. Contact CHRI Administration if you may submit post-submission materials. After the initial peer review phase is completed, additional materials will not be accepted. However, if additional information is requested after a peer review of a grant application has been completed and prior to funding, the applicant will be notified by email.
1.5. Application Submission Date, Late Applications

The electronic (PDF) application must be received by CHRI Administration via the ONLINE APPLICATION PORTAL, no later than 5pm on the submission (or resubmission) deadline specified in the RFA.

Late applications. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a signed cover letter explaining the reasons for the delay must be included with the completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting CHRI Administration in advance will not influence the acceptance of a late application.

1.6. Submission, Review and Award Cycles

Timeline

• Two competitions are offered annually (spring and fall).
• Anticipate total review turnaround time of 10 weeks from the submission deadline.

Application Assignment Information

Competing grant applications submitted to CHRI will be processed through CHRI Administration. The application will be assigned to an appropriate CHRI Scientific Review Panel. Assignment is based on the scientific content of the application and conflicts of interest considerations.

Applicants must not communicate directly with any CHRI Scientific Review Panel member about an application either before or after the review. Failure to strictly observe this policy will create serious breaches of confidentiality in the peer review process. From the time of assignment to the time the review of the application is complete, applicant investigators must direct all questions to CHRI Administration.

1.7. Resources for Finding Help

If after reviewing these application instructions, help is needed in preparing the application, contact CHRI Administration at chri_admin@stanford.edu or calling 650-724-6891.

2. Submission of the Grant Application

Submit a complete application. The application must be complete and accurate at the time of submission. Applications may not be reviewed if they are incomplete, illegible, fail to follow instructions, or present insufficient material to permit an adequate review.

2.1. Bindings and Packaging

Submit the following materials into one PDF document. Collate application materials in this order:

• Face Page (maximum 1 page)
• Budget and Budget Justification (maximum 2 pages)
• Introduction (Resubmissions Only; maximum 2 pages)
• Research Plan (maximum 3 pages)
• Appendix (Figures and References; maximum 3 pages)
• Supporting Documents
CHRI Grant and Postdoctoral Support Application Instructions

- Mentoring Plan (required for Assistant Professors, Instructors, and Postdocs)
- NIH Biosketches
  - Applicant (required)
  - Primary Mentor (required)
  - Other Mentors (required)
  - Co-Investigators (required)
- Letters of Support
  - Primary Mentor (required)
  - Other Mentors (required)
  - Co-Investigators (required)
  - Collaborators (required)
- IRB Approval Letter (if applicable)

2.2. Application Mailing Address
The electronic (PDF) application must be received by CHRI Administration via the ONLINE APPLICATION PORTAL.

3. Preparing the Research Proposal

3.1. Face Page
Item 1. Title of Project
Do not exceed 100 characters, including spaces and punctuation. Choose a descriptive title that is specifically appropriate. A Resubmission application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title.

Item 2. Category
Select one (1) of the Grant Support categories (Pilot, New Idea, Bridge or Postdoc) for which you are applying for:

<table>
<thead>
<tr>
<th>Instructor</th>
<th>Pilot</th>
<th>New Idea</th>
<th>Bridge</th>
<th>Postdoc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistant Prof.</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Associate Prof.</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Professor</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Postdoc</td>
<td></td>
<td></td>
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<td>●</td>
</tr>
</tbody>
</table>

*All applicants that request funding that would extend into any part of the fifth year of postdoctoral training, must provide documentation of approval of the fifth year extension by the OPA--official approval must be attached to the application. For full eligibility criteria, refer to the CHRI Grant and Postdoctoral Policy.

Item 3. Resubmission Application
Check “No” if this is an original new (i.e. never submitted) application to CHRI.

Check “Yes” if this is a resubmission of a previously submitted CHRI application.

Item 4. Principal Investigator (PI)

Name of Principal Investigator (PI) and Degree(s)
Name the one person responsible for the scientific and technical direction of the project. The PI is responsible for the research idea, development methods, supervision and conduct of the study. Indicate up to three (3) academic and professional degrees, or credentials, such as licenses (e.g., R.N.).

Position Title
Provide the academic title of the PI (e.g. Instructor, Assistant Professor, Associate Professor, or Professor, Postdoc). Do not list any other professional titles (e.g., Chief, Director, etc.).

Department, Division
Indicate the department and the division, if applicable, of the PI.

Telephone, SUNet ID, and Email Address
Provide a daytime telephone number (cell phone preferred), SUNet ID, and the appropriate e-mail address (not a website URL).

Research Mentors
Name up to three (3) research mentors: one Primary Research Mentor (to be listed in the first line) and up to two (2) non-primary research mentors. Postdocs, Instructors and Assistant Professors are required to identify at least one research mentor. The Primary Research Mentor must be a Member of the Stanford Child Health Research Institute; in the event the applicant is not a CHRI Member. CHRI membership link available at http://spectrumchildhealth.stanford.edu/

An NIH Biosketch (with Personal Statement) must be submitted for every research mentor named. Attach these in the Supporting Documents. The NIH Biosketch template can be obtained here: http://grants1.nih.gov/grants/funding/phs398/phs398.html

Co-Investigators
Name up to three (3) Co-Investigators involved in this project. An NIH biosketch and a letter of support must be submitted for every Co-Investigator named. Attach these in the Supporting Documents.

Item 5. Total Costs Requested (Must Match Budget Worksheet)

Categories I, II, and III: From the Budget Form Page, enter the "Total Costs." Total Costs must not exceed $35,000. Total Costs must include the 8% infrastructure charge (ISC) taxed by Stanford University on all gift funds.

Category IV: State the requested salary/fringe for the Postdoctoral grant (maximum of $55,000).

Item 6. Human Subjects Research

Check “No” if activities involving human subjects are not planned at any time during the proposed project period. Skip Item 6a.

Check “Yes” if activities involving human subjects are planned at any time during the proposed project period, either at Stanford or at any other performance site or collaborating institution. The CHRI does not require IRB approval of proposed research prior to peer-review of an application. However, any modification of the Research Plan section of the application required by the IRB or to address human subjects’ concerns raised during review, must be submitted for approval before award. To help determine
whether research that involves the use of human data or biological specimens is human subjects research, refer to [http://humansubjects.stanford.edu/](http://humansubjects.stanford.edu/).

**Item 6a. IRB Approval**

Check "No" if IRB approval is pending (under review) or has not been submitted.

Check “Yes” if IRB has approved the study and attach the approval letter in the Supporting Documents section at the end of the application.

**Item 7. Department Financial Manager to be notified if Award is made**

Provide the name and contact of the PI’s department/division financial manager to be notified if an award is made.

**Item 7a. Oracle Financial Org Code for the Award**

Ask the Departmental Financial Manager for the 4-letter organizational code for the PI’s department/division (e.g., WXYZ).

**Item 8. Biostatistics Consultation**

Check "No" if proposed study is not human-based or does not require a power-calculation. It is, however, highly recommended if appropriate.

Check “Yes” to indicate that a biostatistics consult was obtained for the proposed project. For all human-based studies, a pre-award biostatistics consultation is required.

**Item 8a. Spectrum Consultation or Other**

Check “Spectrum” if a biostatistics consultation was provided by Spectrum. Check “Pediatrics” if a biostatistics consultation was provided by Pediatrics. “Other” if the consultation was not provided by either Pediatrics or Spectrum.

As part of a partnership with the Stanford Quantitative Sciences Unit (QSU), CHRI Support Program Applicants may request services as needed to support the success of their research project (most services at no charge to the investigator). Their expertise is available for consultation, the development of grant proposals, and implementation of funded projects. Click here to submit a request directly to the QSU.

Additionally, free pre-award biostatistical consultations can be scheduled through Spectrum’s online Study Navigator ([http://spectrum.stanford.edu/studynavigator](http://spectrum.stanford.edu/studynavigator)).

Applicants can consult with non-Spectrum biostatisticians to fulfill this requirement.

**Item 9. Spectrum Child Health (SCH) Clinical Research Coordinator Services**

Check “No” if SCH clinical research coordinator and/or research nurse is not requested. Consult SCH if applicant needs advice on whether a research coordinator/nurse will be needed for the proposed project or would like more information about this service.

Check “Yes” if a SCH clinical research coordinator and/or research nurse is needed for the proposed project. Submit a request to SCH.

**Item 10. Project Funding Status**

Indicate the funding status of the proposed project. **Check all that apply.**

- Not funded: proposed project is not, and will not be, funded by any other source.
- Partially funded: proposed project may be partially funded by another source.
• Funding pending: the proposed project has been submitted to other funding source(s) and may be potentially funded, in part or in full, by other internal or external sources.
• Funding approved: the proposed project has been approved for funding.
• Federal (NIH): proposed project may be funded by federal sources. Specify in the Budget Worksheet.
• Industry-sponsored: proposed project may be funded by industry sponsor. Specify in the Budget Worksheet.
• Foundation: proposed project may be funded by foundation sources. Specify in the Budget Worksheet.
• Mentored award: proposed project may be funded by a mentored award. Specify in the Budget Worksheet.
• Departmental: proposed project may be funded by departmental sources. Specify in the Budget Worksheet.
• Other: proposed project may be funded by other sources not listed above Specify in the Budget Worksheet.

Item 11. Keywords

Please enter 3-5 keywords separated by semicolons, for example “biomarker; acute kidney injury; stem cell.” Each individual keyword may be up to 100 characters in length i.e. “whole genome sequencing.” Keywords should be present within the application.

Item 12. Project Summary

Do not exceed 200 words. Write a succinct and accurate description of the proposed work. State the application's broad, long-term objectives and specific aims, making brief reference to the child health relatedness of the project (i.e. relevance to the mission of the Stanford Child Health Research Institute). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to others, such that a medical faculty member who is not a specialist in your field, will understand. Avoid describing past accomplishments and the use of the first person.

3.2. Budget

CATEGORY 1, 2 OR 3: Insert a study budget using the Category 1 - 3 Budget Worksheet downloadable at http://spectrumchildhealth.stanford.edu. Category 1, 2 or 3, submit PDF of budget Worksheet.


If awarded, the final budget may be developed in collaboration with CHRI Administration.

PI Salary Support

• Instructors, Assistant Professors must provide a Budget Justification for requesting salary support and how the proposed work will be completed if the entire CHRI budget is allocated for PI salary.
• Postdocs must submit a brief statement requesting his/her specific salary support, and indicate how any remaining salary and research expenses will be funded.

Personnel

Name. Starting with the PI, list the names of individuals who are involved on the project during the budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

Role on Project. Identify the role of each individual listed on the project. Describe their specific functions. Provide a brief budget narrative for ALL personnel by position, role, and percentage FTE.
Totals. Calculate the totals for each position and enter the subtotals in each column where indicated. The 8% ISC charge on the Budget Form is already a formula and is pre-calculated for you.

Non-personnel

Supplies. Itemize supplies in separate categories, such as microarrays, chemicals, radioisotopes, etc. List amount requested and justify each purchase. If animals are to be purchased, state the species and the number to be used.

Patient Care Costs. If inpatient and/or outpatient costs are requested for research with human subjects, provide the amounts requested. Make sure costs reflect Stanford/LPCH/SHC negotiated research discount rates. Check the Spectrum Billing and Budget Workbook for research discounted prices. Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly. If you need help with the Spectrum Billing and Budget Workbook, please email studyfacilitator@stanford.edu for assistance.

Provide specific information regarding anticipated sources for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of the Stanford Clinical and Translational Research Unit (CTRU) or Clinical Translation Science Awards (CTSA) related resources (i.e. Spectrum resources).

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient participation incentives, etc.

Unallowable costs

The following items are not allowable:
- Travel, conference fees, tuition, classes
- Membership dues, journal subscriptions, books
- Office supplies, ITSS communications
- Poster presentations, abstract submissions
- Computer equipment, software, or accessories
- Any other indirect research costs

Budget and Budget Justification.
The applicant must submit a CHRI Budget Worksheet detailing all current and potential other sources of funding for this study. Include a PDF of the Budget Worksheet in the Application as well as submit the Excel document. The CHRI G&P Budget Worksheet is available at: http://spectrumchildhealth.stanford.edu.

3.3. Introduction (Resubmission Applications Only)

Include an Introduction only if this is a Resubmission Application. Summarize the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Reviewer Comments. The Introduction may not exceed two (2) pages. All format requirements apply. See 1.3 “Resubmission Applications” for detailed instructions for current cycle round or future award cycles.

3.4. Research Plan

Do not exceed 3 pages.
3.4.1. Specific Aims
List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

3.4.2. Relevance to Child and Maternal Health
This study MUST address an important and significant maternal and/or child health problem.
Describe the relevance of this research to maternal and/or child health. In this section, be succinct and use plain language that can be understood by a general, lay audience. The CHRI defines “child health” as referring to the expectant mother, oocyte, zygote, embryo, fetus, infant, child, and adolescent (under the age of 21 years of age).

3.4.3. Background and Significance
Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.

3.4.4. Preliminary Studies (if available)
Use this section to provide an account of the principal investigator/mentor’s preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members.

3.4.5. Research Design and Methods
Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, statistically analyzed, and interpreted. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Justify why a specific pathway or gene is being investigated, if proposed. A tentative sequence or timetable for the project may be included here. For Clinical studies, include inclusion/exclusion criteria and sample size determination. A pre-award biostatistical consultation is required for all human-based studies. Describe a data and safety monitoring plan if a data safety monitoring board is involved.

3.4.6. Career Development / Category Justification
Categories I and IV: Career Development. Describe how this funding will contribute to the PI’s career goals.
Categories II and III: Category Justification. Describe how this project qualifies as New Idea (category II) or Bridge Funding (category III) as outlined in the CHRI Grant and Postdoc Policy.

3.4.7. Potential Pitfalls and Contingency Plans
Please describe the potential pitfalls and limitations for your project and discuss alternative approaches to achieve the project aims.

3.4.8. Future Steps
Define follow-up work, long-term sustainability, and how this project will lead to new opportunities for research funding.

3.5. Appendix
Do not exceed 3 pages. Include figures and references in the Appendix section.

3.6. Supporting Documents

NIH Biographical sketches. An NIH Biographical sketch (with Personal Statement) must be submitted for the applicant and each co-investigator and mentor listed on the face page. See NIH Biosketch format and sample at http://grants1.nih.gov/grants/funding/phs398/phs398.html

Letters of Support. Attach all letter(s) of support here. The primary research mentor's letter of support must also address his/her own focus on child health or an expansion of his/her interest into child health research or obstetrics. Letters of support are not blinded and must not be sent separately. Include them as an integral part of the application package in electronic PDF format.

IRB approval. Attach the IRB approval letter (if applicable) here. Do not attach the entire e-protocol.

Pink Sheets (Bridge Funding Only). Attach the NIH pink sheets.

4. The Peer Review Process

4.1. Overview
The peer-review process outlined here is modeled after the NIH. It is intended to ensure that applications are evaluated fairly, equitably, timely, and conducted in a manner free of bias. Each application is assigned a primary and a secondary reviewer. Before the review meeting, each reviewer assigned to an application will give a preliminary impact score for that application based on the five review criteria (see below).


The supervisor/primary research mentor should have significant extramural funding for outstanding research programs and a track record for training researchers. The supervisor/primary research mentor should have a history of being the primary supervisor of successful research trainees.
4.2. Scoring

Reviewers are instructed to evaluate research applications by addressing the five core review criteria (see below) and the project's relevance to child health. For each application that is discussed, a final overall impact score will be given by each review committee member (without conflicts of interest) following the panel discussion. Each member's impact score will reflect his/her evaluation of the overall impact of the project in its entirety, rather than an arithmetic formula applied to the reviewer's scores given to each criterion. The final impact score for each discussed application will be determined by calculating the arithmetic average of all the eligible members' impact scores, and multiplying the average by 10.

All applicants will receive a written critique, called Reviewer Comments, regardless of award and are given the opportunity to address reviewer comments. The Reviewer Comments represents a combination of the reviewers' written comments and scores for individual criteria.

4.3. Evaluation 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 following five core review criteria, and additional review criteria (as applicable for the project proposed).

Core Review Criteria. Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**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, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Investigator(s).** Are the PI, 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?

**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, 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?

**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?
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?