



STANFORD CHILD HEALTH RESEARCH INSTITUTE

MD (Clinical) Trainee Application Instructions

CHRI MD (Clinical) Trainee Application Instructions

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1. General Instructions

1.1. Introduction

These instructions pertain to applications for the Child Health Research Institute (CHRI) MD (Clinical) Trainee program sponsored by the Lucile Packard Foundation for Children's Health. For detailed program policy please refer to the CHRI MD (Clinical) Trainee Policy available at <http://spectrumchildhealth.stanford.edu/>.

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.

Page Margins

- 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 last 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.

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- 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.

SECTION OF APPLICATION	PAGE LIMITS
Face Page	1 page
Budget Worksheet	1 page
Introduction (Resubmissions only)	2 pages
Research Plan	3 pages
Appendix ** (figures and references)	3 pages
NIH Biographical Sketch (per person)	5 pages
Applicant Personal Statement	2 pages
Supervisor Assessment of Applicant	1 page
Mentoring Plan	2 pages

** 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 during Current Award Cycle

Proposals that are not funded in March are allowed to be revised and resubmitted in April in the same review cycle. Formal award letters for both rounds within the 2015 cycle will be issued in June 2015.

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.

Applicants are encouraged to meet with a CHRI reviewer to discuss revisions and suggestions for improvement prior to resubmission. Contact Spectrum Child Health (spectrumchildhealth@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

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be emailed as a PDF attachment and Budget Worksheet must be sent as separate Excel document 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 MD (Clinical) Trainee 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 Spectrum Child Health 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 by 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 and Budget Worksheet in Excel must be received by Spectrum Child Health Administration (spectrumchildhealth@stanford.edu) 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 Spectrum Child Health Administration in advance will not influence the acceptance of a late application.

1.6. Submission, Review and Award Cycles

Timeline

- One competition is offered annually (winter).
- Within this one competition a revision (resubmission) is allowed.
- Proposals are reviewed within 8 weeks of the submission deadline.
- Anticipate total review turnaround time of 8-10 weeks from the submission deadline.

Cycles / year	1x (<i>chance for revision</i>)
RFA	November
Due (1st round)	February
Panel meets	March
Resubmission (2nd round)	April
Award letters	June
Award Amount	Up to 100% salary and incentive bonus (if applicable)

Application Assignment Information

Competing grant applications submitted to CHRI will be processed through Spectrum Child Health. 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 Spectrum Child Health Administration.

1.7. Resources for Finding Help

If after reviewing these application instructions, help is needed in preparing the application, contact Spectrum Child Health Administration at spectrumchildhealth@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 Budget in Excel format in a separate document. Submit the following materials into *one* PDF document. Collate application materials in this order:

- Face Page (maximum 1 page)
- Budget (Statement of Fellow's Salary and Fringe Costs)
- Introduction (Resubmissions Only; maximum 2 pages)

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- Research Plan (maximum 3 pages)
 - Specific Aims
 - Relevance to Child Health
 - Background and Significance
 - Preliminary Studies (if available)
 - Research Design and Methods
 - Career Development
 - Potential Pitfalls and Contingency Plans
 - Future Steps
- Appendix (Figures and References; maximum 3 pages)
- Supporting Documents
 - Applicant Information
 - Updated Curriculum Vitae
 - Personal Statement (maximum 2 pages)
 - Evidence of Acceptance into Fellowship Training Program
 - Evaluation by 3 Referees (excluding mentors and co-investigators)
 - Documentation of External Funding Application (during the first 15 months of initial fellowship training)
 - Supervisor/ Primary Research Mentor Information
 - Applicant Assessment (maximum 1 page)
 - Mentoring Plan (see section 3.6.5; maximum 2 pages)
 - NIH Biosketch and Other Support Page
 - Description of Laboratory, Trainees, Agreement to restriction of clinical duties
 - Non-Primary Mentor Information
 - Letter of Support per non-primary mentor
 - NIH Biographical Sketches (maximum 5 pages per person)
 - Co-Investigator Information
 - Letter of Support per co-investigator
 - NIH Biographical Sketches (maximum 5 pages per person)
 - IRB Approval (if applicable)

2.2. Application Mailing Address

Email the electronic (PDF) application and Budget Worksheet in Excel format to spectrumchildhealth@stanford.edu. Do not send any paper copies.

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. Nominator Name

List the name of the Department Chair or Division Chief who is nominating the applicant.

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. Fellow Applicant

Name of Applicant and Degree(s)

List the name of the fellow nominated. Indicate up to three (3) academic and professional degrees, or credentials, such as licenses (e.g., M.D.).

Position Title

Provide the academic title of the Fellow Applicant (e.g. Clinical Fellow)

Department, Division

Indicate the department and the division, if applicable, of the Fellow Applicant.

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).

Primary Research Mentor / Supervisor

List the Primary Research Mentor (supervisor) in the first line. The primary research mentor (supervisor) must include his/her NIH Biosketch and Other Support Page. Attach these in the Supporting Documents.

Non-Primary Research Mentors

List up to two non-primary research mentors. An NIH Biosketch and letter of support must be submitted for every non-primary research mentor named. Attach these in the Supporting Documents.

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.

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Item 5. Human Subjects Research

Check “No” if activities involving human subjects are not planned at any time during the proposed project period. Skip Item 5a.

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/>.

Item 5a. 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 6. Post-Graduate Year (PGY) of Fellowship Supported by CHRI

Check the PGY level for the year that CHRI funding is requested. The CHRI MD Trainee program supports the 2nd and 3rd years of fellowship only (PGY5 and PGY6).

Item 7. Total Costs Requested for First Year of CHRI Award

The CHRI Trainee Award provides up to 100% salary support plus fringe for up to two years (non-competitive renewal for year 2). No additional expenses are allowed unless the Incentive Bonus applies. If awarded, the final funding amount will be based on the fellow’s internal and external funding situation.

Item 8. Department Financial Manager to be notified if Award is made

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

Item 8a. Oracle Financial Org Code for the Award

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

Item 9. 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. Pre-award study design consultations are available from Spectrum Office of Training and Compliance through the Study Navigator (SN) on-line scheduling system. To request a consult, register your proposal at <http://spectrum.stanford.edu/studynavigator>. Applicants can consult with non-Spectrum biostatisticians to fulfill this requirement.

Item 9a. Spectrum Consultation or Other

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

Item 10. 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 via Study Navigator at <http://spectrum.stanford.edu/studynavigator>.

Item 11. Study Navigator Registration

Check “Yes” to indicate that the proposed study has been registered in the Study Navigator (required). All CHRI MD Trainee research studies must be registered via <http://spectrum.stanford.edu/studynavigator>. For assistance, please email studyfacilitator@stanford.edu regarding the Study Navigator.

Item 12. 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 Budget Worksheet, Item 2.
- Industry-sponsored: proposed project may be funded by industry sponsor. Specify in Budget Worksheet, Item 2.
- Foundation: proposed project may be funded by foundation sources. Specify in Budget Worksheet, Item 2.
- Mentored award: proposed project may be funded by a mentored award. Specify in Budget Worksheet, Item 2.
- Departmental: proposed project may be funded by departmental sources. Specify in Budget Worksheet, Item 2.
- Other: proposed project may be funded by other sources not listed above. Specify in Budget Worksheet, Item 2.

Item 12a. Documentation of External Application

Check “No” if you have not yet submitted an application for external (outside of Stanford) funding.

Check “Yes” if you have submitted an application for external (outside of Stanford) funding.

Funding is *contingent* upon documentation that the applicant has applied, or plans to apply, to an external agency (outside of Stanford) during the first 15 months of initial research training to support their research fellowship, or residency as appropriate with the discipline. Concurrent application or a plan to apply to external funding agencies/sources is required. If the external funding application due date occurs after the July 1 start date for the CHRI funding, initial partial funding will be released, with the remainder awarded once documentation of application for external funding has been received by the Spectrum Child Health administrative office.

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Determination of Funding Level

If the applicant is successful in obtaining external funding for his/her salary, s/he must immediately notify Spectrum Child Health. *In such a situation the CHRI award will be reduced by a comparable amount.*

However, if the applicant is successful in obtaining outside salary funding, an incentive 'bonus' of up to \$15,000 will be awarded to the fellow, to be used for any purpose at the discretion of the mentor. The amount of the incentive 'bonus' will be awarded as follows:

External Award (Salary)	CHRI Incentive Bonus
≥ \$50,000	\$15,000
≥ \$35,000 and < \$50,000	\$10,000
≥ \$20,000 and < \$35,000	\$5,000
≥ \$5,000 and < \$20,000	\$2,500
≥ \$0 and < \$5,000	\$0

The funding level for CHRI Research Fellows requesting a year 2 Non-Competitive Renewal will depend on each fellow's external funding situation during year 2 as outlined above. *The same incentive bonus policy and external application requirement applies in year 2.* Non-competitive renewal is only available to CHRI fellows in their second year of training (PGY5). Funding level is contingent upon availability of funds.

Example:

- Fellow Sally Smith total salary/fringe costs: \$75,000
- Sally applies for external funding within first 15 months of initial fellowship
- Sally applies for the CHRI trainee support and is successful

Scenario A

- Sally receives external funding of \$50,000
- CHRI award funds remaining \$25,000
- Sally receives additional \$15,000 "bonus" incentive
- Total CHRI funding = \$25,000 + \$15,000 = \$40,000

Scenario B

- Sally receives external funding of \$25,000
- CHRI award funds remaining \$50,000
- Sally receives additional \$5,000 "bonus" incentive
- Total CHRI funding = \$50,000 + \$5,000 = \$55,000

Item 13. 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 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

Use Budget Worksheet and include Fellow's Salary and Fringe Costs. If other sources of funding exist, briefly describe these and list them on Item 2 of Budget Worksheet. The CHRI MD Trainee Award provides up to 100% salary support plus fringe for up to two years (non-competitive renewal for year 2 for PGY-5 applicants only) for PGY5 and PGY6 fellows only. The Award shall be used for the fellows' remuneration and benefits (at the level determined appropriate for their particular specialty). No other expenses are allowed (unless the Incentive Bonus applies).

3.3. Introduction (Resubmission Applications Only)

Proposals that were not funded in the 1st round are allowed to be revised and resubmitted again in a 2nd round in same grant cycle. For exact date see 1.5. Application Submission Date, Late Applications above.

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 Health

Using no more than two or three sentences, describe the relevance of this research to 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, 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. 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.

3.3.6. Career Development

Using no more than two or three sentences, describe how this funding will contribute to applicant's career goals.

3.3.7. Potential Pitfalls and Contingency Plans

Please describe the potential pitfalls and limitations for your project and discuss alternative approaches to achieve the project aims.

3.3.8. 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

3.6.1 Applicant Information

The applicant will provide:

- An updated curriculum vitae (CV);
- A personal statement (two-pages maximum) that:
 - Outlines the rationale for the clinical sub-specialty, choice of research area and supervisors, and personal career goals;
 - Includes a statement that in publications arising from this support they will indicate that the applicant was a CHRI Research Fellow; and that he/she will acknowledge LPFCH and the CHRI;
 - Includes a pledge to comply with all reporting requirements both during following the completion of the award;
 - Assures that subsequent to completion of their training, they agree to provide follow-up information to the CHRI regarding their subsequent professional academic achievements.
- Evidence of acceptance into the relevant (sub)specialty fellowship training program (e.g. acceptance letter);
- Evaluation by 3 referees (not including mentors and co-investigators); referees are typically outside the fellow's own department or division;
- Documentation that applicant has submitted (or will submit) during the first 15 months of initial research training an application to an outside (external to Stanford) agency to support her/his research fellowship, or residency as appropriate with the discipline (if not submitted previously at time of application). An email from a funding agency confirming receipt of application, a letter of rejection, and a letter of award are all acceptable.

3.6.2 Primary Research Mentor (Supervisor) Information

The Primary Research Mentor (supervisor) will provide:

- An Applicant Assessment (maximum 1 page)
- Mentoring Plan (maximum 2 pages) (see section 3.6.5)
- NIH Biosketch and Other Support Page

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- Description of their laboratory, including a list of research trainees for whom they have been a primary research mentor / supervisor; and a statement that he/she agrees with the restriction of clinical duties as outlined above (minimum of 75% FTE).

3.6.3 Non-Primary Mentor Information

Up to two non-primary mentors can be named. Each should provide:

- A Letter of Support per non-primary mentor
- NIH Biographical Sketches (maximum 5 pages per person)

3.6.4 Co-Investigator Information

Up to three co-investigators can be named. Each should provide:

- A Letter of Support per co-investigator
- NIH Biographical Sketches (maximum 5 pages per person)

3.6.5 Mentoring Plan

The Mentoring Plan is a critical component of the fellow's application and career success. This section is written by the Primary Research Mentor (supervisor) and can be a maximum of 2 pages. If Mentoring Plan is included in the Mentor Letter, please clearly identify by labeling "Mentoring Plan." Please see Mentoring Plan Document for Instructions. See

<http://spectrumchildhealth.stanford.edu/funding/documents/FY14MentoringPlanGuidelines.pdf>

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).

See http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

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.

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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 Fellow Applicant, 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?