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SYSTEM REGISTRATION AND DELEGATE ASSIGNMENTS

All applicants and delegates must register in the CDI's grant submission system. If you have forgotten your user name or password, please email cdi@kids.wustl.edu to retrieve it or use the "Forgot Password" mechanism on the login page. Users may register and log into the grant submission system at <http://www.childrensdiscovery-application.org/login.php>.

The CDI grants application system has the ability to allow PIs to select a delegate to submit the letter of intent and proposal on their behalf. To use the delegate option, the delegate must also register. After the delegate has registered, then the PI must go to "Designate Delegate" and select the appropriate name from the drop-down list. PIs may only designate one delegate at a time.

LETTER OF INTENT AND PROPOSAL SUBMISSION

All CDI proposals must be routed through the Office of Sponsored Research Services. Note the Face Page requires the signature of an institutional official.

Letters of Intent and Proposals must be submitted via the CDI's grant submission system at <http://www.childrensdiscovery-application.org/login.php> by the applicable due date and time.

LETTER OF INTENT AND PROPOSAL STANDARD DUE DATES

Funding Mechanisms (Abbreviations)	Letter of Intent Deadline	Proposal Deadline	Award Activation	Budget Guidelines
Core Large Initiatives (CORE)	February 1*, 5:00 p.m. CST	April 1*, 5:00 p.m. CST	July 1	Up to \$1,500,000 total costs for up to 3 years
Educational Initiatives (EI)	August 1*, 5:00 p.m. CST or February 1*, 5:00 p.m. CST	October 15*, 5:00 p.m. CST or April 1*, 5:00 p.m. CST	February 1 or July 1	Up to \$50,000 total costs per year for up to 3 years
Faculty Recruitment / Scholar Awards** (FR)	August 1*, 5:00 p.m. CST or February 1*, 5:00 p.m. CST	October 15*, 5:00 p.m. CST or April 1*, 5:00 p.m. CST	February 1 or July 1	Up to \$300,000 total costs over a 5 year period
Interdisciplinary Research Initiatives (II)	August 1*, 5:00 p.m. CST	October 15*, 5:00 p.m. CST	February 1	Up to \$150,000 total costs per year for up to 3 years
Large-Scale Interdisciplinary Research Initiatives (LI)	February 1*, 5:00 p.m. CST	April 1*, 5:00 p.m. CST	July 1	Up to \$1,500,000 total costs for up to 3 years
Postdoctoral Fellowships (F)	August 1*, 5:00 p.m. CST	October 15*, 5:00 p.m. CST	February 1	Up to \$30,000 total costs per year for up to 2 years

* If a deadline falls on a weekend or a University holiday, then the deadline will be moved to the next business day. Example: October 15, 2011 is a Saturday. Proposals for that cycle were due Monday, October 17, 2011. Deadlines are subject to change.

** Department Chairs or Division Chiefs wishing to submit nominations (i.e. Letters of Intent) for Faculty Recruitment/Scholar Awards must obtain the approval of the CDI Executive and Scientific Directors prior to submission.

CONTACTS

For inquiries concerning the logistics of LOI and proposal submission and requirements, please contact the CDI administrator.

For guidance regarding your application's CDI Center designation, please contact the CDI Scientific Director.

To request permission to submit a Faculty Recruitment/Scholar Letter of Intent, please contact the Scientific and Executive Directors.

- **Administrator:** Tim Butts, Email: cdi@kids.wustl.edu
- **Scientific Director:** Mary Dinauer, M.D., Ph.D., Email: cdi@kids.wustl.edu
- **Executive Director:** Gary Silverman, M.D., Ph.D., Email: cdi@kids.wustl.edu

All CDI forms, instructions, and policies may be found at the following URL:
<http://www.childrensdiscovery.org/content/formsandinstructions.htm>.

APPLICANT ELIGIBILITY

Core Large Initiatives, Educational Initiatives, Interdisciplinary Research Initiatives, and Large-Scale Interdisciplinary Research Initiatives may be submitted by any Washington University faculty member(s).

Nominations for Faculty Recruitment/Scholar Awards may be submitted by any Washington University Department Chair or, for the Departments of Medicine or Pediatrics, the Division Chief. Department Chairs or Division Chiefs wishing to submit nominations (i.e. Letters of Intent) for Faculty Recruitment/Scholar Awards must obtain the approval of the CDI Executive and Scientific Directors prior to submission. Though the Chair or Division Chief is submitting the nomination, the Scholar candidate should be listed as the applicant.

Postdoctoral fellowships may be initiated by anyone in a postdoctoral trainee role (e.g. clinical fellow, postdoctoral research associate, etc.) at Washington University at the time of award activation.

Applicants are not subject to citizenship restrictions.

FUNDING MECHANISMS

See the CDI website (<http://www.childrensdiscovery.org/Grants/FundingMechanismsDueDates.aspx>) or the CDI Grants Policies for a description of each funding mechanism. The required documents for each funding mechanism can be found in the Letter of Intent and Proposal Required Documents by Funding Mechanism section.

APPLICATION TYPES

- **New:** an application that is being submitted for the first time.
- **Renewal:** a renewal of an application that was previously or is currently funded. Renewals of existing CDI awards will be considered in rare circumstances if the research proposed endeavors to answer questions of great importance to child health and to significantly further the work outlined in the initial award. The CDI will fund no more than one renewal per project. Faculty Recruitment/Scholar Awards and Postdoctoral Fellowships are not eligible for renewals.
- **Resubmission:** a revised or amended version of an application that was previously submitted to the agency.
- **Continuation:** progress report of funded award.

GRANT SUBMISSION STATUS DEFINITIONS

- LOI - In Progress: applicant initiated a Letter of Intent, but the LOI is incomplete.
- LOI - Pending: applicant submitted a Letter of Intent for agency review.
- LOI - Not Invited: applicant was not invited to submit a full proposal.
- Proposal - In Progress: applicant was invited to submit a full proposal. The proposal has not been submitted for agency review.
- Proposal - Pending: applicant submitted a proposal for agency review.
- Proposal - Not Funded: applicant's proposal was not funded.
- Awarded - Grant: applicant's proposal was funded. Grant will remain in this status until the final year of the project. At that time, its status will change to "Final Reports."
- Final Reports: awarded grant is in the final year of the project.
- Grant Cycle Complete: final report for awarded grant has been accepted.

FORMAT SPECIFICATIONS AND PAGE LIMITS

- Form Pages: CDI form pages can be found at <http://www.childrensdiscovery.org/content/formsandinstructions.htm>. Letters of support should be provided on the appropriate departmental letterhead.
- Format: documents should be single-spaced with one-half inch margins and Arial font size 11.
- Headers and Footers: Headers and footers should not be entered.
- File Format: All documents must be converted into Portable Document Format (PDF) prior to submission.
- Page Limits: page limits do not apply to other components of the letter of intent and/or proposal not listed below.
 - Letters of Intent are limited to one page.
 - The Project Summary is limited to 200 words.
 - Biosketches are limited to 5 pages per investigator.
 - Specific Aims are limited to one page.
 - The Research Strategy should not exceed 10 pages for Core Large Initiative and Large-Scale Interdisciplinary Research Initiative applications, 6 pages for Interdisciplinary Research Initiative or 5 pages for Postdoctoral Fellowship applications.
 - The Project Milestones Timetable should not exceed one page.
 - For Educational Initiatives, the Description of Program and Goals document is limited to five pages.
 - For Faculty Recruitment/Scholar Awards, the Background of the Scholar is limited to two pages, and the Description of Scholar's Research and Goals is limited to four pages.
 - For Postdoctoral Fellowships, the Description of Fellowship Applicant's Research and Goals is limited to one-half page.

KEY PERSONNEL AND PERSONNEL CLASSIFICATIONS

The CDI Grants Policies state: "Key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. For an individual to qualify as a key person, he/she should generally hold a faculty title and their contribution to the project should be vital. Without her/his expertise, the project would not be able to continue."

Mentors of fellowship applicants should be listed as key personnel

Key personnel are required to have measurable effort unless the primary aim of the proposal is to purchase equipment or the key person is a mentor to a fellowship applicant. The associated salary/fringes of the key

personnel's effort may be cost shared. CDI salaries are not subject to the NIH salary cap.

Personnel Classifications:

- **Principal Investigator:** effort required, key personnel. Principal Investigator(s) is/are the individual(s) who have assumed responsibility for directing the project supported by the grant. Multiple individuals may be designated as PIs provided they share the responsibility for leading and directing the project, both intellectually and logistically. Each PD/PI is responsible and accountable for the proper conduct of the project or program including the submission of all required reports. The presence of more than one identified PI on an application or award diminishes neither the responsibility nor the accountability of any individual PI. Fellowship applicants should be listed as the PIs of fellowship proposals. Scholar candidates should be listed as the PIs of Faculty Recruitment/Scholar applications.
- **Co-Principal Investigator:** effort required, key personnel. See definition of Principal Investigator. Note requirements for Multiple PI proposals.
- **Co-Investigator:** effort required, typically key personnel. Co-Investigators are involved with the PD/PI in the scientific development or execution of the project, but are not responsible for the leadership or direction of it.
- **Collaborator:** no effort, not key personnel. Collaborators contribute to the scientific development or execution of the project, but do not commit any measurable effort to it.
- **Consultant:** no effort, not key personnel. Consultants are non-WU employees who provide professional advice or services for a fee.
- **Mentor:** no effort, key personnel. Mentors provide the space, resources, and guidance necessary to enable fellows to complete their research project.

LETTER OF INTENT: REQUIRED DOCUMENTS BY FUNDING MECHANISM

Letter of Intent Components	Core Large Initiatives (LI)	Educational Initiatives (EI)	Faculty Recruitment/Scholar Awards (FR)	Interdisciplinary Research Initiatives (II)	Large-Scale Interdisciplinary Research Initiatives (LI)	Postdoctoral Fellowships (F)
Project Summary	X	X		X	X	X
Letter of Intent	X	X		X	X	X
Biosketches of All Key Personnel	X	X	X	X	X	X
Letters in Support of CDI Grant Proposal	X	X	X	X	X	X

PROPOSAL: REQUIRED DOCUMENTS BY FUNDING MECHANISM*

Proposal Components	Core Large Initiatives (LI)	Educational Initiatives (EI)	Faculty Recruitment/Scholar Awards (FR)	Interdisciplinary Research Initiatives (II)	Large-Scale Interdisciplinary Research Initiatives (LI)	Postdoctoral Fellowships (F)
Online Questionnaire	X	X	X	X	X	X
Online Budget Table	X	X	X	X	X	X
Face Page	X	X	X OSRS approval required after award notification.	X	X	X
Multiple PI Continuation Page (required if "yes" to Multiple PIs)	X	X		X	X	
Project Summary	X	X	X	X	X	X
Detailed Budget for Year 1	X	X	Submitted after award notification.	X	X	X
Budget Justification and Total Project Costs	X	X	Submitted after award notification.	X	X	X
Biosketches of All Key Personnel	X	X	X	X	X	X
Specific Aims	X			X	X	X
Research Strategy	X			X	X	X
Core Users	X					
Description of Program and Goals		X				
Background of Scholar			X			
Description of Scholar or Fellowship Applicant's Research and Goals			X			X
Project Milestones Timetable	X	X	X	X	X	X
Human Subjects (required if "yes" to human subjects)	X			X	X	X
Vertebrate Animals (required if "yes" to vertebrate animals)	X			X	X	X
Leadership Plan (required if "yes" to Multiple PIs)	X	X		X	X	
Literature Cited	X	X	X	X	X	X
Grants, Publications, Abstracts, Presentations and Inventions Form (required if Renewal)	X	X		X	X	
Subaward (Contractual) Agreements (required if "yes" to subagreements)	X			X	X	
Letters in Support of CDI Grant Proposal	X	X	X	X	X	X
Appendix	Optional	Optional	Optional	Optional	Optional	Optional

*For a quick reference guide to the documents required within a proposal, see the *Synopsis of Key Elements by Award Type* under the Instructions area of the CDI website found at <http://www.childrensdiscovery.org/content/formsandinstructions.htm>.

LETTER OF INTENT COMPONENTS AND INSTRUCTIONS

A. Initiating and Updating the Letter of Intent:

1. Log onto the CDI website (<http://www.childrensdiscovery-application.org/login.php>).
2. To initiate a new Letter of Intent, click "START a New Letter of Intent" in the upper right corner of the applicant's home page.
3. Select the appropriate application type. Definitions of each application type can be found above.
 - a. For renewals, enter the CDI Grant ID for the previously funded award. For resubmissions, enter the CDI Grant ID(s) for previous submissions of the project. If this grant has been submitted multiple times, enter Grant IDs for all submissions.
4. Select the appropriate funding mechanism. Definitions of each funding mechanism can be found on the CDI website and in the CDI Grants Policies.
5. Select the CDI Center(s) that are most relevant to the proposed research. Applicants may select more than one Center. If a project applies to all four Centers (which is most common with Core Large Initiatives), select All Centers. Descriptions of each Center can be found on the CDI website and in the CDI Grants Policies.
6. Title of Proposal: limit to 100 characters.
7. Once a grant ID has been created for the LOI, changes to the LOI will automatically be saved upon exiting the system. To retrieve the LOI, go to the home page, find the applicable LOI under the "Letters of Intent" heading and click the "continue" hyperlink after the title.
8. Upload each of the components listed below. Click the "Browse" button to find the file to upload, and the "Upload" to complete the process.

For Faculty Recruitment / Scholar Letters of Intent, the Scholar candidate should be listed as the applicant even though the Department Chair or Division Chief is submitting the nomination.

- B. **Project Summary** (*not applicable for Faculty Recruitment/Scholar Letters of Intent*): limit to no more than 200 words. Use the Project Summary Page to provide a brief background of the proposal and its relevance to the CDI's objectives, outline the proposed specific aims (bullet each aim), and describe the potential impact on child health. Language should be able to be understood by a lay audience. Do not write in the first person. If funded, this summary may be posted on the CDI's website. It may also be used in press releases, as well as the CDI newsletter (which is distributed to donors), and other CDI-related PR. Do not include proprietary or confidential information in the project summary.

- C. **Letter of Intent** (*not applicable for Faculty Recruitment/Scholar Letters of Intent*): limit to one page. Use the Continuation Page. Do not address the letter to the CDI. Use the space to provide all of the necessary details of the project.
1. Provide the project title.
 2. List the team members and explain their roles.
 3. Outline the precise specific aims and describe the broad and high-risk nature of the science. Clearly indicate how the project will support the goals of the relevant CDI center(s).
 4. State the approximate budget and duration for the proposed project.

- D. **NIH Biosketches of Key Personnel**: provide NIH biosketches, including the personal statement, for all key personnel. Review the Key Personnel and Personnel Classifications section above for guidance on which personnel should be listed as key. The biosketch form and sample biosketch can be found on the CDI website. Instructions for the biosketch appear on the biosketch form page. There is no need to include the eRA commons ID. The biosketch for the PI or contact PI should appear first, followed by the biosketches of the other PIs in alphabetical order (if submitting a multiple PI application), and then by the

biosketches of all other key personnel (in alphabetical order).

Fellowship applications should include the biosketch of the trainee followed by the biosketch of the mentor(s).

Faculty Recruitment/Scholar Awards should only include the biosketch of the proposed scholar.

E. Letters in Support of CDI Grant Proposal, LOI stage

For Postdoctoral Fellowships:

1. Letter of recommendation from the trainee's mentor. If the mentor is a Division Chief, one letter will suffice.
 - a. The letter should address the mentor's commitment to the fellow's/investigator's academic growth.
 - b. Fellowship letters should guarantee the protection of the fellow's time to devote to the CDI project.
2. A brief letter from the Division Chief **or** Department Chair (for applicants outside of the Department of Pediatrics or Medicine) acknowledging that they back the application.

For Faculty Recruitment/Scholar Awards:

- A brief letter from the Division Chief **or** Department Chair (for nominees outside of the Department of Pediatrics or Medicine) acknowledging that they will support the faculty scholar through the duration of the award.
 - Faculty Scholar letters should ensure the scientific independence of the Scholar.

For All Other Funding Mechanisms:

- A brief letter from the Division Chief **or** Department Chair (for applicants outside of the Department of Pediatrics) acknowledging that they back the application and will continue to provide financial and logistical support for the contact PI throughout the duration of the award. It is permissible for the Division Chief (in Pediatrics or Medicine) to write this letter if the Division Chief is the applicant. In the case of multi-PI applications, a Division Chief or Chair letter of support for the non-contact PI(s) is encouraged.

These letters should be included in the Letter of Intent as well as the Proposal (in the Letters of Support section).

- F. **Letter of Intent Submission:** once all applicable documents have been uploaded, click "Continue to Submit Letter of Intent." Prior to submitting, please review your merged LOI documents by clicking "Home" and selecting the "view" hyperlink located next to your Grant title. Then click on the "View Merged Documents" button. After verifying that all sections have been uploaded successfully and that the merged file displays correctly, click "Submit Letter of Intent".

If the submission was successful, the applicant will be redirected to the home page of the grants application system. The proposal's status will be "Letter of Intent – Pending." The applicant will also receive a confirmation email.

Note that after a Letter of Intent has been submitted, no changes can be made.

PROPOSAL COMPONENTS AND INSTRUCTIONS

A. **Accessing and Updating the Proposal:** log onto the CDI submission system (<http://www.childrensdiscovery-application.org/login.php>), go to the "Title" column of the Proposals section, then click "continue."

1. Changes will be saved as users complete/update each section. To make changes to a section, users may click on the appropriate section in the top navigation menu.

Ex: Click on Questionnaire to make changes to this section.



B. **Online Questionnaire:** enter applicable information; verify that the data on the Face Page corresponds with the information entered in this section.

1. Multiple PIs: if there are multiple PIs involved in the proposal, please select "yes." Postdoctoral Fellowships and Faculty Recruitment/Scholar Awards may not be submitted as Multiple PI applications. Note the Multiple PI requirements.
2. Subagreements: check "yes" if proposal involves a subagreement. Subagreements are only allowable on Interdisciplinary Research Initiative, Core Large Initiative, and Large-Scale Interdisciplinary Research Initiative applications. Note the Subaward Agreement requirements.
3. Human Subjects: select "yes" if human subjects are involved. Note the Human Subjects requirements.
4. Vertebrate Animals: select "yes" if vertebrate animals are involved. Note the Vertebrate Animals requirements.
5. Click "Add Questionnaire and Continue."

C. **Online Budget Table:** enter applicable information; verify that the data on the Face Page corresponds with the information entered in this section.

1. Budget timeframe: select the number of years of funding being requested. Note the maximum number of years allowable for each mechanism:
 - a. Core Large Initiatives – 3 years
 - b. Educational Initiatives – 3 years
 - c. Faculty Recruitment/Scholar Awards – 5 years
 - d. Interdisciplinary Research Initiatives – 3 years
 - e. Large-Scale Interdisciplinary Research Initiatives – 3 years
 - f. Postdoctoral Fellowships – 2 years
2. After the budget timeframe has been selected, a budget table will appear with pre-populated start and end dates based on the funding mechanism selected. Enter the direct and indirect costs for each budget year. Click "Calculate." The total costs for each year and the project costs will automatically generate. The numbers provided in this section should match the numbers provided on the Face Page, Detailed Budget, and Budget Justification. Click "Add Budget" to continue. Note the maximum total costs allowable for each mechanism:
 - a. Core Large Initiatives – \$1,500,000 over 3 years (there is not a per annum maximum)
 - b. Educational Initiatives – \$50,000/yr
 - c. Faculty Recruitment/Scholar Awards – \$300,000 over 5 years (there is not a per annum maximum)
 - d. Interdisciplinary Research Initiatives – \$150,000/yr
 - e. Large-Scale Interdisciplinary Research Initiatives – \$1,500,000 over 3 years (there is not a per annum maximum)
 - f. Postdoctoral Fellowships – \$30,000/yr

3. To edit the years being requested for a proposal, please click on "CHANGE YEARS" above the budget table. This will allow you to adjust the budget timeframe.
- D. **Face Page:** complete all fields of the CDI Face Page and obtain the appropriate signatures. The original document should be scanned and converted to PDF. Note that CDI proposals must be routed for OSRS approval. Enter the dates of the proposed project period at the top of the form.
1. Select the type of application. Please reference definitions of application types above.
 2. Verify the number of agencies to which this project is being submitted for review.
 3. Select appropriate Center(s). Multiple Centers may be selected.
 4. Select appropriate funding mechanism.
 5. List 3-5 keywords that describe the investigator's research project broadly. Keywords should convey the theme of the project. Examples: diabetes, cancer, gut microbiomes, immune system, malaria, etc.
 6. Enter project title. Limit to 100 characters. Project titles should be descriptive, yet concise.
 7. Provide the requested information for the PI, contact PI (for multiple PI applications), Fellow (for Fellowship applications), or Scholar candidate (for Faculty Recruitment/Scholar Awards). The person listed in item 7 should sign as the PI in item 16. For multiple PI applications, the other PIs should be listed on the Multiple PI Continuation Page. Signatures of the other PIs are not required for submission.
 8. Check the appropriate boxes. If the protocol is pending approval, please indicate "Pending" for item 8a. If the application is a renewal of an existing award and the protocols are different from those proposed in the awarded grant, check "Change."
 9. Check the appropriate boxes. If the protocol is pending approval, please indicate "Pending" for item 9a. If the application is a renewal of an existing award and the protocols are different from those proposed in the awarded grant, check "Change."
 10. Enter the dates of the proposed project period.
 11. Enter applicable IDC rate. If the IDC rate of the grant is 20% and there is equipment budgeted (10% IDC rate), please only list the primary IDC rate of 20%.
 12. Enter the direct and total (direct + indirect) costs requested for the initial budget period. For renewal applications, the initial budget period is the first year of the renewal.
 13. Enter the direct and total (direct + indirect) costs requested for the proposed project period.
 14. List key personnel and their roles on the project. The PI or contact PI should be listed first, followed by the other PIs in alpha order (if submitting a multiple PI application), and then the other key personnel in alpha order. Use a continuation page if necessary. For item 14a, check the appropriate box. If the application is a renewal of an existing award, check "Change" if there has been any change to the utilization of the multiple PI option or if there have been any revisions made to the Multiple PI Leadership Plan since the last funded competitive submission.
 15. List performance sites of all subrecipient institutions.
 16. For multiple PI applications, the contact PI is the only PI signature required. Please also obtain signature from the PI's Department Chair and Institutional Official. For Faculty Recruitment/Scholar awards, only the PI and Dept Chair signatures are needed for submission. When the Faculty Recruitment/Scholar budget is submitted upon award notification, the Face Page will need OSRS signature/approval.
- E. **Multiple PI Continuation Page** (*required for multiple PI applications only. Postdoctoral Fellowships and Faculty Recruitment/Scholar Awards may not be submitted as Multiple PI applications.*): complete fields for all PIs other than the contact PI listed on the Face Page.
- F. **Project Summary** (*applicants may use the same document provided for the Letter of Intent*): limit to no more than 200 words. Use the Project Summary Page to provide a brief background of the proposal and

its relevance to the CDI's objectives, outline the proposed specific aims (bullet each aim), and describe the potential impact on child health. Language should be able to be understood by a lay audience. Do not write in the first person. If funded, this summary may be posted on the CDI's website. It may also be used in press releases, as well as the CDI newsletter (which is distributed to donors), and other CDI-related PR. Do not include proprietary or confidential information in the project summary.

- G. Detailed Budget for Year 1** (*not applicable until award notification for Faculty Recruitment/Scholar Awards*): use the detailed budget page (required for the initial year of the project only) and enter the proposed costs by category. The salary/effort requirements of all personnel on the project, including non-key personnel, should be included. If salary support is not requested for certain personnel, then the salaries of those individuals need not be listed.
1. Refer to the CDI Grants Policies for further guidance on acceptable/ unacceptable budget items, indirect cost rates, key personnel, and equipment. Also, see the Key Personnel and Personnel Classifications section above.
 2. Visit the CDI [Core Resources](#) page to determine if there are any CDI Cores that provide subsidies applicable to your proposal.
 3. Budget period: refer to award activation date for budget period start date.
 4. Project period: please see the limits provided in the budget guidelines above.
 5. Total costs include directs and indirects.

For multiple PI applications, provide one detailed budget. This budget should reflect the combined costs for the proposal, regardless of how the money is to be distributed amongst the PIs. If budget allocation is planned, the distribution of resources to individual PIs should be delineated in the Leadership Plan.

For proposals that include a subaward/contractual arrangement, a detailed budget must be completed for each subrecipient institution. Include the subrecipient's budget after the primary institution's budget. Refer to the Facilities and Administrative Costs section of the CDI Grants Policies for how subaward costs are handled and for the applicable F&A rate.

Faculty Recruitment/Scholar award budgets will be requested upon award notification.

Note that in the event that a grant is awarded with a different budget that was originally requested, the grantee is required to submit a revised detailed budget and budget justification.

- H. Budget Justification and Total Project Costs** (*not applicable until award notification for Faculty Recruitment/Scholar Awards*): use the applicable form page. To enter information in embedded Excel table, double click on the table (Excel table version requires Word 2007 or later; use the Word table version if unable to open the table). Provide amounts requested for each budget category for each year. List direct and indirect cost amounts for each budget year and total each row and column.

In the justification, account for the use of funds in each category for each year of the project. For the personnel category, justify the roles and list effort requirements (in percentages) of all personnel on the grant, including non-key personnel.

For multiple PI applications, provide one budget justification. The budget justification should account for the use of funds in each category, regardless of how the money is to be distributed amongst the PIs.

For proposals that include a subaward arrangement, a budget justification must be completed for each subrecipient institution. Include the subrecipient's budget justification after the primary institution's budget justification.

Faculty Recruitment/Scholar award budgets will be requested upon award notification.

- I. **NIH Biosketches of Key Personnel:** provide NIH biosketches, including the personal statement, for all key personnel. Review the Key Personnel and Personnel Classifications section above for guidance on which personnel should be listed as key. A sample NIH biosketch can be found on the CDI website. Instructions for the biosketch appear on the biosketch form page. There is no need to include the eRA commons ID. The biosketch for the PI or contact PI should appear first, followed by the biosketches of the other PIs in alphabetical order (if submitting a multiple PI application), and then by the biosketches of all other key personnel (in alphabetical order).

Fellowship applications should include the biosketch of the trainee followed by the biosketch of the mentor(s).

Faculty Recruitment/Scholar Awards should only include the biosketch of the proposed scholar.

- J. **Research Plan** (*not applicable for Educational Initiatives and Faculty Recruitment/Scholar applications*): use the Continuation Page for all components of the Research Plan. The research plan should include sufficient information to evaluate the project, independent of any other documents (e.g., previous application).
 1. **Specific Aims:** limit to one page.
 - a. State concisely the goals of the proposed research or Core and summarize the expected outcome(s), including the impact that the results of the proposed research or Core will exert on the research field(s) of the relevant CDI Center(s). List succinctly the specific objectives of the proposed research or Core, e.g., to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, create or enable access to a facility, service or shared resource, etc.
 2. **Research Strategy:** the components of the research strategy should not exceed 10 pages for Core Large Initiative and Large-Scale Interdisciplinary Research Initiative applications, 6 pages for Interdisciplinary Research Initiative or 5 pages for Postdoctoral Fellowship applications. The page limits include all tables, graphs, figures, diagrams, and charts. Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively. Cite published experimental details in the Research Strategy section and provide the full reference in the Literature Cited section.
 - a. Significance:
 - Explain the importance of the problem or critical barrier to progress in the field that the proposed project or Core addresses.
 - Explain how the proposed project or Core will improve scientific knowledge, technical capability, and/or clinical practice in one or more of the CDI Center research focus areas.
 - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
 - Additionally, for Core Large Initiatives, describe the significance of bringing the resource to the CDI and/or WU community. State institutional need and relevance to CDI objectives.
 - b. Innovation:

- Explain how the proposed project or Core challenges and seeks to shift current research or clinical practice paradigms.
 - Describe any novel theoretical concepts, approaches or methodologies, instrumentation/facilities/services or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
 - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
 - Additionally, for Core Large Initiatives, provide information on similar resources at WU, SLCH, or BJC and access to those resources and differentiate proposed resource from those already in existence.
- c. Approach:
- Preliminary Studies for New Applications and Progress Report for Renewal Applications
 1. Preliminary Studies for New Applications: include information on Preliminary Studies *if applicable*. Discuss the PI's preliminary studies, data, and or experience pertinent to this application.
 2. Progress Report for Renewal Applications: provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions.
 - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted.
 - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
 - If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
 - Describe plan for obtaining non-CDI extramural support for this project.
 - Additionally, for Core Large Initiatives, provide a detailed description of resource and plan for the day-to-day management and safe operation of the core. Management of the core includes the tracking of Core usage and the products of Core usage (publications and grants) as well as the advertisement of the Core to the potential user group. Describe how the PI's experience and qualifications would make him/her an ideal candidate to manage the proposed core resource. Explain how this resource will benefit CDI investigators and/or contribute to the goals of the CDI. If the proposed core resource is equipment, quotes may be included in the Appendix.
- K. **Core Users** (*required for Core Large Initiatives only*): no page limit. Use the Core Users form unless the Core Users form does not allow the PI to sufficiently showcase who used the Core and how. In the event the Core Users form is insufficient, PIs are welcome to present the information in another format suitable to the Core. List past and potential users of the core and the department to which they belong. If a user is a member of a PI's lab, please list the PI only. Provide actual use of the core. The Core PI is free to decide how to best calculate proportional use (dollars, core service units, etc.). PIs may utilize the Core Service Units or Core Service Dollars column to auto-calculate usage based on core service dollars

utilized. PIs need not complete information for both Units and Dollars columns (one column is sufficient). Usage percentages should add up to 100%.

New Proposals: List potential users of the core and the department to which they belong. PIs may provide estimated usage figures if desired.

Renewal Proposals: On one table, provide a list of the users who have utilized the core during the initial project period (all years of project) and their actual usage of the Core. On a separate table, list potential users of the core for the renewal project period. PIs may provide estimated usage figures if desired.

- L. **Description of Program and Goals** (*required for Educational Initiatives only*): limit to five pages. Use the Continuation Page. Describe the goals of the educational program and provide evidence of the direct relevance to CDI programs. Outline the details of the program, including time frames, participants, and resources needed.
- M. **Background of Scholar** (*required for Faculty Recruitment/Scholar Awards only*): limit to two pages. The Scholar candidate should use the Continuation Page to provide any additional information not contained in the Biosketch, such as research and clinical training. Detail research accomplishments. If there are consistent themes or issues that have guided previous work, these should be made clear. If your work has changed direction, the reasons for the change should be indicated.
- N. **Description of Scholar's Research and Goals** (*required for Faculty Recruitment/Scholar Awards only*): limit to four pages. Use the Continuation Page.
1. Research Plan: The Scholar candidate should summarize investigations in progress and potential future directions. Discuss potential problems, alternative strategies, and benchmarks for success. Describe how the candidate's current and future research relates to the objectives of the CDI and its Centers.
 2. Describe plans for mentoring of the Scholar.
 3. Provide a list of relevant published and currently planned manuscripts, which includes titles, authors, proposed journals, and anticipated dates of submission as well as a 5-year grant submission plan with anticipated dates of submission.
 4. Conclude with a vision statement from the candidate describing her/his long-term career and academic goals.
- O. **Description of Fellowship Applicant's Research and Goals** (*required for Fellowship Awards only*): limit to one-half page. The applicant should summarize how the fellowship research fits in with prior training, research interests, and future directions. Describe plans for mentoring of the Fellow and provide a vision statement from the candidate describing her/his long-term career and academic goals.
- *Please upload the document in the Appendix section of the grants portal.
- P. **Project Milestones:** limit to one page. Use the Project Milestones Timetable. Briefly describe the project milestones and goals for each aim and each year of funding. Also state what you expect the ultimate goal of the project/initiative to be. For Faculty Recruitment/Scholar Awards, summarize the project milestones and goals for the lab for each of the next five years and state ultimate, long-term research goals. Include plans for applying for subsequent extramural research support.
- Q. **Human Subjects** (*required if human subjects is checked "Yes." Not applicable for Educational Initiatives and Faculty Recruitment/Scholar Awards.*): briefly describe the proposed involvement of human subjects in the work to be conducted, including the characteristics of the population, the anticipated number of

participants, the age range, health status and rationale for the use or exclusion of any specific subpopulation. Indicate if specimens will be taken from individuals, or if specimens exist, indicate if records or dates will be used. Describe plans for the recruitment of subjects and the consent procedure to be followed. Please indicate if recruitment bias is likely and what steps will be taken to limit the bias. State if the Institutional Review Board (IRB) has approved the project or authorized a modification or waiver of consent procedure. Discuss why the risks to the subject in relation to potential benefits are reasonable and acceptable.

- R. **Vertebrate Animals** (*required if vertebrate animals is checked "Yes."* *Not applicable for Educational Initiatives and Faculty Recruitment/Scholar Awards.*): provide a detailed description of the proposed use of the animals, identifying species, sex, origin, age range and numbers of animals to be used. Justify the use of the animals including the choice of species and numbers to be used. Describe the procedures to be used to ensure that discomfort, distress, pain and injury will be minimized. Describe the use of analgesia and anesthesia to be used and the method of euthanasia to be used.
- S. **Leadership Plan** (*required for Multiple PI applications only. Not applicable Faculty Recruitment/Scholar Awards and Postdoctoral Fellowships.*): use the Multiple PI Leadership Plan page to provide the rationale for choosing a multiple PI approach; roles and administrative, technical, and scientific responsibilities of the PIs; fiscal and personnel management coordination; process for making decisions on scientific direction and allocation of resources; data sharing and communication among investigators, and procedures for resolving conflicts. Complete the budget table in the Leadership Plan document if budget allocation amongst the PIs is planned.
- T. **Literature Cited**: no page limit. Use the Continuation Page to list all literature references cited in the summary and/or research plan. Each reference must list the authors in the same sequence in which they appear in the publication, the title, the name of the book or journal, volume number, page numbers, and year of publication. References should be limited to relevant and current literature. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.
- U. **Grants, Publications, Abstracts, Presentations and Inventions** (*only applicable for Competitive Renewals*): use the Grants, Publications, Abstracts, Presentations and Inventions Form Page. Provide a cumulative, comprehensive list for each section, with any updates to a prior report in red. The list should include **ALL** grants, publications, abstracts, presentations and inventions resulting from this CDI project to date, not just for the past year. If the CDI project is a renewal, include products of original and renewal funding. Core Large Initiatives should list grants, publications, abstracts, presentations and inventions that have been made possible by the use of the core. This will require the Core PI to request this information from each of the Core users.
1. **Grants**: provide the agency/mechanism, title, project period, total costs (includes direct and indirect costs) requested/awarded for the project period, and status (pending, funded, completed) of all grants resulting directly from this CDI award. Please DO NOT include subsequent support received from CDI (if applicable) or grants that were not funded.
 2. **Publications and Papers Submitted**: list the complete citation (author(s), title, journal or book, volume, page number, year) of all publications and papers resulting directly from this grant (i.e. CDI should be listed in the grant support section of the publication). Directly following citation or manuscript information, indicate the status of the paper (published, accepted for publication, submitted, or in review).
 3. **Abstracts**: include the status (published/presented or submitted). Abstract should acknowledge CDI support if possible.

4. **Presentations at National or International Meetings**: include title of presentation, name of national/international meeting, and where/when the presentation took place. Presentations should acknowledge CDI support if possible.
5. **Inventions**: provide the title, name of the inventor(s), date reported, and identification number (disclosure number, patent application serial number, or patent number). Note: If no inventions have been made, insert the word "NONE".
 - a. All inventions are to be reported to the CDI on the Inventions/Patent Report form. If there are inventions to report and this form has not been previously submitted, please complete the form and submit it to cdi@kids.wustl.edu as soon as possible.

V. **Subaward (Contractual) Arrangements** (*required only if subawards are proposed. Applicable to Interdisciplinary Research Initiatives, Core Large Initiatives, and Large-Scale Interdisciplinary Research Initiatives only.*): use the Continuation Page to explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. Include a copy of the University's "Statement of Intent to Establish a Consortium Agreement" document for consortium institutions.

W. Letters in Support of CDI Grant Proposal

Applicants may use the same documents, below, provided for the Letter of Intent.

For Postdoctoral Fellowships:

1. Letter of recommendation from the trainee's mentor. If the mentor is a Division Chief, one letter will suffice.
 - a. The letter should address the mentor's commitment to the fellow's/investigator's academic growth.
 - b. Fellowship letters should guarantee the protection of the fellow's time to devote to the CDI project.
2. A brief letter from the Division Chief **or** Department Chair (for applicants outside of the Department of Pediatrics or Medicine) acknowledging that they back the application.

For Faculty Recruitment/Scholar Awards:

- A brief letter from the Division Chief **or** Department Chair (for nominees outside of the Department of Pediatrics or Medicine) acknowledging that they will support the faculty scholar through the duration of the award.
 - Faculty Scholar letters should ensure the scientific independence of the Scholar.

For All Other Funding Mechanisms:

- A brief letter from the Division Chief **or** Department Chair (for applicants outside of the Department of Pediatrics or Medicine) acknowledging that they back the application and will continue to provide financial and logistical support for the contact PI throughout the duration of the award. It is permissible for the Division Chief (in Pediatrics or Medicine) to write this letter if the Division Chief is the applicant. In the case of multi-PI applications, a Division Chief or Chair letter of support for the non-contact PI(s) is encouraged.

Additional Letters for CDI Grant Proposal: Applicants should also include any letters necessary to demonstrate support of key personnel and consortium participants. For consultants, letters should also include rate/charge for services. For Educational Initiatives, include letters of support from potential

speakers or participants from outside of WU if applicable.

- X. **Resubmission Introduction** (*required for resubmissions of all mechanisms*). A resubmission is an application with scientific overlap and/or is an otherwise revised version of a previously submitted application to CDI. Resubmission applications must respond to any issues or feedback from the CDI Scientific Advisory Board's review of the original proposal.

For all resubmissions, please include a 1-page* resubmission introduction document that summarizes how the revised application has been responsive to the prior review:

- additions
- deletions
- other changes to the application

*Please include at the beginning of the Specific Aims document. Note that this one page does not count towards typical page limit.

- Y. **Appendix** (*optional*): applicants may upload one PDF of appendix materials. All materials submitted should be critical to the review of the project. Examples of acceptable appendix materials would be: equipment quotes for grants which propose significant equipment purchases; manuscripts and/or abstracts accepted for publication but not yet published; published manuscripts and/or abstracts if a free, online, publicly available journal link is not available; surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Z. **Proposal Submission**: once all applicable documents have been uploaded, click "Continue to Submit Proposal." Prior to submitting, please review your merged proposal documents by clicking "Home" and selecting the "view" hyperlink located next to your Grant title. Then click on the "View Merged Documents" button. After verifying that all sections have been completed and uploaded successfully and that the merged file displays correctly, click "Submit Proposal".

If the submission was successful, the user will be redirected to the home page of the grants application system. The proposal's status will be "Proposal – Pending." The applicant will also receive a confirmation email. Note that after proposals have been submitted, no changes can be made.