

Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

CCTSI Child and Maternal Health Pilot Program (CMH-Pilot) 2021 Award Cycle – Application Guidelines and Checklist

The proposal should clearly describe a one-year research project using NIH-style structure, comprised of Abstract, Research Plan, References, Multiple PI Plan (if applicable), Career Development Plan (if applicable), Budget and Justification, Biosketches, and Letters of Support. Appendices are not allowed. You may use standard <u>PHS 398 forms</u>, although this is not required unless otherwise noted. Format must be Arial 11 pt font, single-spaced, with ½ inch margins, no footers.

Intent to Submit Form (LOI)

Required Information

- Award category
- Project title minor modification may be made to the final title on the Application Form
- PI contact information: name, degree, academic title (refer to <u>Rank Eligibility Table</u>), institutional affiliation(s), email, phone
- Co-PI contact information (CSU/CU Collaboration awards only): same as above for both the CU investigator and the CSU investigator
- Mentor contact information, if applicable: name, degree, institutional affiliation(s), email, phone
- Co-Investigator(s), if applicable: name, degree, academic title, institutional affiliation(s), email, phone **Questions**
 - 1. Are any investigators involved with this project associated with Colorado State University?
 - 2. Does this study involve collaboration with non-CCTSI Affiliated Institution(s)?
 - 3. Please indicate any areas of expertise you recommend our Review Panel should include.
 - 4. Would you like to request specific individuals with particular expertise (and no conflict of interest) to participate in the Review Panel? If so, provide name, affiliation, email for up to three individuals.

Application Form

Required Information

- Final project title
- Abstract: text only (no special characters or bullet points)
- Updates to contact information for Key Roles: PI, co-PI, Mentor(s), and co-Investigators
- Biosketches for all individuals listed in Key Roles
- Confirm membership for all Key Roles (link) or Become a Member (link)

Questions

- 1. Has any individual listed in a Key Role ever received a CCTSI Pilot Grant Award? If so, indicate pilot grant category, year awarded, application number, project title, etc.
- 2. Human Subject Research
 - a. Does any phase of this project involve the collection or analysis of any form of human data, samples, biospecimen, etc?
 - b. Is it Research? (A systematic investigation, including research (intervention) development, testing and evaluation, designed to develop or contribute to generalizable knowledge.)
 - c. Is this project a Clinical Trial?
 - d. Describe which investigator(s) will be conducting human subject research at which institute(s).

- e. Will you be submitting this study for institutional IRB (eg COMIRB) review? If so, which institutional IRB agencies do you anticipate will review your protocol for human subject research? If not, please provide a brief explanation why you believe this study is exempt from institutional IRB review.
- f. Is this study subject to federal regulations? If not, which exemption (Category 1-8) applies?
- g. Does this project involve collecting genomic data?
- h. Does this project involve use of human embryonic stem cells (hESC) or pluripotent stem cells?
- i. Will your project involve human fetal tissue research?
- 3. Does this project involve Vertebrate Animal Research (VAR)? If so, escribe which investigator(s) will be conducting vertebrate animal research at which institute(s). Which institutional IRB agencies will review your protocol for vertebrate animal research?
- 4. Does the proposed budget include any award funds supporting a collaboration with a non-CCTSI Affiliated Institution in which award funds will be transferred to the non-affiliate organization? If so, provide the date of your Cost Share Budget Review with CCTSI.
- 5. Will this project utilize Technology Cores or BERD Cores? If so, describe.
- 6. Will this project utilize a CTRC? If so, describe.
- 7. Does this project involve students? If so, specify post-doc, graduate, residents, K12 awardees, etc
- 8. Do any of the individuals listed above (Key Roles) qualify as Underrepresented and/or Minority Researchers? Groups that have historically been underrepresented in biomedical research include, but are not limited to: African Americans, Hispanic Americans, Native Americans (including Alaska Natives), natives of the U.S. Pacific Islands, individuals with disabilities and individuals from socially, culturally, economically or educationally disadvantaged backgrounds that have inhibited their ability to pursue research careers.

Documents to Upload

See detailed instructions in the RFA for items included in the Application Checklist (below). All required documents must be combined as a single PDF and submitted using the online Application Form.

Application Checklist

The following proposal documents should be combined as a single PDF:

#	Item	Ø
1	Abstract (250 word limit, single PDF): Applies to all award categories. This concise summary of the project will be used to review your application, and it may be used to announce funded awards.	
2	Research Plan (4 page limit, single PDF): Applies to all award categories. Research plan must be consistent with NIH requirements. Include Specific Aims, Research Strategy (Significance, Innovation, Approach), Background and Preliminary Studies (if applicable), and CCTSI Resources (if applicable).	
3	References (no page limit, single PDF): Applies to all award categories.	
4	Career Development Plan (1 page; single PDF): Applies to Mentored Faculty Awards only.	
5	Letter of Support (LOS): Primary Mentor or two co-Mentors (no page limit, single PDF for all): Applies to Mentored Faculty applicants only. If there are two co-Mentors, a combined letter or two separate letters will be accepted as a single PDF.	
6	Optional Letters of Support (no page limit, single combined PDF): Applies to all award categories. Includes optional LOS from department chairs, consultants, foundations, commercial sources, manufacturers, etc.	
7	Budget (1 page limit, use the Budget Template): Applies to all applications.	
8	Budget Justification (1 page limit, single PDF): Applies to all award categories.	
9	Cost Share Budget (1 page limit, single PDF): Applications may include collaboration with non-CCTSI Affiliated organizations. Refer to RFA for specific instructions.	
10	Cost Share Letter of Commitment (no page limit, single PDF): Applies to applications that include a collaboration with a non-CCTSI Affiliated organization in which award funds will be transferred to that organization.	
11	Biosketches (no page limit, individual PDFs for each Key Role): Applies to all award categories.	
12	CSU OSP Proposal Transmission Letter (no page limit, single PDF): Applies to all CSU applicants listed in any Key Role.	
13	Other: Institutional Prior Approval (no page limit, single PDF): Applicants based at CCTSI Affiliated Institutions are strongly encouraged to work with the sponsored programs office at their institution to meet all pre-application requirements specific to their organization, including applications for federal and non-federal (internally funded) seed grant programs.	