Clinical and Translational Pilot Grants Program
Request for Proposals and
Full Application Instructions - 2025

Goals and Background

The mission of the Delaware CTR ACCEL Program is to accelerate clinical and translational research that addresses health outcomes of Delawareans. The CTR Pilot Projects Program annually solicits applications for funding of projects related to clinical and translational (C&T) research. C&T Pilot grants may be either _Regular C&T Pilots_ or _Community Engagement C&T Pilots_. Regular C&T Pilots will provide funds for a 1-year period; Community Engagement C&T Pilots will provide funds for a 2-year period. A budget of up to $80,000 direct costs may be requested. Both types of Pilots are intended to allow a research team to develop a more substantial basis for independent external support from the NIH.

Deadlines

**Full Applications** are due _Monday, May 20, 2024 by 5:00 PM_. Only those invited after the preliminary Letter of Intent Review will be considered. PIs are strongly encouraged to complete the submission process well in advance of their deadline, as the submission windows will close at 5 pm sharp and _no exceptions will be made_. Partial or incomplete applications will not be reviewed.

Before a proposal can be submitted, the proposal PI must register as an ACCEL user and have a valid ORCID account linked to ACCEL. Proposals must be submitted by the PI. Proposals submitted under another user's ACCEL account will not be accepted.

Eligibility

Grants are given to support clinical or translational work that will addresses health outcomes of Delawareans and facilitate the growth or expansion of the PI's work toward an impactful and independent line of research that will be competitive for external support from the NIH.

PIs must be from one of the ACCEL partner institutions, i.e., University of Delaware, Nemours, Christiana Care, and Delaware State University. Multiple PI (MPI) applications are allowed, as long as all PIs are from ACCEL partner institutions. PIs of Community Engagement C&T Pilot proposals **must** include a community member (not from a partner institution) as a member of the research team.

PIs must hold a faculty appointment or equivalent at the time the award commences. These are individuals who can independently apply for Federal or non-Federal investigator-initiated peer-reviewed Research Project Grants (RPGs). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible PIs.

PIs may not concurrently have research funding from other IDeA Program award mechanisms (e.g., INBRE, COBRE, CTR). If the proposal includes subcontracts, please consult with your institutional PI prior to submitting. Subcontracts to institutions located in non-IDeA states are not allowed. However, services provided in non-IDeA states can be purchased on a fee-for-service basis. Pilots may not overlap with ongoing funded projects.

Credentialing
Investigators who will be working in hospitals may need to obtain credentials and are encouraged to begin that process well in advance of the start date of the grant, as the process can take several months.

Award Information
All pilot awards must consist of clinical or translational research (see https://ncats.nih.gov/translation/spectrum for NIH's definition). In addition, more than half of all pilot proposals awarded by ACCEL must be clinical, i.e., involving human subjects. Further, because community engagement is a priority of the Delaware CTR ACCEL Program, *all* applications (i.e., including Regular C&T Pilot applications) must outline a plan for outreach, involvement, and/or dissemination of their research findings to a relevant community. See the CDC's definition of community engagement for more details.

Timeline
A budget period of up to 12 months (Regular C&T Pilots) or up to 24 months (Community Engagement C&T Pilots) may be requested. Pilots may be granted a no-cost extension of 6 additional months, if adequately justified.

Budget
Up to $80,000 direct costs may be requested for pilot projects. A typical pilot grant will support clinical research coordinators, postdoctoral fellows, or graduate students, as well as appropriate amounts for supplies, travel, etc. PIs are discouraged from requesting salary for this work, instead providing it as an institutional commitment. Whether salary is charged to the grant or not, the *anticipated effort* must be indicated in the budget. For UD investigators, a minimum of 1% cost share is required. Budgets must follow all NIH budget guidelines for allowability of costs.

Consultation with ACCEL Cores
Use of one or more of the ACCEL Cores is encouraged before submission and/or during the project award period. A brief description of some of the ACCEL Core resources is provided below. More detailed information about each of the cores can be found on the ACCEL website.

ACCEL Biostatistics, Epidemiology & Research Design (BERD) Core
Applicants are encouraged to consult with the BERD Core to review their study design, methods, and statistical approaches prior to submission: https://dash.de-ctr.org/consult/submit/berd. The BERD Core also has established mechanisms to obtain access to Medicaid and Medicare claims data as well as to the National COVID19 Cohort Collaborative (N3C) registry (https://covid.cd2h.org/N3C) for investigators with relevant research aims. Requests for BERD Core assistance prior to submission of a Full Application should be made no later than May 2, 2024. Contact Dr. Claudine Jurkovitz for more information.

ACCEL Professional Development (PD) Core

Pilot proposals led by investigators who have not previously been the PI of a funded NIH K or R series grant **must identify a research mentor and work with the PD Core to develop and submit a detailed individual development plan (IDP, written by the PI) and mentoring plan (MP, written by the mentor) as part of the Full Application. Investigators are strongly encouraged to contact the PD Core immediately to maximize assistance.

The PD Core also offers a **Flight School** to help investigators prepare to submit a pilot grant to ACCEL. At the first Flight School session (March/April), submission requirements are reviewed and research ideas for each pilot proposal are discussed. Additional resources needed by investigators are identified. At the second session (April/May), specific aims are reviewed and discussed, and the other components of the proposal are reviewed.
Contact Dr. Rob Akins and copy Julianne Ross for more information about sign up and dates for Flight School. In addition, pilot proposals led by junior investigators or those without prior NIH experience are encouraged to take advantage of career development programs offered. The Junior Investigators Network provides weekly sessions on career development and research proposal writing that can be attended via phone or computer. Contact Dr. Rob Akins and copy Julianne Ross for more information.

ACCEL Community Engagement and Outreach (CEO) Core
The CDC defines community engagement as "…the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people." See the CDC's complete description of community engagement for more details. ACCEL Community Engagement C&T Pilot proposals should include a plan for substantive collaboration and partnership with individuals or groups who are expected to be impacted by the research for the purpose of including their perspectives at multiple stages of the project. In addition, PIs conducting Community Engagement C&T Pilots must complete or show competence in the ACCEL Community Engaged curriculum within 6 months of the pilot project start date.

To facilitate community engagement, _all applicants_ are strongly encouraged to involve the CEO Core prior to submission. The CEO Core helps PIs realize the potential community impact of their work and can aid in making connections to community partners when appropriate. While it is expected that PIs of proposals for Community Engagement C&T Pilots will contact the CEO Core, applicants submitting Regular (non-community engaged) C&T Pilot proposals should also consider a CEO consultation, since all proposals need to address community engagement in the Full Application. Requests for CEO Core assistance should be submitted no later than April 1, 2024. Contact Dr. Lee Pachter for more information.

Application Submission Information
Whether or not internal routing is required prior to submission of the full application is determined by each institution. PIs should work with their institutional ACCEL administrator to assure that all required documents are completed correctly and submitted on time with the application. The following ACCEL research officers should be consulted prior to submission:
ChristianaCare: Claudine Jurkovitz
Delaware State University: Dayna Littleton
Nemours: Ranita Chakrabarti
University of Delaware: Robyne Nizer

Upon submission of the Full Application to the Delaware CTR ACCEL, it may be forwarded to the appropriate institutional office for budget and effort verification.

Full Application Submission Components

The full proposal is similar in format and style to that of an NIH R03 proposal, with a few exceptions. The *Specific Aims* page must be no longer than 1 page and the *Research Strategy* section (with Significance, Innovation, Approach, and Community Engagement subsections) must be no longer than 4 pages. *Further details and step-by-step instructions to submit a Full Application can be found at the end of this document*.

Review Criteria

Full Application Review

Scientific Merit Scoring: Reviewers of the Full Applications are selected based on their relevant research expertise. Reviews use a modified version of the NIH R-type grant application scoring system, in which scores are given for *individual review criteria* as well as *overall impact*. Scores for each may range from 1 (Exceptional) to 9 (Poor). A score of 5 is considered an average score. The individual review criteria are *Significance*, *Investigator(s)*, *Innovation*, *Approach,* and *Environment*. The overall impact score reflects a reviewer's overall evaluation of all aspects of the project (not the numerical average of the individual criterion scores). For pilot grants, the overall impact score indicates the reviewer's assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved as well as it's chance of being developed into a full NIH proposal with a high likelihood of success. Full Applications will be rank ordered by overall impact score.

Training Plan Scoring: PIs who have not previously been the PI of a funded NIH K or R series grant must identify a research mentor and include an Individual Development Plan (IDP) and a Mentorship Plan (MP) with their Full Application. More than one mentor may be included. PIs and their mentors will work with the ACCEL Professional Development (PD) Core to develop their unique IDP and MP. For Multiple PI (MPI) applications, each MPI who has not previously been the PI of a funded NIH K or R series grant must fulfill this requirement. See details provided in the ACCEL PD Core section above. Reviews of these applications will include an additional individual review criterion for the *Training Plan*, and this criterion will be factored into the overall impact score.

Community Engagement Scoring: Regular Clinical & Translational Pilots must include, at a minimum, identification of an appropriate community with which to engage in the research and a described plan to disseminate their research findings to that community. Review of Regular Clinical & Translational Pilots will incorporate evaluation of the community dissemination plan into the individual criterion score for *Approach*, which is then factored into the overall impact score. Community Engagement C&T Pilots must include a detailed community engagement plan and will be scored on the quality of this plan as well as the anticipated impact of the proposal on the community. Reviews of these applications will include evaluation an additional individual review criterion for *Community Engagement Plan*, which will be scored as either 'Outstanding', 'Satisfactory', or 'Not Satisfactory', which will be factored into the overall impact score.

ACCEL Priorities

All pilots must involve research that falls on the translational spectrum (see definition here) and a majority of pilots funded by ACCEL will be clinical research. In addition, ACCEL prioritizes:

- Projects addressing medically underserved populations
- Projects addressing conditions disproportionately affecting Delawareans
- Projects led by junior PIs, defined as any of the following:
    - PIs of junior rank (assistant professor or equivalent)
    - PIs with no prior NIH funding as a PI (not including trainee funding; e.g., NIH F awardees)
    - PIs with no prior NIH R01 funding, or equivalent, as a PI

- o PIs with no prior ACCEL funding (not including prior Mentored Research Development Awardees)
- Projects that are interdisciplinary and/or span multiple regions of the translational spectrum
- At least two Community Engagement C&T Pilots will be recommended for funding, if possible.
- All ACCEL partner institutions will be represented in the pilots recommended for funding, if possible.

Based on overall impact scores and factoring in ACCEL priorities (and community engagement scores, for Community Engagement Pilots), the ACCEL Executive Committee determines which grants to recommend for funding. Final recommendations must be approved by the ACCEL External Advisory Committee before forwarding to NIH for approval. NIH approval is required before an award can be made.

ACCEL Pilot Award Submission Timeline

March 4, 2024 by 5:00 pm	LOI submission deadline- required for full application
May 20, 2024 by 5:00 pm	**Full Application submission deadline**
Aug 20, 2024	Potential awardees notified
October 20, 2024***	Just-In-Time deadline *(IRB/IACUC approval, human subjects certs due)*
November 15, 2024	Proposals sent to NIH for approval
January 1, 2025	Anticipated project start date

***__Please Note:__ *The IRB and/or IACUC approval must be received by this date or the PI risks significant delays or possible forfeiting of the award. In addition, the IRB/IACUC approval letter must reflect that the protocol title exactly matches the ACCEL pilot project title. If it does not, a Letter of Congruency may need to be obtained, or the PI may need to seek approval of a new protocol that exactly matches the ACCEL project.*

Expectations

All pilot awardees are required to attend ACCEL conferences to present their work (Annual Community Research Exchange and Annual Advisory Meeting) and the annual (national or regional) NIH IDeA Conference. They are required to cite the ACCEL grant (NIH U54 GM104941) on all related publications and to submit quarterly interim progress reports and a NIH annual progress report. For mentored awardees, active participation in the mentoring process is required for both mentors and mentees, including completion of mentor reports. Awardees must keep ACCEL profiles up to date (at least twice per year) and respond to ACCEL surveys. If applicable, clinical trial registration and timely reporting of results at ClinicalTrials.gov is required. ACCEL site PIs have direct oversight of all pilot projects and awardees must share project outcomes and progress reports with their site PI. Awardees are responsible for reporting outcomes at award end, up to three years post award end, and as requested during the life of the Delaware CTR ACCEL Program.

Contacts

For questions about the Pilot Grants Program submission and review process, please contact: Megan Wenner, PhD; ACCEL Pilot Projects Program Director

For specific questions related to ACCEL Core resources, please contact the appropriate Core Director:
Robert Akins, PhD and copy Julianne Ross; Professional Development Core Director
Claudine T. Jurkovitz, MD, MPH; Biostatistics, Epidemiology & Research Design Core Director
Lee M. Pachter, DO; Community Engagement & Outreach Core Director

Delaware CTR ACCEL

2025 C&T Pilot Grant Submission Instructions

FULL APPLICATION SUBMISSION INSTRUCTIONS

Applications will be submitted through the Delaware CTR ACCEL Dashboard. Select the correct mechanism from the list of funding opportunities, click the box "Submit Proposal", and follow the prompts to complete all sections and upload documents. Note that before a proposal can be submitted, the proposal PI must register as an ACCEL user and have a valid ORCID account linked to ACCEL. Proposals must be submitted by the PI (or their ACCEL designee); proposals submitted under another user's ACCEL account will not be accepted.

The documents to be uploaded should be created using PHS 398 fillable forms. Documents must be written with Arial 11 pt or larger font. Figure legends or tables may include smaller font but must remain easily legible when printed. Text boxes, footnotes, etc. may not be used to circumvent page/font limits. Pages are to be standard letter size (8½" x 11") with at least one-half inch margins. Documents should be converted to PDF for submission.

Instructions for the Delaware CTR-ACCEL Dashboard Full Application Submission Website:

Project Information Page.
1. Project Title   Enter the title of the project in the text box provided.
2. Project Abstract   Enter the project abstract, using language that would be understandable to a broad scientific audience. Explain the overall aim(s) of the work and the expected impact to be made in the field when the work is completed.
3. Project Lay Description   Enter a description of the project using language that would be understandable to the lay community.
4. Project Discipline(s)   Select 'yes' or 'no' to indicate whether the project is interdisciplinary/multidisciplinary or not. If 'yes', then also identify the different disciplines involved in the project proposal.

Investigator Status Page.
1. Prior NIH funding status   Select 'yes' or 'no' to indicate whether you as the project PI are an ACCEL-defined new investigator. Use the ACCEL CTR definition of a new investigator: any investigator who has not previously been PI of a funded NIH K- or R-series award or equivalent extramural funding. For MPI applications, this question applies to the corresponding (submitting) MPI. Prior NIH funding status for the other MPI(s) will be obtained under the Team Members Page (see details below). *Any PI who is considered by ACCEL to be a new investigator must identify a primary research mentor who will contribute to the science of the project and the mentorship of the PI. The PI must also create and submit an Individual Development Plan and the mentor must develop and submit a Mentorship Plan.*
2. Career stage   Select from the options to indicate whether you as the project PI consider yourself an 'early-stage' investigator, 'mid-career' investigator, or 'senior' investigator. The ACCEL CTR generally considers early-stage investigators to be at the assistant professor or equivalent ranking, mid-career investigators to be at the associate professor or equivalent ranking, and senior investigators to be at the full professor or equivalent ranking. For Multiple PI (MPI) applications, this question applies to the corresponding (submitting) MPI.

Demographics Page.

Select the most correct option for each of the questions about you as the project PI and your personal demographic information. You are permitted to choose 'Prefer not to respond' to any of these questions. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. Questions pertain to identification of gender, race, ethnicity, and physical, mental, or emotional disability.

Disadvantaged Background Determination Page.

Indicate if any of the disadvantaged background categories apply/applied to you personally as the project PI.

Please select all that are applicable to you. You are permitted to select 'Do not wish to provide' to any of these questions. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. If you are uncertain whether one of the categories applies to you, please click on the box in the upper right, "Disadvantaged Background Determination" to read some more detailed information.

Education Page.

Please provide the requested information about your, the project PI's, educational background. Please note, your answers will not be seen by reviewers and do not influence the review of your proposal. Your answers are used solely in aggregate to help inform ACCEL leadership of the demographic makeup of our applicant pool over time. Questions pertain to your highest degree as well as any post-graduate clinical training you may have completed (if none, type "none" in the text box). If you do not know the exact graduation date, please make your best estimate.

Project Classification Pages.

1. <u>Medically Underserved Populations Page</u>   Select 'yes' or 'no' to indicate whether the proposal addresses a medically underserved population in Delaware. If "yes", then indicate which population(s) apply.
2. <u>Medically Underserved Areas Page</u>   Select 'yes' or 'no' to indicate whether the proposal addresses a medically underserved area/region in Delaware. If "yes", then indicate which area(s) apply.
3. <u>Translational Spectrum Classification Page</u>   Select the one or multiple most appropriate region(s) of the translational spectrum addressed by the proposed project. If you are uncertain whether one of the categories applies to you, please click on the box in the upper right, "Translational Science Spectrum Classification" to read some more detailed information.
4. <u>Health Conditions and Risk Factors Page</u>   Select 'yes' or 'no' to indicate if the proposed project addresses any of the health conditions, risks factors, or areas of healthcare focus listed. If "yes", then select all that apply below.

Mentoring Plan Page.

Mentoring Plan; required only for PIs with a mentor.

IDP Page.

Individual Development Plan; required only for PIs with a mentor.

CEO Page.

Select 'yes' or 'no' in response to the question, "Is this a community engagement pilot project submission?" *All Community Engagement C&T Pilots should include a plan for substantive collaboration and partnership with individuals or groups who are expected to be impacted by the research for the purpose of including their perspectives at multiple stages of the project. In addition, PIs of Community Engagement Pilot awards must complete or show competence in the ACCEL Community Engaged curriculum within 6 months of the award start date and the award period is 2 years.*

If "yes", then please also indicate which region of the community engagement spectrum best

describes your proposal. Please click on the box in the upper right, "Community Engagement Spectrum" to read more detailed information on the definitions of these categories.

Budget Page.

Indicate the requested amount of budgetary support in the text box provided. Pilot budgets are capped at $80,000.

Team Members Page.

1. <u>PI</u>   Your name will be automatically populated and assigned the role of PI.
2. <u>Multiple PIs</u>   Select 'yes' or 'no' to indicate whether the project involves multiple PIs (MPIs). Selecting 'yes' will trigger the button "Add New PI" to appear in the top right corner. Click "Add New PI" and provide the additional (second) PI's information and biosketch. Also provide the additional PI's career stage and prior NIH funding status (see descriptions above). If the additional PI Is considered by the ACCEL CTR to be a new investigator, then that PI must identify a primary research mentor. Please note, for MPI applications, the PI completing the application in the Dashboard will be considered the contact PI to whom all correspondence will be addressed.
3. <u>Add New Team Member</u>   Click this button to add all other team members. Additional team members may include co-investigators (CIs), consultants, mentors, and/or community / clinical partners, if appropriate.
4. <u>Biosketches</u>   Biographical sketches are required for most team members: a biosketch is required for all PIs, co-investigators, collaborators, and mentors; a biosketch is optional for community or clinical partners. All co-investigators, collaborators, and mentors named as team members should also be listed on the Project Summary Page (see below) and vice-versa. If a community / clinical partner has provided a biosketch, they should also be listed on the Project Summary Page. Do not upload the PI's biosketch here; that will be done in a later section. See details below for information on how to complete Biographical Sketches.
5. Click "Yes" or "No" in response to the question, "Is this the first time this group of team members has collaborated?"

ORCID Setup Page.

If you have not yet setup your ORCID account and linked it to ACCEL, you will be instructed to do so here.

Files Page.

1. <u>Human Subjects</u>   Click "Yes" or "No" in response to the question, "Does this project involve human subjects?" If you select "Yes", you will be required to submit the Human Subjects Forms (see below).

If your project involves human subjects, please also answer the following question: "Based on your answers to section 1.4 (Clinical Trials Questionnaire) on the PHS Human Subjects and Clinical Trials Information Form, does this study meet the definition of a Clinical Trial (i.e. all answers to 1.4.a-1.4.d on the questionnaire are "Yes")?"

2. <u>Vertebrate Animals</u>   Click "Yes" or "No" in response to the question, "Does this project involve vertebrate animals?" If you select "Yes", you will be required to submit the Vertebrate Animals Forms (see below).
3. <u>Supporting Files</u>

Upload all the completed project forms in the appropriate locations. Recall that forms should be created using [PHS 398 fillable forms](). Documents must be written with Arial 11 pt font. Pages are to be standard letter size (8½" x 11") with at least one-half inch margins. Documents should be converted to PDF format for submission.

- **Face Page** – *required*
      Upload the completed Title Page / Face Page ([Form Page 1]()).

- **Project Summary Page** – *required*
  Upload the completed Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells Page ([Form Page 2]()). The [Project/Performance Site Format Page]() may be appended to this and submitted as a single PDF if additional space is needed.

- **Detailed Budget** – *required*

   Upload the completed Detailed Budget for Initial Budget Period Page ([Form Page 4](#)).

- **Budget Justification** – *required*

   A detailed budget justification must be provided. There is no specific form, but the NIH required format must be followed. A link the University of Delaware's template is [here](#).

- **Biographical Sketch(es)** – *required*

   Upload the completed Biographical Sketch, using the [Biographical Sketch Format Pages](#), not to exceed 5 pages per person, for each of the following personnel:
   - PI – *required*
   - Other Key Personnel – *if applicable*

   Biosketches must be provided for every person identified on Form Page 2 and will be uploaded on the Team Members page of the application submission site.

   Detailed instructions for completing a NIH biosketch may be found [here](#) and a sample biosketch may be found [here](#).

- **Prior IDeA award(s)** – *required*

   Identification of all prior IDeA funding, and the successes from those funds, must be provided. Here, prior IDeA funding refers to any research support from a CTR, INBRE, COBRE or the DHSA program. This form should identify each prior funding mechanism and provide a brief description of the progress made on that prior work, especially any successes leveraging those funds to gain independent external support. If this is a renewal request, strong justification must be provided for additional funding. *PIs who have not had prior IDeA support must still upload a page with a statement verifying that they have had no prior IDeA funding*. Use [Continuation Format Pages](#) for this document; 1 page maximum.

- **Specific Aims** – *required*

   List succinctly each of the specific objectives of the research proposed. State concisely the overall goals of the proposed research and summarize the expected impact that the results will have in the relevant research field. Use [Continuation Format Pages](#) for this document; 1 page maximum.

- **Research Strategy** – *required*

   The Research Strategy should be organized into four sections entitled Significance, Innovation, Approach, and Community Engagement. Use [Continuation Format Pages](#) for this document; 4 pages maximum. Although each section does not have its own page limit, it is recommended that the Approach section be the most detailed. A general guideline (but not requirement) for the page length of each section is: Significance, ½-1 p; Innovation, ¼-½ p; Approach, 2-3 p; Community Engagement, ⅛-½ p. Within the Approach section, a statistical analysis subsection is required. Within the Community Engagement section, Community Engagement (CE) Pilot applications should include a detailed plan for community engagement consisting of: identification of the community(ies) to be impacted by the work; a description of the anticipated impact of the proposal on the community; identification of any community partners and their specific role(s) in the project, if appropriate; and a clear plan for disseminating the research findings to the community. Strong CE Pilots will identify outcomes that are valued by the target community and will involve community members at all stages of the research. Regular Pilot applications need not include this level of detail, but must include, at a minimum, a description of the anticipated impact of the proposal on the target community and a plan to disseminate the research findings to the community. For Regular Pilots that are on the basic science end of the translational spectrum, the discussion of anticipated impact on the community may be how this line of work is expected to lead to future community impact.

- **References** – *required*

   All works cited in the application should be listed in a separate document entitled References (no page limit). Use [Continuation Format Pages](#) for this document; no page limit. In-text references should be provided either by author last name and year or by number in the body of the application and the References section should provide a listing of the complete citation for each of these works. Hot links *are not acceptable*

within the references.

- **Multiple PI (MPI) Leadership Plan** – *if applicable*
  If the proposal involves more than 1 PI, a leadership plan must be included that addresses: roles and responsibilities of each PI, fiscal and project management coordination, the process for making decisions on scientific direction and allocation of resources, data sharing and communication among investigators, publication and intellectual property (if needed) policies, and procedures for resolving conflicts. The plan must also identify which PI is the contact PI, to whom all correspondence will be addressed. Use Continuation Format Pages for this document; no page limit.

- **Human Subjects Forms** – *if applicable*
  If the proposal involves the use of human subjects, upload the completed PHS Human Subjects and Clinical Trials Information Form, with embedded Human Subject Study Record Form(s), as appropriate. Please note, depending on the type of human subjects research being proposed (i.e., if the work includes one or more NIH-defined clinical trials), each Study Record form may require extensive and detailed information, therefore *PIs should allocate appropriate time to complete these forms prior to the deadline*. Instructions for completing these forms may be found here.

- **Vertebrate Animals Forms** – *if applicable*
  If the proposal involves the use of vertebrate animals, please utilize the vertebrate animals use checklist and use Continuation Format Pages to upload a description of the procedures, justification, and minimization of pain and distress.

- **Letter(s) of Support** – *required*
Letters of support should be on institutional letterhead and may not exceed 2 pages per letter.
  o PI's Department/Unit Head – *required*
This letter should provide an assessment of the PI's potential for a sustained, impactful influence in his/her relevant research field and to be recognized for such with future NIH funding; a description of how the PI's research fits within the clinical and translational mission of the Delaware CTR-ACCEL Program; and a description of the departmental and/or institutional support for the PI with regard to the specific proposal (e.g., protected research time, laboratory space, access to clinical populations, etc.).
  o Mentor – *required if PI is an ACCEL new investigator*
This letter should provide a description of the mentor's qualifications and commitment to providing scientific and career mentorship to the PI and the mentor's assessment of the PI's strengths and commitment to research. For MPI applications where both PIs are ACCEL new investigators, both mentors must include letters.
  o Others – *if applicable*
Other letters of support may be appropriate, to demonstrate the availability of specific resources and/or collaborators/co-investigators, and/or clinical/community partners for the project. If multiple letters of support are included, they should be appended to one another and submitted as a single PDF.

  Sources Page.
Select all categories of events or processes that led to the proposed work, if any.

  Tracking/EVAL Page.
Click "Yes" or "No" in response to a brief series of questions about your current or anticipated utilization of ACCEL Core resources.

  Summary Page.
Check to be sure all sections have been completed and all documents have been appropriately uploaded. Make any file edits necessary. When complete, click the "Submit" button at the bottom of page.

***Remember to adhere to page and formatting requirements and to upload all necessary documents. Applications that are incomplete or not in compliance with the formatting requirements will be administratively withdrawn without review. ***