Developmental Research Project Program

Pilot Grants Request for Applications (2024-2025)

Background

The Delaware IDeA Network of Biomedical Research Excellence (DE-INBRE) is an NIH and State of Delaware funded program that catalyzes multidisciplinary biomedical research initiatives in order to build Delaware's capacity to do biomedical research. DE-INBRE accomplishes its mission by supporting investigator driven research projects, undergraduate research training, student/faculty professional development, and research infrastructure/core facilities/data access. The DE-INBRE network consists of five network partner institutions (NPIs):

- The University of Delaware (UD)
- Delaware State University (DSU)
- Delaware Technical Community College (DTCC)
- Christiana Care Health System (CCHS)
- Nemours Children's Hospital (Nemours)

DE-INBRE also works with several affiliated institutions including the Wilmington VA Medical Center (Wilmington VA), Delaware Public Health Laboratory (DPHL), Delaware Health Innovation Network (DHIN), and the Delaware Biosciences Association. Research faculty with PI eligibility employed by these institutions are also eligible to receive support from DE-INBRE.

Objectives

The DE-INBRE Developmental Research Project Program (DRPP) focuses on providing Delaware's early stage (ESI) and new investigators with the critical seed funding and expert mentoring needed to develop research programs that

1) Answer important research questions relevant to NIH's mission,
2) Are competitive for subsequent NIH research grants (K, R15, R16, R35, R01, etc.), and
3) Serve as research training sites for Delaware's undergraduate, graduate, and postdoctoral students.

Such investment in early career faculty/clinician scientists is essential to sustain and expand the critical mass of productive biomedical researchers that Delaware needs to grow its capacity to perform biomedical research and train Delaware's biomedical research workforce. We anticipate that Pilot Project awards (PPs) (*up to $40k for 1 year*) will be available and competed each year over the next 5 years (2023-2027) and Research Project awards (RPs) (*up to $80k per year for 2 years*) will be competed in 2024 and 2026, pending renewal of DE-INBRE's NIH support.

Special Note for 2023-2024: The Delaware INBRE Program is in its final year of funding. Although a renewal application has been submitted, there is currently no guarantee of additional funding. Thus, 2024 DE-INBRE Pilot Project funding is contingent upon successful renewal of the Delaware INBRE Program by NIH.

Submission Deadlines

Letter of Intent Deadline (via Piestar RFx system):

11.59pm ET, September 24, 2023

Application Submission Deadline (via Piestar RFx system):

11:59pm ET, October 22, 2023

Award Information

The **Pilot Project** awards are mentored, one-year grants (*up to $40K*) that provide seed funding to support new research directions. Pilot Project award applications must address an important research question relevant to NIH's goals and proposals addressing topics across NIH's mission are welcome. However, investigators whose projects focus on Clinical Translational / Community Engaged Research involving Human Subjects are encouraged to direct their applications to the DE-CTR program.

Contact the DE-INBRE office at info@de-inbre.org or DRPP director, Anjana Bhat at abhat@udel.edu, if you are unsure about your eligibility or the relevance of your research question. The type of awards included under the pilot project mechanism are:

i. **Take-off awards** that prioritize funding of new research directions with no requirement for pilot data.
ii. **Booster awards** that will support ongoing studies needing additional support to establish feasibility and/or collect pilot data to increase competitiveness for either DE-INBRE Research Project awards (offered in 2024 and 2026) or other funding mechanisms.
iii. **Delaware data science awards** that fund projects seeking to use data derived from Delaware's biomedically relevant databases such as UD-supported Medicaid claims data, Delaware Health Information Network (DHIN) "All Payers- based claims" data, or Electronic Health Records (EHR) from Christiana Care, or Nemours Children's Hospital's PEDSnet data. This mechanism is intended to improve the health of Delawareans while providing our investigators with more data science research opportunities.
iv. **Note**: Data science projects involving national datasets (e.g. N3C, ECHO, or Omics data, etc.) are eligible for Take-off or Booster funding mechanisms depending on whether they are new ideas by new/early stage investigators or somewhat established ideas by senior investigators.

    a. **UD's Medicaid Claims Data Access**: UD's Center for Community Research and Service (CCRS) at the Biden School of Public Policy & Administration manages Delaware Medicaid data for research in close collaboration with the Delaware Division of Medicaid and Medicare Services (DMMA). For budgeted effort on this award, CCRS offers assistance to PIs by supporting statistical analyses and obtaining IRB approval for the project. They will collaborate with the PI's team to develop their protocol, identify the appropriate and available variables that can be built from the Medicaid claims and conduct statistical analyses. For more information, please contact Dr. Katie Gifford (katig@udel.edu). Note that all projects involving use of Medicaid data must be approved by DMMA and any publication from these projects require submission to DMMA for review.

    b. **Delaware Health Care Claims Database (HCCD)**: The state of Delaware's All Payer Claims Database, powered by Delaware Health Information Network (DHIN), collects healthcare claims, enrollment and provider data from Medicare, Medicaid and the seven largest commercial health insurers. The fee schedule varies based on the complexity of the dataset, but de-identified datasets are available at a reduced cost. These costs will need to be budgeted on this award application. To explore what's available, principal investigators (PIs) should first complete an HCCD application form with details regarding the goals of the project, the variables of interest and data security information. Once reviewed, the next step is for the PI to present the proposal at a monthly meeting of the HCCD Committee, which is tasked with oversight of data access requests and is comprised of representatives from the data senders, including hospitals and payers. To note: IRB approval should ideally be in place prior to the HCCD committee meeting. A data use agreement (DUA) between DHIN and the PI's institution will be required

once the project is approved for funding, and any publications or presentations featuring the HCCD data must be approved by the Committee prior to publication or presentation. PIs are encouraged to begin the process for obtaining IRB and HCCD Committee approvals and for executing the DUA early so that they are in place by March 15th, 2024. To get started, please complete the HCCD application form and a member of the DHIN team will follow up with you on your request within a week's time. Working with the DHIN team prior to submitting an application, is highly recommended to determine the feasibility of the project and to receive assistance with the application itself. For more information, please contact DHIN Strategic Relationship Manager Juan Arjona at juan.arjona@dhin.org.

c. **ChristianaCare EHR Data Access**: For budgeted effort on this award, the ChristianaCare data analyst team will extract EHR data to develop a de-identified, research-ready database based on PI's research questions following close collaborations between the PI's team, ChristianaCare data analyst team, as well as a ChristianaCare clinical content expert, co-Investigator. The data variables and data dictionary will be developed in collaboration with the PI's team. Statistical analysis support will be available through the CTR-ACCEL BERD Core. IRB approval will need to be sought at both the PI's institution and at ChristianaCare. A data use agreement between ChristianaCare and the PI's institution will need to be in place before the work begins. PIs are encouraged to begin the institutional IRB approvals and DUA processes early so that they are in place by **March 15th, 2024**. For more details, contact Dr. Claudine Jurkovitz (cjurkovitz@christianacare.org), Director of the BERD Core.

d. **Nemours PEDSnet Data Access**: For budgeted effort on this award, Nemours Children's Hospital's Biomedical Research Informatics Center (BRIC) data science team is able to extract pediatric EHR data from within their health system as well as the larger PEDSnet database. Access to the PEDSnet national data requires submission of a PEDSnet Collaboration Request for review. That would not be necessary for access to Nemours data alone, but in all cases, potential investigators must first discuss their project with Nemours' PEDSnet site Co-PI, Dr. Tim Bunnell to be sure their project is feasible for PEDSnet. All analysis of the national PEDSnet data must be completed within the PEDSnet Data Coordinating Center (DCC) and at present requires collaboration with a Nemours data scientist who is trained to conduct studies within the DCC. Statistical analysis support will be available through the CTR-ACCEL BERD team. IRB approval will need to be sought at both the PI's institution and Nemours, which would serve as the IRB of record for PEDSnet studies. Data use agreements may need to be in place before the work begins. The Nemours data science team is willing to collaborate with the PI's team to develop the research question and extract appropriate data (for local Nemours data) or run analyses within the DCC. PIs are encouraged to begin the institutional IRB approvals and DUA processes early so that they are in place by **March 15th, 2024**. For more details, contact the Nemours site Co-PI, Dr. Tim Bunnell (tim.bunnell@nemours.org).

v. **Additional Criteria**: Take-off awards will prioritize funding of early stage and new investigators who need to collect feasibility data in order to be competitive for larger grants. Both new, early stage, and senior investigators will be considered for Booster and Delaware Data Science awards, with early stage and new investigators getting priority. For all mechanisms, investigators who have only limited access to research resources will be prioritized over those with substantial start-up packages from their home institutions or other research funding.

Eligibility

DE-INBRE Pilot applicant must:

i. Hold a full-time tenured, tenure-track, or equivalent faculty/clinician/research scientist appointment as well as research faculty with PI eligibility (with independent investigator status) at their institution. Note: staff, graduate students, clinical fellows, and post-doctoral scholars are not eligible;
ii. Be employed by a DE-INBRE partner or affiliate institution; (UD, Nemours, CCHS, DSU, DTCC, Wilmington VAMC, etc.);
iii. NIH-defined "new investigators" are eligible for all award types; NIH-defined "Early-Stage Investigators (ESIs)" are particularly encouraged to apply.
iv. NIH-defined "senior investigators" can apply for Booster or DE data science awards only.

Investigators are prohibited from receiving simultaneous support as PI or co-PI from more than one Institutional Development Award IDeA source. Investigators who have active support from other (IDeA) mechanisms (e.g., Centers of

Biomedical Research Excellence [COBRE], Center for Translational Research [CTR]), IDeA States Pediatric Clinical Trials Network [ISPCTN] are not eligible for **simultaneous** DE-INBRE Pilot Project funding. If you have questions about this policy, please reach out to DRPP Director, Dr. Anjana Bhat.

Expectations for Protected Time

NIH NIGMS expects that Pilot Project Investigators funded through DE-INBRE to devote at least 25% of their overall professional effort (equivalent to 3.0 person months) to career development and research activities. Applicants will need to provide a letter in the application packet from the appropriate chair, dean, or supervisor ensuring that the applicant will have this level of protected time.

Mentors

Applications from NIH early stage and new investigators **require a mentor and a mentoring plan**. Delaware INBRE Pilot Projects have a strong mentoring component for early stage and new investigators. Along with academic merit, mentorship plans, descriptions of research environment, and indications of institutional support are all key factors in determining an application's strengths. Accordingly, applicants must identify a mentor who will help guide their project.

The Primary Mentor (or Mentoring Team) is expected to have an established track record of NIH funding and training investigators. The primary mentor must:

i. Be a full-time, established investigator with a history of independent funding.
ii. Be experienced in the area of the applicant's proposal
iii. Demonstrate commitment to the applicant's career development
iv. Have an established track record of training new / ESI faculty or fellows at the applicant's career stage.

Applicants are encouraged to identify more than one mentor as this is often advantageous in providing expert advice in developing sustainable programs. The applicant should work with their mentor(s) in preparing the Pilot Project application. Potential applicants having difficulty identifying an appropriate mentor are encouraged to reach out to the DRPP Director, Anjana Bhat at abhat@udel.edu for assistance.

Submission Requirements

Piestar RFx Login Setup

Both, the Letter of Intent and the Full Proposal must be submitted using the DE-INBRE Piestar RFx system. UD applicants should log into the Piestar system using their UD credentials (via CAS SSO). Non-UD applicants must create their own username and password for the DE-INBRE Piestar RFx system. Once an account is created, an applicant can apply for any DE-INBRE funding opportunities in the future using the same log in information. The Piestar system is compatible with firewalls and security protocols at all DE-INBRE partner and affiliate organizations. If you have problems setting up your Piestar account, you can contact INBRE-evaluation@udel.edu.

Letter Of Intent (LOI)

A 1- to 2-page letter of intent must be submitted by September 24, 2023 (11.59 pm ET) and should include a descriptive title of proposed research, name, address, and phone number of the principal investigator(s), Names of other key personnel, names of participating institutions, the PP Award mechanism you are applying to (Take-off, Booster, or DE Data Science Awards), and a concise description of your proposed project with sufficient detail to identify expert reviewers for your proposal.

Full Proposal Submission

Proposals should upload the requested information specified below using currently approved NIH forms/formats. All pages must be prepared using 11 point or larger Arial, Helvetica, Georgia, or Palatino Linotype fonts (non-condensed),

single (or higher) paragraph spacing, and ½ inch margins. Forms and formatting are similar to those of NIH R type, small grant proposals. Proposals include the following sections.

1. *Cover Letter* (1-2 pages): This letter should indicate the title of the proposal, the mechanism you are applying to (Take-off, Booster, or DE Data Science), the "big picture" context of the study, the knowledge gap, and potential impact of the study, if completed and a list of 3-4 potential scientific reviewers familiar with the proposed research. These potential reviewers need not be from Delaware. Professional familiarity with the applicant is allowed, however, a potential reviewer should not have a significant conflict of interest.
2. *DE-INBRE Proposal Cover Page:* Use this cover page attachment.
3. *Project Summary* (<30 lines), *Public Heath Relevance Statement/ Narrative* (2-3 sentences): Follow guidance here.
4. *Project/Performance Sites, Senior/Key Personnel Details*. Follow guidance here and here. Items 3 and 4 can be provided together using this form.
5. *Biographical Sketches* (<5 pages each): Provide Biosketches for PI and Key Personnel including the primary mentor, other members of the mentoring team, and collaborators who would play a significant role in accomplishing the goals of the proposal. Also, review NIH Biosketch policy and the recommended Sciencv system details.
6. *Budget:* Provide an itemized, detailed budget form for the period of May 01, 2024 – April 30, 2025. Provide a written budget justification to match the items listed in the budget per these budgetary guidelines.
7. *Specific Aims Page* (1 page): Follow guidance on Specific Aims here and here. It is recommended that new/ESI applicants work closely with their mentors on this section. This document should end with an explicit impact statement specifying why this work if successful will make a sustained impact on the field of study.
8. *Research Strategy* (6 pages): Follow guidance on Research Plan here and here. It is recommended that applicants work closely with their mentors on this section which includes Significance, Innovation, and Approach (including Preliminary Data, if available).
9. *Bibliography & References Cited* (no page limits): Follow guidance here.
10. *Resources and Environment* (no page limits): Provide a description of the facilities and resources available to you that will enable you to successfully carry out your research objectives (e.g. lab space, equipment, collaborations, existing data sets, patient populations).
11. *Undergraduate Inclusion Plan* (1-2 pages): Describe plans for engaging undergraduate students in your research.
12. *Individual Development Plan* (1-2 pages): The IDP should include mentor names, applicant's overarching career goals (broad, general, long-range statements), specific objectives in the next few years in four different career development domains: clinical, teaching, research, and leadership. Include SMART objectives that are specific, measurable, short-term actions and are designed to achieve applicant's goals.
13. *Mentoring Plan* (1-2 pages): A Mentoring Plan is provided by the primary mentor and should include proposal PI (mentee) and mentor names and titles, mentor's past research and training record (their own research expertise and funding record, as well as the number of past mentees they trained and the mentees' career trajectory including positions held and grant/research productivity). Explain the mentor's understanding of the PI (mentee)'s goals for developing further expertise. In addition, describe how the mentor will support the PI (mentee) in achieving the specific goals stated including future proposal development for NIH and other extramural funding (e.g., meeting frequency, topics covered, and grant writing guidance). Names and roles of any other mentors and their roles can also be explained.
14. *A letter of support from the primary mentor*: The letter should certify primary mentor's willingness to be a mentor for the proposed research project, a discussion of the candidate's potential to become an independent investigator, details of existing mentoring or working relationship (if any), and any additional specifics of the planned mentoring interactions during the funding period. In cases where there are multiple mentors or a mentoring team, this letter should indicate that the mentoring plan was designed jointly and should indicate each mentor's full understanding and commitment to the PI's research progress.
15. *A letter of Support from the PI's Department Head/Chair*: Letter should indicate the level of institutional support. The letter must include assurance that the applicant will have sufficient time available over the course of the PP to participate in the proposed research program.
16. *Other Support File & Start Up Funds Available*: Follow guidance provided here.

17. *Letter(s) of Support from Core Directors, if applicable*.
18. *Letter of Support from Collaborators, if applicable*.
19. *Plans for Human Subjects Research, if applicable* (no page limits): Follow guidance provided here and here. See specific bullets by clicking to below.
20. *Plans for Vertebrate Animal Use, if applicable* (no page limits): Follow guidance provided here, for this section. See specific bullets by clicking to below.
21. *Human Subjects Clinical Trials Forms*: Follow guidance provided for Form G, for this section. Use this Human Subjects and Clinical Trials form template.
22. *Statement of success from prior awards (1 page), if applicable*: PIs who have led a project supported by CTR, DE-INBRE, COBRE grants should include a progress report on the prior work, including their success in leveraging that research into independent external support and explaining why further support is necessary.

Documents needed if project is considered for funding (Just in Time)

23. *IRB and IACUC Approvals, if applicable*: If the proposed study is considered human subjects research or if the proposed study will involve vertebrate animals, applicants must submit documentation that IRB and/or IACUC approval is pending with their application. While pending status typically does not negatively influence scientific merit, failure to secure IRB or IACUC approval will bar authorization to begin the award. Copies of appropriate IRB and IACUC approval letters must be provided by **March 15th, 2024,** or the proposal may not move forward.
24. *Plans for Data Management and Sharing*: Follow guidance provided here. You can sign in with your institution's email id to see DMSP plan exemplars shared by other PIs found here.
25. *Revised biosketches consistent with NIH guidelines may be requested*.

Funding Level and Award Period

Applicants will be expected to submit itemized budgets at levels that reflect justified projected needs up to and not exceeding: $40k in direct costs for the funding period of one year (starting May 1, 2024, pending NIH grant renewal). A typical DE-INBRE Pilot Project will provide support for undergraduate or graduate students or a postdoctoral fellow, and appropriate amounts for

i. PI summer salary (i.e., buyout of PI salary is permitted). However, institutional policies and employee expectations vary across DE-INBRE institutions. Therefore, petitions for PI salary buyout will be reviewed on a case-by-case basis by the RDC. RDC recommendations will be forwarded to the DE-INBRE PI, Dr. Melinda Duncan (duncanm@udel.edu) for final decision with oversight and review by the DE-INBRE External Advisory Committee (EAC) and, as appropriate, NIH Program Officials.
ii. Supplies
iii. Travel
iv. Use of DE-INBRE affiliated centralized core facilities and/or data science resources.
v. Contractual or consultative work (if applicable)

DE-INBRE Pilot Project awards are designed to provide funding for 12 months. After that, new and early stage investigators could apply for a Research Project award. Research Project awards are designed to provide funding for a period of up to 24 months. The anticipated start date for this cohort of DE-INBRE Pilot Project awards is May 01, 2024 (pending NIH grant renewal).

Reporting Requirements

DE-INBRE investigators are required to sign agreements that set out the conditions of their participation. Investigators must submit research reports and financial updates at intervals outlined in their agreements and to provide periodic updates on career progress after the completion of DE-INBRE support. In addition, they will be required to participate in DE-INBRE professional development events and program evaluation activities. They will be required to present

posters and/or talks at External Advisory Committee Meeting(s), and the DE-INBRE research conference to be held in Spring 2025.

Anticipated timeline

September 24, 2023, 11.59pm ET: LOI submission deadline

October 22, 2023, 11.59pm ET: Full Application submission deadline

Late December 2023 - Early January 2024: Potential awardees notified

March 15, 2024: Just-In-Time deadline (IRB/IACUC approval letter, Data Use Agreement approval, DMSP and other documents needed)

March-April 2024: Proposals sent to NIH for approval

May 01, 2024: Anticipated project start date (pending NIH grant renewal)

Cover Page for DE-INBRE PP Award Application - 2023

1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*

2. PILOT PROJECT MECHANISM (check one): Take-off Booster DE Data Science

3. PRINCIPAL INVESTIGATOR and PRIMARY MENTOR INFORMATION

3a. PI NAME (Last, first middle)	3b. PI DEGREE(S)	3h. PI eRA Commons Name
3c. PI POSITION TITLE	3d. PI MAILING ADDRESS *(Street, city, state, zip code)*	
3e. PI DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3f. PI INSTITUTION		
3g. PI TELEPHONE *(Area code, number and extension)* TEL:	PI E-MAIL ADDRESS:	
3i. MENTOR NAME (Last, first middle)	*3j. MENTOR DEGREE(S)*	*3p. MENTOR eRA Name*
3k. MENTOR POSITION TITLE	*3l. MENTOR MAILING ADDRESS (Street, city, state, zip code)*	
3m. MENTOR DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT		
3n. MENTOR INSTITUTION		
3o. MENTOR TELEPHONE Area code, number and extension) *TEL:*	*MENTOR E-MAIL ADDRESS:*	

4. HUMAN SUBJECTS RESEARCH No Yes	4a. Research Exempt No Yes	If "Yes," Exemption No.
4b. Federal-Wide Assurance No.	4c. Clinical Trial No Yes	4d. NIH-defined Phase III Clinical Trial No Yes

5. VERTEBRATE ANIMALS No Yes	5a. Animal Welfare Assurance No.

6. PROPOSED PERIOD OF SUPPORT	**7. COSTS REQUESTED FOR YR 1**		**8. TOTAL COSTS REQUESTED**	
From *Through*	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)

9. PRINCIPAL INVESTIGATOR ASSURANCE I certify that the statements herein are true, complete and accurate to the best of my knowledge. I agree to accept responsibility for the scientific conduct of the Delaware INBRE Project and to provide all required project and career progress reports if a grant is awarded as a result of this application.	**SIGNATURE OF PRINCIPAL INVESTIGATOR:**	DATE

10. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

Name

Title

Address

Tel:

E-Mail:

DETAILED BUDGET FOR INITIAL BUDGET PERIOD

FROM | THROUGH

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$**
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$**

Grant Writing Training Resources

1. Written Resources
    a. NINDS Grant Writing Pages & NIAID Grant Writing Pages
2. Video-based Training
    a. NIH Grants Fundamentals
    b. NIH Grant Application Tips
    c. SuRE Grant Writing Resources A & SuRE Grant Writing Resources B
    d. JIN Youtube Podcasts – Grant Writing Tips & Tricks & DE-CTR-ACCEL Career Development Zone
    e. To join the Junior Investigators' Network (JIN), please email erin.riegel@nemours.org
3. Other Blogs & Websites
    a. Edge for Scholars

Additional Specific Details

Plans for Human Subjects Research

i. Protections for Human Subjects.

a. For research that involves non-exempt, human subjects research (see 45 CFR Part 46), the investigator should discuss the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five criteria: risk to subjects, adequacy of protection against risks, potential benefits to the subjects and others, importance of the knowledge to be gained, data and safety monitoring for clinical trials

b. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the applicant should discuss: the justification for the exemption, human subjects involvement and characteristics, sources of materials.

c. More guidance is provided here and here.

ii. Inclusion of Women and Minorities: Applicants must detail how they will assure that women and minority groups are included in any clinical research in a manner that is appropriate to the scientific question under study. Follow guidance here.

iii. Inclusion Across the Lifespan: To comply with the NIH's Inclusion Across the Lifespan Policy, applicants must explain how they will ensure that individuals are included in clinical research in a manner appropriate to the scientific question under study so that the knowledge gained is applicable to all those affected by the condition. Follow guidance here.

iv. Planned Enrollment: Use the planned enrollment table format provided in the Human Subjects and Clinical Trial Form.

Plans for Vertebrate Animal Use, if applicable:

The vertebrate animal use justification and protection section should cover:

i. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve vertebrate animals. Identify the species, strains, ages, sex and total number of animals by species to be used. If dogs or cats are proposed, provide the source of the animals.
ii. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
iii. Minimization of Pain and Distress: Describe the interventions to minimize discomfort, distress, pain and injury. These include analgesia, anesthesia, sedation, palliative care and humane endpoints.
iv. Euthanasia: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification. Follow guidance provided here, for this section.