



***Developmental Research
Project Program
2019 Funding Cycle***

**Pilot Project Request for Applications
and
Application Instructions**

Application Submission Deadline

11:59pm, May 15, 2019

Contents

Request for Proposals	3
Background, Goals, and Objectives	3
Table 1: Grants that may be targeted by a Pilot Awardee.....	3
General Program Description	3
Mentoring Requirement	3
Scope of Pilot Research.....	4
Types of Pilot Grant Submissions.....	4
Research Independence Awards (\$80,000 per year for up to 2 years):	4
Research Engagement Awards (\$80,000 per year for up to 2 years):	4
Collaborative Research Pipeline Grant (\$25,000 maximum per grant):.....	5
Eligibility.....	5
Submission Requirements	7
Proposals include the following sections:.....	7
Review Processes	12
Review Criteria for Pilot Proposals	12
DE-INBRE Applicant and Institutional Support Considerations	12
Submission Instructions	15
Table 2. Anticipated Pilot Project Application, Review, and Awards Timeline.....	15
Table 3: Summary of pilot research project application structure.....	17
Contact Information.....	19
CHECKLIST FOR SUCCESSFUL AIMS PAGES*	20
Cover Page for DE-INBRE Pilot Project Application - 2019	21
REFERENCES CITED.....	22

Request for Proposals

Background, Goals, and Objectives

A fundamental goal of Delaware INBRE (DE-INBRE) is to develop broad-based biomedical research capabilities that support the growth of a diverse, self-sustaining biomedical research enterprise in the state. To accomplish this goal, DE-INBRE supports a statewide network including the University of Delaware (UD), Delaware State University (DSU), Christiana Care Health System (CCHS), Nemours - Alfred I. duPont Hospital for Children, Wesley College, and Delaware Technical Community College (DTCC). Principal objectives of this network are to increase research engagement across DE-INBRE institutions and to increase the number of independent investigators in the state. Pilot Awards are offered to support these objectives.

Three types of pilot awards are offered through the DE-INBRE Developmental Research Project Program (DRPP): *Research Independence Awards*, *Research Engagement Awards*, and *Collaborative Research Pipeline Grants*. These awards support research and educational activities that lead to grant applications that clearly propel an investigator or a DE-INBRE institution toward sustainable research programs. Pilot investigators are expected to leverage the considerable resources available to them through DE-INBRE to develop and submit one or more competitive research or education grant applications. Depending on the specific needs of the individual applying for a Pilot Award and their institution, a large number of potential follow-on grant applications may be considered appropriate (for examples, see Table 1).

Research Independence Award	Research Engagement Award [†]	Collaborative Research Pipeline Grant
NIH R01	NIH R15	NIH R25
NSF CAREER	NIH R34	NSF REU
NSF PECASE	NIH K01	NSF IUSE [‡]
NIH R41/42	NIH K07	NIH R13
NIH R43/44	NIH K08	
NIH P01	NIH K23	
NIH P20	NIH K25	
	NSF RUI/ROA	

Table 1: Grants that may be targeted by a Pilot Awardee.

General Program Description

The three DE-INBRE-sponsored Pilot Award mechanisms have two features in common: 1) they are written and executed in conjunction with a mentor or mentoring team suitable to the applicant and their experience; 2) they are driven by at least one underlying research question within the broad scope of DE-INBRE's goals. For the purposes of the DRPP, all funded investigators are considered researchers.

Mentoring Requirement

Delaware INBRE Pilot Projects have a strong mentoring component. Along with academic merit, mentorship plans, descriptions of the 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 mentor should be an active investigator in the area covered by the DRPP Pilot Grant proposal and must be committed to the goals articulated in the proposal. Applicants are encouraged to identify more than one mentor as this is often advantageous in providing expert advice in developing sustainable programs. The principal mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage. The candidate must work with their mentor(s) in preparing the Pilot Project application.

[†] Proposals to develop R15 applications are most desired; however, the DE-INBRE will also consider proposals that engage clinicians in the development of clinical trials (R34) or that engage young faculty in career development activities (K-grants). If you wish to apply for a Pilot Award to support development of a grant submission other than an R15, please contact the DE-INBRE office before submission at info@de-inbre.org.

[‡] There are three Improving Undergraduate STEM Education (IUSE) programs: [Education and Human Resources \(IUSE: EHR\)](#); [Hispanic-Serving Institutions \(HSI Program\)](#); [Pathways into Geoscience \(IUSE: GEOPATHS\)](#)

Scope of Pilot Research

Pilot grant applications, regardless of funding mechanism, must address an important, underlying research challenge or question. Proposals addressing a wide range of topics are welcome, but Pilot Project research must be categorized within DE-INBRE's broad areas of focus: cancer, cardiovascular disease, and neuroscience research. There has been important progress in these three areas to improve the health of Delawareans, but significant work remains, and applicants are encouraged to address health, healthcare, and health equity needs in the state. In particular, the DE-INBRE welcomes applications that investigate factors related to health equity within one or more of DE-INBRE's three focus areas. In addition, each DE-INBRE institution has identified its own research priorities, and applicants are encouraged to discuss their planned applications with the DE-INBRE leadership at their home institution to assure alignment with these priorities.

Applicants are encouraged to consider a broad scope of potential scientific domains in their research, including

- molecular / cellular biology
- bioinformatics/data science
- clinical imaging
- advanced diagnostics and screening
- epidemiology
- disparities in health or healthcare
- simulation and modeling
- whole organisms, organ systems, tissue
- physiology/pathophysiology
- policy research
- physical activity and social participation
- leveraging existing data or health informatics resources

Within a scientific domain, Pilot Projects typically reflect one of four stages of research: 1) development of technologies or methods for assessment or intervention, 2) fundamental, basic research, 3) translational research, or 4) clinical research. Intended to seed future funding and program growth, DE-INBRE Pilot Projects may take the form of:

- Analysis of existing data or integration of datasets
- Development and/or validation of novel instrumentation or methods
- Small, self-contained feasibility projects
- Acquisition and analysis of data needed to support subsequent grant submissions

Types of Pilot Grant Submissions

The DE-INBRE supports three types of Pilot Project submissions:

Research Independence Awards (\$80,000 per year for up to 2 years):

The goal of the Research Independence Award is to support investigators to advance toward research independence by receiving an NIH research grant. These awards support promising investigators to obtain substantial research funding and to become established researchers who are no longer considered new investigators by the NIH. Pilot investigators are expected to leverage the considerable resources available to them through DE-INBRE to develop and submit one or more competitive research grant applications by the end of their Pilot Award support. NIH R01 grants are the gold standard to indicate research independence, and DE-INBRE Research Independence Awards leading to the submission of an R01 application are preferred, but submissions that lead to comparable, institutionally-appropriate grants that clearly support an investigator's development to an R01-level of independence are also supported by this mechanism. Depending on the career development needs of the individual applying for a Pilot Award, the nature of their research and mentoring teams, and the priorities of their home institution, other grants may be considered appropriate targets for a Research Independence Award (see Table 1).

Research Engagement Awards (\$80,000 per year for up to 2 years):

Research Engagement Awards, seek to build competitiveness for faculty applicants in the DE-INBRE network working at a Primarily Undergraduate Institution (PUI) or a hospital. The goal of the Research Engagement Award program -

supporting individual investigators to advance toward research independence by receiving an NIH research grant - is essentially the same as for the Research Independence Awards, the Research Engagement Award grant program parallels the Research Independence Awards.

The primary goal of the Research Engagement Awards is to support the development of small scale research project grants, especially R15 / Academic Research Enhancement Awards and R15 / Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. In addition, DE-INBRE will consider proposals from investigators developing other grants, including R34 / Clinical Trial Planning Grants, or research career development grants like the NIH K07 / Academic Career Development Award⁵ (see Table 1).

Collaborative Research Pipeline Grant (\$25,000 maximum per grant):

Collaborative Research Pipeline Pilots will fund collaborative projects targeted at strengthening the pipeline for biomedical research in Delaware. These grants support teams of faculty to create new research training opportunities for students in Delaware. These training opportunities will take advantage of current research programs and state-of-the-art technologies available in the state. Potential supported projects include course-based undergraduate research experiences (CUREs) that involve students in authentic research experiences as part of a class, collaborations that integrate faculty and students from PUIs into research projects at DE-INBRE clinical or research intensive partners, or small faculty research projects aimed at expanding research training opportunities for students at PUIs. For CUREs, authentic research experiences have been defined as including eight elements:¹⁻³

- Novel questions
- Student-generated questions
- Development of a hypothesis
- Experimental design
- Data collection
- Presentation or publication of the research
- An unknown scientific outcome
- A minimized role of the instructor

Collaborative Research Pipeline projects will bring together multiple faculty members in an interdisciplinary, and ideally, inter-institutional partnership. The overall goal for the mechanism is to build the DE-INBRE network and strengthen Delaware's biomedical research pipeline by supporting partnerships focused on increasing research education opportunities for students. By supporting cross-institutional research education partnerships and building competitiveness for external research education grants such as R25 grants from NIH, or the Research Experiences for Undergraduates (REU) and Improving Undergraduate Stem Education (IUSE) grants from NSF (see Table 1).

Applications will be competitively reviewed like the other DE-INBRE pilot mechanisms. Following the model of other pilot grant programs through the DRPP, evaluation of Collaborative Research Pipeline Pilots will parallel NIH review criteria used by NIH reviewers to evaluate research education grants. An additional criterion will be an assessment of the potential for the project to lead to external research education funding.

Eligibility

Pilot Investigators

Regardless of the type of submission, DE-INBRE Pilot applicant must:

- i. Hold a full-time tenured, tenure-track, or equivalent faculty appointment;
- ii. Be based at a DE-INBRE partner institution;

⁵ K07 / Academic Career Development Awards support investigators to develop curricula, to foster development of promising teacher-investigators, or to strengthen teaching programs.

- iii. Fulfill the criteria of an NIH *New Investigator* (<https://grants.nih.gov/policy/early-investigators/index.htm>).

Early-Stage Investigators (ESIs) are particularly encouraged to apply. ESIs are a subset of the NIH New Investigator category (see <https://grants.nih.gov/policy/early-investigators/index.htm> for details) being within 10 years of their terminal degree or their medical residency. Senior faculty having extensive programmatic and institutional experience who also qualify as NIH New Investigators are also eligible and encouraged to apply. Non-career employees such as consultants, post-doctoral fellows, visiting scientists, and limited-term researchers are not eligible.

Eligible applicants with a record of prior DE-INBRE support may compete for new awards. However, these DE-INBRE investigators must document sufficient outcomes and progress from past INBRE support to be deemed competitive.

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] or Center for Translational Research [CTR]) are not eligible for DE-INBRE Pilot Projects unless they separately petition the DE-INBRE Director of Research to explore eligibility status prior to submission of an application. PIs may, however, involve collaborators in a DE-INBRE Pilot Project who are simultaneously funded by other IDeA sources.

Applicants are strongly encouraged to collaborate with institutions and organizations in Delaware and/or other IDeA states. A list of IDeA states can be found at <https://www.nigms.nih.gov/Research/DRCB/IDeA/Pages/default.aspx>. Individuals from non-IDeA states may not receive DE-INBRE funding as a PI or co-PI, and any involvement of theirs with DE-INBRE Pilot Project must be limited to technical assistance (i.e., no scientific contribution). If there is a need for a scientific contribution from collaborators from non-IDeA states, please contact the DE-INBRE Director of Research for guidance.

Mentors

DE-INBRE uses a definition of mentorship established by Abedin et al.⁴:

Research mentorship refers to a dynamic, collaborative, reciprocal, and sustained relationship focused on an emerging researcher's acquisition of the values and attitudes, knowledge, skills, and behaviors necessary to develop into a successful independent researcher.

With this definition in mind, each applicant will identify a primary mentor for their Pilot Project. Applicants are also encouraged to identify additional mentors to act as a mentoring team if advantageous for providing expert advice in all aspects of their proposed Pilot Award program. The Primary Mentor (or Mentoring Team) is expected to have an established track record of funding and training investigators. In general, unless exceptions are specifically allowed by the DE-INBRE Director of Research, 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 junior faculty or fellows at the applicant's career stage.

In cases where Mentoring Teams are used, a clear plan explaining how the team will collaborate to assure support for the investigator and how any conflicts or differences will be managed must be provided. In addition, all team members, applicants and mentors, are expected to complete routine assessments during the course of any research funded by the DE-INBRE.

Submission Requirements

Proposals should use forms specified below. Continuation pages must be prepared using 11 point or larger Arial font (non-condensed), single (or higher) paragraph spacing, and ½ inch margins. Forms and formatting are similar to those of NIH R type proposals. Proposals include the following sections.

1) Cover Letter (less than 1 page)

This letter should indicate:

- i.* The title of the Pilot Proposal
- ii.* The mechanism of support being sought (Research Independence Award, Research Engagement Award, or Collaborative Research Pipeline Grant)
- iii.* The thematic area(s) addressed by the research (neuroscience, cardiovascular, or cancer research), and, the “big picture” context of the study including, as applicable, the health, health equity, or healthcare challenges addressed by the research.
- iv.* A list of three or four potential scientific reviewers familiar with the area of their 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 (see http://grants.nih.gov/grants/peer/peer_coi.htm for guidance).

2) DE-INBRE Proposal Cover Page

(use attached form)

3) Summary, Relevance, Project/Performance Sites, Senior/Key Personnel

Use NIH Pages 2&3: (https://grants.nih.gov/grants/funding/phs398/398_fp2.docx)

4) Budget

Itemized budget for each year of the Pilot Project, and a budget for the entire proposed period. Use PHS 398 Forms 4 and Form 5. Provide budget justification as directed on forms. (https://grants.nih.gov/grants/funding/phs398/398_fp4.docx and https://grants.nih.gov/grants/funding/phs398/398_fp5.docx)

5) All Personnel Report and Biographical Sketch(es)

Provide information on all personnel who would work on the project using the form https://grants.nih.gov/grants/funding/phs398/398_personnelreport.docx.

Provide 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. Use the general NIH format at <https://grants.nih.gov/grants/forms/biosketch.htm> (see https://grants.nih.gov/grants/policy/faq_biosketches.htm for detailed information and FAQs and <http://www.ncbi.nlm.nih.gov/sciencv/> for the recommended SciENCv profile system).

6) Specific Aims Page

Limit to 1 page; it is recommended that applicants work closely with their mentors on this section. A checklist to help guide the construction of the Specific Aims Page is provided on page 20.

7) Research Plan

Limit 6 pages; it is recommended that applicants work closely with their mentors on this section.

Provide a sound research project that is consistent with the applicant's level of research development and the goal of advancing toward independence as an investigator. Organize the research plan as indicated for NIH R type grants as detailed at <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf>. For examples of NIH grants, check out the samples at <https://www.niaid.nih.gov/grants-contracts/nine-new-sample-niaid-grant-applications>.

Include sections on:

- Significance: The Significance section should include discussion of
 - The significance of the work to the thematic area(s) of DE-INBRE
 - As appropriate, the potential for the work to improve the overall health, health equity, or healthcare of Delawareans
 - As appropriate, the potential for the work to enhance education and support the pipeline for biomedical research in Delaware.
 - The importance of the problem (or critical barrier) to progress in the field
 - The underlying rationale for the line of research and the rigor of prior research that supports the need for the proposed research
 - How scientific knowledge, technical capabilities, and/or clinical practice might be improved by the envisioned line of research
 - How successful completion of the pilot would lead to future studies that address concepts, methods, technologies, treatments, services, or preventative interventions driving the field
- Innovation: The Innovation section should address
 - The degree to which the application challenges or seeks to shift current research or clinical practice paradigms through the use of novel theoretical concepts, approaches or methodologies, instrumentation, or interventions
- Approach: The Approach section should include discussion of
 - The overall strategy, methodology, and analyses, which should be well-reasoned and appropriate to accomplish the specific aims of the project
 - The rigorous and strict application of methods to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results
 - Potential problems, alternative strategies, and benchmarks for success presented
 - Biological variables, such as sex, age, weight, and underlying health conditions; in particular, especially consideration of sex is a biological variable

8) Resources and Environment (no limit)

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). Use https://grants.nih.gov/grants/funding/phs398/398_resources.docx

9) Undergraduate Inclusion Plan (limit to 1 page for Research Independence Awards; no limit for Research Engagement Awards; no limit for Collaborative Research Pipeline Grants)

Describe plans for engaging undergraduate students in your research activities.

10) Individual Development Plan ([online form](#)).

To complete the IDP, which is done online, the applicant should have available

- a. Correct spelling of primary and co-mentors' names
- b. The applicant's over-arching career goals. Note that these should be broad, general, long-range statements of purpose.
- c. Specific objectives in four different career development domains: clinical, teaching, research, and leadership. Objectives are specific, measurable, short-term actions designed to achieve to applicant's goals).
- d. Estimates of productivity over the last 12 months including manuscripts submitted/published and grants submitted/awarded.

11) Mentoring Plans ([online form](#)).

Completed by each mentor online. To complete the mentoring plan, the mentor should have available

- a. The Pilot Investigator's (mentee's) name and proposal title
- b. A list of previous mentees/trainees, their current positions, and an estimate of how many grants each received while being mentored.
- c. A summary statement indicating the areas in which the investigator will develop Clinical and Translational Research expertise.
- d. The names and roles of any other mentors who will assist on the project.

12) A letter of support from the primary mentor

The letter should expand on the mentoring plans as needed, especially regarding the mentors' experience with other mentees at the candidate's level of training, a discussion of the candidate's potential to become an independent investigator, details of the 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 research progress of the applicant.

13) 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 Pilot Project to participate in the proposed research program. The letter should also indicate that the applicant is eligible to receive a DE-INBRE Pilot Project award as an NIH "new investigator" in a career or career-conditional appointment.

14) Letter(s) of Support from Core Directors

If the resources needed to successfully carry out the research include DE-INBRE Core Facilities or shared equipment, a letter from the Core Resource Director indicating the availability of the resource(s) and estimating the costs associated with its/their use must be include.

15) Letter of Support from Collaborators, if applicable

Letters of support from collaborators are permitted. Collaborators should focus on their role in supporting the proposed research.

16) Plans for Human Subjects Research, if applicable

Follow guidance found at <https://www1.udel.edu/research/pdf/Humans.pdf>; this section should cover:

a. Protections for Human Subjects.

- i. 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:
 1. risk to subjects
 2. adequacy of protection against risks
 3. potential benefits to the subjects and others
 4. importance of the knowledge to be gained
 5. data and safety monitoring for clinical trials
- ii. 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:
 1. the justification for the exemption,
 2. human subjects involvement and characteristics,
 3. sources of materials.

b. 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. For basic guidance on the NIH criteria, see https://grants.nih.gov/sites/default/files/Decision%20tree-%20Sex-gender%20race-ethnicity_508final%204-12-18.pdf.

c. 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 researched diseases/conditions. For details on the NIH policy, see <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>.

d. Planned Enrollment

Use forms found at <https://grants.nih.gov/sites/default/files/PHS-Inclusion-Enrollment-Report.pdf>

17) Plans for use of vertebrate animals, if applicable

See <https://olaw.nih.gov/guidance/vertebrate-animal-section.htm>. The vertebrate animal justification and protection section should cover:

- a. 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.
- b. 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).
- c. 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.
- d. 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.

18) 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 Pilot application. While pending status typically does not negatively influence scientific merit, failure to secure IRB or IACUC approval will bar authorization to begin a Pilot Project.

If requested during the *Just in Time* phase of review (see Table 2, below), **copies of appropriate IRB and IACUC approval memos must be provided by August 9, 2019, or the proposal may not move forward.**

19) Statement of success from Prior Awards, if applicable

PIs who have led a project supported by CTR, DE-INBRE, COBRE, or DHSA grants should include a short section (1 page maximum) outlining the progress on that prior work, including their success in leveraging that research into independent external support and explaining why further support is necessary. Use NIH continuation forms— <http://grants.nih.gov/grants/funding/phs398/continuation.docx>.

Review Processes

Review Criteria for Pilot Proposals

DE-INBRE Pilot Projects will be selected for award based on the following major, minor, and administrative criteria:

Major

- i. Overall scientific/biomedical research merit as determined by:
 - 1) Significance
 - 2) Investigators
 - 3) Innovation
 - 4) Approach
 - 5) Environment;
- ii. Individual Development Plan and potential to achieve goals of research program
- iii. Strength of mentorship plan and mentor's/mentoring team's capabilities
- iv. Undergraduate participation and engagement of research trainees

Minor

- i. Use of applicable DE-INBRE supported core instrumentation centers
- ii. Strength of inter-institutional collaborations, if proposed.
- iii. Potential for proposed research to improve the health / healthcare of Delawareans and to advance health equity.

DE-INBRE Applicant and Institutional Support Considerations

General Considerations

- i. Does the Pilot Applicant have the potential to develop as an independent and productive researcher?
- ii. Is the applicant's academic, clinical (if relevant), and research record of high quality?
- iii. Is there evidence of the applicant's commitment to meeting the program objectives to become an independent research investigator?
- iv. Do letters of institutional support indicate that the applicant is a new or early-stage investigator in a career or career-conditional appointment?
- v. Do letters of institutional support demonstrate evidence for appropriate institutional support for the applicant to become and maintain independent investigator status?

Career Development Plan/Career Goals & Objectives

- i. What is the likelihood that the plan will contribute substantially to the scientific development of the applicant leading to scientific independence?

- ii. Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- iii. Are there adequate plans and timeline for the mentor and applicant to monitor and evaluate the applicant's research and career development progress?

Mentorship Plan

- i. Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- ii. Does the mentor(s) adequately address the applicant's potential and his/her strengths and areas needing improvement?
- iii. Is there adequate description of the quality and extent of each mentor's proposed role in providing guidance and advice to the applicant?
- iv. For mentoring teams, is there a plan in place describing how the mentors will work together and how conflicts or differences will be managed?
- v. Is the mentor's description of the elements of the research career development activities, including formal course work, adequate?
- vi. Is there evidence of the mentor's or mentoring team's previous experience in fostering the development of independent investigators?
- vii. Is there evidence of previous research productivity and peer-reviewed support?
- viii. Are there adequate plans for monitoring and evaluating the applicant's progress toward independence as an INBRE investigator?

Protected Time

NIH NIGMS expects that Pilot Investigators funded through DE-INBRE will devote at least 50% of their overall professional effort (equivalent to 6.0 person months) to career development and research activities. Institutions must provide release time for project investigators, thus permitting a significant time commitment to the research enterprise. To allow flexibility to investigators who cannot devote 6.0 consecutive months throughout the year, their effort can be distributed over the year to achieve a total of 6 person months; (for example, 3.0 person months during academic year and 3.0 person months in summer to account for a yearly 6.0 person months effort). Pilot Project applications must include a letter from the appropriate chair, dean, or supervisor ensuring that the applicant will have this level of protected time.

Funding Level and Award Period

Applicants will be expected to submit budgets at levels that reflect justified projected needs up to and not exceeding \$80k in direct costs per year for the Research Independence and Research Engagement Awards and \$25,000/year for Collaborative Pipeline Awards. They will be required to provide itemized, not modular, budgets, using NIH-approved forms (specifics provided below). A typical DE-INBRE Pilot Project will provide support for graduate or undergraduate students or a postdoctoral fellow and appropriate amounts for

- supplies
- travel
- use of core facilities (if applicable)
- contractual or consultative work (if applicable)

PI summer salary is discouraged, and buyout of PI salary will generally not be 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 DE-INBRE Research Committee. Research Committee recommendations will be forwarded to the DE-INBRE PI for final decision with oversight and review by the DE-INBRE External Advisory Committee (EAC) and, as appropriate, NIH Program Officials.

DE-INBRE Pilot Projects are designed to provide funding for a period of up to 24 months, with an option for successful PIs to apply to the Research Committee for an additional 6-month period of DRPP support for their project to “bridge” a potentially unfunded period prior to the start of external funding. To compete for bridge funding, investigators must have successfully submitted their required major grant submission. While the criteria for awarding bridge funding may differ for each institution, the awards will be based on the documented need to support ongoing activities and the potential to receive the major grant award.

The anticipated start date for this cohort of DE-INBRE Pilot Projects is November 1, 2019.

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 various Delaware INBRE events.

Submission Instructions

Applications are required to conform to NIH formatting requirements (e.g. fonts, style, margins, spacing) as outlined at http://grants.nih.gov/grants/writing_application.htm#tips. See Table 3 for guidance on the required application structure and page limits. Applications must be submitted by email as a **single file in .pdf format**. The file should follow this naming convention: **ApplicantLastName_ApplicantFirstName_INBRE.pdf** (e.g. Smith_Jane_INBRE.pdf.) Applications should be sent to info@de-inbre.org.

Table 2. Anticipated Pilot Project Application, Review, and Awards Timeline

March 1, 2019	Request for Pilot Project Applications released
TBD (in late March)	OPTIONAL: DE-INBRE Pilot Program online/in-person orientation, discussion of submission requirements, and Q&A session for faculty interested in applying. Contact us at info@de-inbre.org for login details to join this session.
TBD (in late March)	OPTIONAL: DE-INBRE Pilot Program online/in-person orientation, discussion of submission requirements, and Q&A session for faculty interested in applying. Contact us at info@de-inbre.org for login details to join this session.
TBD (in late March)	OPTIONAL: DE-INBRE Pilot Program online/in-person orientation, discussion of submission requirements, and Q&A session for faculty interested in applying. Contact us at info@de-inbre.org for login details to join this session.
May 15, 2019	<p>Pilot Project Applications due to Director of Research:</p> <p>At this point, all Delaware INBRE Pilot Project applications will undergo an initial administrative review, and applications found to be missing scientific components will be returned to the applicant without review.</p> <p>The Director of Research will work with the remaining applicants to address any administrative issues to assure the completeness of each application (<i>documentation that the work has received IRB approval or that IRB review is has been scheduled will be required prior to review</i>).</p> <p>The scientific components of each application are shared with the leaders of the three DE-INBRE Research Themes (Neuroscience, Cardiovascular Disease, and Cancer Research)</p>
By May 23, 2019	Full applications distributed to the leaders of the three Research Themes
By June 6, 2019	<p>Theme leaders send applications to Scientific Reviewers:</p> <p>Each application will be read by non-conflicted reviewers following criteria modeled after the NIH Review Criteria (http://grants.nih.gov/grants/peer/guidelines_general/Review_Criteria_at_a glance-research.pdf). Each criterion will be evaluated for strengths and weaknesses and given a summary score. Career and mentorship plans will be similarly reviewed.</p>
By July 8, 2019	Scientific reviews completed and returned to the Director of Research

<p>During week of July 8-12, 2019</p>	<p>Research Committee discusses applications and reviews; generates a prioritized list of each type of project based on scientific merit.</p> <p>Similar to NIH Study Section, each reviewer will make an initial recommendation for each project by weighing the scientific merit, individual development plan, and mentorship plan. The Research Committee will discuss and all members will score the proposal.</p> <p>The list of prioritized projects will be submitted to the Delaware INBRE PI.</p> <p>Upon completion of the review and prioritization processes, each Delaware INBRE applicant will be sent a full packet containing relevant review and prioritization materials for their Pilot Project and will be encouraged to discuss these materials with their mentors.</p>
<p>Between July 15 and Aug 9, 2019</p>	<p>DE INBRE PI and INBRE Steering Committee meet to finalize priority order of projects recommended for funding.</p> <p>External Advisory Committee meets with DE-INBRE PI to finalize recommendations and returns recommendations to DE-INBRE PI.</p> <p>The Director of Research is notified of the funding decisions and contacts applicants for updated documentation and Just in Time information.</p> <p>Pilot Investigator Participation Agreements are distributed for signature.</p> <p><i>All JIT documents (including IRB and IACUC approval memos) and signed investigator agreements must be provided to the Director of Research by Aug 9, 2019.</i></p>
<p>Between Aug 9 – Sep 20, 2019</p>	<p>DE-INBRE PI consults with NIH Program Office regarding final approval of Pilot Awards.</p>
<p>Sep 23, 2019</p>	<p>Notification of Pilot Project awards and finalization of institutional documentation.</p>
<p>Nov 1, 2019</p>	<p>All Pilot Projects begin.</p> <p>After Pilot Projects are awarded, institutional representatives, along with the Director of Research in some cases, will meet with each new Delaware INBRE investigator. The purpose of these meetings will be to discuss the respective projects, investigators' broader career goals, institutional expectations, the mentoring structure, and any obstacles and challenges.</p>

Table 3: Summary of pilot research project application structure

#	Section	Page Limit	Content
1	Cover Letter	1	Explain any irregularities with the submission; make specific review request This letter will not be shared with reviewers.
2	Delaware INBRE Proposal cover page	1	Use form provided at the end of this document. Form must be signed and dated as indicated.
3	NIH Pages 2 & 3	NIH Limits	http://grants.nih.gov/grants/funding/phs398/fp2.docx
4	Budget	NIH Limits	Provide an itemized budget for each year of the Pilot Project, and a budget for the entire proposed period. Download the PHS 398 forms fp4 and fp5.1. Provide budget justification as directed on forms. http://grants.nih.gov/grants/funding/phs398/fp4.docx http://grants.nih.gov/grants/funding/phs398/fp5.docx
5	Biographical Sketches	NIH Limits	Use the current NIH format. https://grants.nih.gov/grants/forms/biosketch-blankformat.docx
6	Specific Aims	1	Describe the significance and innovation of your research; list concrete objectives/aims; note why investigative team is suited to the work.
7	Research Plan	6	Summarize the Significance, Innovation, and Approach.
8	Resources and Environment	2	Describe the scientific environment and how it will contribute to the probability of success; e.g., institutional support, equipment, resources, volunteer populations, collaborations.
9	Undergraduate Inclusion Plan	1 for Research Independence Awards; No limit for Others	Describe the plans for engaging undergraduate students in your research activities.
10	Initial Individual Development Plan	Click for online form	Provide requested information, long term goal(s), specific objectives, and recent accomplishments; prepare with input from primary mentor
11	Mentoring Plan	Click for online form	Provide basic details of mentor qualifications and general plan for interactions – completed by primary mentor
12	Letters from Primary Mentor and mentoring team members	No limit	Explain the relationship(s) with the applicant. Outline relevant previous experience. Expand on the mentoring plans as needed. See details above.

13	Letter from PI's Department Head / Division Chief	No Limit	See details above.
14	Core Support Letters	No limit	Letters/emails from the Director of any DE-INBRE Core resource that would be used in the research.
15	Letters of support from collaborators (optional)	No Limit	See details above.
16	Plans for Human Subjects Research (if applicable)	No Limit	See details above.
17	Plans for use of vertebrate animals (if applicable)	No Limit	See details above.
18	IRB and IACUC approval letters (if applicable)	No Limit	See details above.
19	Statement of success from Prior Awards, (if applicable)	1 page for each prior award	See details above.

Contact Information

For questions related to the following topics, please contact:

Delaware INBRE PROGRAMS			
Delaware INBRE	Steven J. Stanhope	stanhope@udel.edu	302-831-3496
Pilot Awards / Mentoring	Robert Akins	robert.akers@nemours.org	302-651-6811
Undergraduates / Training	Melinda Duncan	duncanm@udel.edu	302-831-0533
Budget	Dawn Montgomery	dawnm@udel.edu	302-831-4331
Evaluation	Laura Lessard	llessard@udel.edu	302-831-6857
Core Facilities	Jeff Caplan	jcapan@udel.edu	302-831-3403
Bioinformatics	Shawn Polson	polson@dbi.udel.edu	302-831-3235
COLLABORATING WITH DE-INBRE PARTNER INSTITUTIONS			
Christiana Care Health System	Scott Siegel	ssiegel@christianacare.org	302-733-4730
Delaware Technical Community College	John McDowell	jmcdowe8@dtcc.edu	302-453-3775
Delaware State University	Hacene Boukari	hboukari@desu.edu	302-857-6511
Nemours – Alfred I. duPont Hospital for Children	Erin Riegel	erin.riegel@nemours.org	302-651-5776
University of Delaware	Shelly Lasko	slasko@udel.edu	302-831-4549
Wesley College	Malcolm D’Souza	malcolm.dsouza@wesley.edu	302-736-2528
COLLABORATING WITH DE-INBRE AFFILIATED AND OTHER DELAWARE INSTITUTIONS			
DelawareBio	Shelly Lasko	slasko@udel.edu	302-831-4549
Wilmington VA medical Center	Office, Asst Chief of Staff for Research	lashaunda.isaac@va.gov	302-994-2511 x 4457
Bayhealth	Angeline Dewey	Dewey@bayhealth.org	302-422-3311
Wilmington University	Shelly Lasko	slasko@udel.edu	302-831-4549

CHECKLIST FOR SUCCESSFUL AIMS PAGES*



Successful *Aims Pages* communicate most/all of the following information (although not always in this order):

- Big picture / context / significance of study
- Long term goal of the research
- Narrowed picture / focused area of application
- Complication / need / unanswered question addressed by study
- Specific goal of the proposed work
- Why this PI?
- Rationale for study / development of central hypothesis
- Central hypothesis
- Specific aims
 - Logical and flowing from central hypothesis?
 - Each has own sub-hypothesis (stated or unstated)?
 - Independent of other aims (i.e., if this aim fails, can the others still be accomplished?)
 - Potential / ideal outcome clear? What does accomplishing this aim tell you?
- Conclusion about proposed work
 - Clearly novel / impactful
 - Addresses long term goal; improves big picture problem

*Developed by Dr. Robert Akins based on feedback from experienced reviewers and from data and presentations on the Northwestern University CLIMB program (<https://www.youtube.com/user/CLIMBProgram>), especially *The Patterns of Introductions in AIMS Page*, with thanks to Dr. Rick McGee for sharing.

Cover Page for DE-INBRE Pilot Project Application - 2019

1. TITLE OF PROJECT <i>(Do not exceed 81 characters, including spaces and punctuation.)</i>			
2. RESEARCH FOCUS AREA Cancer Research <input type="checkbox"/> Cardiovascular Research <input type="checkbox"/> Neuroscience Research <input type="checkbox"/>			
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 <i>(Street, city, state, zip code)</i>	
3e. PI DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT			
3f. PI INSTITUTION			
3g. PI TELEPHONE <i>(Area code, number and extension)</i> TEL:			
3i. MENTOR NAME <i>(Last, first middle)</i>		3j. MENTOR DEGREE(S)	3p. MENTOR eRA Name
3k. MENTOR POSITION TITLE		3l. MENTOR MAILING ADDRESS <i>(Street, city, state, zip code)</i>	
3m. MENTOR DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT			
3n. MENTOR INSTITUTION			
3o. MENTOR TELEPHONE <i>Area code, number and extension)</i> TEL:			
4. HUMAN SUBJECTS RESEARCH		4a. Research Exempt If "Yes," Exemption No.	
<input type="checkbox"/> No <input type="checkbox"/> Yes		<input type="checkbox"/> No <input type="checkbox"/> Yes	
4b. Federal-Wide Assurance No.	4c. Clinical Trial	4d. NIH-defined Phase III Clinical Trial	
<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	
5. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> 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		SIGNATURE OF PRINCIPAL INVESTIGATOR:	DATE
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 Pilot Project and to provide all required project and career progress reports if a grant is awarded as a result of this application.			
10. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE		11. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION	
Name		Name	
Title		Title	
Address		Address	
Tel:		Tel:	
E-Mail:		E-Mail:	
12. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE:		SIGNATURE OF OFFICIAL NAMED IN 11.	DATE
I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		<i>(In ink. "Per" signature not acceptable.)</i>	

REFERENCES CITED

- 1 Spell, R. M., Guinan, J. A., Miller, K. R. & Baeck, C. W. Redefining Authentic Research Experiences in Introductory Biology Laboratories and Barriers to Their Implementation. *CBE Life Sciences Education* **13** (2014).
- 2 Rahm, J., Miller, H. C., Hartley, L. & Moore, J. C. The value of an emergent notion of authenticity: Examples from two student/teacher–scientist partnership programs. *Journal of Research in Science Teaching* **40**, 737-756 (2003).
- 3 Brownell, S. E. & Kloser, M. J. Toward a conceptual framework for measuring the effectiveness of course-based undergraduate research experiences in undergraduate biology. *Studies in Higher Education* **40**, 525-544 (2015).
- 4 Abedin, Z. *et al.* Deriving competencies for mentors of clinical and translational scholars. *Clin Transl Sci* **5**, 273-280 (2012).