**2025 HHDC Grant Program
– Request for Applications**

HAROLD HAMM DIABETES CENTER AND STEPHENSON CANCER CENTER NOVEL PILOT PROJECT GRANT:
This program supports projects aimed specifically at collaboration between researchers in diabetes and cancer. The HHDC-SCC novel pilot grant provides up to two years of funding to establish new research projects on cancer and diabetes or closely related topics. Proposals may include basic, translational, clinical, bioinformatic, behavioral, or community-based research approaches, and must also include a cancer component.

Funding and timeline
$70,000 per year for up to 2 years.

Initial support is awarded for one year. Funding can be extended for a second year, if funds are available, based on: 1) successful achievement of identified milestones; and 2) the quality of specified milestones to be met during the next year of funding. Those investigators requesting funds beyond $70,000 in any one year may apply with the permission of the Director of the HHDC.

Funding Priorities
Applications should be closely aligned with the mission of the HHDC to increase understanding about the causes and consequences of diabetes and closely related cardiometabolic conditions like obesity, liver disease, and cancer, as well as strategies for prevention or treatment of these conditions. Additionally, proposals that address one or more of the following themes are HHDC funding priorities:

Theme 1: **Diabetes and Obesity, origins within the first 1000 days of life or changes across the lifespan.** These are proposals that aim to gain basic science and clinical knowledge on the inter-relationship of obesity and diabetes during fetal development and early life, or across the lifespan. For example, we are interested in studies of the genetic, epigenetic, and environmental basis of susceptibility to developing insulin resistance, metabolic dysregulation, inflammation, macrovascular and microvascular diabetic complications, obesity, and diabetes.

Theme 2: Translational Research. We encourage new collaborative projects between a Principal Investigator (PI) who is a basic scientist and a PI who is a clinician or clinical scientist. These projects must focus on patients or patient samples. At least one of the two collaborating PIs must be from the College of Medicine. If you are applying for this paired Basic/Clinical award, please specify this within the Letter of Intent, and detail the roles of the collaborators.

Theme 3: **Clinical Research/Public Health**. We seek proposals to investigate new treatments, interventions, and technology for diabetes management, along with strategies to raise awareness, promote prevention, or improve diabetes care. Proposals that address health disparities related to diabetes, and early-stage clinical investigators are particularly encouraged. It is strongly anticipated that the results of these pilot projects will eventually permit investigators to compete successfully for extramural sources of research support such as the NIH, American Diabetes Association, JDRF, etc.

Eligibility

The PI and/or MPI of any HHDC grant application must be a Member of the HHDC; the co-investigators do not have to be members at the time of application but if successful are encouraged to become Members or Associate Members of the HHDC during the tenure of the grant. Recipients of **active** HHDC grants may not apply for or hold another HHDC grant or Team Science grant as project PI or MPI.

Eligible applicants fall into one of three categories, listed in order of priority:

1. New investigator without current or past major independent research support (e.g., NIH R01, P01 or equivalent). K awardees are encouraged to apply. Applications from new investigators (within 5 years of first full academic appointment and never having received independent federal funds) are given special consideration during peer review and at the time of funding. Eligible applicants must have a faculty appointment or equivalent with a modified title such as Research Assistant Professor.

MD and PhD fellows and senior postdoctoral fellows who have completed a minimum of 24 months of a fellowship are also eligible in this category. However, fellows must have a formal mentor and include a letter of support from their mentor(s) that: 1) confirms that they have documented, suitable expertise to design and carry out the proposed experiments as an independent investigator; 2) describes the trainee's path to independence; 3) confirms that a defined mentoring plan is in place; 4) states that the proposed project belongs to the trainee and represents an independent line of investigation that the mentee can build upon; and 5) documents departmental support that will be available to the trainee during the 1-2 year period of the proposed project (please limit letter to 2 pages maximum). This letter is not required to be submitted with the Letter of Intent but must be part of the final application. Please note that the fellow will be considered the PI of the application, but the mentor will need to be named as the PI for routing the grant through the Office of Research Administration at OUHSC.

2. Established, funded investigator with no previous work in diabetes or related areas who will apply their expertise to a diabetes or related problem.

3. Established investigator in diabetes or related areas who will test the feasibility of a new or innovative idea that represents a significant departure from their funded research. Emphasis will be given to projects that initiate a new collaboration with one or more investigators active in diabetes or related research or establish a new approach or analysis that will increase the likelihood of future external funding.

Two-Step Application Process

1. Letter of Intent (LOI):

A Letter of Intent is due to HHDCGrants@ouhsc.edu by **5:00 pm on January 13, 2025**. The purpose of the LOI is to provide an initial description of your proposed project so that the HHDC Grants Review Committee can determine: if the proposed project fits within the HHDC research mission; the novelty, significance, and feasibility of the proposed project; if appropriate collaborators have been identified; and the likelihood of the findings to support future external grant applications once successfully completed. Basic science/pre-clinical projects must describe the clinical-translational significance. Applicants may submit project ideas that were previously declined, but they should state how the project has been revised to overcome prior limitations. Resubmitting the same project without revisions is unlikely to be successful.
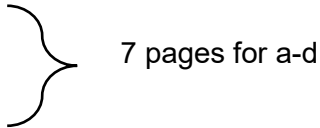
Applicants selected for full application submission will be notified by **January 31, 2025**. You may also receive suggestions for improvement, or recommendations to submit to another funding mechanism. The projected start date for the award will be **July 1, 2025**.

The template for the LOI is included at the end of this document. The required elements include:
1. Face Page with investigator names and contact information.
2. Personal Statement that describes the expertise of the PI and investigative team.
3. Project Title.
4. Project Lay Summary.
5. Project Specific Aims. Be sure to include a well-constructed study question. (1 page maximum)
6. Contact information for 3 external reviewers. The LOI will not be considered for an invitation for a full proposal submission without completion of this section. See details in the template.
7. Total budget amount requested.
8. NIH Biosketch(es) for the PI and <u>all</u> senior Co-investigators.

2. Full Application:
2a. A complete application consists of the following:
1. Face Page.
2. Budget.
3. Budget Justification. Provide a budget and detailed justification for only one year (first year if this is a new application or second year if this is a renewal). If this is a new application, and you expect to request a second year, please include a section at the end of the justification that **briefly** describes the budget for Year 2. Use the subtitle, "If this project is approved for continuation in Year 2." This is not a place to insert a full study plan for Year 2. It is sufficient to briefly state which budget items are expected to remain similar from Year 1 to Year 2. The focus should be on key budgetary changes expected to occur in Year 2 to accomplish the anticipated study plan. As a reminder, Year 2 funding is not guaranteed; it is contingent on demonstrating significant progress in Year 1, as described in the Post Award Conditions, below.
4. PI Biographical Sketch (use current NIH format). Biographical sketches for other key personnel should be included in the Appendix.
5. Resources and Environment (use current NIH format).
6. Research Plan (7-page limit), to include:
   a. Specific Aims.
   b. Background and Significance.   } 7 pages for a-d
   c. Preliminary Studies.
   d. Experimental Design and Methods.
7. Literature cited.
8. Sections 8a and 8b do not count toward the page limit. However, as with NIH grants it is not appropriate to use this section to add preliminary data, methods, or other information that does not fit within the Research Plan.
   a. Human Subjects (if appropriate): Follow the NIH guidelines to describe plans for protection for human subjects; inclusion of women, minorities, and individuals across the lifespan; subject recruitment and retention; and data and safety monitoring.
   b. Animal Care and Use Plan (if appropriate): Follow the NIH guidelines to include information on the species, strain, ages, sex and number of animals to be used; justification for number and number of animals used; plan for veterinary care;

plans for minimizing discomfort, distress, pain, and injury; and methods of euthanasia and reasons for selection.

9. Timeline for current project that includes milestones, deliverables, and future plans for how these results will lead to extramural funding; include names of funding agencies you plan to submit to and a timeline for submission; maximum of 1 page.

10. Appendix: Biographical Sketch for other key personnel. If the PI has a Temporary Faculty Appointment, include a letter from the Department Chairperson and approval from the Vice President for Research.

11. Letter of support from the primary mentor, if the applicant is a fellow, that includes the components outlined in Section 1 above.

2b. Formatting: Font and margin specifications must be followed for the LOI and Full Application. The approved font options include two serif fonts (Palatino and Georgia) and two sans serif fonts (Arial and Helvetica). Font must be 11 points or larger. Use at least one-half inch margins (top, bottom, left, and right). Any figures or tables should use fonts and images that are large enough to read at normal print size.

2c. Routing and approval by Authorized Official: In accordance with OUHSC policy, a SoonerTrack routing form should be submitted **at least three to five full business days prior to the March 18, 2025 grant application deadline**. Applicants are expected to work with their assigned Sponsored Program Administrator (SPA) for review of the application, and to confirm the deadline for routing.

Once the review is complete, the Face Page of the application must be signed by the ORA Official (or equivalent signing official at institutions other than OUHSC) before the PI submits the final application to HHDC.

External Applicants will need to use their own institution's offices for any grant processing, and comply with the March 18, 2025 grant application deadline above.

Applicants who are selected for funding are responsible for getting the approval of the Institutional Review Board, Institutional Animal Care and Use Committee, Radiation Safety Committee and Institutional Biosafety Committee, where applicable. Applicants do not need to submit this information unless it is requested by HHDC. All protocols must be approved by the relevant review committees before funds are awarded.

2d. Submission of the Final Application: Send the final application by e-mail to HHDCGrants@ouhsc.edu no later than **5:00 pm**, on Tuesday, **March 18, 2025.** Please title the application attached to the e-mail: HHDC-SCC NovelPilotProject [PI Last Name, First Name]. **Please submit the application as a single file in pdf format.** Failure to follow these steps could cause your application to be overlooked and not reviewed by the HHDC Grants Review Committee.

Program restrictions
A. The maximum initial project period is 12 months. Support for a second year of the project up to $70,000 will be considered, if funds are available, and the progress report demonstrates successful accomplishment of research goals, development of the project, and significant progress towards submission of a major grant application.

B. The maximum budget request is $70,000 for direct costs only. Each budget item should be carefully justified as necessary for the project. Domestic travel is allowed and includes

travel within and between any of the 50 states of the United States and its possessions and territories and travel between the United States and Canada and within Canada. Publication fees may be included.

C. Funds <u>may not be requested</u> for the following:
1. Clerical support, including office supplies, except those carefully justified as specifically required for research purposes.
2. Office equipment or furniture, laboratory furniture, or therapeutic equipment.
3. Alterations and renovations.
4. Hospital per diem charges.
5. Purchase of books, periodicals, or library services.
6. Foreign travel (any travel outside of Canada and the United States and its territories and possessions).
7. Laboratory equipment costing over $5,000.
8. Indirect costs.

D. Salary and fringe benefits may be requested for OUHSC Principal Investigator(s) up to $25,000 in total (salary + fringe benefits = $25,000). If the proposed project has multiple Principal Investigators, salary and fringe benefits may be split between the OUHSC Principal Investigators. No salary or fringe benefits are permitted for non-OUHSC Principal Investigators, including investigators from OU Norman, OMRF, and other non-OUHSC institutions. Co-investigators are not eligible for salary support.

E. Salary and fringe benefits for research staff, students, postdoctoral research fellows, residents, fellows, and faculty with Temporary Faculty appointments who are not senior/key personnel on the grant are allowed.

F. Any unspent funds must be returned upon termination of the grant.

G. HHDC may allow a no-cost extension if circumstances warrant it. All requests for a no-cost extension must be submitted to the Office of Research Administration **AT LEAST 40 CALENDAR DAYS PRIOR** to the end date of the grant. The submission to ORA must include the HHDC Contract and Budget Modification Request Form and the Progress Report Template.

H. Re-budget requests must be submitted on the HHDC Contract and Budget Modification Request Form to the Office of the Research Administration and approved by HHDC. Any significant change in the budget (e.g., deviation of expenditures in a single category, increase or decrease by 25% or more of the total amount awarded) will require approval from the HHDC.

Review Criteria
The HHDC Grants Review Committee will solicit evaluations of each proposal from two external reviewers and one local reviewer. Outside reviewers will be specifically selected for each application based on their subject matter expertise. Local reviewers will be selected who are not in the same department and do not have a conflict of interest with the project PI. Applicants are required to provide the names of at least three potential outside reviewers in their LOI to help the committee efficiently secure the two required evaluations. However, final selection of the outside reviewers will be made by the HHDC Grants Review Committee. HHDC Grants Review Committee will use the expert reviewers' comments to complete a final evaluation and reach a funding decision.

Reviewers will evaluate the application for scientific merit according to the following criteria:
1. Feasibility and scientific merit.
2. Soundness of the approach and research design.
3. Quality and appropriateness of data analyses.
4. Potential of the research to attract extramural funding upon completion of the project.

Scoring for scientific merit will use NIH Study Section Guidelines. Scientific Priority scores range from 1.0 (highest priority) to 9.0 (lowest priority).

Applicants will receive an NIH-style summary that includes strengths and weaknesses after the review is completed.

Post Award Conditions
A. Grant administration
   Questions about grant administration (e.g., budget modifications, changes in project personnel, extensions) should be addressed to the Sponsored Program Administrator assigned to the PI (find your SPA: https://research.ouhsc.edu/Research-Administration/About-ORA/SPA).
B. Progress reports:
   1. Awardees who request a second year of funding will be required to: a) send a brief notice of intent to continue by the deadline for new letters of intent (currently in January) and, b) submit a revised proposal that includes progress report, a revised research plan, budget, and budget justification for year 2. Proposals for year 2 will undergo full review alongside new proposals.
   2. A progress report is due to HHDC within 30 days of project termination. It is the responsibility of the PI to submit the Progress Report. HHDC will provide a Progress Report template with detailed descriptions for each section to the PI. The report shall include a summary of research results; concise summary of significant discoveries, outcomes and progress in layman's terms; funding that has been secured with the help of HHDC dollars; manuscripts published, submitted, or in preparation; presentations at professional meetings; and any technology development and patents derived from HHDC funds.
   3. Upon request by HHDC, the PI will provide periodic updates about funding that has been secured with the help of HHDC dollars; manuscripts published, submitted, or in preparation; presentations at professional meetings; and any technology development and patents derived from HHDC funds.

C. **New in 2025:** New awardees are required to attend the HHDC Diabetes Research Symposium, held each November at the OUHSC campus, as a requirement for a second year of support. Awardees are highly encouraged to submit an abstract to the meeting by the second year of funding.

Questions:
For questions and/or for special exception of the announcement approval, please contact HHDCGrants@ouhsc.edu.

UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

HAROLD HAMM DIABETES CENTER

LETTER OF INTENT: HHDC-SCC Novel Pilot Grant Program

Contact PI/ Team Leader: _____

PI Title/ Rank: _____

Institution/ College/ Department: _____

Campus Address: _____

Phone: _____

Email: _____

Provide the following for Each Investigator on Project:

Investigator: _____

Title/ Rank: _____

Institution/ College/ Department: _____

Campus Address: _____

Phone: _____

Email: _____

Repeat for each investigator

PERSONAL STATEMENT (Briefly describe why the Contact PI is well-suited for the role(s) in this project and the reason for the application. No more than 250 words):

PROJECT TITLE (200 character limit):

PROJECT SUMMARY (layman's terms, no more than 250 words, 1 page maximum):

SPECIFIC AIMS (1 page, NIH format):

Required: External Reviewer Recommendations. Please provide the name, credentials, and email address of at least 3 external reviewers with relevant subject matter expertise. The list should consist of people who are able to provide an unbiased, objective assessment of the proposal. However, they should not be current or former mentors, collaborators, or trainees of the PI or Co-investigators. External reviewers should be at institutions outside of Oklahoma but within the United States. An example of what is expected is included.

Name	Location	Email	Areas of expertise
Example: Jane Doe, MD, PhD	Department of Physiology, Alaska State University	Doe.jane@alaskast.edu	Mouse models of obesity and diabetes; GLP1-RA treatments

Total Budget Amount Requested: $_____

The following template pages are for full applications only. Use these if your letter of intent is approved and you've been invited to submit a full application.

After the template pages, add blank pages for the remaining pieces of the application as described in the instructions.

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UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER

HAROLD HAMM DIABETES CENTER

HHDC-SCC Novel Pilot Grant Application

Contact PI/ Team Leader: _____

PI Title/ Rank: _____

Institution/ College/ Department: _____

Campus Address: _____

Phone: _____

Email: _____

Provide the following for Each Investigator on Project:

Investigator: _____

Title/ Rank: _____

Institution/ College/ Department: _____

Campus Address: _____

Phone: _____

Email: _____

Repeat for each investigator

PROJECT TITLE (200 character limit):

PROJECT SUMMARY (layman's terms, no more than 250 words, 1 page maximum):

_____   _____
Signature of Principal Investigator   Date

_____   _____
Signature of ORA Official   Date

<u>BUDGET</u>

PERSONNEL For personnel who will be paid from the grant, list % time effort, salary, fringe benefits, and total. For people who will not be paid, list % time effort.

Name/Position	% Effort	Salary	Fringe Benefits	Total

EXPENDABLE SUPPLIES (Separately list items such as biochemicals, glassware, and animal purchases):

TRAVEL (Travel will be reimbursed at actual and reasonable expense):

OTHER COSTS (Include payments to study participants, animal per diem and housing costs, if applicable):

TOTAL COSTS (Not to exceed $70,000) $_____

BUDGET JUSTIFICATION: