

# BETA CELL BIOLOGY CONSORTIUM

## 2008 PILOT AND FEASIBILITY PROGRAM



**Definition:** The Pilot and Feasibility Program provides research support for a limited time (one or two years) to enable eligible investigators to explore the feasibility of a concept related to the mission of the Beta Cell Biology Consortium (BCBC) and generate sufficient data to pursue it through other funding mechanisms. The pilot and feasibility studies are intended to: (1) allow exploration of possible innovative new leads or new directions for established investigators in stem cell biology, developmental and regenerative biology of the pancreas and beta-cell replacement therapeutic strategies; and (2) stimulate investigators from other fields of science to lend their expertise to research in these areas. Pilot and feasibility study support is not intended for large projects by established investigators which would otherwise be submitted as separate research grant applications.

The NIH allows federal funding for research using human embryonic stem cells (hESCs) and an NIH registry for hESC lines has been established. The BCBC will support efforts in the characterization of these hESCs as they relate specifically to the differentiation of islet cell types, in particular, pancreatic beta cells. Pilot and feasibility studies through the Consortium are required to specifically list the hESC line (refer to <http://escr.nih.gov/>) that will be used in the study, submit an MTA without reach through restrictions. Additional information on the use of hESC lines is available at: <http://stemcells.nih.gov/index.asp>.

**Requirements:** Projects are restricted to \$100,000 annually in direct costs for up to 2 years. All recipients of these funds will be required to sign an agreement that outlines rules for the sharing of information and reagents before any funds will be dispersed. Recipients will also be required to attend the semiannual meetings of the BCBC. The sharing agreement is available for review at <http://www.betacell.org/pilot/>.

**Eligibility and related guidelines:** Investigators eligible for pilot and feasibility funding generally fall into three categories: (1) new investigators without current or past NIH research support as a principal investigator, (2) established investigators with no previous work in beta cell biology who wish to apply their expertise to a problem in this area, and (3) established investigators in beta cell biology who propose testing highly innovative ideas that represent a clear departure from ongoing research interests. All eligible investigators must have faculty appointments and be independent investigators. Postdoctoral fellows or their equivalent are not eligible. Each pilot and feasibility study proposal should state clearly the justification for eligibility of the investigator under one of the above three criteria.

A proposed pilot and feasibility study should present a testable hypothesis or alternatively, a strong scientific rationale for the development of an essential reagent, assay, or innovative technology that would advance the development of therapeutic strategies for beta-cell replacement therapy or restoration of beta-cell mass in situations of type-1 diabetes or severe type-2 diabetes. The proposal should clearly delineate the questions being asked, detail the procedures to be followed, and discuss how the data will be analyzed. It must be on a topic related and complementary to the mission of the BCBC (see <http://www.betacell.org>). Areas of research particularly relevant to the current effort of the consortium include, but are not limited to:

- production of human beta-cells for cell replacement strategies,
- beta-cell regeneration and regulation of beta-cell mass,
- small molecules or secreted factors controlling beta-cell fate or beta-cell regeneration, or
- non-invasive imaging of beta-cell mass *in vivo*.

Projects should be highly focused since funding for these studies is modest and is limited to two years or less. Any one investigator is eligible only once for this support, unless the additional proposed pilot and feasibility study constitutes a real departure from his/her ongoing research. Please direct any questions or comments about this program to the NIDDK Program Director whose contact information is below.

**Application:** PHS 398 forms should be used for submitting a pilot and feasibility study. Each project should begin with a face page, abstract, and budget pages, which should be followed by information requested in Sections 2 through 14 of the research plan (<http://grants1.nih.gov/grants/funding/phs398/phs398.pdf>) for the PHS 398. It should be submitted generally using the NIH research project application format, but the description of the proposed research (sections 2-5) should be limited to five pages. All applications should be submitted no later than September 30, 2008. Instructions for electronic submission of a complete PDF document will be available at <http://www.betacell.org/pilot/> by August 1, 2008.

**Review and funding procedure:** The scientific merit of the application will be determined by a primary review involving either current BCBC participants, external advisors, or other scientists chosen by the NIDDK. An assessment of programmatic relevance and funding decision will be made by the Principal Investigator of the BCBC Coordinating Center together with NIDDK staff. The review is expected to occur by October 31, 2008 with funding initiating on or shortly after that date.

Funding for these projects will be provided via a subcontract from the BCBC Coordinating Center at Vanderbilt University. It is anticipated that five to eight projects will be funded via this mechanism depending on budget, indirect cost rate, scientific merit, and programmatic relevance. All expenditures will be subject to standard NIH guidelines for subcontracts. Applicants should budget accordingly for the required travel.

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