UF | UNIVERSITY of FLORIDA

Health Center Institutional Review Board

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MEMORANDUM

DATE: May 1, 2015

TO: Mark A. Atkinson, Ph.D.
Box 100275

FROM: R. Peter Iafrate, Pharm.D.
Chair, IRB-01

SUBJ: IRB Protocol #51-2013 **Expires on 04/27/2016**

TITLE: EXPEDITED/BANK: THE NETWORK FOR PANCREATIC ORGAN DONORS WITH DIABETES

Expedited re-approval of this research project with your consent form was granted on **04/27/2015**. Your re-approval period is from **04/27/2015** to **04/26/2016. Enclosed is the dated, IRB-approved Informed Consent Form which must be used for enrolling subjects into this project during this time period**.

You are responsible for obtaining renewal of this approval prior to the expiration date. Re-approval of this project must be granted before the expiration date or the project will be automatically suspended. If suspended, you may not do any of the following: (1) enroll or screen any new subjects, (2) perform any study interventions, unless the IRB finds that it is in the best interest of individual subjects to continue participating in research interventions or interactions, (3) collect, use, or report any data, and/or (4) receive any study funding.

The IRB has approved exactly what was submitted. Any change in the research, no matter how minor, may not be initiated without IRB review and approval, except where necessary to eliminate hazards to human subjects. If a change is required due to a potential hazard, that change must be promptly reported to the IRB.

Any (a) serious and unexpected adverse events and (b) unanticipated problems involving risk to subjects or others, must be reported to the IRB, in writing, within 5 working days.

Upon completion of the study, you are REQUIRED to submit a summary of the project to the IRB office.

RESEARCH RECORDS must be retained after completion of the research. Researchers must comply with the longest applicable standard according to current institutional policies. UF & Shands researchers must retain research records for a minimum of three years or longer depending if any of the following are involved: HIPAA, medical treatment, patents, or contractual language with a sponsor. For research involving the VA records must be retained indefinitely until VA regulations establish a shorter retention period. Lastly, research data is the property of the institution and you must comply with all institutional requirements before destroying, copying, or transferring any research data. Additional information is available at: http://irb.ufl.edu/irb01/data.html (item number 4).

If VAMC patients will be included in this project, or if the project is to be conducted in part on VA premises or performed by a VA employee during VA-compensated time, you must obtain approval from the VA Research and Development Committee before initiating the research.

You are responsible for notifying all parties about the re-approval of this project, including your co-Investigators and Department Chair. If you have any questions, please feel free to contact the IRB-01 office at (352) 273-9600.

Cc: IRB File
VA Research Center
Clinical Research Center