UF Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board

FWA00005790

PO Box 100173
Gainesville FL 32610-0173
Tel: (352) 273-9600
Fax: (352) 273-9614

MEMORANDUM

DATE: July 12, 2013

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

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

EXPIRES: Tuesday, July 01, 2014

SUBJECT: EXPEDITED IRB #51-2013

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

You have received IRB approval to conduct the above-listed research study. Approval of this study was granted on July 1, 2013. Enclosed is the dated, IRB-approved Informed Consent Form that must be used for enrolling subjects into this project from July 1, 2013 through June 30, 2014. This study is approved as expedited as it poses minimal risk and is approved under the following expedited category/categories:

Expedited #3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings, if collected in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth, if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane before or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylatic scaling of the teeth and the process is accomplished in accordance with accepted prophylatic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

You are responsible for applying for renewal of this study prior to the expiration date. Re-approval of this study must be granted before the expiration date, or the study will automatically be suspended. If suspended, new subject accrual must stop. Research interventions must also stop unless there is a concern for the safety or well-being of the subjects. You MUST respond to the Continuing Review questions within 90 days or your study will be referred to the Board for termination.

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.

If applicable, only a qualified clinician may be responsible for study-related healthcare decisions.

Any severe and unanticipated side effects or problems and all deviations from federal, state, university, or IRB regulations must be reported, in writing, within 5 working days.

Upon completion of the study, you are REQUIRED to submit a summary of the study and a Study Closure report 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 study, or if the study is to be conducted in part on VA premises or performed by a VA employee during VA-compensated time, review by the VA Research Development Committee is required.

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

cc: IRB file / VA Research Center / Clinical Research Center