UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

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DATE: 3/21/2016

TO: Mark Atkinson
1275 Center Drive
Gainesville , Florida 32610

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

IRB#: **IRB201600029**

TITLE: The Network for Pancreatic Organ Donors with Diabetes

Approved as Expedited	**Expires on: 3/17/2017**

You have received IRB approval to conduct the above-listed research project. Approval of this project was granted on 3/17/2016 by IRB-01. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

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 subgingival 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 prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.]

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). [Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. (45 CFR 46.101[b][4].) This listing refers only to research that is not exempt.]

Approval Includes, but is not limited to:

Dated and watermarked IRB-approved Informed Consent Forms:

- Addendum 2 Donor Risk Assessment PI Version dated 05/15/2013
- Addendum 1 Consent for the Donation of Anatomical Gifts PI Version dated 05/15/2013
- ICF Deceased Donor PI Version 05/15/2013

Consent Waiver Type(s):

Modification of Informed Consent	Written Informed Consent is obtained in a non-standard way, e.g. delaying written informed consent

Approval of Continuing Review of IRB study #51-2013 as a converted study

Principal Investigator Responsibilities:

The PI is responsible for the conduct of the study. Please review these responsibilities described at:
http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html
Important responsibilities described at the above link include:

- Using currently approved consent form to enroll subjects (if applicable)
- Renewing your study before expiration
- Obtaining approval for revisions before implementation
- Reporting Adverse Events
- Retention of Research Records
- Obtaining approval to conduct research at the VA
- Notifying other parties about this project's approval status

Study Team:

Irina	Kusmartseva	Study Coordinator
Todd	Brusko	Co-Investigator
Clive	Wasserfall	Co-Investigator
Mingder	Yang	Study Coordinator