Health Center Institutional Review Board
FWA00005790

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DATE: 2/1/2019
TO: Mark Atkinson
1275 Center Drive
Gainesville, Florida 32610
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01
IRB#: **Continuing Review for IRB201600029**
TITLE: The Network for Pancreatic Organ Donors with Diabetes

Approved as Expedited: Continuing Review	**Expires on: 2/10/2022**

On 1/31/2019, the IRB re-approved you to continue conducting the above-listed research project. **The new approval period is 2/10/2019 through 2/10/2022.** This study is approved as expedited because it poses minimal risk and is approved under the following expedited categories:

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings, if collected in a non-disfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth, if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); 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; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane before or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 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 non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Approval Includes:

Dated and watermarked IRB-approved Informed Consent Forms (Deceased, Addendum 1, and Addendum 2)**.**

Consent Waiver Type:
Modification of Informed Consent
Written Informed Consent is obtained in a non-standard way,

e.g. delaying written informed consent

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:

Todd	Brusko	Co-Investigator
Michael	Clare-Salzler	Co-Investigator
Xu	Zeng	Other
Maria	Beery	Study Coordinator
Harry	Nick	Co-Investigator
Clive	Wasserfall	Co-Investigator
Mingder	Yang	Study Coordinator
Irina	Kusmartseva	Study Coordinator
William	Clapp	Other
