**Health Center Institutional Review Board**
FWA00005790

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DATE: 1/2/2018
TO: Abhilash Koratala
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GAINESVILLE , Florida 326100224
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01
IRB#: **IRB201702864**
TITLE: Real-time Kt/V tracking profile as a predictor of dialysis access recirculation

| **Approved as Expedited** | **Expires on: 12/26/2020**<br>**Discretionary Policy in Effect** |
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You have received IRB approval to conduct the above-listed research project. Approval of this project was granted on 12/26/2017 by IRB-01. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are generally not eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate to the age, weight and health of the individual.

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, but is not limited to:**

Protocol

**Consent Waiver Type(s):**

**Waiver of Documentation of Informed Consent**

The researcher will still inform the potential subject about the research and seek to obtain consent, sometimes by including an IRB approved written statement that includes the mandatory elements of consent. However, consent of the subject is not documented by having the subject sign an Informed Consent form.

**HIPAA Waiver Type(s):**

to enroll subjects in the 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

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