



APPROVAL

June 21, 2017

Ramona Nicolau-Raducu
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Dear Dr. Ramona Nicolau-Raducu:

On 6/21/2017, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Fluid Management and Blood Pressure in Kidney Transplant Patients: A Multicenter Observational Study
Investigator:	Ramona Nicolau-Raducu
IRB ID:	20170399
Funding:	None
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none"> •Fluid BP protocol in KTx (2) (2).docx •List of Variables to be collected (1).docx

The IRB approved the study from 6/21/2017 to 6/20/2020 inclusive. The study is approved with a waiver of informed consent and a waiver of HIPAA authorization. Before 6/20/2020 or within 45 days of the approval end date, whichever is earlier, you are to submit a completed Continuing Review to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 6/20/2020 approval of this study expires on that date.

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system. If your study indicates JHS as a performance site, as the PI, you must ensure that you have been granted permission by the JHS Clinical Research Review Committee (CRRC) prior to commencing study activities at JHS. Such approval is reflected

by receipt of a JHS CRRC Approval Letter. If you have any questions regarding this process, please contact the JHS Office of Research at 305-585-7226.

Should you have any questions, please contact: Karen Legagneur, IRB Specialist, (phone: 305-243-7786; email: kx1566@med.miami.edu)

Sincerely,

*[This is a representation of an electronic record
that was signed electronically and this page is
the manifestation of the electronic signature]*

Khemraj (Raj) Hirani, MPharm, Ph.D., RPh, CCRP, CIP, RAC, MBA
Associate Vice Provost for Human Subject Research

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