Scott & White Institutional Review Board
Federalwide Assurance #FWA00003358
IRB Registration #IRB00000706

Notification of IRB Action

To: Kirill Lipatov, MD

cc: Susan Seago, MD; OSRA

Project ID: 160281

Title: Early oral feeding in ICU patients with diabetic ketoacidosis.

Level of Review: Expedited
Expedited Review Category: 45 CFR 46.110(b)(1)(5)

Date of Action: 12/14/2016

Type of Action: Approval

Approval Period: 12/14/2016 to 12/13/2017

Continuing Review Deadline: 11/13/2017*

***You are responsible for ensuring IRB approval is obtained for the continuation of your project by submitting the required progress report and supporting documentation by the continuing review deadline.**

Items Reviewed: Submission reference #: 056901

Submission Components			
Form Name			**Outcome**
Initial Review Submission Form			Approved
Review Response Submission Form			Acknowledged
Application, Version 1.2			Approved
Study Document			
Title	**Version Number**	**Version Date**	**Outcome**
Datasheet	Version 1.1	N/A	Approved
Protocol	Version 1.2	08/01/2016	Approved

Waiver of consent/authorization: The IRB has waived the requirement for informed consent based on 45 CFR 46.116 (d). The IRB has 1) waived the requirement for authorization based on 45 CFR 164.512 (2) (ii) and 2) determined the use of existing protected health information is necessary to do the research. Moreover, the IRB has waived the requirement for authorization to use decedent protected health information based on 45 CFR 46.164.512 (i) (1) (iii).

Investigator Responsibilities:

- Conduct the study according to the currently approved protocol, institutional policies, and all applicable regulations
- Obtain approval from the IRB of any changes in the research prior to implementation except where necessary to eliminate apparent immediate hazards to human subjects. Such urgent changes must be reported to the IRB within five (5) working days.
- Personally supervise or conduct the research and ensure appropriate delegation of tasks
- Maintain complete and accurate study records and make them available for inspection
- Notify the IRB Office of any external inspections of the research
- Report unexpected adverse outcomes to the IRB within five (5) working days of knowledge of each occurrence
- Assume responsibility for initial and continuing review of the research by the IRB

IRB Responsibilities:

- Review and have authority to approve, require modifications in or disapprove all research activities
- Ensure all requirements for approval of research are satisfied in accordance with federal regulations
- Report any serious or continuing non-compliance by investigators to the appropriate institutional officials, the Office for Human Research Protections, the Food and Drug Administration and any other appropriate regulatory agencies
- Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- Determine that all criteria for IRB approval of research are met as stipulated in the federal regulations
- Require that information given to subjects as part of informed consent is in accordance with federal regulations
- Conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year, including the authority to observe or have a third party observe the research

Signature applied by Tracy Troxell on 12/14/2016 09:36:00 AM CST

Authorized Representative of the Scott & White IRB