THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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To: Maria Ferris
UNC Kidney Center

From: Biomedical IRB

Approval Date: 1/22/2017
Expiration Date of Approval: 2/21/2017
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Modification
Expedited Category: Minor Change to Previously Approved Research,4.Noninvasive clinical data,7.Surveys/interviews/focus groups
Study #: 07-0352

Study Title: Successful Transition to Adulthood with Therapeutics (STARx)

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

We are adding Miranda van Tilburg to the personnel for this study.

Investigator's Responsibilities:

If applicable, your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=07-0352.

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Coretta Jenerette, School of Nursing
Eniko Rak, Allied Health Sciences
Miranda van Tilburg, Medicine-Gastroenterology
Yi Zhong, Economics