Yale University

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To:	Marc Auerbach, M.D.
From:	**Yale Institutional Review Board**
Date:	12/21/2016
Committee Action:	**Exemption Granted**
IRB Action Date:	12/21/2016
IRB Protocol #:	1612018709
Study Title:	Fluid Administration with LifeFlow vs Push/Pull.

Educational Research Conducted in Educational Settings. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:i) research on regular and special education instructional strategies, orii) research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods

Exempt studies do not require annual IRB review. Modifications to exempt research do not need a formal IRB review unless the proposed revision affects the exempt status of the protocol. Such changes may include, but are not limited to, addition of collection of identifiers when the original protocol included anonymous data only, addition of children or prisoners as study subjects, or addition of procedures that could potentially increase risk to subjects. See the Exemption Guidance (100 GD9) for more information and examples.

Whenever an exempt protocol is modified (regardless of the type of change), updated versions of all research documents affected by the change must be sent to the IRB Office for the file. Revisions to the documents must be tracked. Changes that do not require IRB review will not be acknowledged formally.

Investigators are also required to promptly report any unanticipated problems or complaints to the IRB.

Statistical Plan:

A sample size of 8 teams per group was calculated from a published abstract to detect a 3 ml/sec improvement in the rate of fluid administration (power=0.08, alpha 0.05). Nine teams per group (total of 27 teams) were enrolled due to concerns about the study functioning per protocol. Descriptive data are shown as median (interquartile range) and mean (SEM). The distributions of the outcome variables were normal and results from parametric tests are presented. Differences between 2 groups were also evaluated by comparison of median and mean differences with their associated 95% confidence intervals (CIs). Comparisons involving 3 groups were made with 1-way ANOVA or Kruskal-Wallis tests. Correlation was calculated as a Pearson coefficient. Categorical variables were analyzed with the 2 tailed tests. A P .05 was considered to be significant throughout. All data analysis was completed using SPSS (IBM Corp. Released 2011 IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp).