FIRST TRIAL POST-RANDOMIZATION FREQUENTLY ASKED QUESTIONS

Additional details available at www.TheFirstTrial.org

QUESTION: How many programs are participating in the FIRST Trial?
ANSWER: 154 hospitals (118 programs) are enrolled in the FIRST Trial. Overall, 91% of eligible hospitals are participating.

QUESTION: How long does the trial run?
ANSWER: The trial runs through the 2014-2015 academic year. However the waiver runs for two years: 2014-2015 and 2015-2016 academic years. Data collection will continue until June 30, 2016.

QUESTION: What outcomes are being measured?
ANSWER: We will be comparing clinical outcomes (e.g., morbidity, mortality, length of stay) and resident perceptions/wellbeing. Details are available at www.TheFirstTrial.org

QUESTION: When can we expect results from the FIRST Trial?
ANSWER: We hope to have results in early spring 2016. We would hope that this would result in an ACGME policy change in time for the 2016-2017 academic year.

QUESTION: Will an interim analysis be conducted?
ANSWER: Yes, we will conduct an interim analysis in January 2015 that will be reviewed by our Data Safety Monitoring Board. Results will not be released publicly.

QUESTION: Will programs be required to submit duty hour logs and rotation schedules?
ANSWER: Yes, but we are still determining the exact process for this. We will be in touch soon with details, but we are committed to making this process as easy as possible for programs.

QUESTION: What else will programs have to do for the FIRST Trial?
ANSWER: There is not much else that you will need to do. We will survey the residents during the ABSITE with a standard ABS ABSITE survey vetted by the ABS Board of Directors. We will also ask Program Directors/Coordinators to fill out a brief survey in July 2014 and June 2015.

QUESTION: Are any of the data identifiable with respect to patients, residents, or hospitals?
ANSWER: No patients, residents, or hospitals will be identified publicly in any way including publications, presentations, or websites. The data being analyzed will have no patient or resident identifiers and will be HIPAA compliant. The hospital names are only used so we know to which study arm your hospital was assigned. We will not disclose publicly which hospitals are in the intervention arm vs. the control arm.

QUESTION: Does the FIRST Trial address the intern supervision rule?
ANSWER: No. Based on feedback from the ACS, ABS, ACGME, and APDS, we have not addressed the supervision rule. This study is focused on duty hour requirements, no supervision issues. We can imagine undertaking such a study in the future.