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: Which hospitals are covered by the ACGME waiver?
ANSWER: The ACGME waiver applies to all hospitals where your residents rotate. All affiliate, children's, VA, county, etc. hospitals are covered by the ACGME waiver. Your residents follow the intervention arm rules no matter where they go. The ACGME will send you the official waiver in mid April 2014.

QUESTION: Are programs in the intervention arm required to make all of the changes specified on the table of suggested changes?
ANSWER: No. Many common duty hour requirements have been eliminated, and we have suggested ways to revise your resident schedules and policies; however, you are not required to implement all of these changes. You can also change your resident schedules and policies throughout the year as needed. We will be asking you to report what changes have been made, and we will be monitoring what changes have been made. We would like your program to make the suggested changes, but those decisions are entirely up to you.

QUESTION: A Hospital receives residents from two different residency programs. Which rules do they follow?
ANSWER: From the information you provided about where residents rotate, there was only one instance where this would be a problem. If there is an overlap, please notify us and we will work through it with you and the ACGME. The ACGME has extended a lot of latitude to programs in this study, so there should be no problem no matter which rules are followed at that Hospital.

QUESTION: What do we do if residents from other specialties (i.e., orthopedics, OB/Gyn, Anesthesiology, Emergency Medicine) or other hospitals (i.e., visiting residents) are on a general surgery rotation with flexible duty hours (intervention arm)?
ANSWER: To ensure uniformity in patient care, non-general surgery and visiting residents will be subject to the same duty hour requirements (intervention or control arm) that are applied to general surgery residents when rotating on general surgery services. Residents from other specialties and hospitals will be subject to the same duty hour requirements while rotating on a general surgery service. It is recommended that in these situations program directors reach out to discuss these changes with their fellow program directors in other specialties/programs to explain the duty hour changes that these residents may face during their general surgery rotation.
In June, you will be asked to provide the ACGME a list of all other programs at your hospital and a list of other hospitals that send you residents. The ACGME will use this list to ensure that these residents are covered by the flexible duty hours and the ACGME waiver for intervention arm hospitals.

QUESTION: We have an integrated Vascular Surgery residency program. Can our vascular residency program participate?

ANSWER: No. Only General Surgery residency programs can participate. However, if your General Surgery residency program is randomized to the flexible duty hours arm, then integrated Vascular Surgery residents will follow the flexible duty hours while they are rotating on General Surgery services. The same applies for any other integrated residencies (e.g., cardiac, plastics, etc.). Even when your general surgery residents rotate on the Vascular Surgery Service, they can abide by the Intervention Arm's flexible duty hour requirements.

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 and no supervision issues. We can imagine undertaking such a study in the future.

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: 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: 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.