September 2014

Dear Program Director,

Please find attached updated information on the iCOMPARE trial studying two different duty hour schedules in Internal Medicine training programs.

1. Executive Summary
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3. Participant Responsibilities
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Please visit iCOMPAREstudy.com for additional information and to contact us directly.
EXECUTIVE SUMMARY

iCOMPARE is randomized trial of two duty hour regimens in graduate medical education.

**Rationale:** Policy limiting duty hours in graduate medical education training programs has become a central point of debate amongst stakeholders. Evidence from human chronobiology and sleep science argues for shorter shifts, because fatigue leads to errors. Evidence from operations research argues for more continuity because patient handoffs also lead to errors, and may reduce the effectiveness of education necessary to produce independent clinicians for the nation’s future. No existing research helps navigate resident duty hour policy between these competing considerations. The goal of iCOMPARE is to provide evidence to help policy makers evaluate whether the duty hour standards that limit consecutive work hours for trainees should be changed.

**Design:**
- The trial focuses on trainees in Internal Medicine training programs, comparing two duty hour regimens:
  - the current standards, which include a 16 hour maximum continuous work period for interns, or
  - a more flexible schedule, constrained by 3 simple rules for all trainees:
    - 80 hours maximum duty per week*
    - 1 day off in 7*
    - In-house call no more frequent than q3 nights*
    - averaged over a 4-week period
- iCOMPARE uses a single-year randomized design, which means that each program will be assigned randomly to one of the two duty hour regimens. The trial interventions will occur between July 2015 and June 2016.
- This design parallels the FIRST trial in surgery, conducted from July 2014 to June 2015, which is looking at duty hour regimens among surgical trainees.
- The ACGME has granted waivers of duty hour standards for participating programs from July 2015 to at least June 2019. The waivers extend to trainees from other specialties that include rotations in Internal Medicine (e.g., Emergency Medicine).
- Outcomes will be measured in patient safety and trainee education.
- Outcome data will be derived from both existing sources, including Medicare claims, ACGME and APDIM surveys, and ACP in-training examination scores, as well as trial-specific beginning and end of year surveys.

**Recruitment:** Eligible programs include ACGME accredited Internal Medicine training programs which meet criteria for program size, patient volume, and patient population. Programs can check eligibility and complete a brief application by visiting iCOMPAREstudy.com.

**Further information:** The study is led by investigators at the University of Pennsylvania, Johns Hopkins University, and the Brigham and Women’s Hospital/Harvard Medical School.

iCOMPARE is likely to have an immediate influence on residency training policy. Participation in this study is an opportunity for program directors to be involved in these efforts. Duty hour regulation has transformed graduate medical education in ways that are well-meaning, but not evidence based. iCOMPARE will add evidence to the resident duty hour debate.
ELIGIBILITY AND PROGRAM SELECTION

ELIGIBILITY:
iCOMPARE is designed to measure differences across a broad set of outcomes, requiring the inclusion of sufficient numbers of trainees and patients. Eligible programs will meet the following inclusion criteria:

1. Sufficient presence of residents in their hospital(s):
   → Affiliation with hospital(s) in top 50% of resident to bed ratio (R:B ratio > 0.105)
2. Sufficient numbers of trainees:
   → Programs in the top 75% by trainee size (> 36 trainees)
3. Sufficient volumes of Medicare fee for service patients with diagnoses in which mortality is being measured (for a list of included diagnoses, please see the website):
   → Affiliation with hospital(s) in the top 75% of relevant Medicare patient volume (> 439 patients annually)
4. Ability and willingness to meet obligations of participation (see next section)

SELECTION:
• We estimate that approximately 200 programs meet the eligibility criteria.
• Please visit iCOMPAREstudy.com to apply. Preliminary eligibility is determined by using externally collected data on program size and patient mix which may not be up to date. If your program is not listed as eligible, and you are interested in volunteering, you can request an individual assessment of your program eligibility using data you provide directly. We encourage you to indicate this on our website.
• Programs can apply to participate on the website until 30 Sep 2014. Applications will be reviewed on a rolling basis starting in mid-August. Programs that are selected for iCOMPARE will be notified and asked to seek DIO approval. Programs that have submitted DIO approval will be assigned to one of the two duty-hour regimens beginning in September.

ACGME WAIVERS:
The ACGME has approved waivers of duty hour standards for the programs who enroll in iCOMPARE for from July 2015 through at least June 2019, or until action is taken on the duty hour policies. The waivers extend to all trainees that rotate through participating Internal Medicine programs (e.g. Emergency Medicine, Medicine-Pediatrics).
PARTICIPANT RESPONSIBILITIES

A. The Participating Program will:
1. Have continued accreditation status by the ACGME.
2. Be willing to commit to the study procedures for the full year.
3. Receive institutional permission from the DIO to participate.
4. Develop duty hour schedules that adhere to the arm to which they are randomly assigned:
   a. “control”—adherence to current 16h duty hour limits (current standards)
   b. “intervention”—3 rules:
      i. 80 hours maximum duty per week*
      ii. 1 day off in 7*
      iii. In-house call no more frequent than q3 nights*
           * averaged over a 4-week period
5. Provide iCOMPARE with a template of the assigned schedule.
6. Provide a list of all trainees with their hospital contact information for AY2014-15 and AY2015-16.

B. Program Directors and Trainees will complete:
FREQUENTLY ASKED QUESTIONS

1. **What is the duration of duty hour waivers?**
   The ACGME has approved to duty hour waivers to participating programs from July 2015 through at least June 2019, or earlier if ACGME action is taken on the policy.

2. **What will be required of the program?**
   The work required by the program we believe is minimal. We will need a contact list for all trainees (to send surveys) and a copy of the control and intervention schedules.

3. **How and when will I know if my program can participate?**
   Programs can check their eligibility at iCOMPAREstudy.com. This list is based on public data which may not be complete. If not listed as eligible, we encourage programs to request eligibility assessment by completing a short on-line form.

   Programs can apply to participate on the website until 30 Sep 2014. Applications will be reviewed on a rolling basis starting in mid-August. Programs that are selected for iCOMPARE will be notified and asked to seek DIO approval. Programs that have submitted DIO approval will be assigned to one of the two duty-hour regimens beginning in September.

4. **Do I have to go through the IRB at my institution?**
   There is a possibility of IRB exemption for this study that is being explored. If IRB review is required, the University of Pennsylvania IRB has agreed to be the IRB of record for all of the enrolled programs. Individual Internal Medicine training programs may choose to use the Penn IRB for that purpose and we expect that most will. However, if individual sites prefer to use their own IRB, we will support that process with templated forms and materials.

5. **What are the consent procedures?**
   Programs will complete an agreement form with DIO approval to participate. Programs will inform their applicants of the program’s participation in iCOMPARE during the AY2015-2016 recruitment season. Trainees participating in iCOMPARE will consent by completing the study surveys.

6. **If I am in New York State where IPRO duty hour limits are in place, can I participate?**
   No. The IPRO limits of 27h will not change and therefore New York programs will not be eligible.

7. **To which level of trainee does the intervention apply?**
   The intervention applies to ALL trainees, PGY 1-3.
8. **What will happen to the external rotators in my program from other specialties?**
   All external rotating trainees (e.g. Emergency Medicine) must adhere to the study schedules. The ACGME has provided waivers for all such trainees in participating institutions.

9. **If our residents rotate in multiple hospitals, are we required to adjust schedules at all sites?**
   You can use the schedule at all of the hospitals through which your trainees rotate. However, data will only be collected from hospitals that meet criteria for data collection. The iCOMPARE investigators can identify those hospitals in your program for you. For every hospital in which data will be collected, the study schedules must be used.

10. **If our residents rotate at a hospital that hosts residents from more than one program, can that hospital be included?**
    It depends. It can be included for data collection if all the programs included agree to participate. Also, all the programs at one hospital will be randomized to the same duty hour schedule for operational feasibility. Each of these situations will be considered individually by the iCOMPARE team and the programs involved.

11. **Can I include the VA where my residents rotate?**
    Data from VA hospitals will not be included in the trial outcomes, however programs can use the study schedules at VA hospitals.

12. **Do I have to implement the new schedule in all of the rotations?**
    We prefer that all rotations adhere to the study schedule to which the program is randomized. However, we also recognize this will not always be possible.

13. **Is it mandatory to include ICUs in the study?**
    It is preferred but not mandatory.

14. **Can I get help making schedules for my program?**
    Yes, the iCOMPARE team will be available for consultation in developing schedules and will be able to share ideas across participating programs.

15. **How much effort will it take for my trainees to participate?**
    It should be minimal. The interns and residents will adhere to schedules created by the program for the assigned duty hour schedule arm and will also be asked to complete two surveys during the year. One survey will be given as a baseline in June 2015 and one at the end of the year in June 2016.

16. **What should I explain to applicants during recruitment for interns starting in 2015 and 2016?**
    All applicants to participating programs must inform applicants of participation status and randomization scheme. The iCOMPARE team will provide enrolled programs with a standard informational document to share with all of their applicants.
17. What are the benefits to my program?
   Programs will benefit by having direct involvement in informing issues central to the US healthcare system—the training model of our physicians, which is a core tenet of professionalism and practice-based improvement.

18. Will this study affect national policy?
   We believe this study will have direct implications on national policy. The ACGME has declared support for the trial and is encouraging programs to participate.*

19. Who is directing the study?
   iCOMPARE investigators are collaborating from the University of Pennsylvania, Johns Hopkins University and the Brigham and Women’s Hospital. The Clinical Coordinating Center is based at the Perelman School of Medicine at University of Pennsylvania and the Data Coordinating Center is based at the Bloomberg School of Public Health at Johns Hopkins University.

20. Can we participate as a military (Non-VA) hospital?
   No unfortunately. We are only able to capture data from Medicare patients.