**BACKGROUND**

The IRB review and approval process has long been criticized for delaying the initiation of clinical trials. Metrics generated by the Mayo Clinic Center for Translational Science Activities’ IRB Telephone in 2009 recognized the Mayo Clinic–IRB’s highest IRB review time of the 37 participating institutions.

Mayo Clinic and Yale University collaborated on the following initiatives to further examine the speed of IRB reviews and process:

- **Primary Focus:** Identify and describe process improvements implemented at Mayo in a quality improvement project.
- **Secondary Focus:** Identify and compare process improvements implemented at Mayo to be applied at Yale.

The summary data collected from the 2009–2011 period was used to evaluate the effectiveness of the redesigns of processes that were implemented at Mayo and to consider how they might be applied at Yale.

**METHODS**

**Primary Focus**

1. Collect and compare data pertaining to the completion time of the types of protocols requiring review by a fully convened IRB. **Figure 1**

2. Compare IRB turnaround times for two multicenter trials with the same FDA number. **Figure 2**

3. Map IRB processes to determine similarities and gaps. **Figure 3**

4. Identify and discuss key process improvement initiatives.

**Secondary Focus**

- Analyze the quality of the IRB application for the studies reviewed by the Mayo IRB.

- Conduct focus groups with the research community to determine areas of the IRB application that were difficult to review.

**ANALYSIS AND RESULTS**

**ANALYSIS**

**Primary Focus**

- The time required for regulatory review was collected and analyzed through May 2011.
- Feedback from the focus groups resulted in revision of the four areas of the IRB application that the Yale IRB most frequently required revisions of research teams.
- Each requested revision was correlated with the question on the application that the IRB office and primary reviewer just prior to the fully convened IRB reviewing the protocol.

**METHODS**

**Secondary Focus**

- Each requested revision was correlated with the question on the IRB application for the Mayo clinic.

- Out of almost 200 inquiries sent to research staff requesting revisions or clarifications, four areas of the IRB application were found to be predominant areas of concern:

- Members of the Yale research community were invited to participate in focus groups concentrating on the four areas of the IRB application.

- **Lessons Learned.**

- Both institutions have comparable work flows and knowledgeable staff.

- Mayo Clinic’s quality improvement initiatives, similar to the application of the same methodology to the resources available to them at relatively small costs. A rapid-cycle quality-improvement project provides a model for quick and efficient quality improvement.

**REFERENCES**