April 4, 2014

Dear Colleagues,

For the past year, the Committee on Human Research (CHR) has been working with Fabrice Beretta from the CTSI's Planning, Evaluation & Tracking unit applying a Lean Six Sigma process to identify ways to streamline the CHR's new study application and review processes for Full Committee and minimal risk (e.g. Expedited Review) research.

The overall goals of the CHR project are to reduce the amount of work effort required from the CHR staff, CHR committee members and Chairs, and the research team by simplifying application forms, improving the quality of submissions, identifying and eliminating non-value-added work, and improving coordination between the committees and the Principal Investigator.

This project coincides with a larger campus-wide Office of Research strategic initiative to reduce the lead time from clinical research protocol identified to first patient discharged (currently an average of 129 days). The clinical research onboarding project includes parties from all of the main stakeholders involved in study initiation, including:

- Office of Research
- Ethics and Compliance
- Clinical Research Informatics Support Services (CRISS)
- CTSI Clinical Research Services (CRS)
- UCSF Medical Center
- UCSF departmental research program managers

CHR's Planned Initiatives

Over the coming months, the CHR will implement a number of changes designed to improve the new study submission and review process. These changes include:

- Reducing the time permitted for response to requests for changes (April 2014)
- Reducing pre-review screening delays by establishing **minimum submission standards** (May 2014)
- "Fast Track" to CHR review for well-prepared applications, which will go straight to a full committee meeting agenda. Under Fast Track, the PI must be available for questions by phone during the meeting (pilot February-May 2014)
- Release of a new social/behavioral research (SBER) study application (June 2014)
- Improving and simplifying the biomedical research study application form (June-July 2014)
- Improving coordination between the committees and the research team (Pilot February-May, 2014)

Expected Outcomes

As a result of these project initiatives, by mid-2015 we expect to achieve:

- Reduced work for research staff, CHR staff, and IRB members
- 50% reduction in the average number of submission rounds required for Full Committee study approval (from 4.5 to 2.25 rounds)
- 50% reduction in the days from Full Committee study submission to review at a convened CHR committee meeting (from 52 to 26 days)
- Significant reduction in average times to approval for new Full Committee and Expedited Review research, currently 78 days for Full Committee research and 56 days for Expedited Review.

Details about each of the initiatives will be provided in individual CHR bulletins as they are rolled out. More information, including details about the project and results of the data analysis, are available on the CHR Lean Process Improvement Project website.

We want to thank you for your cooperation and support during the transition time. The contact person for the project is Liz Tioupine. As always, please feel free to contact me directly if you have any questions or concerns about this project.
Sincerely,

Elizabeth Boyd, PhD
Associate Vice Chancellor, Ethics and Compliance