U Medical School dean: We're making progress on research reform

Counterpoint: There are no shortcuts, and we are taking the necessary steps to implement the changes.

By Brooks Jackson   FEBRUARY 24, 2016 — 6:14PM

Last July, the University of Minnesota Board of Regents approved a plan to reform the university's research practices, particularly research involving human participants. We made a commitment to fully implement these reforms by June 2016, and we are on track to meet that goal.

This is a top priority for the U. In health care, our commitment is to our patients. Research involving human participants plays a vital role in delivering new treatments and cures, but the most important factor in the design and implementation of any research is patient safety. Minnesotans depend on the U to be part of tackling the most difficult health issues, from cancer or Alzheimer's to infectious disease or mental health. Our promise to Minnesota is not only to conduct this important research but also to operate using best practices and at the highest ethical standards.

The external review that we commissioned last year and the report from the legislative auditor showed we were not living up to the standards we had set, so we developed a comprehensive plan to get better. That implementation plan is guiding our current efforts.

One step in the implementation plan is to transfer management of clinical trials in the Department of Psychiatry to the University's Clinical and Translational Science Institute (CTSI), which has particular expertise in clinical research. To understand the necessary staffing and steps to manage these trials, CTSI commissioned an analysis of the department's studies. That review was initiated last summer and was presented to the Board of Regents earlier this month. Not surprisingly, the report echoes many of the findings of earlier reports, and it helped clarify some of the areas that are most in need of oversight. Our critics claim the report proves our reform efforts are failing (“U research lapses show self-reform is failing,” Feb. 19). In reality, the report is an important step toward our goal.

It's true that our work is not yet complete. More than 60 recommendations came out of our review process last year. The reforms we're making are urgent, but they also must be undertaken in a manner that ensures success. Today we are just more than halfway through our implementation timeline, and much important work is ahead. While some may want us to jump right from the starting gate to the finish line, true reform requires intentional steps along the way. There are no shortcuts.

The U has been transparent about progress on the implementation plan. We issue monthly reports to the Legislature (see http://advance-har-alerts.umn.edu). Over the last seven months significant, concrete steps have been taken:

• All interventional drug trials in psychiatry were suspended pending re-review of ethics and study design by Quorum Review IRB. New applications continue to be reviewed by Quorum pending full implementation of the recommendations.

• Compass Point Research reviewed 100 random studies, including in psychiatry, to assess compliance with institutional regulations and best practices.

• The head of the Psychiatry Department has stepped down, and we are searching for a new leader for the department.

• We have increased monitoring in the Psychiatry Department, specifically, and through the institutional review board both to work with investigators on best practices and to ensure compliance.

• The Psychiatry Department has endorsed the plan to transfer management of clinical
trials to CTSI, including requirements for new training and oversight.

- The U has prohibited recruitment of psychiatry patients who are on a 72-hour hold.

- The IRB has made significant changes in the number of members, level of expertise, and the quality of the documentation to ensure more rigorous and timely review of studies.

- Faculty in the Center for Bioethics developed new coursework entitled "Standards for Research with Human Participants," and the center has hired staff to ensure appropriate and ongoing training for investigators and research staff.

This is just a partial list of the work that we have completed; much work remains. While some steps are concrete, such as developing an electronic monitoring system to better track clinical research, others will require ongoing education, communication, monitoring and culture change.

Effective reform takes time and sustained effort. U leadership — including President Eric Kaler, the Board of Regents and me — are committed to this work and are investing the time and resources to get it done right. We are addressing the fundamental issues in order to build a program that will be a leader in protecting participants while at the same time conducting important research that improves people's lives. That is our goal and we know that the people of Minnesota expect nothing less.

Brooks Jackson is dean of the University of Minnesota Medical School.