



# Compliance TODAY

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SEPTEMBER 2018

**Strengthening the  
relationship between  
DOJ attorneys  
and compliance  
professionals**

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an interview with  
**Michael D. Granston**



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by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

# 4th and long or 1st and 10

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**I**t's been a year since my life was turned upside down. In that time, my research compliance life has been the only part of my life that is somewhat normal. Every day has presented me with new challenges and some chaotic times. Your life as a research



Willenberg

compliance professional is probably very similar. You need to be on both the offensive and defensive sides to manage the research playbook.

One forward pass that is not yet certain is the revised Common Rule, which has been postponed yet again. According to Laura Odwazny, a Senior Attorney

with the U.S. Department of Health and Human Services, who spoke at the Research Compliance Conference in Austin last June, the goal of the update was to provide three burden-reducing provisions. These include: (1) a revised definition of "research"; (2) eliminating Institutional Review Board (IRB) review of certain funding proposals and grant applications; and (3) no continuing review for certain low-risk research, unless an IRB requires it.

How will you "move the ball" *if* and *when* these changes happen? Will you view these changes as a touchdown or a fumble? It may be extremely hard to put the changes in place.

Lisa Murtha, a Senior Managing Director at Ankura, provided a "Research Year in Review" in Austin as well, which outlined FDA and NIH regulatory updates, new research-related enforcement initiatives, and settlements. As a research

compliance community, we all need to strengthen our review of changes annually. With research fraud allegations on the rise, more and more grant management questions, and a review of the CMS system used to pay Medicare Advantage Organizations on the radar, you need a knowledgeable research compliance officer as your quarterback. Provide support for optimization as you prepare for kickoff continually.

Artificial intelligence and security will likely put points on the scoreboard that we are not even considering today.

What does 2019 mean for research compliance? There will certainly be rookies who bring our attention to new challenges that we have not considered. Artificial intelligence and security will likely put points on the scoreboard that we are not even considering today. Not all of us will score a touchdown in our daily work! Think about your challenges and what you have to offer, and consider putting in a submission for speaker consideration at the 2019 Research Compliance Conference. Submissions are being accepted now through September 30<sup>th</sup>. As a team member on the research gridiron, do not look at your career as a 4<sup>th</sup> and long, but rather each day as a 1<sup>st</sup> and 10! 🏈