

## Report on Research Compliance Volume 15, Number 2. February 28, 2018

### Planning Done, Indiana U. to Apply Some New Common Rule Provisions

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By Theresa Defino

After years of planning, Indiana University was “ready to flip the switch” on changes to its human subjects protections program to comply with the revised Common Rule published in January 2017. Then, like the rest of the world, on Jan. 17 of this year—two days before the compliance deadline—IU officials learned that the government was imposing a delay of at least six months (see story, p. 1).

Regardless of the delay, IU plans to take advantage of some of the burden-reducing options for its non-federally funded research, such as new categories of exempt studies and being able to forgo continuing institutional review board review (IRB) for some studies.

IU had been preparing to comply with changes in a revised Common Rule from the time it was in the draft stages (*RRC 3/16*, p. 7). And it decided early on that, delay or no delay, it would move forward with changes in its non-federally funded research, according to John Baumann, IU associate vice president for research compliance.

### Process Sparked Emotional Roller Coaster

Baumann first described the development of IU’s implementation plans for the final revised Common Rule at a conference in November sponsored by PRIM&R. He updated his remarks and IU’s plan for *RRC*. IU’s experiences may prove instructive to institutions as they consider ways to move forward in light of the delay, as well as afterward when compliance is required.

Like his compliance colleagues, Baumann has experienced a range of emotions during the long process leading up to the interim final rule.

“My first reaction was clear panic,” he said, referring to the Sep. 2015 proposed rule. “The idea [was] that the sky is falling and everything is changing; everything we knew to be true was no longer true and God knows what we’re going to do about it. My second reaction was, well, maybe it’s not such a big deal. Maybe, actually, some of the changes that are being talked about or are being required are just an extension of what we’re already doing so it’s not really a major change,” said Baumann.

He added that his third and final reactions, respectively, were ones of “negotiation” and “a bit of acceptances,” along the lines of two other stages of grief defined by Elizabeth Kübler-Ross.

When the new interim final rule calling for a delay until July 19 was published, Baumann felt a resurgence of those early feelings, with “relief and frustration battling each other.” The interim final rule didn’t fulfill his hope that the effective date would remain Jan. 18 but that the compliance date would be delayed. Instead it harmonized both dates to July 19.

In planning and executing implementation of the revised Common Rule, IU is striving to accept the “new reality we’re facing” and to assume “responsibility to adapt to it in the best way that fits both our institution’s culture

and environment, as well as the general principles” embodied in the regulations, Baumann said.

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