



ACADEMIC MEDICAL CENTER-INDUSTRY ENGAGEMENT PROJECT WORKING WITH INDUSTRY LEARNING MODULE SERIES COMPLIANCE

Following are transcripts of the videos that are part of the learning module.

Slide #6

William Pierce

Compliance and conflicts of interest are considerations that will always be with us as we have interactions with the government and the academy and the private sector industry. A lot of times compliance is considered to be drudgery, and sometimes that's correct, but most of the time it's there to protect people from negative unintended consequences.

You can access this video at: <https://vimeo.com/203183961/3872436485>

Slide #30

Anantha Shekhar

The biggest thing to remember for a clinician is that there are very specific guidelines as to what one should do. So, for example, any kind of direct income, whether it's for actually doing the research, or being a consultant on a research protocol, or any other activities that involve financial transaction between an industry and a physician, it has to be completely disclosed. Now, of course the industry is also expected to disclose that through the Sunshine Act, so the fact that one receives a check from company X but you didn't report that is no longer going to be acceptable, because it'll be reported in the Sunshine Act, down on the website. So once you disclose that right up front, the second thing that people mistake often is that they sort of think that if you did not receive any money, but provided consultations or provided some kind of guidance, then you don't have to declare a conflict. Well, that's, again, not true. A conflict can be nonfinancial. It could be intellectual; it could be sharing different kinds of downstream credit, etc. So one should disclose those kinds of interactions as well, that they are a consultant without pay, or those relationships, because oftentimes the perception of conflict is the most damaging thing to a credibility. So a disclosed conflict is by far – it immunizes you from any kind of reputational damage.

You can access this video at: <https://vimeo.com/203183625/437c9fff4c>



Slide #32

Mark Breedlove

If you want to deal with industry, my advice to you would be don't be afraid of it. I think in a lot of ways, we've all been kind of conditioned that industry is bad, or you know, you've got to be very, very careful. It's okay to engage in a conversation and understand, that's how innovation happens. That's how great ideas get born. We bring in – together – expertise from academia, and researchers to companies that have a long history of building innovative products and bringing solutions to patients. So don't be afraid of it, number one. The second thing is, there's a process that every manufacturer has to go through when they're providing funds. Take the time to understand that process. It's on everybody's website.

You can view this video at: <https://vimeo.com/203183806/f5fb397241>

Slide #35

It's not a game of "gotcha," it's not a police action--and we have thousands of people in the university who make these disclosures and in reality there are just a few dozen that have to have significant management plans. So it may be a bit of burden but it's not something that stops people from accomplishing what they set out to do.

You can view this video at: <https://vimeo.com/203184016/59bc68a1f8>

Slide #36

Speaker Biographies:

William Pierce: I'm Dr. Bill Pierce, I am the Executive Vice President for Research and Innovation at the University of Louisville. By training I'm a chemist and a pharmacologist and after about 25 or 30 years of doing that and founding a company of my own I was asked by the President to drop that and help other people. And now, as Vice President, that's what I do— help our faculty, and trainees, and students get their research out into the world.

ANANTHA SHEKHAR: I'm Anantha Shekhar, Executive Associate Dean for Research at IU School of Medicine. I'm a professor of medical research and psychiatry and neuroscience, and I'm also the Director of the Indiana Clinical and Translational Sciences Institute.

MARK BREEDLOVE: I'm Mark Breedlove. I'm Vice President and Global Business Unit Leader for Peripheral Intervention at Cook Medical.

You can view this video at: <https://vimeo.com/203183851/dd2b2fafb3>