



NCURATV 2008 Satellite Broadcast Workshop Series

Complex Agreements

Program Schedule

Aired on June 10, 2008

Viewing at KUMC, 1027 Orr-Major

September 24, 2008

9:00 AM – 1:00 pm CDT

Moderator

Geoff Grant, President, Research Advocacy

Faculty:

Michele Codd, Assistant Director, Institute for Software Integrated Systems, Vanderbilt University

Todd Guttman, Associate Vice President for Research, Office of Research Compliance, The Ohio State University

Erica Kropp, Director, Research Administration & Advancement, University of Maryland Center for Environmental Science

Time EST	Segment Time	Main Topic	Key Issues	Supplemental Information
9:00	00:05	Welcome	Kathleen Larmett	
9:05	00:30	Overview of Complex Agreement	<ul style="list-style-type: none"> • Definition of a complex agreement • How has the landscaped changed? • New players • Areas of risk <ul style="list-style-type: none"> ○ Publications ○ Conflicts of interest ○ Disclosure information ○ Protection of information ○ Unsophisticated partners ○ Financial/accounting 	
9:35	00:25	Coordination (<i>Case Study Part 1</i>)	<ul style="list-style-type: none"> • Role of the administrator • Significant others <ul style="list-style-type: none"> ○ OGC ○ Tech transfer ○ IIRB/IACUC ○ Research security ○ Compliance ○ Hospital billing • Standard terms and agreements collaborators 	Georgia Institute of Technology Teaming Agreements http://www.osp.gatech.edu/policies/teaming.shtml Purdue University, Office of the Vice President for Research http://www.purdue.edu/research/vpr/policies/deadlines.shtml
10:00	00:30	Intellectual Property Agreement Issues (<i>Case Study Part 2</i>)	<ul style="list-style-type: none"> • Conflict of interest • Data use agreements • Material transfer agreements • License agreements • Data right clauses • Who owns what? 	NCURA's link of Living Studies in University-Industry Negotiations http://www.ncura.edu/content/regions_and_neighborhoods/resources/docs/studies.pdf The Bayh-Dole Act: A Guide to the Law and Implementing Regulations http://www.cogr.edu/docs/Bayh_Dole.pdf

				<p>Cornell University Law School, Patent Rights in Inventions Made with Federal Assistance http://www4.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html</p> <p>University of Maryland, MTAs http://www.umresearch.umd.edu/ORAA/mta/</p> <p>COGR Data Rights Document http://206.151.87.67/docs/DataRetentionIntroduction.htm</p>
10:30	00:15	<p>Break NCURA Upcoming Events</p>		
10:45	00:05	Welcome Back	Kathleen Larmett	
10:50	00:20	Human Subjects and Animal Use (Case Study Part 3)	<ul style="list-style-type: none"> • Who reviews what? • Assurance agreements • HIPAA/ confidentiality • GWAS • Indemnification • Subject compensation for injury • Multi-sites/clinical trial agreements • Clinical trial billing 	<p>HHS, Office for Human Research Subject Protections (OHRP) http://www.hhs.gov/ohrp/</p> <p>Association for the Accreditation of Human Research Protection Programs, Inc. http://www.aahrpp.org/www.aspx</p> <p>HHS, Office of Laboratory Animal Welfare (OLAW) http://grants.nih.gov/grants/olaw/</p> <p>Association for Assessment and Accreditation of Laboratory Animal Care http://www.aaalac.org/about/index.cfm</p> <p>HHS, Medicare Clinical Trial Policies http://www.cms.hhs.gov/ClinicalTrialPolicies/01_Overview.asp#TopOfPage</p>
11:10	00:30	Export Controls, ITAR, Access Restrictions, Chemical/Bio Security (Case Study Part 4)	<ul style="list-style-type: none"> • Restrictive clauses • No foreign nationals • Proprietary information • Non-disclosure agreements (NDA) • International collaboration 	<p>Export Controls and Universities: Information and Case Studies http://www.cogr.edu/docs/Export%20Controls.pdf</p> <p>ITAR Definition http://en.wikipedia.org/wiki/International_Traffic_in_Arms_Regulations</p> <p>MIT Office of Sponsored Programs: Export Control</p>

				http://web.mit.edu/osp/www/ExportControls/index.htm Stanford University Export Control Decision Tree http://www.stanford.edu/dept/DoR/exp_controls/tree/ National Archives and Records Administration, Electronic Code of Federal Regulations, Title 22- Foreign Relations, Subchapter M, Parts 120-130 http://ecfr.gpoaccess.gov/cgi/t/text/textidx?sid=a5d12a23a5dfe0e4495181703bdae79a&c=ecfr&tpl=/ecfrbrowse/Title22/22cfrv1_02.tpl
11:40	00:15	Break NCURA Upcoming Events		
11:55	00:05	Welcome Back	Kathleen Larmett	
12:00	00:25	Best Practices <i>(Case Study Part 5)</i>	<ul style="list-style-type: none"> • Auditing, account reconciliation and sponsor monitoring • Flow-through provisions in subawards • More extensive debarment and pending litigation representations • Language not appropriate 	NCURA Presentation: Facilitating Large and Complex Proposal Efforts http://www.ncura.edu/content/educational_programs/sites/49/handouts/docs/Tuesday1030/T1030F.PPT
12:25	00:20	Summary and Conclusions		
12:45	00:05	Broadcast Wrap-up	Kathleen Larmett	
12:50	3:30			

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