



The Common Rule: Regulatory Changes

Program Agenda:

- 5:30 – 6:00 pm – Registration & Networking
- 6:00 – 7:00 pm – Educational Presentation
- 7:00 – 7:30 pm – Group Discussion

Program Description: On January 19, 2017, the Department of Health and Human Services (HHS) released a much-anticipated final rule modernizing the protections for human subjects involved in research. Known as the "Common Rule" because it falls under the jurisdiction of several Federal agencies, it differs in key respects from what was proposed. The final rule has an effective date of January 2018, subject to the regulatory review procedures implemented by President Trump on January 29, 2017.

Upon completion of this seminar, attendees should be able to:

- Identify those provisions of the common rule that are on hold pending review and those that are finalized.
- Describe new research subject consent form requirements.
- Describe the changes to consent requirements for future and secondary research.
- Identify the low risk categories of research that will be exempt from the Common Rule.

Target Audience: CRC's, Project Managers, Investigators, Regulatory, Compliance, CRA's, any other research focused personnel.

Speaker: Lorraine Duthe, Esq., Compliance Officer for Kaleida Health, has led the Office of Research and Sponsored Projects for the health system for the past five years.

All Attendee's must register

Date: May 15th 2017

Time: 5:30-7:30 pm

Location: Children's Hospital Lung Center 4th floor Conference Room
140 Hodge Street, Buffalo, NY

Speaker: Lorraine Duthe

Registration Cost:

- \$0 Chapter Members
- \$5 all other attendees

Contact hours: 1.0 Contact hours have been applied for through ACRP. Membership is not required for online registration of contact hours.

To receive contact hours: Purchase the contact hours, sign in at the registration desk, and attend the program. Log on to the ACRP website then "ACRP Learning Portal" to complete the evaluation no later than 30 days following the event and obtain the online certificate.

Contact Hour Cost:

- \$0 Chapter Members
- \$15 ACRP Members
- \$30 Non-Members

Refund Policy: No refunds will be honored unless the program is cancelled by the chapter.

Level: Intermediate