OHRP Educational Workshop Agenda June 6, 2019 Advanced Technology Research Facility (ATRF) Frederick, Maryland		
8:00 – 8:45 a.m.	**Registration**	
8:45 a.m.- 8:55 a.m.	**Welcome and Opening Remarks (FNLCR and OHRP)** **Dr. Leonard Freedman, Chief Scientific Officer, FNLCR**	**10 min**
8:55a.m. – 10:15 a.m.	Module 1: What Changed in the Common Rule OHRP staff will provide an overview of the revisions to the Common Rule: why the revisions came about, what changed, how the revisions impact existing research and research approved under the revised Rule, and what this means for investigators and IRBs. This will be an instructional presentation. There will be time for Q&A. Learning Objectives Attendees will be able to: 1. Describe the major changes made to the Common Rule 2. Explain which studies will need to comply with the revised Common Rule 3. Describe some of the impact of the revisions to the IRB processes for investigators and IRBs **Speaker: OHRP - Jaime Hernandez**	**80 min**
10:15 – 10:30 a.m.	**Break***	**15 min**
10:30 – 12:00 p.m.	Module 2: Research with Biospecimens and Data OHRP staff will engage the audience in the exploration of how the Common Rule impacts research with biospecimens and data. We will help the audience understand our interpretation of common terms used in association with this kind of research, how to make use of the flexibilities in the revised Common Rule to conduct research with biospecimens and data, and what to consider in terms of informed consent and the IRB process. This will be an interactive presentation utilizing polling technology. There will be time for Q&A. Learning Objectives Attendees will be able to: 1. Understand the key terms used in association with research with data and specimens in the revised Common Rule 2. Describe the flexibilities for doing research with data and specimens available under the revised Common Rule 3. Explain the major differences for research with data and specimens conducted under the pre-2018 (“old”) and the revised Common Rule **Speaker: OHRP - Yvonne Lau**	**90 min**

12:00 p.m. – 1:00 p.m.	**L U N C H ***	**60 min**
1:00 p.m. – 2:30 p.m.	Module 3: Facilitating Informed Decision-Making in Clinical Research: Requirements and Flexibilities in the revised Common Rule OHRP staff will provide an overview of the regulatory requirements for informed consent under the revised Common Rule and use clinical case scenario(s) to help the audience consider how informed consent might be improved and what could be done to fulfil the new informed consent requirements. This will be an interactive presentation that engages audience in open discussion. Learning Objectives Attendees will be able to: 1. Describe the changes related to informed consent under the revised Common Rule 2. Understand OHRP's rationale behind the key changes to the informed consent document under the revised Common Rule 3. Explain how the key new requirements for informed consent for clinical research could be met **Speaker: OHRP - Misti Anderson, Yvonne Lau**	**90 min**
2:30 – 2:45 p.m.	**Break***	**15 min**
2:45 - 3:45 p.m.	***Other Topics: Certificates of Confidentiality and OHSRP (NIH) Perspective; Open Discussion*** **Speaker (s): Elonna Ekweani, Public Health Analyst, Office of Science Policy (NIH); Dr. Jonathan Green, OHSRP (NIH)**	**60 min**
3:45 – 4:00 p.m.	**Final Q&A**	**15 min**

* Own arrangement

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