

Advisory Committee on  
Organ Transplantation(ACOT)

March 13, 2015

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Office for Human Research Protections  
Office of the Assistant Secretary for Health  
Department of Health and Human Services

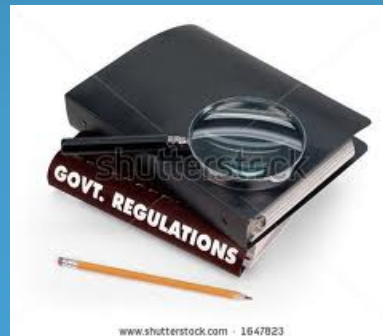
# Outline

- OHRP Mission
- OHRP Organization
- Office of the Director
- Division of Compliance Oversight
- Division of Education and Development
- Division of Policy and Assurances

# Office for Human Research Protections (OHRP)

## Mission

- Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS), in accordance with the HHS protection of human subjects regulations, 45 CFR part 46.



# Office for Human Research Protections (OHRP)

## Mission, Con't

- By providing clarification and guidance, developing educational programs and materials, and maintaining regulatory oversight.



## OHRP Organization

- Office of the Director
- Division of Compliance Oversight
- Division of Education and Development
- Division of Policy and Assurances

## Office of Director

Jerry Menikoff, MD, JD, Director

- Secretary's Advisory Committee on Human Research
  - Provides technical and logistical support to SACHRP
  - Director serves as the Executive Secretary for SACHRP
  - SACHRP advises the HHS Secretary on issues of human subject protections

## Office of Director

Jerry Menikoff, MD, JD, Director, con't

- Provides training to institutions involved in international research, to help ensure that ethical protections are afforded to those who participate in research outside the U.S.



# Division of Compliance Oversight (DCO)

Kristina Borrer, PhD, Director

- Evaluates written substantive indications of noncompliance with HHS protection of human subjects regulations, 45CFR part 46.
- Typically asks involved institution to investigate the allegations and provide OHRP with written report.



## Division of Compliance Oversight (DCO)

Kristina Borrer, PhD, Director, Con't

- OHRP then determines what, if any, regulatory action needs to be taken to protect human subjects.
- Conducts on-site evaluations at research institutions, either in response to indications of possible serious non compliance or on a not-for cause basis.

Division of Education and Development  
Yvonne Lau, MBBS, MBHL, PhD, Director

- Conducts national and regional conferences
- Provides guidance to individuals and institutions conducting HHS-supported human subjects research
- Participates in professional, academic, and association conferences and meetings

## Division of Education and Development

Yvonne Lau, MBBS, MBHL, PhD, Director, Con't

- Develops and distributes resource materials in an effort to improve protections for human research subjects
- Helps institutions assess and improve their human research protection programs through QI consultations.

# Division of Policy & Assurances

## Irene Stith-Coleman, PhD, Director

- Prepares policies and guidance documents and interpretations of requirements for human subject protections
- Disseminates this information to the research community



# Division of Policy & Assurances

Irene Stith-Coleman, PhD, Director, Con't

- Coordinate appropriate HHS regulations, policies and procedures within HHS and with other federal agencies
- Administers the Assurances of Compliance , Federalwide Assurances (FWA), process
- Implements the Institutional Review Boards Registration process

