OHRPP Updates

February 14, 2019

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- OHRPP Staffing Announcement
- Revised Common Rule
- Expansion of ability to use Commercial IRBs
- FDA regulations update

OHRPP Staffing Announcement

NEW Assistant Director, Education and Quality Improvement:

Moore Rhys

Education & Training:

- **Including Investigator training and CITI online coursework**
  http://ora.research.ucla.edu/OHRPP/Pages/EducationTraining.aspx

Quality Improvement:

- **Including Post approval reports and on-site reviews**
  http://ora.research.ucla.edu/OHRPP/Pages/EducationTraining.aspx

Revised Common Rule Updates

- **UCLA OHRPP Human Research News – Sent to campus February 12, 2019**
  - Transitioning Projects to the 2018 Revised Common Rule
  - Continuing Review
  - **NEW Annual Principal Investigator (“PI”) Assurances for Eligible Studies**
  - Exempt Determinations and Limited IRB Review
  - Broad Consent
  - Grant Congruency Review
  - Commensurate Protections for Research that is not Federally Supported
  - **NEW** General Requirements for Informed Consent – Key Information Summary
  - **NEW** Basic and Additional Informed Consent Requirements
  - **NEW** Investigator Responsibility: Consent Form Posting

RCR Updates – Annual PI/FS Assurances

- **January 2019 Human Research Policy Board approved process for studies that no longer require continuing review**
- **To be completed by the Principal Investigator and Faculty Sponsor (as applicable)**
- **webIRB processes are in development – we will provide demonstration at future RAF meeting.**
- **Overall, studies that do not require continuing review will still need the PI/FS to login to webIRB annually to assure:**
  - The study remains ongoing;
  - No changes were made to the research that were not submitted to the IRB in advance of implementation;
  - No reportable events (PARs) took place that were not reported to the IRB.

Revised Common Rule Updates

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See details in January 2019 RAF presentation

- http://www.research.ucla.edu/ora/training/documents/Jan-19/RAF-2019-01-OHRPP.pdf

Expansion of Ability to use Commercial IRBs

- **January 2019 Human Research Policy Board approved expansion beyond industry-sponsored research, at the discretion of the OHRPP Director.**
  - Example: NIH multi-site study where UCLA is primary awardee.

- **OHRPP is working on revising guidance and the website – Updates will be provided at future RAF meetings.**

FDA Regulations Update

- **Proposed Rule for Waiver Guidance on IRB Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.**
  - Comments period closed February 13, 2019.

- **It appears that the FDA is moving to harmonize with the DHHS regulations; more information appears to be coming by mid-year (likely with a NPRM/comment period)**

Questions?

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UCLA Office of the Human Research Protection Program (OHRPP)