Research Protections (RP) / Education and Quality Improvement Program (EQUIP) Unit:
Laverne Estanol, Jessica Sheldon, Vickie Langille

UCI Revised Common Rule webpage:
https://research.uci.edu/compliance/human-research-protections/researchers/2018-common-rule-requirements.html

OHRP FAQs:

REVISED COMMON RULE
Implementation Provisions for Federally Supported Studies

NIH
NOT-OD-19-050
1/2/19

OHRP DRAFT GUIDANCE
45 CFR 46.101(i)
1/10/19
NIH POLICY: NOT-OD-19-050

**EXCEPTION**

45 CFR 46.101(c - i)

FEDERAL DEPARTMENT OR AGENCY SUPPORTING THE STUDY RETAINS FINAL DETERMINATION ON WHETHER AN ACTIVITY IS COVERED BY THIS POLICY

**REQUIRE COMPLIANCE WITH THE REVISED FEDERAL POLICY ON 1/21/19**

- NON-EXEMPT STUDIES CONDUCTED/SUPPORTED BY HHS (ADOPTED 45 CFR 46), INITIATED ON / AFTER JANUARY 21, 2019
- ONGOING STUDIES THAT VOLUNTARILY TRANSITION TO THE REVISED FEDERAL POLICY

**ACTIONS THAT REQUIRE TRANSITION**

*action directly supports the conduct of human subjects research activities*

- NEW (possibly also a Fellowship award)
- RENEWAL
- SUPPLEMENTS (possibly Diversity award)
- FLOW-THROUGH TO UCI (a New, or a Renewal)

**NOT AN ADMINISTRATIVE ACTION**

- Resource-Based awards (Training, Program, Center) generally are not used for the conduct of human subjects research activities
  
  **EXCEPTION (requires transition):** Pilot Funding, Seed Funding

- Federally supported non-exempt Human Subjects Research protocols given an A3 Extended Approval require a short IRB check-in every 3 years (usually occurs with Training awards)

- Supplements (Administrative award)
- Modifications
- Flow-Through (Continuings)
- Continuings: not applicable (NIH no longer requires)
- No Cost Extensions (an extension of the award period)
**Timeline 1: General Mechanics of the Transition Provision**

**Beginning of Delay Period**
- All studies must comply with the pre-2018 Requirements.

**Exception:** An institution may voluntarily elect to transition a study or studies to the 2018 Requirements.*
  - During the delay period, these transitioned studies comply with the pre-2018 Requirements + the three burden-reducing provisions of the 2018 Requirements.

**General Compliance Date of the 2018 Requirements + End of Delay Period**
- All studies initiated on or after this date **must** comply with the 2018 Requirements.
- All studies transitioned to the 2018 Requirements during the delay period must comply with the entirety of the 2018 Requirements on and after this date.
- On and after this date, all other ongoing studies must comply with the pre-2018 Requirements unless an institution voluntarily elects to transition the study to comply with the entirety of the 2018 Requirements.

* If an institution wishes to take advantage of the three burden-reducing provisions of the 2018 Requirements during the delay period the institution must first determine (and the IRB or institution must document) that a study or set of studies will transition to comply with the 2018 Requirements. As described above, during the delay period, studies that have transitioned to comply with the 2018 Requirements must comply with the pre-2018 Requirements + the three burden-reducing provisions of the 2018 Requirements. On and after January 21, 2019, those transitioned studies must comply with the entirety of the 2018 Requirements.