Dear Cal State LA Community:

The Department of Health and Human Services’ Office of Human Research Protections (OHRP) issued final revisions to the Federal Policy for the Protection of Human Subjects (a.k.a. the "Revised Common Rule") on January 18, 2017. The compliance date will be January 20, 2019, which means that the majority of changes will go into effect on that day.

These changes to the Revised Common Rule will affect all research institutions that conduct human subjects research in the United States. Therefore, Cal State LA is announcing significant changes and important dates in order to facilitate the transition to the Revised Common Rule.

Note: For additional details about the content below, click on the blue links. As always, the most current information is available on the Office of Research, Scholarship, and Creative Activities IRB website.

What Will Change With the Revised Common Rule

- **New and Revised Definitions** (§46.102)
  - New Definitions
    - Clinical Trials, Identifiable Biospecimens, Public Health Authority, and Written or In Writing
  - Revised Definitions
    - Human Subject, Research, Intervention, and Legally Authorized Representative

- **Revised Vulnerable Populations** (§46.111)
  - Removed “pregnant women”
  - Replaced “handicapped or mentally disabled persons” with “individuals with impaired decision-making capacity”
  - Added “economically or educationally disadvantaged persons”

- **New and Revised Categories of Exempt Research** (§46.104)
  - Revisions to Exempt Categories
    - New restrictions have been added to the exemptions – only taste and food quality study exemption remains the same
    - Certain exemptions will allow for the inclusion of vulnerable populations
    - Some exempt research will require “limited IRB review”
  - New Exempt Categories
    - Research involving benign behavioral interventions in conjunction with the collection of information from adults
    - Secondary research uses of identifiable private information or biospecimens
    - Broad Consent (exempt categories 7 and 8) is not being adopted by Cal State LA at this time

- **Full Board/Expedited Applications**
  - Consent Process (§46.111) – Updated with additional elements of consent. The Cal State LA consent form template will reflect these new elements.
Continuing Review for IRB-Approved Studies (§46.109) – Continuing review will no longer be required for some minimal risk research, including studies that have progressed to the point that they involve one or both of the following:
  - Data analysis, including analysis of identifiable private information or biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Expedited to Exempt
  - Some current expedited studies may qualify for an exempt category at the time of continuing review.
  - Some proposed research that would have required expedited review may now qualify for an exempt category.

Single IRB (sIRB) (§46.114(b)) The Revised Common Rule added the requirement that institutions within the United States that engage in cooperative/multi-site research must rely upon approval by a single IRB for research that is conducted in the U.S.A. The compliance date for this part of the regulations is January 20, 2020.

What Will Change at Cal State LA

- **IRB Applications** – On December 12, 2018, we anticipate the rollout of the IRBNet Smart Forms, which will only be used for application submission under the Revised Common Rule. Smart Forms are fillable online forms that will replace the current Word document application format. Features and anticipated benefits to investigators include:
  - Investigators will always be using the most recent application
  - Creates an individualized checklist of all IRB-required documents
  - Move easily from one type of application to another, if needed

- **For Existing IRB-Approved Studies**: No immediate action will be required. However, if continuation is needed, investigators will be notified with further instructions. If investigators plan to modify their existing IRB-approved study, see “Applications Under Review” below.

- **For Applications Submitted or Under Review**:
  - **Before December 12, 2018**: These IRB applications must be approved before January 18, 2019. If the review process extends beyond January 20, 2019, the application will need to be converted to the Smart Forms to be in compliance with the Revised Common Rule.
  - **On or After December 12, 2018**: These IRB applications will be submitted using the Smart Forms and will only be approved after January 20, 2019.

Note: The IRB submission process will not change. Applications will still need to be submitted through IRBNet and will be reviewed in the order received.
**Workshops**

- **IRBNet Smart Forms:**
  - Thursday, November 29, 2018, 3:00 – 5:00 PM, Student Affairs Room 110
  - Wednesday, December 5, 2018, 3:00 – 5:00 PM, Administration Room 313

- **IRB Revised Common Rule Process:**
  - Monday, November 26, 2018, 3:00 – 5:00 PM, Administration Room 313
  - Tuesday, December 4, 2018, 3:00 – 5:00 PM, Administration Room 313

**If you have questions, please contact:**

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