REVISED COMMON RULE

TRANSITION PLAN

SUMMARY OF TOP 7 NEW ELEMENTS

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

OHRP FAQs:
Research will continue to follow the pre-Common Rule and/or FDA rule

*NOTE:* Research must transition to the 2018 Common Rule and/or FDA rule if a protocol is (or will be) associated with new or renewal federal funding awarded on/after January 21, 2019 (opt to submit an eMOD or a new eAPP application)

All research, regardless of funding/support, will follow the 2018 Common Rule and/or FDA rule

Research approved on / after January 21, 2019

Research approved * prior to January 20, 2019

Research will continue to follow the pre-Common Rule and/or FDA rule
1. Obtains information or biospecimens, or

A living individual about whom an investigator conducting research:

2. Obtain, use, study, analyze, generate identifiable private information or identifiable biospecimens

HUMAN SUBJECTS

Scholarly / Journalistic activities

Public Health Surveillance

Activities performed for/by a criminal justice agency

NOT HUMAN SUBJECTS RESEARCH

Reduces regulatory burden
normal educational practices not likely to adversely impact students’ opportunity to learn

criteria iii specifies that an IRB can conduct a limited review for studies in which identifiable information is obtained/recorded

research involving benign behavioral interventions with adult subjects, in conjunction with the collection (verbal, written, data entry, audio/visual recording) of information is permitted with prospective consent and at least one of three additional criteria are met ★

secondary research for which consent is not required is permitted if at least one of three additional criteria are met ★

A Limited IRB Review is performed at an IRB Expedited Subcommittee meeting by an IRB Chair or an IRB Chair-designee.

DETERMINATION OF NON-EXEMPT HUMAN SUBJECTS RESEARCH

1. **Is it research?**
   - Yes → **Does it involve human subjects?**
   - No or Activities deemed not to be research → **STOP**

2. **Does it involve human subjects?**
   - Yes → **Is it exempt?**
   - No → **STOP**

3. **Is it exempt?**
   - Yes - Does it involve exemptions 2(iii), 3(i)(C) → **Require limited IRB review that exemption conditions are satisfied**
   - No → **STOP**

Legend: New to the revised Common Rule
3. IRB REVIEW OF RESEARCH

CONTINUING REVIEW IS NOT REQUIRED

Research is limited to only: data analysis, or accessing follow-up clinical data (performed as part of clinical care)

Research received Limited IRB Review

Research eligible for expedited review

Reduces regulatory burden
4. CRITERIA FOR IRB APPROVAL

- Removes **pregnant women** and **handicapped/mentally disabled** as a vulnerable population
- Specifies **individuals with impaired decision-making capacity and economically/educationally disadvantaged** as a vulnerable population
- Include adequate provisions to protect privacy of subjects and the confidentiality of data

*Reduces regulatory burden*
Any institution engaged in an **NIH** cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the US

★ Reduces regulatory burden
• **New Requirement:** Begin with a concise and focused presentation of the key information that facilitates comprehension

• **New Flexibility:** Investigator may obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility without informed consent of prospective subject (note: HIPAA must be addressed, as applicable)

• **New Requirement:** When a clinical trial has reached the status of *closed to recruitment*, posting one IRB-approved clinical trial consent form is required for a clinical trial supported by a federal department
7. DOCUMENTATION OF INFORMED CONSENT

Key information is presented first

INFORMED CONSENT

Research that targets a distinct cultural group where a signed consent is not the norm, the IRB may waive written consent when: research is minimal risk, and there is another mechanism for documenting consent★

★Reduces regulatory burden
8. TRANSITION IMPLEMENTATION

Efficiency 1: Re-evaluation of Level of Review

Efficiency 2: Elimination of Annual IRB Review ★

Consent Requirement 1: Key Info

Consent Requirement 2: One New Basic Element

Consent Requirement 3: Three New Additional Elements

Consent Requirement 4: One New Criterion for Waiver of Informed Consent

TRANSITION TO 2018 COMMON RULE

Transition Checklist:

★ Except Expedited research regulated by FDA or supported by DOJ
New Limitation: not likely to adversely impact students' opportunity to learn

New Flexibility: **criteria iii** allows research where disclosure outside the research would place subject at risk

New Limitation: **criteria iii** subject must authorize use of deception permitted via prospective consent

New Flexibilities:
1) research involving benign behavioral interventions with adult subjects
2) **criteria C** allows research where disclosure outside the research would place subject at risk

New Flexibilities:
1) information or biospecimens do not need to be “existing” at time of IRB application
2) identifiers may be recorded
3) consent not required (note: HIPAA authorization must be addressed, as applicable)

New Limitation: **criteria iii** PHI cannot be disclosed outside of UCI Health

A **Limited IRB Review** required to ensure adequate provisions to protect privacy & confidentiality
10. TRANSITION IMPLEMENTATION

KEY INFORMATION

1: Research is voluntary

2: Purpose, expected duration, and procedures

3: Risks & Discomforts

4: Benefits to participants or society

5: Alternative procedures or treatments, if any
11. TRANSITION IMPLEMENTATION
NEW CONSENT ELEMENTS

Basic Element: Notice about whether information and biospecimens collected as part of the current research might be stripped of identifiers and used for future research

Additional Element: Statement that the subject’s biospecimens may be used for commercial profit and that subject will not share in this commercial profit

Additional Element: Statement regarding whether clinically relevant research results, will be disclosed to subjects, and if so, under what conditions

Additional Element: Research involving biospecimens, whether the research will or might include whole genome sequencing

Consent Checklist: https://research.uci.edu/forms/docs/irb-checklists/checklist-informed-consent.docx
New Criterion: When identifiable private information or identifiable biospecimens collected, IRB must determine that the research could not practically be carried out without using the information/biospecimens in an identifiable form.