UCI Office of Research

Common Rule Changes Ahead in 2018:
EXEMPT RESEARCH

For the first time since it was issued in 1991, the Common Rule — the set of federal regulations for ethical conduct of human-subjects research — has been updated. Most of the new requirements, many of which increase flexibility and reduce administrative burden are *anticipated*[1] to start on January 19, 2018. We believe the changes will provide efficiencies for the research community and for the human research protections program.

Here's What You Need To Know:

- The 2018 exempt research categories have been revised and expanded. There are now 8 categories.
- At UCI, lead researchers (and faculty sponsors if applicable) will be allowed to self-determine some exemption. There are exceptions where UCI IRB confirmation will be required.
- Exceptions to exempt self-determination include:
  - Research with children as a subject population
  - Department of Justice supported research
  - Research where subjects may be identified and there is a reasonable risk to the subject based on information collected during the research
  - Research involving HIPAA
  - Research involving the storing, maintaining and secondary research use of private information and identifiable biospecimens
- An Exempt Self Determination Tool will be released January 19, 2018. The tool will be similar in format to the Non-Human Subject Research Determination Form.
- Exempt research will be confirmed either by lead researchers (and faculty sponsors, when applicable) or the IRB staff.
- Lead researchers (and faculty sponsors, when applicable) can renew their exempt research every 3 years. An abbreviated, 'Short' Continuing Application can be submitted to the IRB for a quick renewal of the research.

Exempt Categories for 2018:

Category 1: ***Revised*** to state that research involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Category 2: ***Revised*** to allow data collection to include audio and video recording. Also identifiable information can be collected. The regulations require that limited IRB review be conducted in such instances. Note: This category still only allows for passive observation of children.

Category 3: ***Replaced*** to include benign behavioral interventions (brief in duration, harmless, painless, not invasive, not offensive or embarrassing). Also will allow for the information collected to be identifiable. The regulations require that limited IRB review be conducted in such instances. The category is for adult subjects only. Also deception is allowable when subjects are prospectively consented in advance (aware that research involves a level of deception).

Category 4: ***Revised*** to include secondary research use of identifiable private information or identifiable biospecimens. No consent is required as long as 1 of 4 criteria are met (e.g., publically available information, information recorded such that subjects cannot be readily ascertained). Information or biospecimen collection allows for both retrospective and prospective collection. HIPAA may apply.

Category 5: ***Revised*** to allow research supported by a federal agency (not just conducted) to qualify for exemption.

Category 6: ***Unchanged*****.** Allows for taste and food quality evaluation and consumer acceptance studies if certain criteria are met. This category is very uncommon at UCI.

Category 7: ***NEW*** to include the **storage** of identifiable biospecimens and identifiable private information. The regulations require that limited IRB review be conducted. Broad consent is required.

Category 8: ***NEW*** to include the **secondary analysis** of identifiable biospecimens and identifiable private information. The regulations require that broad consent for the storage, maintenance, and secondary research use was obtained and that limited IRB review be conducted.

[1] In October the Office of Human Research Protections requested a one-year delay in the implementation of the revised Common Rule. The request is under consideration by the Office of Management and Budget.