IMPLEMENTATION OF NEW COMMON RULE

☐ DEFINITION OF RESEARCH

- Not scholarly and journalist activities (e.g. oral history, journalism, biography, literary criticism, legal research, historical scholarship), including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.

☐ EXEMPT RESEARCH CATEGORIES REVISED/NEW CATEGORIES

- A1-Research conducted in established or commonly accepted educational settings, that specifically involves normal educational that are not likely to adversely impact students' opportunity to learn required educational content or the assessments of educators who provide instruction.
- A2-Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior.
- A3-(NEW)-Research involving benign behavioral interventions in conjunction with collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information of collection.
- A4-Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable bio-specimens.
- A5-Public benefit and service programs research and demonstration projects.

☐ EXPEDITED REVIEW

- No continuing review of expedited research unless the IRB has a reason to require it and can justify that reason
- No continuing review for projects conducting data analysis only
- Expedited categories of IRB review will be annually evaluated by the Research Integrity Office

☐ CONTINUING REVIEW

- Continuing Review no longer required* for:
  - Research approved by expedited review

- Research interventions completed and only involving:
  - Data analysis, including identifiable private information or identifiable biospecimens
- Accessing follow-up clinical data from clinical care procedures

☐ INFORMED CONSENT

- New required element of consent required for collection of identifiable info or identifiable specimens. Whether or not identities are removed, the consent must state:
  - unspecified future research may occur without additional consent; *or* that the information or biospecimens will not be used for future research

- New required section of consent:
  - "key information" must be presented first with sufficient detail for subjects understanding of reasons to participate – a revised FAU consent template will be provided
  - For clinical trials supported by federal funding, one IRB-approved consent form used to enroll participants must be posted on publicly available website
  - Waiver of documentation of consent — new additional exception for subjects for whom signing documents is not the cultural norm

☐ SINGLE IRB REVIEW

- Single IRB review will be required for all federally funded cooperative research studies effective January 2020
- Reviewing IRB must be identified by funding department or agency or proposed by the lead institution

☐ NEXT STEPS

- Complete the new CITI course "Revised Common Rule"
- Review the Office for Human Research Protections (OHRP) website, Electronic Code of Federal Regulations (e-CFR), 2018 Requirements at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- Review the OHRP's Revised Common Rule Educational videos and Draft guidance documents at: http://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html
- Further OHRP guidance documents to follow
- January 21, 2019-Revised Common Rule Effective Date