

# 2018 REVISED COMMON RULE

## *What's New in Human Subjects Research Compliance?*

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# A long time in coming - so what's its Impact?

## ► For Researchers:

- Revised definition of Human Subjects Research (HSR)
- Federally-funded, minimal risk, Expedited studies no longer require annual review (some exceptions for FDA)
- More research will qualify for Exempt level review
- New Informed Consent Requirements!

# Definition Changes

- 46.102(e) - Definition of Human Subjects includes *identifiable biospecimens*
- 46.102(l) - Examples of what are not considered human subject research

# New and Revised Exempt Categories

- ▶ Category #3 - benign, behavioral interventions. Includes written or audio responses from adult subjects
- ▶ Former UCB Category #7 is now #70
- ▶ And, what does not fit in #3 now - yet is non-federally funded, minimal risk - may fit in #70. Exclusions apply.

# Informed Consent Changes

- ▶ Biggest change is requirement for *Key Information* at top of consent form
- ▶ Details of other changes - 45 CFR 46.116
- ▶ Details for documentation of informed consent – 45 CFR 46.117
- ▶ See CPHS/OPHS website for revised and “old” templates
- ▶ Federally funded, new or amended studies **MUST** use the new consent template

# What's New for CPHS?

- ▶ Grant-Protocol comparison is GONE!
- ▶ Limited IRB Review for some Exempt level categories
- ▶ 46.109(f) - Continuing review is not required when:
  - ▶ Research is eligible for expedited review; or,
  - ▶ Research limited to only data analysis; or,
  - ▶ Accessing follow-up clinical data (performed as part of clinical care).

Note: For tracking purposes, studies are approved for 10 years

## *Continued:*

- ▶ Mandates the use of a single IRB (sIRB) for multisite studies – effective 1/2020. For NIH-funded research, effective 1/25/18.
- ▶ Change in Vulnerable Populations
  - 46.111(a)(3) & 46.111(b) - Vulnerable populations: Pregnant women and handicapped/mentally disabled populations are no longer considered vulnerable.
  - Individuals with impaired decision-making capacity and economically/educational disadvantaged are considered vulnerable population.

# Transition Plans

- ▶ Federally-funded protocols must transition on or before their continuing review expiration date
- ▶ Non-federally funded new protocols are encouraged to use revised consent form templates
- ▶ New exempt protocols and exempt amendments for protocols predating 1/21/19 will follow 2018 requirements
- ▶ Most PIs won't notice much, if anything different
- ▶ Two sets of policies for foreseeable future...



# *Questions?*

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