Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Final Rule
Discussion: Overview of Changes

Overview of Changes Effective January 21, 2018

- ***OHRP Video: What's New in IRB Review Under the Revised Common Rule***

https://www.youtube.com/watch?v=zDsUUs9j3sQ&feature=youtu.be

Most Relevant Changes for Committee Members

- ***Eliminating Continuing Review for minimal risk research***
- ***Eliminating requirement for IRB to waive informed consent for screening, recruiting, or determining eligibility for prospective subjects***
- ***Eliminating grant application or other funding proposal review***
- ***Single IRB review***

Eliminating Continuing Review for Minimal Risk Research

- Research on the list can undergo expedited review unless the reviewer determines that the study involves more than minimal risk----**when this happens, the review must document why the determination was made**

- At a meeting when the committee determines that something is minimal risk but not eligible for expedited review categories 1-7, continuing review would be required: 1 year for federally funded, 3 years for not federally funded.

- Accredited institutions must have an alternate process to maintain oversight over the research initially approved using the expedited procedure, as long as the research is ongoing: **UGA will require Progress Reports at the same intervals as above. HSO will review these.**

Eliminating Waiver of Consent for Screening, Recruiting, or Determining Eligibility

- The IRB must still make sure that approval criteria **for these activities** can still be met.

Eliminating Review of Grant or Funding Proposal

- Contracts (e.g., industry sponsored trials) must still be reviewed to ensure that accreditation-required elements are included. Sponsored Projects does this.
  - IRB will need to review for FDA-regulated trials

Single IRB Review

- Already required for NIH funded studies
- Will apply to other federal agencies in January, 2020
- Many institutions are trying to do this already
  - UGA has joined SmartIRB and will be hiring a person to administer all collaborative research so that UGA will be able to offer sIRB services.
- IRB will need to learn how to review for non-UGA sites --- local context, ancillary reviews, main study vs. addition of sites

Portal Changes

- **Revised Submission Form**
- **Revised Checklists**

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Revised Common Rule:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html