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Research: Institutional Review Boards and the Common Rule

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The Common Rule is a set of ethics regulations governing biomedical and behavioral research on human subjects.[1] Adherence to the Common Rule is mandatory for federally funded projects involving research on human subjects where the sponsoring agency has adopted the Common Rule. Some agencies that have adopted the Common Rule are the Department of Agriculture, Department of Education, Department of Transportation, Department of Justice, National Science Foundation, and NASA. Agencies that have not adopted the Common Rule are the Social Security Administration, the Department of Homeland Security, and the Central Intelligence Agency (CIA). The changes, as stated in the Notice of Proposed Rulemaking (NPRM), issued January 19, 2017, may require changes in the grant review process of Institutional Review Boards (IRBs) and Offices of Integrity (ORIs). The updated changes required by the federal rules may also result in higher costs and workloads.[2]

Furthermore, communicating these new changes to principal investigators (PIs), project directors, and others results in questions regarding how projects can be reviewed efficiently and effectively and still maintain compliance. Thus, the University of Kentucky's Internal Audit department, in response to the recent changes to the Common Rule, undertook a survey to attempt to answer some of the following questions:

- How will the Common Rule changes affect the operations of ORIs and IRBs?
- What changes will ORIs make in reaction to the new requirements in the Common Rule?
- Will the changes to the Common Rule necessitate significant modifications in procedures or processes?

Major changes to the Common Rule

The changes to the Common Rule encompass new definitions, new interpretations, and new rules that have the potential to affect the ability of universities to meet the demands of the predicted increase in research protocols. Some of these changes (most effective January 19, 2018) are:

- Informed consent forms must be characterized by greater clarity and focus, and promote the research subjects' understanding of the project.
- Some clinical trials must post the informed consent form online.
- Researchers have the option of using broad consent for secondary research that uses identifiable private information and identifiable biospecimens.
- New exempt categories of research projects that are low risk have been established.

- Institutions are required to have a single IRB for evaluating multi-site research, or documentation when the single IRB is not appropriate (effective January 20, 2020).
- The need for a continuing review has been eliminated under certain circumstances.
- Documentation is required for reliance arrangements with non-institutional IRBs.

The research community has had ample notification of the changes as published in the January 19,2017 NPRM. The Advance Notice of Proposed Rulemaking of 2011 and the NPRM of 2015 provided fair warning of these changes.[3] The research community thought many of the proposed changes were rules whose time had come. Kaiser reiterated the great relief among certain critics that written consent for using specimens leftover from clinical care or specific studies would not be required under the new rules.[4] The new ruling also helped prevent privacy issues where specimens could be linked to individual subjects. Mann stated that "Under the final rule, informed consent forms for research participants must be written more clearly and include a summary of the most important information at the beginning."[5] Many would agree.

Unnecessary jargon and rule revelations clouded the consent process. Most IRB and ORI staff members would also agree that placing greater emphasis on reviewing higher-risk projects reduced the burden on IRBs. Jaschik stated that:

> Early reactions from social science groups to the changes in the common rule were positive. Various provisions suggest that institutional review boards, which must review proposals to study humans, work to understand the needs of different kinds of researchers, and that there are different levels of risk associated with taking an experimental drug and answering confidential survey questions.[6]

Broadening the definition of what is actually exempt research would allow greater flexibility in IRB reviews and might reduce workloads.

Klitzman's landmark survey of 60 IRBs found that many felt centralized IRBs and local IRBs offered both advantages and disadvantages. Local IRBs were thought to provide more "local knowledge" of the research subjects while also providing greater participation in better "curbside consults" with principle investigators, facilitating mutual trust. These qualities were thought to be absent in centralized IRBs. On the other hand, the use of local IRBs of multi-site research projects might result in duplication and redundancy in the review process.[7]

Pyle confirmed this opinion when stating that local IRB reviews might cause significant approval delays. According to Pyle, one example of these delays would be where local IRBs might require protocol-level changes in the informed consent documents to meet individual policies, further delaying the approval process. Pyle believed that increased delays would occur in conjunction with increased costs, thus making the central IRB more efficient and effective in comparison to local IRBs.[8]

These positive reactions have also been accompanied by apprehension. Gearhart felt that central/independent IRBs would not have the same leverage as local IRBs to suggest corrective actions. Thus, central IRBs might approve projects with less formal analysis. In contrast, Gearhart continued by mentioning that local IRBs experience high turnover and are usually staffed with volunteers; whereas, external IRBs usually are staffed with professional reviewers that are dedicated to their positions.[9] Some believe that the adoption of the single IRB

might discourage small projects and prevent others from happening.[4] Mann voiced the Association of American Medical Colleges' thesis that the single IRB requirement needed to be flexibly applied. Most observers concluded that the adoption of the single IRB and other new rules must be accompanied by some flexibility to allow fair and expedient review processes.[5]