# COMMON RULE CHANGE: IMPLICATIONS FOR CANCER REGISTRY LINKAGE STUDIES

## Background

The protection of human subjects in federally-funded research is governed by the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP)[1] which has developed federal policy including the Common Rule, a 1981 rule of ethics (revised in 1991), regarding biomedical and behavioral research involving human subjects in the US.[2] This rule provides guidance to Institutional Review Boards for oversight of human research.

The Common Rule is the baseline standard of ethics by which any government-funded research in the U.S. is held; nearly all U.S. academic institutions hold their researchers to these statements of rights regardless of funding. In January 2017, the Common Rule was amended in several ways;[3] the original compliance date of 1/25/18 has been delayed to 1/21/19 for most elements[4] to provide additional time for preparations necessary to implement the changes.

"Accelerating clinical research studies benefits researchers, research participants, and all who stand to gain from research results. Today, the time it takes to go from a sound research idea to the launch of a new, multi-site clinical research study is too long. A major contributor to the delay is that too many institutional review boards (IRBs) are reviewing the protocol and consent documents for the same study, often with no added benefit in terms of the protections for research participants. To address this bottleneck, NIH has issued a new policy to streamline the review process for NIH-funded, multi-site clinical research studies in the United States. The **NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research** sets the expectation that multi-site studies conducting the same protocol use a single IRB to carry out the ethical review of the proposed research."

**Francis S. Collins, M.D., Ph.D.**
**Director, National Institutes of Health**
**June 20, 2016**

## Common Rule Change

One change that will impact some central cancer registry-based research is requirement of the use of a single IRB for cooperative research, i.e., projects that involve more than one institution. **"Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research."**[3]

Cooperative research is defined as "research conducted at more than one institution."; the NIH compliance date for this element is January 20, 2020.[3,4]

## Why Was This Done?

Review of a multi-site study by the IRB of each participating site involves significant administrative burden. When each participating institution's IRB conducts a review, the process can take many months and significantly delay the initiation of research projects and recruitment of human subjects into research studies. Use of single IRBs in multi-site studies has been shown to decrease approval times for clinical protocols and may be more cost-effective than local IRB review.[5,6]

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Both HHS and FDA previously allowed multi-site studies to use joint review or rely on the review of another IRB.[9,10]

There is no evidence that multiple IRB reviews enhance protections for human subjects. In fact, the use of single IRBs may lead to enhanced protections for research participants by eliminating the problem of distributed accountability, minimizing institutional conflicts of interest, and refocusing IRB time and resources toward review of other studies.[7-10] Both HHS and FDA previously allowed multi-site studies to use joint review or rely on the review of another IRB.[11,12]

# What is a Single IRB?

The concept of a single IRB, or central IRB (CIRB), has long been utilized by the federal government supporting humans subjects research. In this model, multiple institutions participating in a common protocol all rely on one IRB review and approval. At the National Cancer Institute, these include:

- Adult CIRB – Late Phase Emphasis (reviews National Cancer Institute Cancer Therapy Evaluation Program (CTEP) sponsored Phase 3 adult clinical trials)
- Adult CIRB – CTEP Early Phase Emphasis
- Pediatric CIRB - CTEP sponsored Pilot, Phase 2, and Phase 3 pediatric clinical trials
- Cancer Prevention and Control CIRB - reviews cancer prevention and control studies.

The National Cancer Institute's Division on Cancer Control and Populations Sciences is establishing a new central IRB dedicated to minimal risk studies, such as linkages of cancer epidemiology cohort studies with central cancer registries.

# How Does This Impact Cancer Registries?

- Cohort studies that conduct linkages with central cancer registries currently find that many registries require local IRB to review and approve the study.
- OHSRP through 45 CFR 46 has determined that cohort linkages are considered minimal risk studies and can be reviewed via expedited process.
- Given the new NIH policy that a Single IRB will be used for multi-site studies funded by the NIH, NCI will create a new central IRB devoted to this type of research.
- Local IRBs can opt to use the Central IRB to perform the review and approval for minimal risk studies
- Local context issues will be incorporated into the Central IRB review
- Another Common Rule change that will simplify many central cancer registry cohort studies, is the elimination of the requirement for annual continuing review.[4]

# Benefits of a Central IRB

- Eliminate duplicative IRB review (beyond initial institutional IRB approval).
- Ensure consistency of IRB reviews.
- Allow local/state IRBs to concentrate more time on other reviews.
- Reduce multiple (or varying) local/state requests for protocol changes that necessitate re-review by institutional IRB.
- Decrease administrative burden on research staff.
- Reduce timeline for approval and release of data.
- Contribute to more timely science and discovery.

# Additional Resources

- Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html
- Guidance on Exceptions to the NIH Single IRB Policy https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html
- Single IRB Policy for Multi-site Research https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
- NIH Single IRB (sIRB) Policy https://osp.od.nih.gov/clinical-research/irb-review/
- Implementation of the sIRB policy https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/

# References


[1]https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html

[2]https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

[3]https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf (p. 7265)

[4]https://www.federalregister.gov/documents/2018/06/19/2018-13187/federal-policy-for-the-protection-of-human-subjects-six-month-delay-of-the-general-compliance-date

[5]Wagner TH, et al. Costs and benefits of the National Cancer Institute Central Institutional Review Board. J Clin Oncol. 2010; 28:662-666.

[6]https://www.nih.gov/about-nih/who-we-are/nih-director/statements/single-irb-policy-streamline-reviews-multi-site-research

[7]Emanuel EJ, et al. Oversight of human participants research: identifying problems to evaluate reform proposals. Ann Intern Med. 2004; 141(4):282-291.

[8]Menikoff J. The paradoxical problem with multiple-IRB review. N Engl J Med. 2010; 367:1591-1593.

[9]Menikoff J, Kaneshiro J, Pritchard I. The common rule, updated. N Engl J Med 2017; 376:613-615.

[10]http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm

[11]http://www.hhs.gov/ohrp/policy/protocol/cirb20100430.html

[12]McLaughlin RH, Gomez SL, Deapen D, Induni M. Human subjects protection and cancer surveillance research: revised regulations, expanded opportunities. Cancer Res; 2017; 77(12); 1–4.