COMMON RULE REQUIREMENT FOR MINIMAL RISK RESEARCH: IMPLICATIONS FOR IRB REVIEW OF CANCER REGISTRY-BASED RESEARCH

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 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 to 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]

What is Minimal Risk Research?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[4]

As institutions, IRBs, and researchers integrate the new rules into their practices, we hope that the greater protections provided to research participants will result in greater trust in the research enterprise and that the new flexibility offered to researchers and IRBs will foster creative and innovative ways of further improving the oversight of the human-subject protection system.

Menikoff J, Kaneshiro J, Pritchard I. The common rule, updated. NEJM 2017; 376:613-615

What Are the IRB Changes?

✓ Expedited Review

§46.110 **Expedited review** procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.[5]

(b) An IRB may use the expedited review procedure to review either or both of the following:

1. Surveys, interviews, self-reports, direct and indirect observations of individual and group behavior, other verbal or computer-assisted interactions or assessments, non-invasive physical or behavioral tasks, manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health, and epidemiologic research. Examples include:
   a. Measures of performance on cognitive, perceptual, neuropsychological, behavioral and other related tasks employing non-invasive technologies (e.g., paper and pencil assessment, computerized tasks, remote data collection using mobile devices).
   b. Interviews, questionnaires, surveys, focus groups, and internet-based data collection on personal experience, identity, language, relationships, attitudes, beliefs and practices.
   c. Psychiatric diagnostic or symptom assessments in healthy or mentally ill populations conducted by clinicians or trained interviewers (with appropriate mechanisms for clinical back-up or referral).
   d. Measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers).
   e. Methods used in ergonomics and human factors research including cognitive, human-computer, physiological and bio-mechanical measures in consumer, industrial, and biomedical settings.
   f. Qualitative and quantitative data collection through observation, participant observation and interaction with groups in naturalistic settings (including the internet).

g. Surveys on personal and family finances, consumer preferences and decision-making.
h. Assessments of compliance with medication or treatment regimens.
i. Surveys to establish effectiveness of public health interventions.

✓ Discontinuing Continuing Review for Expedited Review

Under the revised Common Rule, **continuing review is not required** for:

- Research that is eligible for expedited review,
- Exempt research conditioned on limited IRB review,
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,
- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

Importantly, the IRB can override this default and still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision.[6]

What is Expedited Review?

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in §46.108(b).[7]

How Does This Impact Cancer Registries?

- OHSRP through 45 CFR 46 has determined that cohort linkages are considered minimal risk studies and can be reviewed via expedited process.
- Registries for which IRB approval is required for participating in linkage and other minimal risk patient contact studies should observe a faster IRB approval.
- Once expedited approval is obtained there is no requirement for annual continuing review.[8]

Are Studies Initiated Before January 21, 2019 Subject to the Revised Common Rule as of that Date?

It depends. If an institution takes no action, studies initiated before January 21, 2019 will continue to be subject to the pre-2018 Common Rule. However, if an institution takes action to transition a study or studies to the revised rule during the delay period (July 19, 2018 through January 20, 2019), those studies will then be required to comply with the revised Common Rule as of January 21, 2019.[9]

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.ecfr.gov/cgi-bin/text-idx?SID=7f5862546652623faa6cddc27c5d1c02&mc=true&node=se45.1.46_1102&rgn=div8

[5] https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf

[6] 45 CFR 46.109(f), 46.110, and 46.115(a)(8) of the revised Common Rule https://www.ecfr.gov/cgi-bin/text-idx?SID=7f5862546652623faa6cddc27c5d1c02&mc=true&node=se45.1.46_1102&rgn=div8, p. 7205

[8] https://www.ecfr.gov/cgi-bin/text-idx?SID=14664322084999a9c069f305791494f8&mc=true&node=se45.1.46_1110&rgn=div8

[9] https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html
Commentary: Menikoff J, Kaneshiro J, Pritchard I. The common rule, updated. N Engl J Med 2017; 376:613-615.