
SPECTRUM HEALTH

SPECTRUM HEALTH

Key Changes to the Common Rule – Regulations for Protection of Human Subjects (45 CFR 46)

Office of Research Oversight
January 2019

SPECTRUM HEALTH

Final Revisions to the Common Rule

Final Revisions to the Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protections of Human Subjects (the Common Rule). The Final Rule was published in the Federal Register on January 19. 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

~ HHS.gov website

Final revision available at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf

SPECTRUM HEALTH

Key Changes

- **Eliminates continuing review** for most new minimal risk research
- **Expands exemption categories** and changes the review processes
- **Reframes informed consent information** and adds required elements
- **Requires single IRB review** of research involving external collaborators (effective January 2020)

What's not Changing?

Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners

Continuing Review

- Continuing review is eliminated for **new** studies reviewed via expedited review
  - The IRB can require continuing review for a study if there is cause
- This change does not apply to FDA regulated studies
- Modifications, RNI's and Study Completions are still required to be submitted to the IRB
- Additional information such as study progress reports, DSMC/B, Protocol Deviations, etc. should be submitted to the IRB as an RNI

Informed Consent Changes

Changes include the addition of the “key information” page which is patient focused and should provide a “concise and focused presentation of key information” up front and in an easily understandable way

- Key information includes:
  - Voluntary participation
  - Summary of research procedures
  - Risks
  - Benefits

New template is now available on our website and was sent out in communication on December 21st

SPECTRUM HEALTH

New Informed Consent Elements

New required consent element

- De-identified data or biospecimens may be shared for future research (or not) and a description of what that potential research might include.

New consent elements (if applicable)

- Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
- Clinically relevant results will be returned (or not) and an explanation of how this will occur
- Research will involve whole genome sequencing

Other Consent Related Changes

- For federally-sponsored clinical trials, a copy of an IRB approved consent form must be posted on Clinical Trials.gov. There are no restrictions on which version must be posted. Posting can take place any time after recruitment closes but not later than 60 days after the last study visit by any subject.
- *OHRP defines a clinical trial as: "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effect of the interventions on biomedical or behavioral health-related outcomes."*

Single IRB Review Requirement

Requires that all federally-sponsored research with multi-institutional collaborators be reviewed by one designated IRB of Record

- Not required until January 2020 for federally funded research

Changes to IRB Manager

- Changes have been made to multiple xForms
- If continuing review is no longer required for a study an expiration date will not be present
- Documents that would be submitted at time of continuing review such as progress reports, protocol deviations, etc. should be submitted through the RNI xForm
- RNI form was revised to allow for acknowledgement of information items as needed or per sponsor request

Changes to Forms/Templates

- Many of the IRB Forms and Templates have been revised to conform to the new requirements
- All new documents will be available online as of January 21, 2019 on the website
- Informed Consent Template is available NOW
- Any questions: please let us know at irbassist@spectrumhealth.org

Timeline for Transition

- The new rule is effective January 21, 2019 for federally funded research
- Research approved on or after January 21 must be compliant with new rules
- Research approved before January 21 will be approved under current rule

Common Rule Resources

Find revised documents on our website:

https://www.spectrumhealth.org/research-and-clinical-trials/researchers-and-students/researchers/forms-and-policies

Check the Department of Health and Human Services website for updates to the revised Common Rule:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

IRB Contact Information

If you have questions, contact the IRB Office at 616-486-2031 or irbassist@spectrumhealth.org


SPECTRUM HEALTH