Implementation of the Revised Common Rule

OVERVIEW
Revisions to the Federal Policy for the Protection of Human Subjects (45 CFR 46), also known as the Common Rule, are due to go into effect January 21, 2019. This document summarizes plans for implementation of the revised Common Rule at St. Joseph Health (SJH).

IMPLEMENTATION PLAN

• Studies subject to the Common Rule

In general, human subjects research conducted or supported by a Federal department or agency (e.g., NIH) is subject to the Common Rule. All studies subject to the Common Rule must adhere to either (1) the revised rule, if received by the Institutional Review Board (IRB) on or after January 21, 2019, or (2) the pre-2018 version of the Common Rule, if initially approved by the IRB prior to January 21, 2019.

All new studies received by the IRB on or after the January 21, 2019, implementation date (or received prior, but not scheduled to be reviewed until on or after that date) will be pre-reviewed by the SJH Human Research Protection Program (HRPP) staff for determination of applicability of revised Common Rule requirements.

In general, studies initially approved prior to January 21, 2019, will remain subject to the pre-2018 version of the Common Rule, with limited exception as outlined below. These previously approved studies will not transition to the revised rule, and will retain their existing level of review and all other IRB requirements.

The only studies initially approved prior to January 21, 2019, that SJH intends to transition to the revised Common Rule are studies determined to present minimal risk to participants for which the requirement to obtain informed consent was waived by the IRB. At the time of the next scheduled continuing review, such studies will be reviewed by the IRB in accordance with the revised Common Rule requirements.

While the SJH intends to limit the studies transitioned to the revised Common Rule at this time, the SJH HRPP reserves the right to transition individual studies on a case-by-case basis or general classes of studies to the revised rule. The basis for such decisions will be documented at the time of transition or announced via updated guidance, as appropriate.

• Studies subject to the Common Rule and FDA Regulations

Studies subject to the Common Rule and FDA regulations (21 CFR 50, 56, etc.) must adhere to both sets of regulations to the extent they are congruent. Where they differ, the more stringent regulations apply. For example, additional informed consent requirements of the revised Common Rule must be addressed in consent forms for federally-supported FDA-regulated clinical investigations, while FDA’s requirements with regard to expedited and continuing review must be followed for such investigations.

• Studies subject to FDA Regulations, not subject to the Common Rule

Non-federally-supported FDA-regulated clinical investigations must adhere to FDA regulations, and may, but are not required to, apply provisions of the Revised Common rule that are not inconsistent with FDA regulations. For example, additional elements of informed consent
specified in the revised Common Rule may be included in consent forms for non-federally-supported FDA-regulated clinical investigations.

FDA’s guidance on Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations will be used as a guideline for applying provisions of the revised Common Rule to FDA-regulated clinical investigations.

• **Studies not subject to the Common Rule or FDA Regulations**

For studies not subject to the Common Rule or FDA regulations, in general, SJH intends to apply the same definitions, requirements, etc. of the revised Common Rule at this time, except as noted elsewhere in this document or other policy or guidance documents.

The following provisions the revised Common Rule will not be required for studies not subject to the rule:

- Clinical trial consent forms are not required to be posted to a publicly available website (45 CFR 46.111(h)).
- Reliance upon approval by a single IRB is not required for cooperative research (45 CFR 46.114).
- IRB records are not required to document the rationale for a determination that research presents more than minimal risk to participants or for conducting continuing review of research that otherwise would not require continuing review (45 CFR 46.115(a)(8); 45 CFR 46.115(a)(3)).

The SJH HRPP may also, on a case-by-case basis, determine that the application of specific provisions of the revised Common Rule are not appropriate for a given study not subject to the Common Rule or FDA regulations. Such determination will be documented at the time of review.

In addition, SJH continues to adopt additional commensurate review methods for research not subject to the Common Rule or FDA regulations as outlined in guidance titled, “Protections for Non-Federally Funded, Non-FDA Regulated Human Research.”

• **Continuing review**

The revised Common Rule removes the requirement for continuing IRB review for certain categories of research. While continuing review is no longer required, the research is still under IRB and HRPP purview and investigators will continue to be required to submit any proposed modifications to the research (amendments), including changes in study personnel, for IRB approval prior to implementation, as well as promptly reporting to the IRB any potential unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, etc.

For studies that no longer require continuing IRB review, SJH will continue to require the submission of a study progress report from investigators at the anniversary of the initial IRB review of the research, until the study is closed. The submission of an annual progress report is necessary to keep the SJH HRPP apprised of the status of the research and accruals for general reporting purposes, as well as to allow SJH HRPP staff to confirm that research personnel are up-to-date with regard to completion of research education training, financial
interest disclosures, etc. Requirements for continuing IRB review and annual reporting are outlined in guidance titled, “Continuing Review.”

**Informed consent requirements for studies not subject to the Common Rule**

The revised Common Rule introduces new requirements for informed consent, including (1) additional elements of consent for research that involves the collection of identifiable private information or biospecimens and (2) the addition of a concise and focused presentation of key information at the beginning of informed consent (45 CFR 46.116).

With regard to (1), in general, the SJH HRPP intends to apply the additional elements of consent to all research that involves the collection of identifiable private information or biospecimens, to the extent the elements are applicable to such research, including studies not subject to the Common Rule. Consent forms for non-federally-supported FDA-regulated clinical investigations may, but are not required to, include these additional elements.

With regard to (2), the addition of a concise and focused presentation of key information at the beginning of informed consent will not be required for studies not subject to the Common Rule at this time. However, the inclusion of this information is allowable, encouraged by the SJH HRPP, and may be required by the IRB on a case-by-case basis if it is determined that this information is essential to ensuring participant comprehension. The SJH HRPP will evaluate the implementation of the key information requirement for studies subject to the Common Rule and make a determination at a later date regarding whether or not the requirement should be applied to research not subject to the rule.

**Broad consent**

Use of a broad consent process for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is a new option under the revised Common Rule. Broad consent as described in the revised Common Rule is not in addition to traditional informed consent, but separate from traditional informed consent.

As part of the Providence St Joseph Health (PSJH) enterprise, the SJH HRPP has determined not to implement a broad consent process at this time along with the PSJH IRB Hub partners. This determination is based on an assessment that there is insufficient infrastructure in place to support the implementation of a broad consent process in a manner compliant with the requirements outlined in the revised Common Rule. Specifically, the provisions of the revised Common Rule that will require a mechanism to track the consent process. The infrastructure needs, and the limitations they place on the utility of implementing a broad consent process have been outlined by the Secretary’s Advisory Committee on Human Research Protections (SACHRP):

*Extensive and seamless IT system capacity will be necessary for any institution or health system to implement fully a broad consent tracking system, as both broad consents as well as refusals to consent (unless the materials are destroyed) must be tracked over the lifetimes of persons who give broad consent and persons who refuse to give such consent. Due to these systems requirements for electronic tracking processes, SACHRP expects that, practically speaking, institutions or systems without interconnected, interfacing and fully interoperable medical records systems will not be able to implement and benefit from the broad consent regimen established in the Final Rule. A “confederated,” non-IT-unified health system will simply not be able, without significant error, to track these consents and refusals to consent. These logistical barriers will greatly limit the utility of the broad consent option.*
Given the infrastructure needs summarized above, and SACHRP’s assessment that “the broad consent option...does not substantially change researchers’ preexisting ability to make use of de-identified biospecimens and data, or their access to identifiable biospecimens and identifiable data via waiver or other means,” SJH HRPP has determined that implementation of a broad consent process as described in the revised Common Rule is not appropriate or necessary at this time. The SJH HRPP may reconsider implementation of a broad consent process in the future should further guidance regarding broad consent be released by the Office for Human Research Protections (OHRP) or the above-noted infrastructure needs be sufficiently addressed.

REFERENCES


Federal Policy for the Protection of Human Subjects (Pre-2018 Version)

FDA’s Guidance on Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations

SACHRP Recommendations for Broad Consent Guidance (July 26, 2017)