St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

Greetings IRB Members!
Please read below for current updates on the
SJH Human Research Protection Program.

January 2019

HRPP Updates

HAPPY NEW YEAR!

Help Us Ensure Your Membership Information is Up-to-Date

As we prepare to re-apply for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), we need ensure the accuracy of IRB member records. You should have recently received an e-mail from Susan O'Brien or Theresa Tuckman asking you to provide or update information regarding your indications of experience, representative capacity, etc. If you haven't already, please respond to the e-mail by Friday, February 8, 2019. Thank you for assistance with this crucial component of our AAHRPP application.

Revised Common Rule – Updated Guidance and Forms

The revised "Federal Policy for the Protection of Human Subjects," also known as the Common Rule, went into effect January 21, 2019. As previously discussed, the HRPP Office has updated several guidance documents and application forms for compliance with the revised Common Rule, which are now available on the HRPP website here: https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/.

A Summary of Significant Revisions to the guidance and forms is provided at the end of the newsletter for reference. Please review the revised guidance documents as you have time.

If you have any questions about the revised Common Rule, guidance or forms, please contact Adam Pucci, HRPP Manager, at Adam.Pucci@stjoe.org.

Summary of Significant Revisions to SJH HRPP Guidance and Application Forms (1/21/2019)

OVERVIEW

The St. Joseph Health Human Research Protection Program (SJH HRPP) has revised several guidance documents and application forms to address revisions to the Federal Policy for the Protection of Human Subjects (45 CFR 46), also known as the Common Rule, that are effective January 21, 2019. This document summarizes the significant revisions to the guidance and forms for the SJH research community.

GUDIANCE DOCUMENTS

- **Implementation of the Revised Common Rule (NEW)**
    - Summarizes plans for implementation of the revised Common Rule at St. Joseph Health.
    - Describes how provisions of the revised Common Rule, including changes to informed consent and continuing review requirements, will be applied to research subject to different federal regulations (i.e., FDA-regulated research) or no federal regulations (i.e., non-federally-supported, non-FDA-regulated research).

- **Determining if a Project is Human Subjects Research (REVISED)**
    - Aligned definition of "Human Subject" and what does not constitute "Research" with the revised Common Rule.
    - Incorporated discussion of when QI/QA activities do or do not involves research from previous "Research vs. Quality Assurance" guidance document which is now retired.
    - Added discussion of how formal determinations of whether a project involves human subjects research are made, noting that the HRPP has final authority to make such determinations.

- **General IRB Submission Process and Communication of Results (REVISED)**
    - Revised to discuss process for conducting Limited IRB Review when required for certain categories of Exempt research per the revised Common Rule.
    - Expanded discussion of the Expedited IRB Review process.
    - Reiterated requirement that Principal Investigators (PI) are to be copied on e-mail submissions of documents that do not contain their signature. Similarly, the HRPP Office is to copy PIs on IRB requests.

- **Levels of IRB Review (REVISED)**
    - Aligned definitions of various terms with the revised Common Rule.

- Aligned categories of research that qualifies for Exemption from IRB review with the revised Common Rule.

- Changed scope of the SJH Exemption category for non-regulated research due to the Common Rule's expansion of Exemption categories. SJH Exemption Category X (previously "7") now pertains to research involving no greater than minimal risk that is limited to the collection and/or analysis of existing or prospectively collected identifiable private information or identifiable biospecimens, and where there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

- Expanded discussion of the review of Exempt research, including ethical standards for such research and the HRPP Office review process.

- Revised to discuss process for conducting Limited IRB Review.

- **Informed Consent Guidance (REVISED)**

  - Aligned terminology with that of the revised Common Rule.

  - Added discussion of new general requirements for informed consent entailed in the revised Common Rule, including the presentation of "key information" at the start of the consent form, and the requirement to post clinical trial consent forms on a Federal website.

    Note: The SJH HRPP will not require some of the new informed consent requirements for non-Federally funded research (i.e., research not subject to the Common Rule). Please see the guidance *Implementation of the Revised Common Rule* for information on the standards to be applied for studies not subject to the Common Rule.

  - Revised discussion of standards for conducting the informed consent process, including the PIs oversight of the process and the involvement of appropriately delegated, trained and experienced study personnel in this process, per previous HRPP guidance.

  - Clarified for California sites that when the Experimental Subject's Bill of Rights is required to be presented to participants, the form should be signed and dated by participants.

    Note: The SJH HRPP has considered the signature at the end of the consent form to apply to both the Bill of Rights and the consent form who both documents are presented to subjects as a single document. However, to more fully ensure compliance with California law the SJH HRPP has determined that participants should separately sign and date the Bill of Rights in addition to the consent form. The SJH HRPP will implement this requirement on a go forward basis for studies approved on or after January 21, 2019. Consent forms for studies approved on or after this date will have signature lines inserted into the Bill of Rights. Studies approved prior to January 21, 2019 may continue to utilize their currently approved Bill of Rights, with the signature at the end of the combined Bill of Rights and consent form addressing the signature requirement.

  - Expanded discussion of requirements for obtaining informed consent from non-English speakers, including the addition of the requirement that the use of full translations of consent forms will be required after two uses of a short form in a given language for a given study.

- Reiterated requirement that when the Short Form consent process is used, the witness must sign the short form and the English consent form.

- Clarified that when the Short Form consent process is used the witness may be an adult family member of the participant.

- Added discussion of consent requirements for continued data collection following participant withdrawal from a clinical trial, consistent with FDA guidance.

- **Waiver of Consent or Documentation (REVISED)**

  - Revised to address changes to standards for waiving informed consent or documentation of consent per the revised Common Rule and FDA guidance, including the permissibility of consent waivers for minimal risk FDA-regulated research**,** new requirements for consent waivers for research involving identifiable information or biospecimens, and new conditions for consent waivers for research involving public benefit and service programs.

- **Amendments to Previously Approved Research (REVISED)**

  - Reiterated that the requirement for IRB review of amendments applies to all research approved by the IRB, including Exempt research subject to Limited IRB Review, and research for which continuing review is not required.

  - Clarified that in the event a change to approved research is implemented prior to IRB approval because it was deemed necessary by the investigator to eliminate apparent immediate hazards to participants, the change must be promptly reported to the IRB and that the IRB will consider whether the changes were consistent with ensuring participants' continued welfare and should be approved going forward.

- **Continuing Review (Renewals) (REVISED)**

  - Added discussion of certain categories of research that will no longer require continuing IRB review, including the process for maintaining IRB and HRPP oversight of such research.

    Note: the removal of the continuing review requirement is generally only applicable to non-FDA-regulated minimal risk research approved on or after January 21, 2019. Investigators will be informed at the time of IRB approval whether or not their study requires continuing IRB review. IRB approved research that does not require continuing review is still under IRB and HRPP purview. Investigators must continue to submit any amendments for IRB approval prior to implementation, as well as promptly report any potential unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, etc. Investigator will also be required to submit a study progress report to the HRPP at the anniversary of the initial IRB review of the research, until the study is closed. HRPP staff will inform investigators of the requirements for reporting study progress prior to the due date of the report.

  - Added discussion of the requirements for closing studies with the IRB.

- **Protections for Non-Federally Funded, Non-FDA Regulated Human Research (REVISED)**
    - Renamed document (previously "Protections for Non-Federally Funded Human Research").
    - Changed scope of SJH Exemption Category X (previously "7") as described above.

APPLICATION FORMS

- **Exemption from IRB Review Application (REVISED)**
    - Revised to align categories of research that qualifies for Exemption from IRB review with the revised Common Rule.
    - Updated questions for clarity, completeness, and to address new requirement for Limited IRB Review for certain categories of Exempt research.

- **Request to Waive or Alter Consent (REVISED)**
    - Revised to align with changes to waiver criteria entailed in the revised Common Rule.

- **Request to Waive Documentation of Consent (REVISED)**
    - Revised to align with changes to waiver criteria entailed in the revised Common Rule.