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.

May 2019

HRPP Updates

Revised Policies, Guidance, Templates and Forms

The HRPP Office has updated several policies, guidance documents, consent form templates, and submission forms that went into effect May 20, 2019. The revised documents are now available on the HRPP website located here: https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/. A *Summary of Significant Revisions* to the documents is provided at the end of the newsletter for reference. Please review the revised documents as you have time.

In general, the document revisions are intended to clarify and streamline HRPP and IRB submission and review processes. Most impactful to members are the revisions to submission forms and the Research Education policy.

Submission forms were thoroughly reviewed and updated to ensure clarity in instructions and that all the information the IRB needs to complete its review is provided. Through the revisions we hope to eliminate confusion and common requests for additional information during the HRPP staff pre-review and IRB review of submissions. Also of note, new study submissions are now required to include a signed Principal Investigator Attestation form in which the PI attests to assuming overall responsibility for the study, compliance with applicable regulations, IRB requirements, etc.; and, to facilitate the IRB's consideration of deviations and internal serious adverse events occurring over the lifetime of a study, researchers will be required to submit all Deviation Summary Logs and Serious Adverse Event Summary Logs, as applicable, for prior years of a study at the time of continuing review.

The Research Education policy updates extend the requirement for IRB members (and researchers) to renew research training from every two years to every three years.

If you have any questions about the revised documents please contact Adam Pucci, HRPP Manager, at Adam.Pucci@stjoe.org.

Summary of Significant Revisions to SJH HRPP Policy, Guidance, Templates and Forms (May 20, 2019)

OVERVIEW

The St. Joseph Health Human Research Protection Program (SJH HRPP) has revised several policies, guidance documents, consent form templates and submission forms, effective May 20, 2019. This document summarizes the significant revisions to the documents for the SJH research community.

POLICIES

- **SJH Institutional Review Board (IRB) Policy (REVISED)**
    - Revised to align definitions and processes with revisions made to the Federal Policy for the Protection of Human Subjects (45 CFR 46). Additional minor revisions made to provide procedural details regarding implementation of policy.

- **SJH Human Subjects Protection Research Training and Education Policy (REVISED)**
    - Revised to extend requirement to renew training to every three years.

- **SJH Conflict of Interest in Research Policy (REVISED)**
    - Revised to clarify current oversight and implementation of the policy. Revisions include measures to improve the efficiency of the disclosure and review process, including eliminating redundant processes and allowing for the development of procedures for management of non-significant financial interests according to approved standards without prior review by the Conflict of Interest Review and Oversight Committee (COIROC). Defined the term "Organizational Financial Conflict of Interest." The definition of the term "Significant Financial Interest" revised to align with federal regulations.

    Note: This policy can be found on the Central Office of Research Administration (CORA) webpage under "Policies": https://www.stjhs.org/center-for-clinical-research/central-office-of-research-administration/policies/

GUDIANCE DOCUMENTS

- **Getting Started with a New Research Study (REVISED)**
    - Updated discussion of each step in the study start-up process to provide additional details and align with current practices and requirements.

- **Materials Required for IRB Review (REVISED)**
    - Updated to provide complete list of current requirements for different types of submissions to the IRB.

Note: New study submissions to the IRB are now required to include a signed *Principal Investigator Attestation* form in which the PI attests to assuming overall responsibility for the study, compliance with applicable regulations, IRB requirements, etc. This form is also required with requests to change PIs.

- **Table for Reporting to IRB (REVISED)**
  - Updated to provide complete and current list of required forms and reporting timeframes for different types of submissions to the IRB.

- **Guidance for Research Education (REVISED)**
  - Revised to extend requirement to renew training to every three years.
  - Revised discussion of process for tracking training status and removing researchers with expired training to align with current practice.

    Note: HRPP staff will inform study teams of researchers that are out of compliance with training requirements at the time of continuing IRB review/annual progress reporting. Researchers that do not complete training by the date of IRB review will be removed from the study and no longer allowed to participate in research until training is renewed. Research privileges may be reinstated upon renewal of training and IRB approval of a personnel amendment to add the researcher back to the study. Note: Personnel amendments are to be submitted using the *Study Personnel Addition Form.*
  - Updated instructions for first-time CITI registration and users affiliated with another institution in CITI.

- **Privacy and Confidentiality (REVISED)**
  - Added discussion of Certificates of Confidentiality (CoC) issued for certain NIH-funded research consistent with 2017 updates to NIH CoC policy.

- **Expanded Access to Investigational Drugs, Biologics or Devices (Compassionate Use) (REVISED)**
  - Added discussion of process for obtaining IRB Chair concurrence in lieu of IRB review for single patient expanded access requests for treatment use of drugs consistent with 2017 updates to FDA expanded access guidance.
  - Added discussion regarding access to investigational drugs under 2018 Right to Try Act.

- **Planned Emergency Research (REVISED)**
  - Revised to clarify that prior FDA review is required for emergency research involving FDA-regulated products in which an exemption to the informed consent requirement is requested and that when consent is not able to be obtained prior to the research

intervention, consent for continued participation should be obtained as soon as possible after the initiation of research, whenever feasible.

- **Review of Investigational Device Studies (REVISED)**

  - Revised to clarify that device risk determinations may be made via the expedited review procedure for studies involving non-significant risk devices that are determined to present no greater than minimal risk and to qualify for expedited review.

- **Scientific or Scholarly Review of Human Subjects Research Protocols (REVISED)**

  - Revised to clarify who may attest to the scientific or scholarly validity of studies presented for expedited IRB review or exemption from IRB review, including that individuals with a conflicting interest may not provide attestation, and to clarify acceptable forms of documentation of scientific or scholarly review.

- **Conflict of Interest Review and Oversight Committee (REVISED)**

  - Added appendix with general guidelines for managing common disclosure scenarios with the understanding that the COIROC may require more or less stringent management plans depending on the nature of a disclosure, study, etc.

  - Revised process to reflect that depending on the nature of the disclosure, some financial interests may be managed according to the guidelines without prior approval by the COIROC or SVP/Chief Risk Officer.

  - Reiterated requirement that investigators must submit updated disclosure forms within 30 days of entering into any new financial or other relationships between annual disclosures.

  Note: This guidance can be found on the CORA webpage under "CORA Process": https://www.stjhs.org/center-for-clinical-research/central-office-of-research-administration/for-researchers/cora-process/

- **Emergency Use of a Test Article (Drug, Biologic or Device) (REVISED)**

  - Title and references updated.

TEMPLATES

- **Informed Consent Form (including HIPAA) (REVISED)**
- **Parental Permission Form (under 7) including HIPAA (REVISED)**
- **Parental Permission-Assent Form (ages 7-11) including HIPAA (REVISED)**
- **Parental Permission-Assent Form (ages 12-17) including HIPAA (REVISED)**

  - Added signature lines to the Experimental Subject's Bill of Rights.

- Added template language to address new elements of informed consent required by the revised Federal Policy for the Protection of Human Subjects (45 CFR 46) that went effect earlier this year. New elements include:

    - Presentation of key information at the start of the consent form
      (note: this element is only required for Federally-funded research; may be included for other research.)

    - Discussion of potential future use of information or specimens
      (note: this element is only required for Federally-funded and unfunded research; recommended for FDA-regulated research.)

    - Discussion of potential use of specimens for commercial profit
    - Discussion of disclosure of clinically relevant research results
    - Discussion of use of whole genome sequencing
      (note: these elements are only required if applicable for Federally-funded and unfunded research; recommended for FDA-regulated research.)

- Updated template language regarding Certificates of Confidentiality (CoC) consistent with NIH guidance.

- Added template language for informing participants regarding mandatory infectious disease reporting.

- Simplified template language regarding pregnancy prevention in conformity with the Ethical and Religious Directives for Catholic Health Care Services.

- Updated template language regarding reimbursement for research-related injuries for Medicare beneficiaries.

- Updated list of entities that may see participants' information to include SJH Center for Clinical Research and HRPP in addition to IRB.

- **Participant Information Sheet (REVISED)**

    - Template language and instructions revised throughout for clarity.

    - Added language to address new requirement to discuss the potential future use of participant information.

- **Participant Information Sheet for Online Surveys (NEW)**

    - This template is provided for use when developing consent information for research involving online surveys.

- **Short Forms (English, Farsi, Korean, Spanish, Vietnamese) (REVISED)**

    - Added signature lines to the Experimental Subject's Bill of Rights and moved to first page.

- Added language to address new requirement that the short form state that key information was provided to participants at the start of informed consent.

- Updated text for contacting the HRPP for consistency with main consent form template.

- Revised HIPAA form for consistency with main consent form/HIPAA template.

Note: The use of the short form consent process and documents must be prospectively approved by the IRB for a given study – see the document *Informed Consent Guidance* for more information. Currently-approved studies that have been issued short forms will continue to use those versions of the forms. New studies submitted to the IRB for review requesting to use short forms after May 20, 2019, should use the revised versions.

- **Single Patient IND Informed Consent Form (NEW)**

  - This template is provided for use when developing consent forms for single patient expanded access requests for treatment use of investigational drugs, biologics or devices.

- **Protocol Template Guidance (NEW)**

  - This template is provided as guidance to aid investigators in developing formal research protocols.

- **Treatment Plan (Compassionate Use Protocol) Guidance (NEW)**

  - This template is provided as guidance to aid physicians in developing treatment plans for single patient expanded access requests for treatment use of investigational drugs, biologics or devices.

SUBMISSION FORMS

- **Clinical Research Trial Questionnaire (REVISED)** ***[to be used for initial submissions of clinical trials.]***

  - Sections updated throughout to ensure capture of all information necessary for CORA, HRPP and IRB reviews, provide clearer instructions, and remove redundant, unnecessary questions.

  - Participant Protections section expanded to obtain additional information necessary to address the criteria for IRB approval, including specifying how the risks of research are justified by anticipated benefits, providing additional details regarding screening activities and monitoring plans, confirming standards for obtaining informed consent will be followed, and clarifying plans to enroll/obtain consent from non-English speaking individuals.

- **Research Intake Form (REVISED)** ***[to be used for initial submissions of nursing / non-interventional research.]***

  - Instructions updated throughout for clarity.

- **Principal Investigator Attestation (NEW)**

  - This new form, which is required with all new study submissions, requests PIs to attest to assuming overall responsibility for the study, compliance with applicable regulations, IRB requirements, etc.

- **Amendment to Previously Approved Research Form (REVISED)**

  - Revisions made to remove unnecessary questions, provide clearer instructions, and to obtain additional information necessary to facilitate the IRB's review of amendments, including study status, participant status, and plans for sharing new information with participants.

- **Study Information Report (REVISED)**

  - Revisions made to remove unnecessary questions and provide clearer instructions, including clarification for when study-related information may be submitted using the *Study Information Report* vs. the *Amendment to Previously Approved Research Form* in general and for revised Investigator's Brochures.

- **Study Personnel Addition Form (NEW)**
- **Study Personnel Removal Form (NEW)**

  - These new forms replace older forms for adding or removing personnel from studies. The new forms are simplified and provide clearer instructions. Note: The *Amendment to Previously Approved Research Form* should no longer be used to request approval of personnel changes.

- **Continuing Review Report (REVISED)**

  - Revisions made to provide clearer instructions and to prompt investigators to provide additional information necessary to facilitate the IRB's continuing review of research, as applicable. For example, the form now prompts researchers to clarify the status of any re-consenting of participants required by the IRB and uses of short forms with non-English speakers during the prior year.

  Note: To facilitate the IRB's consideration of deviations and internal serious adverse events occurring over the lifetime of a study, researchers will be required to submit all Deviation Summary Logs and Serious Adverse Event Summary Logs, as applicable, for prior years of a study at the time of continuing review.

- **Deviation Summary Log (REVISED)**

  - Revisions made to provide clearer instructions for reporting deviations at the time of continuing review and to obtain additional information necessary to facilitate the IRB's consideration of deviations, including the date a deviation was identified by the researchers.

- **Serious Adverse Event (SAE) Summary Log (REVISED)**

  - Revisions made to provide clearer instructions for reporting internal serious adverse events at the time of continuing review and to obtain additional information necessary to facilitate the IRB's understanding of the expectedness of events and their relatedness to the research.

- **Attestation of Scientific/Scholarly Review of Human Subjects Research (NEW)**

  - This new form may be used to obtain documentation of scientific or scholarly review for studies presented for expedited IRB review or exemption from IRB review – see the guidance document *Scientific or Scholarly Review of Human Subjects Research Protocols* for more information.