1 PURPOSE

1.1 This guidance establishes the process for the Principal Investigator (PI) of any qualifying Sharp HealthCare (SHC) investigator-initiated clinical trial to register the trial with ClinicalTrials.gov

1.2 This guidance begins before the PI submits a SHC investigator-initiated clinical trial to the Institutional Review Board (IRB).

1.3 The guidance ends when the PI submits the results of the clinical trial to ClinicalTrials.gov.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 Before a SHC investigator-initiated clinical trial is submitted to the IRB for review, the PI must determine whether the research activity requires registration (i.e., meets the definition of an applicable clinical trial per https://clinicaltrials.gov/ct2/manage-recs/faq#act). Applicable clinical trials must be registered with ClinicalTrials.gov within 21 calendar days after the first human subject is enrolled.

4 RESPONSIBILITIES

4.1 The PI is responsible for:

4.1.1 Determining whether their investigator-initiated research meets the definition of an applicable clinical trial.

4.1.2 Registering applicable clinical trials via the ClinicalTrials.gov Protocol Registration and Results System (PRS) per 42 CFR 11, Subparts A and B.

4.1.3 Submitting clinical trial updates and results via the ClinicalTrials.gov Protocol Registration and Results System (PRS) per 42 CFR 11, Subparts C and D.

4.1.4 Posting one IRB-approved consent form on a publicly available website approved for such posting, if the clinical trial is conducted or supported by a Federal department or agency per 45 CFR 46.116(h).

5 PROCEDURE

5.1 Determine whether the investigator-initiated clinical trial meets requirements for registration.

5.2 Contact the Director of Research to request registration for the PI and to authorize access to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

5.3 The PI logs into the ClinicalTrials.gov Protocol Registration and Results System (PRS) portal using the SHC entity access information provided by the Director of Research.

5.4 The PI registers their investigator-initiated clinical trial and provides all required clinical trial registration information. Applicable clinical trials:

5.4.1 Can be registered with ClinicalTrials.gov after at least one IRB has approved the clinical trial.

5.4.2 Must be registered within 21 calendar days after the first human subject is enrolled

5.5 The PI or designee provides the “ClinicalTrials.gov Identifier” to the SHC IRB via the “ClinicalTrials.gov Identifier” section on page one of *FORM: Initial IRB Review Application (HRP-211).*

5.6 Posting of Consent Forms for Federally-Funded Clinical Trials - When the investigator-initiated clinical trial is conducted or supported by a Federal department or agency, the PI posts one IRB-approved informed consent form on a publicly available website approved for such posting.

5.6.1 As of 8/28/2018, the Office of Human Research Protections (OHRP) identified two publicly available federal websites that satisfy the consent form posting requirement. These include:

5.6.1.1 ClinicalTrials.gov for studies that are registered on ClinicalTrials.gov.

5.6.1.2 A docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

5.6.1.2.1 To use regulations.gov to satisfy the 45 CFR 46.116(h) requirement, the PI or designee must submit the informed

consent form as a comment to the appropriate docket folder (Docket ID: HHS-OPHS-2018-0021), per the instructions available at https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html.

5.6.2 When posting must occur - The informed consent form:

5.6.2.1 Must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.

5.6.2.2 Should be uploaded at the same time the Overall Status is updated to reflect the trial is closed to recruitment.

5.6.3 Which informed consent version to post – Per the Revised Common Rule, the version of the informed consent document posted must:

5.6.3.1 Be IRB-approved.

5.6.3.2 Have been used to enroll a participant in the clinical trial. The version of the consent that should be posted is the most recent IRB-approved version that was used to enroll a participant.

5.6.4 Redacting information from the consent form prior to posting - Any requests to redact certain information prior to posting must be submitted to the Federal department or agency supporting the clinical trial. Only the Federal agency or agency supporting the clinical trial may permit or require redactions to the information posted.

5.7 The PI updates clinical trial information and submits clinical trial results via the ClinicalTrials.gov Protocol Registration and Results System (PRS) within the time frame required per 42 CFR 11, Subparts C and D.

6 MATERIALS

6.1 FORM: Initial IRB Review Application (HRP-211)

7 REFERENCES

7.1 42 CFR 11; 45 CFR 46.116(h)

7.2 ClinicalTrials.gov Frequently Asked Questions

7.3 ClinicalTrials.gov "Why Should I Register and Submit Results?

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.