1 PURPOSE

1.1 This guidance establishes the process for the principal investigator (PI) of 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 IRB.

1.3 The guidance ends when the PI registers the clinical trial with ClinicalTrials.gov (or the determination is made that registration is not needed) and the registration information is documented in the IRB application.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY STATEMENT

3.1 Before a SHC investigator-initiated clinical trial is submitted to the IRB for review, the PI is responsible for determining if the study qualifies for registration with ClinicalTrials.gov, and if so, registering the trial and documenting registration information in the appropriate section of *FORM: Initial IRB Review Application (HRP-211)*.

4 RESPONSIBILITIES

4.1 The PI is responsible for registering the trial with ClinicalTrials.gov if qualified.

4.2 The PI is responsible for submitting study results on the ClinicalTrials.gov as defined by ClinicalTrials.gov.

5 PROCEDURE

5.1 Determine if the 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 SHC organizational listing on clinicaltrials.gov.

5.3 The PI to log into the SHC entity access site for ClinicalTrials.gov.

5.4 The PI will register the study and complete all appropriate forms.

5.5 The PI will fill out the clinical trial identifier on *FORM: Initial IRB Review Application (HRP-211)* in the section titled CLINICAL TRIAL REGISTRATION on page one of the form.

5.6 The PI will update study information and submit results within the time frame required by ClinicalTrials.gov (https://clinicaltrials.gov/ct2/manage-recs/background).

6 MATERIALS

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

7 REFERENCES

7.1 https://clinicaltrials.gov/ct2/home

7.2 https://clinicaltrials.gov/ct2/manage-recs/background

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