I. POLICY

Physicians and nurses shall use Epic to document anything of clinical relevance to the care and safety of the research study participant by using progress notes and other standard clinical documentation. Scheduling, registration, order and other Epic administrative and clinical workflows shall be used, and are required when the conditions below apply.

II. PURPOSE

To ensure the safety of our research study participants, study teams must use Epic to document all clinically relevant data, including any procedure considered more than minimal risk by the Institutional Review Board (IRB) overseeing the research.

III. PROCESS

A. Epic must be used for registration, scheduling and ordering for all research related activities if any of the following apply:
   1. Activities occur in Johns Hopkins Health System (JHHS) inpatient and ambulatory spaces (regulated and unregulated) where Johns Hopkins Medicine (JHM) revenue cycle and access policies apply.
   2. Biospecimen samples are collected and sent for analysis by a JHHS clinical lab.
   3. The research study includes diagnostic radiology services with a JHHS clinical read.
   4. The medication is supplied or supported by the Investigational Drug Service (IDS).

B. Research teams requesting an exception to the above requirement should provide their justification for the exception to the Office of Clinical Research Support Services (CRSS), who will work with the Vice Dean for Clinical Investigation to determine if the exception will be allowed.

C. The Sidney Kimmel Comprehensive Cancer Center Clinical Research Office (CRO) will designate studies enrolling participants with cancer required to use Beacon treatment plans or EPIC order sets for clinical trial treatment intervention.

IV. REFERENCE

Policy HIM004 – Legal Medical Record Policy
V. REVIEW CYCLE

Three (3) years