I. Purpose

This policy outlines the requirements for Epic utilization for research, and procedures for creating, revising, and completing an Epic Research Study Record.

This policy aligns with the Medical Records and Health Information Policy, Code of Federal Regulations (CFR), International Council for Harmonization (ICH) Good Clinical Practice (GCP) (E6), and guidelines that apply to the involvement of human research participants in clinical research.

II. Definitions

Legal Medical Record: The record released upon request for accrediting, regulatory, and reimbursement purposes and released to the patient, family, and others if authorized. It is used to familiarize readers with the patient's status; document care, treatment, and services; plan for discharge; document the need for care, treatment and services; assess the quality of care, treatment, and services; determine reimbursement rates; justify reimbursement claims; pursue clinical or epidemiological research; and measure outcomes of the care, treatment and service process. The legal record includes paper documentation, scanned documentation, filmed images, microfilm, and the electronic medical record. It does not include aggregate or derived data, research records, and administrative or business records.

Medical Record: The documentation of the healthcare services provided to an individual at the Medical Center. It is individually identifiable data, in any medium, collected and/or used in documenting healthcare or health status.

III. Policy Statements

All studies that meet Epic Electronic Health Record (EHR) utilization criteria as outlined within this policy must associate research participants and research-related encounters conducted at the Stanley Manne Children's Research Institute/Children's Hospital of Chicago Medical Center to the appropriate Epic Research Study Record. Study record association procedures are described in the Epic Research Study Record Association Policy.

Any study meeting the Epic EHR utilization criteria below will be subject to Epic utilization requirements:

A. The study is given an Institutional Review Board (IRB) risk determination of *greater than minimal risk;*

B. Any of the Manne Research Institute/Medical Center ancillary support services are involved in the conduct of the study/study procedures, including but not limited to: Anesthesiology, Cardiopulmonary Lab, Clinical Research Unit, Emergency Medicine, Investigational Drug Service (IDS) Pharmacy, Medical Imaging, Ophthalmology, Pediatric Intensive Care Unit (PICU), or Research Laboratory.

C. The study will generate research patient care costs.

IV. Procedures/Expectations

DISCLAIMER: This policy was developed solely for the use of Stanley Manne Children's Research Institute. The information contained herein shall not be relied upon by individuals or entities outside the Research Institute for accuracy, timeliness, or any other purpose.

A. Epic Research Record Creation, Updates and Completion:
    a. Research Record Requests are initiated by the study team and initiated by submitting a Research Record Request Form to the Clinical Trials Office, along with any required supporting documents.
    b. Research Record Requests are processed within in four (4) business days once complete, accurate documentation has been submitted.
    c. Requests may require supporting documentation as indicated within the request form, including but not limited to:
        i. Current IRB approval/closure letter.
        ii. A Copy of the Sponsor Award Summary Notification or other documentation received from Post-Award Financial Management for studies classified as charge types, and/or an email approval from the Division Administrator for the use of an existing fund.
        iii. Investigational Drug Exemption (IDE) documentation from the Sponsor.

B. Record Updates:
    a. Most updates may be performed by the study team following the applicable Tip Sheet available in the Epic Learning Home Dashboard for Research.
    b. Updates related to research billing, assigned fee schedules, fund numbers, as well as other related fields are required to be updated by the Clinical Trials Office. These updates may be requested following steps Aa-b.

C. Record Completion:
    a. Record completion/closure/deactivation must be performed by the Clinical Trials Office, closures may be requested following steps Aa-b.
    b. Records cannot be reactivated once closed.
    c. Prior to record closure, study teams must verify that that reconciliation of all billing activity associated with the study/funds is complete and confirm that all possible charge and late charge activity has been reconciled.

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Approvals:

Research Professionals Steering Committee: April 17, 2020
Director, Research Compliance: September 25, 2020
Chief Operating Officer, Manne Research Institute: January 5, 2021
Associate Chief Research Officer, Clinical Trials: January 19, 2021