I. Purpose

This policy outlines the procedures for associating a research participant and/or study visit/procedure to an Epic Research Study Record.

II. Definitions

Encounter Association: The process within the electronic health record (EHR) by which an Epic Research Study Record is associated to an encounter.

Order Association: The process within the EHR by which an Epic Research Study Record is associated to an order.

Patient Association: The process within the EHR by which an Epic Research Study Record is associated to a research participant.

III. Policy Statements

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

Study visits which include inpatient, observation, outpatient surgery or anesthesia services, and include any research patient care costs, must also submit the applicable Research Request Form for billing purposes.

IV. Procedures/Expectations

A. Patient association is completed through the Research Studies Activities in Epic. For studies that meet Epic utilization criteria the following applies:
    a. It is required to complete patient association and include an active start and end date for all patients who participate in a study (i.e., consented, scheduled, etc.).
        i. Active start date – the date informed consent was obtained from the participant or legally authorized representative (LAR).
        ii. Active end date – the date research participation ends (i.e., study activity completed, participant withdrawn, etc.) and has been changed to an inactive enrollment status.
    b. Participant ID is necessary for study participants utilizing the Clinical Research Unit (CRU) and Investigational Drug Service (IDS) Pharmacy.

c. Consent is to be obtained and the process documented following the Medical Center's Institutional Review Board Policy and Procedure Section 11: Informed Consent Process. Study teams are to follow the instructions available on ResearchPedia for placing research scans in Epic.

d. It is optional to complete patient association for all patients who are approached about participating in a study. This can be determined by the Principal Investigator (PI) on a study-by-study basis as there are tracking benefits related to the reporting functionality in Epic.

e. An enrollment status needs to be specified during patient association, and this status should be updated as study participation progresses (i.e., identified, enrolled, ineligible, completed, etc.).

f. A research participant must be associated to the study with an active enrollment status (Active: Consented – In Screening, Enrolled, or Follow Up) for the following to occur:
    i. Encounter association to be completed.
    ii. Order association to be completed.
    iii. Research status to be visible in the patient header.
    iv. In Basket notifications when participants are seen in the Emergency Department or admitted to an inpatient unit.

g. If a study team feels that patient or encounter association requirements are not feasible for a study, a request and justification can be submitted to CRS@luriechildrens.org.

B. Encounter and Order Association

a. Studies utilizing any of the Manne Research Institute/Medical Center ancillary support services including but not limited to: Anesthesiology, Cardiopulmonary Lab, CRU, Emergency Medicine, IDS Pharmacy, Medical Imaging, Ophthalmology, Pediatric Intensive Care Unit (PICU), or Research Laboratory must follow the steps to ensure proper Epic Research association of research encounters and orders occurring within those areas.

b. Inpatient, Observation, Outpatient Surgery and Anesthesia Services
    i. If a study participant visit includes inpatient, observation, outpatient surgery or anesthesia services, and includes any research related charges, the applicable Research Request Form must be submitted. This form is used to notify the teams involved in the prior-authorization and billing of upcoming research-related services.
    ii. Study teams must also follow the linking admissions process to ensure the proper association.

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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