I. PURPOSE:

The purpose of this document is to outline the policy regarding the tracking of clinical research participants ("participants") at the Feinberg School of Medicine.

Background

The implementation of Epic across Northwestern Memorial Healthcare Corporation (NMHC) and its affiliated hospitals (Project One) includes a new research module and workflow. The new workflow is designed with the safety and security of our patients and participants in mind. The NMHC and Feinberg teams have worked to ensure the right information is shared between our institutions to enhance the research team and patient/participant experience, while maintaining billing compliance standards and without compromising safety.

The enhancements to Epic and Study Tracker enable research teams to track information about studies, participants, and their activities. The workflow is as follows:

1. Enter your study information in Study Tracker;
2. Enroll your participant(s) into Study Tracker. Information about your participant and the study they are on will now electronically be sent to Epic;
3. Record the interaction (encounter) with your participant; and
4. Review and verify the billing-related information recorded in the patient electronic health record.

II. POLICY STATEMENT:

Study Information

1. All clinical research studies overseen by the NU IRB involving FSM faculty, regardless of where performed, are required to provide the following information in Study Tracker:
   a. The Department, Institute or Center at FSM providing study support services for the study.
   b. The chart string where the financial activity for the research study is recorded.
   c. The sp# number of the grant and contract submitted to fund the study (if applicable). In addition, a link to InfoEd is available in Study Tracker so the STU and sp# can be linked in the InfoEd system.

2. All studies approved by the NU IRB with a Feinberg School of Medicine faculty member PI are required to fill out the Study Properties tab in Study Tracker. This tab contains information about the study, recruitment information, and whether the study will use NMHC medical services. If NMHC medical services will be used for the study after March 3, 2018, additional tabs are required and a study record must be created in Epic. If no NMHC medical services are used for the study, information will not be sent to NMHC for study record creation.
3. For studies requiring NMHC medical services, the “Epic Billing” tab must be completed. This tab contains information about billing for the study and who will be responsible for reviewing charges in Epic.
   a. All study team members who will either review charges or wish to see information about upcoming participant appointments or admissions must be indicated under “Study Team Members With Access to Epic” in Study Tracker. This is referred to as the “Charge Review List” and is shared with NMHC for study record purposes.

Budget Creation

4. All studies that enroll participants after March 2018 are required to build and maintain a new budget in Study Tracker.
5. Activities that take place during the course of the study must be entered and tracked in the Study Tracker under the study budget tab. Costs that are study-based and participant-based should be recorded and tracked.
   a. Those activities that involve NMHC services are displayed in the Study Budget’s NMHC charge review view and will be used to confirm charges in your Epic worklist are recorded correctly.

Participant Enrollment

1. All participants must be entered into Study Tracker within one business day of a scheduled research event.
2. In order to have a valid participant entry, you must enter the NMHC MRN, first name, last name, DOB, race, ethnicity, and gender. If available, these items will pull in from Epic once the valid MRN is entered.
3. Participants entered into Study Tracker must have their enrollment status on the study recorded within one business day of initial study entry. Please refer to the enrollment status table for all valid Study Tracker statuses. All participants must have status changes entered within one day of the status change.
4. All participants must have a date when they begin study participation (i.e. enrollment statuses of “Consented” or “On-Study”). A valid “active” enrollment status (i.e. “consented” or “on study” and date must be recorded to enable proper integration with Epic.
5. All participants must have a valid “inactive” enrollment status (i.e. enrollment statuses of “Completed or “Withdrawn”) and date recorded when a participant has completed all study related activities.

Encounter Linking in Epic

6. Once a participant has scheduled a research event, an encounter must be linked to the research study.
7. Encounter linking must occur as soon as a visit is scheduled or within one business day of the visit.

Billing Review in Epic

8. If an encounter has been appropriately linked to a study, charges from that event will appear in the study team worklist for review. Only those team members who have been added to the charge review list under the Epic billing tab in Study Tracker will see charges.
9. Charge review must occur within three days of the appearance of the charge.
10. Failure to comply with these policies may lead to sanctions. For repeated or severe violations, sanctions up to and including loss of PI privileges, administrative suspension of activities, loss of faculty appointment, department or unit financial penalties, or dismissal from the university are possible.

Procedure for studies with NO medical services

Participant Entry
1. Participant information must be entered into Study Tracker within one business day of study entry.
2. To have a valid entry, you must record, first name, last name, DOB, NIH race and ethnicity, and gender and a valid entry status.
3. After the participant is consented into the study, the valid, signed consent form must be uploaded into Study Tracker within 14 days of the consent event.
4. A final study disposition is required when a participant has completed all study related activities.
5. Participants on studies with no medical services will NOT flow to NMHC. To address privacy issues in sensitive studies, Study Tracker supports the use of pseudonymous identifiers; however, this feature is enabled on a study-by-study basis and must be approved in advance. (contact studytracker@northwestern.edu) to request a pseudonym exception.

III. PERSONS AFFECTED:
All FSM faculty and staff with studies involving human subjects under the purview of the NU IRB (including studies submitted to a centralized IRB) are affected by this policy. This also includes studies submitted to the joint adult/pediatric IRB. This currently does not include studies approved by solely by the Lurie Children’s Hospital (LCH) IRB and performed at LCH.

IV. DEFINITIONS:
Charge Review: Reviewing participant charges occurs after an encounter is linked and a participant completes a research event. The charges from that encounter will appear in the study team’s worklist for review and study team members with charge review permissions will indicate if the charge is research or standard of care and verify the information has been reviewed before patient billing can take place.

Charge Review List: A list of study team members who are responsible for updating participant charges. Those on the charge review list also see admissions and upcoming visits for their participants in Epic. The list is populated in Study Tracker on the “Epic Billing” tab, which is only active if the study requires NMHC medical services.

CMS National Coverage Decision for Routine Costs in Clinical Trials (310.1): Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Medicare will not cover:
- The investigational item or service (unless covered outside of a research study)
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the research study

eIRB (electronic Institutional Review Board system): Portal for electronic submission of research proposals to the IRB

Encounter: A clinical contact with a patient. For example, office visits, admissions, and triage calls are encounters. If more than one evaluation or procedure takes place at that visit, it is still usually considered one encounter. However, patients can have multiple encounters in a single day if they visit multiple departments, such as an office visit and subsequent visit to the Diagnostic Testing Center. In billing applications, charges or other transactions can be associated with encounters.

**Enrollment Status, as defined in Study Tracker:**

<table>
<thead>
<tr>
<th>Enrollment Status (from StudyTracker)</th>
<th>Epic Status Bucket</th>
<th>Send to Epic?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Screened</td>
<td>Pre-Consent</td>
<td>No</td>
</tr>
<tr>
<td>Screening</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>Consented</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>On Study</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>Randomized</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>E-Consented</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>Off Treatment</td>
<td>Active</td>
<td>Yes</td>
</tr>
<tr>
<td>Completed</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Lost to Follow-Up</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Invalid</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Failed (study adherence)</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
<tr>
<td>Screen Fail</td>
<td>Inactive</td>
<td>No</td>
</tr>
<tr>
<td>Death</td>
<td>Inactive</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Epic Status Bucket: Pre-consent**

*Pre-screened:* the participant fits the general criteria for the study. Meets inclusion/exclusion criteria

**Epic Status Bucket: Active**

*Screening:* the participant is in the screening process and visit involves medical services.

*Consented:* the participant has signed informed consent form.

*On Study:* the participant has passed screening and is enrolled on the study, including participants on studies with a waiver of consent.

*Randomized:* the participant has been assigned to a study arm/drug.

*E-Consented:* the participant has signed an electronic informed consent.

*Off Treatment:* all medical services required by the study and provided by NMHC have been completed. (billing **not** completed)

**Epic Status Bucket: Inactive**

*Invalid:* automatically set by Study Tracker when a participant has been incorrectly enrolled into a study.

*Completed:* the participant has completed all aspects of the study, including active monitoring or follow-up.

*Follow-Up:* the participant has completed the treatment phase of the study and is no longer receiving treatment but is being followed or monitored. (billing is completed)
Withdrawn: the participant has withdrawn from the study of their own accord.
Failed (study adherence): the participant is no longer eligible for this study or is non-compliant with the study requirements.
Screen Fail: the participant has failed to meet screening requirements.
Lost to Follow-Up: the participant was in follow-up but can no longer be reached. Status is unknown.
Death: the participant has died. Please indicate reason in notes. Common reasons: Protocol Disease, Protocol Treatment, Unrelated to Protocol, Unknown.

HIPAA: Health Insurance and Portability and Accountability Act of 1996 and the privacy regulations under that Act.

Institutional Review Board (IRB): A federally mandated body that reviews and approves research in accordance with federal regulations including, but not limited to DHHS regulations at 45 CFR 46 and its subparts, as well as FDA requirements at 21 CFR 50 and 21 CFR 56. When research involving products regulated by the FDA is funded, supported or conducted by FDA and/or DHHS, both the DHHS and FDA regulations apply. The IRBs have a central role in ensuring that human subject research is planned and conducted in an ethical manner, and in compliance with federal and state regulations.

Medical Services: Medical services include all research related tests or procedures used for research eligibility screening and diagnosing or treating disease.

Medicare Secondary Payer Rules: Cited at 42 USC 1395(b) (2) (A) (ii) and 42 CFR 411.32(a) (1), these rules essentially state that Medicare regulations preclude payment when... “payment has been or can reasonably be expected to be made under a liability insurance policy or plan. An entity that engages in a business, trade or profession shall be deemed to have a self-insured plan if it carries its own risk…in whole or in part.” [42 USC 1395]. “The clinical trial sponsor’s agreement with trial participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such injury occurs… [and] must make payment without regard to an individual’s Medicare eligibility.” [42 CFR 411.32(a) (1)].

Participant Record Creation: In order to have a participant record sent to Epic, the following must be true:

1. The MRN must be validated and recorded in Study Tracker
2. The “active” activity must be recorded in Study Tracker
3. The participant must be assigned to a budget arm in Study Budget

Principal Investigator (PI): The individual with primary responsibility for the design and conduct of a research project. The PI is also responsible for ensuring that all individuals who work under the supervision of the PI and participate in the conduct of the research have adequate education in order to discharge their duties in a manner that is consistent with the federal regulations for protection of human subjects as well as with this policy and with the specific requirements of the NU IRB.

Protected Health Information (PHI): Any patient or individually identifiable health information.

Research: As defined by the Department of Health and Human Services (DHHS), a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. DHHS regulations further define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains either: (a) data through intervention or interaction with the individual or (b) identifiable private information.

Research Fee Schedule: A NMHC research pricing catalog, comprised of all services from the NMHC Charge Master, but discounted at a percentage of the current fiscal year’s NMHC Charge Master rates. These rates are applicable only to NU IRB approved research studies.
Research Pricing Exception: An approved reduction in the research price(s) published in the current fiscal year’s NMH Research Fee Schedule for: A clinical test/facility fee; group of clinical tests (constituting a clinical procedure)/facility fees, or a group of clinical procedures/facility fees. The latter, is often referred to as a Research Case Rate Bundle. Research Case Rate Bundles may be established through the Office of Research (OOR) in certain instances where the Principal Investigator, on behalf of the study Sponsor, has requested that a flat rate be accepted for a group of procedures/facility fees for each subject enrolled in a particular research study. The Research Case Rate Bundle may include bedded patient stays, outpatient surgical procedures, and other groups of research related procedures/facility fees.

Routine Costs (Routine Medical Services): Routine costs in clinical trials include items or services:
- Typically provided outside of a research study (e.g., conventional care)
- Required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular for the diagnosis or treatment of complications

Sponsor: For the purposes of this policy, a sponsor is limited to a person or entity that provides funding to cover the expenses to conduct the research study. A study sponsor is usually the entity that developed the drug or device being used in a clinical investigation, but could also be any person or entity that serves as funding source for the research study. Therefore a sponsor can be external to Northwestern (e.g. drug or device company, an NIH Institute...etc) or internal to Northwestern (such as an NU Department, NMF grant…etc).

Study Record Creation: In order for a study record to be created and information sent over to NMHC the following information must be true:

1. The study must be in an approved status with the NU IRB; this can be confirmed in Study Tracker.
2. NMHC must be noted as a performance site with the IRB; this can be confirmed in Study Tracker.
3. The NMHC services question must have a recorded answer of “yes”.
4. A study budget must be created in Study Tracker.

V. POLICY UPDATE SCHEDULE:
No less than every three (3) years, but more frequent updates may be conducted as required.

VI. RELEVANT REFERENCES:

Regulatory References:
- Common Rule, 45CFR Part 46 and Subparts
- The Belmont Report
- Health Insurance Portability and Accountability Act (HIPAA)
- 45CFR Part 160 and Part 164
- Illinois Medical Studies Act (735 ILCS 5/8-2101)
- CMS National Coverage Decision Clinical Trial Policy

Other references:
Northwestern University Office for Research, Policies and Procedures:
http://www.research.northwestern.edu/policies