Purpose:
To outline the completion of research related activities within One Chart to ensure that research and non-research providers have appropriate clinical information related to the study in order to provide the best patient care and ensure patient safety.

1. Proper creation and use of a Research Study Administration Record in One Chart.
2. Required documentation.
3. Appropriate use of information from non-Nebraska Medicine organizations available in One Chart.
4. Guidelines for the appropriate use of tools available for research recruitment within One Chart.

Definitions:
Clinical Trials Management System (CTMS): This application supports management of therapeutic protocols and subjects. The CTMS allows administrative, regulatory, financial, and clinical functions to interact in a centralized area.

Enrollment Status: Term utilized to indicate a patient’s status in a study. Options include: Identified, Interested, Ineligible, Declined, Waiting for Consent, Screening, Enrolled, Completed, Withdrawn, Follow-Up

Institutional Review Board (IRB): composed of members from a variety of scientific disciplines and individuals from the community, assists investigators in the protection of the rights and welfare of human subjects.

One Chart Order Set: a general term including inpatient order sets, order panels, ambulatory smart sets, treatment plans and therapy plans.

One Chart | Patient Research Recruitment Tools: Research recruitment tools available in Nebraska Medicine’s patient portal. This includes patient messages and research recruitment requests.

Opt-In for Research: a patient who has agreed to have their records reviewed and be contacted for research studies for which they may be eligible.

Outside Information: information available and/or visible in the patient’s chart that originates from an organization outside of Nebraska Medicine or their Community Connect partners.

Research Study Administration (RSH) Record: research study record in One Chart that contains information about the study, including the PI, Coordinator, study description, and billing setup.

Research Encounter: a patient encounter (outpatient, inpatient, on-the-fly) in which any research related activity is occurring

Research Recruitment Best Practice Advisory (BPA): a visible or non-visible alert triggered by charting or documentation in a patient’s record to assist with research recruitment.

Policy:
1. RSH Record Requirements
   I. Research studies with the following University of Nebraska Medical Center IRB classifications require a Research Study Admin Record in One Chart:
i. Interventional/Therapeutic
ii. Human Biological Materials Research
iii. All other study classifications are addressed on an as needed basis

II. Research studies that originate in the CTMS will not have an active RSH record until:
   i. The appropriate approvals have been documented in the CTMS.
   ii. The following information is supplied to the One Chart team by the Research Coordinator or PI:
      a) Short study title, study description, PI and Research Coordinator Contact information

III. If the research study is not built in the CTMS but the IRB classification requires RSH build, the following information must be supplied to the One Chart Research Team by the Research Coordinator or PI:
   i. IRB number, grant number (WBS, MXH, Cost Center, or none), NCT number, full study title, short study title, study description, Principal Investigator (PI), Research Coordinator(s), contact information, investigational medication/drug name (if applicable)
   ii. The above information will also be required for RSH build that is requested by the PI, Research Coordinator, or One Chart Research Team before build will begin.
   iii. The Research Study Admin Record will not be activated in One Chart until all the above information is received.

2. Required Documentation for Clinical Research
I. All individuals performing research in UNMC/Nebraska Medicine facilities will be required to abide by this policy and document in the patient’s medical record in accordance with policy MS22.

II. Additional documentation required for research not specifically addressed in policy MS22 includes:
   i. Patient enrollments: documentation must include the name of the Research Coordinator, the patient’s enrollment status, enrollment start date/end date, documentation of informed consent, and branch assignment if applicable.
   ii. A signed copy of the research consent must be included in One Chart in accordance with policy MS14 and IRB HRPP Policy 5.1.
   iii. Patient enrollments will be updated as the patient progresses through the clinical trial.
   iv. Patients with no existing Nebraska Medicine record must be registered as a Nebraska Medicine patient and given a medical record number (MRN).
   v. All patient research encounters should be linked to the appropriate study in order to ensure charge review by the Research Biller in compliance with policy MI19.
   vi. All orders performed as part of a research study must be entered into One Chart.
   vii. Research orders must be entered into One Chart.
      a) Procedures that are performed on study supplied devices must be entered in One Chart using the designated order as identified by the One Chart Research Team.
      b) Research Nurse Coordinators may enter orders and pend them for provider signature or use written or telephone order modes.
      c) Non-Licensed Coordinators may enter orders and pend them for provider signature or use a written order mode.
      d) All chemotherapy orders will be placed from an approved treatment plan.
      e) All infused medication orders will be placed from an approved therapy plan.
      f) All research orders must be linked to the appropriate research study and associated with a research diagnosis (z00.6).

III. All medications administered as part of a research protocol require an order and must be documented on the patient’s Medication Administration Record (MAR).
   i. Medication orders must contain all elements of a required medication order (see policies MS05, MS09 and MM02).
   ii. Protocol amendments must be submitted to the One Chart Research Team at the time of IRB submission to ensure timely and appropriate updates to associated One Chart build.

IV. All encounters must have appropriate note documentation.

3. Appropriate Use of Outside Information Available in the Electronic Medical Record for Research
I. Outside information should not be used for research recruitment or research that is non-interventional.
II. Outside information may be used to provide treatment as part of a clinical trial for which a patient has consented to participate in, to assist in clinical decision making, or to exclude a patient from participating in a clinical trial per protocol exclusion criteria for patient safety.

4. Appropriate Use of One Chart Recruitment Tools
I. PI’s and/or Research Coordinators may request One Chart tools to assist with research recruitment
   i. Requests for One Chart recruitment tools should be made to the One Chart Research Team using the appropriate request form (see attachments).
ii. All requests should comply with Decision Support policy IM36.

II. All recruitment methods available require IRB approval.
   i. Documented IRB approval for use of recruitment tool must be provided to the One Chart Research Analyst before One Chart build can occur.

III. All recruitment tools must go through the appropriate committee approval processes before being activated.

IV. The One Chart Research Team will suggest changes or alternate One Chart recruitment methods based on build needs and/or limitations of original request in order to increase likelihood of successful recruitment and to stay in compliance with previous mentioned policies.

5. Research in the event of a Downtime
   I. Follow the standard downtime procedure and policies for your location
   II. Communication will come from Research Leadership regarding the impact of the downtime to Research Activities, including appointments, procedures, testing, and lab work
   III. Utilize the Research Downtime Order form that can be obtained by your Research Leadership

The Nebraska Medical Center Related Policies:
   o IM35 - Enterprise Electronic Order Set Development and Maintenance
   o IM36 - EHR Clinical Decision Support Development and Maintenance
   o MS22 - Contents of Medical Record
   o MS05 - Investigational Drugs
   o MS09 - Medication Orders
   o MS14 - Consents and Permits
   o MI19 - Research Billing Process
   o HRPP5.1 - Informed Consent

Staff Accountability:
Clinical Research Operations Committee: 1/13/2021
Clinical Governance Committee: 2/18/2021

<table>
<thead>
<tr>
<th>Department Approval</th>
<th>Administrative Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed</td>
<td>s</td>
</tr>
<tr>
<td>Title:</td>
<td>Chief Transformation Officer</td>
</tr>
<tr>
<td>Department:</td>
<td>Enterprise Applications</td>
</tr>
</tbody>
</table>

Vice President for Research, Nebraska Medicine