PURPOSE
This policy describes the insurance verification and pre-determination process for clinical trial patients within Nebraska Medicine.

POLICY
This process pertains to the completion of insurance pre-authorization for all patients who are eligible to participate or who have consented to participate in an Interventional therapeutic clinical trial at UNMC and Nebraska Medicine. Observational studies do not require predetermination (Patient registries are an example of an observational study).

DEFINITIONS (https://clinicaltrials.gov/ct2/about-studies/glossary)

Pre-determination: This term is often used interchangeably with Pre-Authorization. The pre-determination of benefits process allows the medical provider to send the insurance company a statement listing proposed treatments or tests. Within a specified time period (i.e. Days, possibly weeks), the insurance company will generally respond with a statement noting that the treatment or test is approved (authorized) or not. A pre-determination number is often provided. Per Medicare requirements predetermination is not required and there are no policy exclusions for participation in a clinical trial.

Insurance verification: The Patient Access Services (PAS) Financial Counselor will contact the insurance company to review patient specific benefits and coverage.

Interventional Study: A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Observational Study: A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment. A patient registry is a type of observational study.

Note: All registries are observational; however not all observational studies are registries.

Study synopsis: A brief description of the study purpose and treatment plan.

Study matrix: The study matrix is a table noting which study tests/procedures are considered standard of care and will be submitted to insurance and which study tests/procedures are considered study related and will be covered under the study.

Clinical Trial Exclusion Clause: This clause may be written into the patient's insurance policy. The patient is financially liable for all costs related to the clinical trial in this case.

SOC: Standard of Care as determined by the Coverage Analysis.

PROCEDURE
A. INSURANCE REVIEW –
   ALL patients who are eligible to participate or who have consented to participate in a therapeutic clinical trial will be subject to primary and secondary insurance verification by PAS Financial Counselors.
Step 1. For the patient who has been identified as eligible for consent or a patient who has already consented, the Research Coordinator/Assistant will submit the Clinical Trial Insurance Predetermination Form to Patient Access Services. The patient should be made aware that a request will be submitted for information from their insurance payer.

Information that should be included with the form: Study synopsis and Study Matrix

The form, including the attachments, should be emailed to Patient Access Services (PASFinancialCounselors@nebraskamed.com):
- Subject line of email should read: Clinical Trial Patient Protocol Pre-Authorization Request
- IF YOUR PATIENT IS HIGH PRIORITY (i.e. inpatient Leukemia, urgent treatment needed) please communicate this in your subject line and in the body of the email.

Step 2. The Patient Financial Counselor will review the patient's insurance coverage.
   a. The patient's individual policy will be reviewed to determine whether it has a clinical trial exclusion clause.
   b. The PAS Financial Counselor will complete the second part of the Clinical Trial Insurance Predetermination Form to indicate if there is a policy exclusion and if it is appropriate to move forward and consent the patient if not already consented. This will be emailed back to the Research Coordinator/Assistant with the insurance information.
   c. If there is no exclusion clause, the PAS Financial Counselor will proceed with a Pre-authorization if required by the insurance policy. It is not necessary to wait for receipt of the pre-authorization number to start treatment unless advised to do so by the PAS Financial Counselor.
      - A cost estimate will be used to provide the best estimate of the cost of services provided when participating in a clinical trial. Items designated on the matrix as Standard of Care being billed to insurance will be used in the cost estimation with the exception of medications from the pharmacy.
   d. If the policy has a clinical trial exclusion clause, the patient should be made aware by the Research Coordinator/Assistant. The patient should know that he/she is financially liable for all costs related to the clinical trial in this case and what those costs include at this point by PAS. At this time, the patient has the option to request an appeal, which in this case may cause a delay in the start of treatment. Or the patient may opt to request pre-authorization and proceed with the treatment without waiting for the response from the insurance payer. The patient should be informed that he/she is financially liable for all charges if pre-authorization for the clinical trial is denied. Or the patient may decide to not participate in the clinical trial.
      - If the patient decides to assume financial responsibility the patient will be provided with a cost estimate to inform them of their out-of-pocket costs; they will need to sign a non-cover waiver form. Account activity 228 – DOS not eligible for Financial Assistance will be added to applicable DOS
      - Research Coordinator/Assistant will notify the IRB if a patient is denied coverage and chooses to continue participation in the trial.
   e. In the case of the un-insured, Patient Access Services will provide direction and instruction on health care coverage options for the patient. Access Financial Counseling may personally contact the patient to discuss these options and assist in the initiation of the required paperwork. Patient care should be delayed until Access Financial Counseling determines it is okay to proceed with the clinical trial. Until health care coverage is established for the patient, the patient should know that he/she is financial liable for all costs related to the clinical trial.

   Note: For all patients, regardless of insured or non-insured, a Referral Entry will be created. Under the Misc Flags enter the 'Clinical Research Trail' flag

B. DOCUMENTATION –
   a. All correspondence between Research Coordinator/Assistant and PAS Financial Counselor will be documented on the Clinical Trial Insurance Predetermination Form. All entries and/or changes to information on the form should be dated.
   b. The Research Coordinator/Assistant should print out the communication for the study file.
   c. The Research Coordinator/Assistant should document significant issues and communications with the patient in the patient electronic medical record. (i.e. patient request to move forward without pre-authorization - informing the patient that he/she is financially liable - and noting the patient understanding).
   d. Patient Access Services will document all communication with the insurance by creating a referral entry and documenting all the requested services in the referral entry notes within One Chart.

STAFF ACCOUNTABILITY
Patient Access Manager- Financial Counseling
Department Approval
Signed [s]: Collonteen Renee Thompson
Title: Patient Access Manager
Department: Financial Counseling

Administrative Approval
Signed [s]: Jennifer Hirschbrunner
Title: Access Operations & Interpretive Services Director

Director