University of Nebraska Medical Center

**Center for Clinical and Translational Research Standard Operating Procedure**

Nebraska Medicine

Section: **Clinical Research Center**
Date Created: **July 26, 2018**

Title: **Pre-Authorization Insurance**
Date Last Reviewed/Modified:

SOP Number: **SOP- 65**
Version Number: **1**

**PURPOSE:** The purpose of this Standard Operating Procedure (SOP) is to explain the insurance pre-authorization process for the Clinical Research Center (CRC) supported studies.

**SCOPE:** This SOP applies to the completion of the insurance pre-authorization process performed by CRC staff for CRC supported therapeutic clinical trials.

**PERSONNEL RESPONSIBLE:** CRC Manager, Director of Clinical Research Operations, Study Coordinators and/or other staff.

**DEFINITIONS:**

- **Pre-determination** - This term is often used interchangeable 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 (e.g., days, possible 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.
- **Insurance Verification** - The Patient Access Services (PAS) Financial Counselor will contact the insurance company to review patient specific benefits and coverage.
- **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 patients' insurance policy. The patient is financially liable for all costs related to the clinical trial in this case.

**PROCEDURES:** All Research Coordinators and/or designee are responsible to ensure the insurance pre-authorization is completed per Nebraska Medicine (NM) SOP 2001.2 Insurance Determination.

The process includes the following:

1. For all patient 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.
2. Research Coordinator will inform participant that a request will be submitted to their insurance payer.

3. The Research Coordinator will Download and complete the Clinical Trial Insurance Predetermination Form: http://www.unmc.edu/cctr/resources/
4. Information to include with completed form includes study synopsis and study Matrix/CTMS Billing Grid (located in clinical Trials folder)
5. Form and attachments are to be emailed to Patient Access Services PASFinancialCounselors@nebraskamed.com with subject line "Clinical Trial Patient Protocol Pre-Authorization Request".
6. PAS Financial Counselor will inform Research Coordinator whether or not it is okay to proceed with study treatment and any additional information that is applicable.
7. If the patient's insurance policy has a clinical trial exclusion clause as determined by PAS Financial Counselor, the Research Coordinator is to inform the patient.
8. Research Coordinator will print out the Clinical trial Insurance Predetermination form and all supporting communication and place in the patient's study file (binder).
9. Research Coordinator will 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 she/he is financially liable – and noting the patient understanding).
10. For additional details review Nebraska Medicine Study Initiation 201.2 Insurance Pre-Authorization Insured and Non-insured SOP.

**RESOURCES:**

**UNMC:** #8008 Clinical Research and Clinical Trail Professional and Technical Fee Billing Process.

**Nebraska Medicine:**

- MI 19 Research Billing Process
- SOP 201.2 Insurance Pre-Authorization Insured and Non-insured

**Staff Accountability:**

Developed By: Lead, Clinical Research Center
Research Nurse Coordinator, Clinical Research Center

Reviewed By: Director of Clinical Research Operations, Clinical Research Center

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## Department Approval

Signed LuAnn Larson, BSN
Director of Clinical Research Operations

Signed
Medical Director of Clinical Research Center