I. POLICY

Clinical Research Billing Orientation (CRBO) and Clinical Trial Management System (CTMS) Training Compliance

II. PURPOSE

These online courses introduce study team members to the Prospective Reimbursement Analysis (PRA), clinical research billing procedures, and the purpose and process of registering study subjects into the Clinical Trial Management System. Live training sessions, reference materials and start-up support supplement this overview.

III. DEFINITIONS

<table>
<thead>
<tr>
<th>Clinical Research Billing Compliance</th>
<th>On-line course detailing the Prospective Reimbursement Analysis (PRA) and Clinical Research Billing Compliance processes.</th>
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<tr>
<td>Clinical Trial Management System</td>
<td>CTMS is a web-based tool designed to organize and maintain information including protocol information, registration of study participants, and management of study accruals. The CTMS interfaces with EPIC providing information about the study, study participants and subject billing.</td>
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IV. RESPONSIBILITY

A. Clinical Research Billing Orientation (CRBO) training is required for all study team members, including the Principal Investigator (PI), who have the potential to consent subjects to a Clinical Research Study or Clinical Trial.

B. Clinical Trial Management System (CTMS) training is required for the Principal Investigator (PI) on studies with a Prospective Reimbursement Analysis (PRA).
V. PROCESS

A. Studies submitted to the IRB are reviewed by Clinical Research Support Services to determine if a Prospective Reimbursement Analysis (PRA) is required. If a PRA is required, Clinical Research Support Services (CRSS) checks to ensure the PI and study team members consenting subjects to the study have completed the Clinical Research Billing Orientation training, and the PI has completed the Clinical Trial Management System (CTMS) online training.

B. If either training requirement has not been met, a PI approved draft PRA will be held in the CRSS IRB workspace until the CRBO and CTMS training requirements have been completed. The IRB can “table” studies that have not completed these training requirements.

C. Once the Clinical Research Billing Compliance (CRBO) and Clinical Trial Management System (CTMS) training has been completed by the required study team members, the PI approved draft PRA is forwarded to IRB for their scheduled review.

D. Effective January 1, 2021, the training requirements for clinical research studies that require a PRA have been revised. The Clinical Research Billing Orientation (CRBO) training must be retaken every 3 (three) years. When a new research application is submitted in eIRB, study team members will be notified if they are required to retake the CRBO training.

VI. REVIEW CYCLE

Three (3) years