**Integrating Clinical Care and Research: Things You Should Know**

Emory Healthcare (EHC) conducts hundreds of clinical trials each year, so you are likely to encounter a patient participating in or considering a clinical trial if you have not already. Medical professionals play a vital role in clinical research. Strict rules have been put into place by federal agencies and sponsors, so clinical research has a lot of requirements and moving parts in order to preserve research integrity, human subjects’ protection, patient safety, and to ensure quality research results. Medical professionals are tasked with going above and beyond their normal level of care and monitoring with exacting vigilance and scrutiny when interacting with or treating patients on clinical trials even when they are very familiar with the drug or procedure being utilized for the research. Please be aware that Emory has special protections in place for research patients. These protections go above and beyond clinical protections, including the presence of the Institutional Review Board (IRB) whose job it is to protect the welfare and safety of research patients. The IRB reviews research to ensure compliance with federal (e.g., FDA) regulations, sponsor requirements, and monitoring the behavior of doctors, nurses, and other health care providers conducting the research.

**Where can I learn about clinical research?**

EHC has provided educational modules on clinical research in the HealthStream Learning Center (HLC) entitled “Human Subjects Research at Emory: Understanding the Nurse’s Role” (Part 1 & Part 2). Please review these modules before assisting patients in clinical research. The modules provide a brief overview of clinical research, including the importance of adhering to clinical research protocols.The modules address:

* Clinical research nursing procedures for human subjects enrolled in clinical trials at EHC hospitals and clinics
* Compliance guidelines with EHC policies & procedures regarding the safety of human subjects and ethical conduct of research
* Provide guidance to and consent for patients who wish to enroll in clinical trials

The Principal Investigator (PI) or study team coordinator will provide training prior to you performing any research activities for their study. Please review the Clinical Research Key Point Summary (CKRP) on whom to contact if you haven’t received training on the protocol.

**When am I likely to come into contact with research?**

Emory Woodruff Health Sciences Center, of which EHC, is an integral member is considered an Academic Medical Center whose trifold mission includes: education, clinical practice, and research. Emory is known for its robust research and clinical trials mission. You are likely to encounter patients on trials throughout the hospitals and clinics when…

* You are administering medication (pill or infusion) or involved with a procedure or device in a way that could be different than standard of care such as drug, dose, frequency, rate, level of monitoring, etc.
* You are administering an investigational drug
* An investigational device has been placed into a patient who is then moved to the floor

**Who is participating in clinical research?**

Procedures should be in place to help you identify which patients are participating in clinical research. A research patient should have already gone through the consent process with the research team by the time you encounter him or her. Participation in clinical research is completely voluntary. You should be aware that the patient can withdraw from the research at ANY TIME. If a research patient refuses care, you should stop the care as soon as possible, assuming there’s no obvious risk to the patient from abrupt withdrawal of the care. If there is an obvious risk, come to a reasonable withdrawal point and contact the research team. In such cases, you must notify the PI and or clinical study team at once.

**How do I confirm the patient is in a clinical research study or on a clinical trial?**

In addition to confirming with the patient, you can also confirm that the patient is on a clinical trial by viewing Powerchart in the Electronic Health Record (EHR). There will be an ‘On Clinical Trial’ banner indicated under the patient’s name. Staff can find supporting documents for the clinical trials, such as the Investigational Drug Data Sheet, Clinical Research Key Points, and the prospective reimbursement analysis by clicking on the “On Clinical Trial” banner and selecting “Initial Protocol.” Research consents signed by a patient are located in Powerchart under “Clinical Notes.”

**What do I need to know when working with research patients?**

Once you identify a patient as participating in clinical research, you should locate the Clinical Research Key Points, the Investigational Drug Data Sheet, and the signed consent in Powerchart. The EHR is embedded with documents that provide 24 hour emergency contacts in addition to information about study medications, treatments, or procedures to be administered by nurses and/or clinical staff. The study team monitor and document side effects, drug interactions, clinical events, and any clinical procedures contraindicated or associated with increased risk in research subjects. Any protocol deviation or unexpected side effect requires immediate notification to the PI, research coordinator, and/or study team member.

If you are providing care driven by clinical research, make sure you are familiar with these documents and that you follow the physician’s orders exactly. In experimental drug trials, study participants may be randomized to different arms of the study. It is important that as a care provider that you are familiar with:

* The rate, frequency, and dosage based on the clinical trial arm, and details of the administration of the drug or treatment
* Any special safe handling precautions for the investigational drugs
* Special physical or psychological monitoring of the patient while on study and during and after drug administration
* Any additional considerations for side effects or patient management as well as any procedures or special instructions for monitoring outside of routine care
* Collection of any specific research data in addition to standard-of-care information (such as obtaining sitting, standing, and lying blood pressures or timed blood draws or physical assessments)

**What do I need to know about monitoring, documenting, side effects and adverse reactions?**

You should report *all* side effects to the research team because the research team and sponsor will want as much detail as possible to ensure quality and safety in research results. Be proactive about asking patients how they are feeling, tracking all side effects, and documenting everything.

If there are any adverse reactions which negatively impact the patient, ask yourself:

* Do the orders contain any modifications I should automatically implement upon the discovery of an adverse reaction?
* Do I know who to call to report an adverse reaction? Do I know when and how quickly I should escalate an adverse reaction?

If there has been a deviation from the research team’s orders (for patient safety reasons, by necessity, or by accident), you must report it to the research team immediately.

If you witness 1) an adverse reaction which negatively impacts a patient, 2) a deviation from research team orders, or 3) an act of noncompliance by another medical professional or research team member, you should report it even if you are not involved with the care of the affected patient or with the particular research study.

**What do I need to know about dispensing medications to research patients?**

The study team is required to utilize the Investigational Drug Service (IDS) pharmacy for dispensing research drugs. The IDS provides a drug summary in Powerchart to indicatethe dosage, side effects, drug interactions, and dispensing amount. The PI or the study team are NOT allowed to bring outside drugs, whether investigational or other, into the hospital for patient use or administration. All drugs must be delivered directly to the pharmacy from the company for verification, documentation, management, and dispensing.