How Research Differs from Job Duties

	Research Staff	Clinical Staff Job Duty
Goal/Focus	Answer research question	Provide safe patient care
Guiding Documentation	Research protocol; Research Standard Operating Procedures (SOPs)	Doctors' orders; Clinic Policies and Procedures; CMS Conditions of Coverage
Medical Data Access	May require HIPAA waiver, contract, consent form, and organizational access	Patient information access via electronic medical record is provided as part of employment
Patient Interaction	Specific to procedures outlined by approved study protocol; generally does not involve assessing patients	May include assessing patients; unique to the specific needs of a patient during treatment
Equipment Interaction	Generally do not touch dialysis machines/equipment	Adjust machine settings as needed per order
Certification/Licensure	**FDA**- no written guidance about research staff roles **Industry standard**- Principal investigator is an MD, DO, PhD **Most organizations and IRBs**- require Good Clinical Practice (GCP) training certification	Federal/State Requirements for nurses, patient care technicians (PCTs), and medical providers (doctors, nurse practitioners, physician assistants)

Clinical Research vs. Medical Treatment

	Clinical Research	Medical Treatment
Intent	Answer specific questions through research involving research volunteers	Address needs of the individual patient
Funding	Paid for by private industry (device or drug manufacturers) and government agencies (e.g. NIH, PCORI) Billing to the government may require a coverage analysis	Health insurance premiums paid by patient; insurance claims paid by health insurance plan
Consent	Requires informed consent or opportunity to “opt out” of participation	May or may not require informed consent
Institutional Review Board (IRB)	Required	Not Required
Timeframe	Depends on the research protocol	Requires real-time decisions; patient-specific
Release of Findings	Publications/ Presentations	Individual medical records are not released to the general public
Billing	Invoice sponsor or possibly on claim	Claim

Source: https://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/default.htm

Clinical Research vs. Quality Improvement

	Human Subjects Research	Quality Improvement
Purpose	Designed to develop or contribute to generalizable knowledge	Designed to implement or assess a new process or program
Starting Point	Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	Knowledge-seeking is integral to management team for delivery of care
Design	Rigid protocol that usually remains unchanged throughout research	Adaptive, iterative design
Benefits	May or may not benefit current participants	Directly benefits a process; may or may not benefit patients
Risks	May put participants at risk	Does not increase risk to patients with exception of loss of privacy or confidentiality of data
Participant Obligation	No obligation of individuals to participate	Participate as part of care
Endpoint	Answer research question	Improve program, process, or system
Adoption of Results	Little urgency to share results quickly	Results rapidly adopted into local care delivery

Source: https://irb.research.chop.edu/quality-improvement-vs-research