

## Preparatory to Research

Prepare a research protocol, develop a research hypothesis, or identify prospective research participants

Primary Goal: Determine feasibility of a potential research project

For additional information, refer to the Investigator Manual for IRB Submissions:  
<https://www.uhhospitals.org/uh-research/research-and-clinical-trials/core-offices/institutional-review-board/irb-policies>

**Step 1:** To apply, complete the Use and Disclosure of Protected Health Information Preparatory to Research Investigator's Certification ("[Certification Form](#)")

**Step 2:** Submit to the UH Privacy Officer at [Compliance@UHHospitals.org](mailto:Compliance@UHHospitals.org)

**Step 3:** After Certification Form has been approved, begin review of PHI. Review of PHI must cease before expiration of the Certification Form.

**Step 4:** Once the investigator has determined feasibility, and / or has a plan to engage in research or research-related activity, the investigator must submit to and be approved by the UHCMC IRB.

**PHI may NOT be used to contact patients until and unless IRB approval has been obtained.**

**NOTE:** Preparatory to research is not intended to fast-track the recruitment of research subjects. It is intended to help investigators determine the feasibility of a potential research project.

## Research

Engage in any **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**

Primary Goal: Test or support hypothesis

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**SOP GA-105** – Investigator Responsibility for Study Team Training and Documentation

**Step 1:** Write a research protocol

**Step 2:** Obtain department approval

**Step 3:** Submit to the electronic IRB system for review and approval.

**Step 4:** Once IRB approval has been obtained, research activities may begin.

## Quality Improvement

Improve systems and processes with the intention to improve outcomes

Primary Goal: Improve patient care, assessment, and monitoring

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**Step 1:** Submit a request for a determination of "Non Human Subjects" research to the electronic IRB system.

**Step 2a:** If the activity is determined to be solely Quality Improvement, retain the documentation and conduct the QI activity.

**Step 2b:** If the activity is determined to have research elements, submit a research protocol

**NOTE:** A project cannot be assumed to be Quality Improvement simply because the ultimate goal is improving quality of patient care. If the project intends to randomize patients to different treatment groups and/or establish scientific evidence to demonstrate the comparative efficacy of an intervention, then the project is considered research.