# Human Subjects Research Process

## Proposing and Submitting Research

Start

Evaluate the project to determine whether it fits the definition of HSR

Unsure whether the proposal constitutes HSR?

YES

NO

Submit a Request for Human Subjects Determination to the IRB

Does the Study qualify as HSR?

NO

YES

Complete the CITI Human Subjects Protection Training (current certificate required of all study personnel)

Design and Submit study via the online MAESTRO application system (PI)

Sign and submit Principal Investigator's Assurance (SI, PI)

## Reviewing and Approving Research

Review, Sign off and submit the application to IRB (Co-PI, FA and DH)

Wait for IRB project review

Is the study approved by IRB?

YES

NO

Can the study be approved?

NO

YES

Review, address feedback from IRB and resubmit

**Notation:**

Collaborative Institutional Training Initiative (CITI)
Co-Principal Investigator (Co-PI)
Department Head (DH)
Faculty Advisor (FA)
Human Subjects Research (HSR)
Institutional Review Board (IRB)
Principal Investigator (PI)
Student Investigator (SI)

## While Conducting Research

- Follow federal and state regulations, university policies and ethical principles
- Adhere to the study procedures approved by IRB
- Report deviations, violations or unanticipated problems to the IRB

⚠ **Stop research and notify the IRB if human subjects are at immediate risk of harm**

Are there changes to the IRB-approved research study?

NO

YES

Submit modification form to the study via MAESTRO before they are implemented

Wait for IRB review

Are changes approved?

YES

NO

Review, address feedback from IRB and resubmit

## Research Completion

Will research continue beyond the approved expiration date?

NO

YES

Submit a request for continuance through MAESTRO

Is extension approved?

YES

NO

Complete research:

- Notify the IRB of study completion
- Closure by filling out the Final Report form on the Maestro online system

End