

RUTGERS HEALTH QUICK START GUIDE

INVESTIGATOR-INITIATED CLINICAL RESEARCH STUDIES

Define Your Research Question

1

Make it clear, focused, and address a gap in existing knowledge. Use the [NIH's Human Subject Research Decision Tools](#) or the [Rutgers IRB Decision Tools](#).

Secure Funding

2

If needed, identify funding sources for personnel, materials, data, and fees.

Find [Rutgers Funding Opportunities](#)

Develop a Study Protocol

3

To ensure scientific validity, use Rutgers' [Protocol](#) & [Consent Form Templates](#).

For Phase II or III clinical trials, try the [NIH-FDA Clinical Trials e-Protocol Tool](#).

Obtain Scientific & Ethics Approvals

4

First, submit to the Rutgers Health Scientific Review Board using the [SRB Form](#).

After SRB approval, initiate your [eIRB Submission](#).

Assemble a Qualified Team

5

Ensure that all study staff have completed [CITI Training](#) and have completed their electronic Conflict of Interests.

Obtain Partner Hospital Approval

6

To obtain permission from UH-Newark or RWJBH to recruit from, utilize clinical services, & collect Epic data, see the IRB's [Performance Site guidance](#).

Additional Considerations

7

- For help with your IRB submission, contact [IRB Draft Services](#)
- For statistical help, contact [RUBIES](#)
- If the study meets the NIH or FDA definition of a clinical trial, the study must be [registered with ClinicalTrials.gov](#)
- Be sure to close out the study in eIRB once data analysis is complete
- For record retention support, consult with [Rutgers' Records Retention Program](#)