

Steps to Initiate a Clinical Research Study in Department of OBGYN

Investigator

Research Success Core

- Formulate hypothesis for the project
- Perform a literature review to assess what has been done and identify knowledge gap. If desired, [request librarian assistance](#)
- Refine the hypothesis to address the knowledge gap in the literature.
- Request consultation with a [statistician for experimental design and power analysis](#)
- Submit [Request to Initiate Clinical Research](#) to Research Success Core (RSC)
- Present study and budget to OBGYN Research Committee. If RSC services are needed, specify the RSC services the PI is requesting during presentation (*see final box below)

If desired, meet with RSC to discuss research approach, logistics and required resources, etc.

RESEARCH COMMITTEE APPROVAL?

Yes

Write IRB protocol, which is one component of the IRB application, and [submit to RSC](#)

No

Revise and Resubmit to Research Committee

RSC can help PI revise protocol to make it eligible for Research Committee approval

If PI prefers to submit IRB application, RSC staff must be listed on the IRB application to assist with ongoing compliance and future audits

RSC can assist with IRB questions

Using the PI's IRB protocol, the RSC can complete and submit the IRB application

IRB approval

Proceed with Research Study

*** Include in proposal to Research Committee:**

- Supervise and mentor trainees
- Work with statistician to analyze data
- Write manuscript for presentation and publication
- RSC must have all approval documentation and compliance, and consents because the RSC is audited by the IRB

Optional RSC services: Consent patients, order supplies, prepare study kits, collect specimens, administer questionnaires, perform data entry, ship specimens, arrange participant compensation, maintain records and ensure compliance activities are complete.