

## FACT SHEET - What is OB/GYN Clinical Research Unit (CRU) Review?

It's a two-part process consisting of:

### 1. Scientific and Scholarly Validity Review

- During protocol development, peer reviewers are selected from Ob/Gyn faculty and staff based on investigator input and CRU Lead recommendations. Reviewers provide constructive feedback and resource suggestions to enhance protocol quality, and promote a smoother submission process.
- The main points that peer reviewers consider are:

#### **The goals of the CRU peer-review**

*In reviewing CRU protocols, please consider and comment on the following items:*

1. Study Design – is the rationale clear and study design adequate?
2. Feasibility – are the procedures, enrollment goals and study timeline feasible?
3. Is the proposed study of appropriate scientific quality and/or validity?
4. Does the proposed study raise any ethical concerns or questions?

\*\*Note: If your study protocol has already had a scientific and scholarly validity review process, the CRU Lead will conduct an expedited review of the protocol. Examples of previous scientific and scholarly validity reviews include but are not limited to those conducted by a federal agency (e.g., NIH, FDA, etc.) or an industry sponsor.

### 2. Financial and Operational Feasibility Review

- The department conducts financial review of the study budget.
- We go beyond a review of your budget spreadsheet. We consider the department's operational resources you may need. Examples include: how to budget for effort provided by research professionals (e.g., Clinical Research Coordinators, Biostatisticians), how to pay for and order any clinical/lab supplies needed, and how to prepare for recruitment and retention of participants.

### CRU Review Timeline

- CRU review takes a **minimum of two weeks (10 business days)** to complete.
- The earlier you submit your study protocol, budget details or draft, and [CRU Protocol Intake Form](#) to the [OB/GYN Research Support Form](#), the better prepared we are to provide you with a quality and timely review process!

**Need Support?** Contact Kendall Seigworth, MPH, Regulatory Specialist and CRU  
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