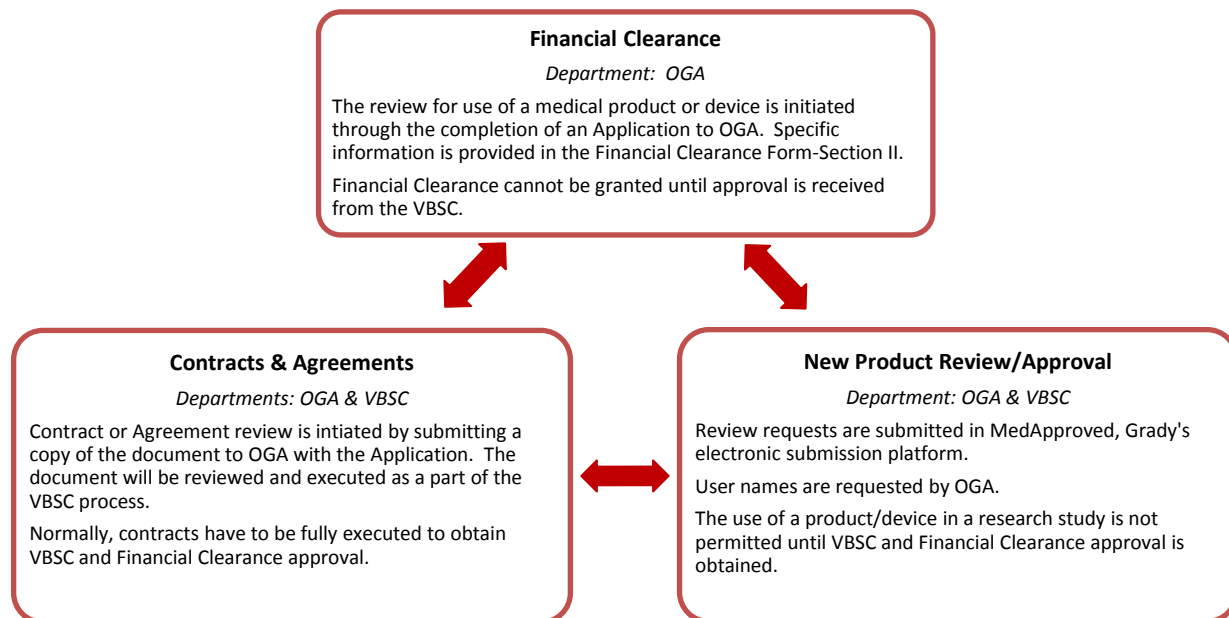The process for granting approval to use a medical product or device in research at Grady is a collaborative effort between Grady's Office of Grant Administration (OGA) and Value Based Selection Committee (VBSC). The VBSC is the reviewing body that ensures consistent consideration of new products and devices at Grady. This submission requirement is applicable to all categories of medical products and devices (i.e. FDA approved, investigational, humanitarian use, etc.).

Many of the steps involved in the review/approval process are concurrent; however, the PI's/designee's initial point of contact should be with OGA and the submission of a Financial Clearance Application Packet (Application).

Financial Clearance

Department: OGA

The review for use of a medical product or device is initiated through the completion of an Application to OGA. Specific information is provided in the Financial Clearance Form-Section II.

Financial Clearance cannot be granted until approval is received from the VBSC.

Contracts & Agreements

Departments: OGA & VBSC

Contract or Agreement review is intiated by submitting a copy of the document to OGA with the Application. The document will be reviewed and executed as a part of the VBSC process.

Normally, contracts have to be fully executed to obtain VBSC and Financial Clearance approval.

New Product Review/Approval

Department: OGA & VBSC

Review requests are submitted in MedApproved, Grady's electronic submission platform.

User names are requested by OGA.

The use of a product/device in a research study is not permitted until VBSC and Financial Clearance approval is obtained.

To avoid unnecessary delays in the review process please do the following:

- Notify OGA as soon as it is determined that the proposed study or trial indicates the use of a medical product or device (investigational or otherwise).

  Note: If the medical product/device is already approved for use at Grady, VBSC review may not be required. Contact OGA to discuss the specifics of your Application.

- When submitting a review request in MedApproved, identify the submission as being related to a research study/clinical trial. Provide the IRB number and upload research documents.

- Be prepared to facilitate the Sales Representative or Study Sponsor (i.e. Supplier) with the Vendormate process.

- Be able to identify the Grady Department Leader where this study will take place.

- Direct all questions regarding the VBSC submission and review to the VBSC Reviewers.

- Direct all questions regarding the Financial Clearance to OGA at grants@gmh.edu.

Please Note:

- Once approval is granted, Financial Clearance submission is required to amend the scope of use of the product/device; and, an annual update regarding continued use is also required. Contact OGA for guidance prior to the expiration of ROC approval.

Current forms available on the OGA Webpage