Medical Products & Devices
Obtaining Approval for Use in Research

Office of Research Administration
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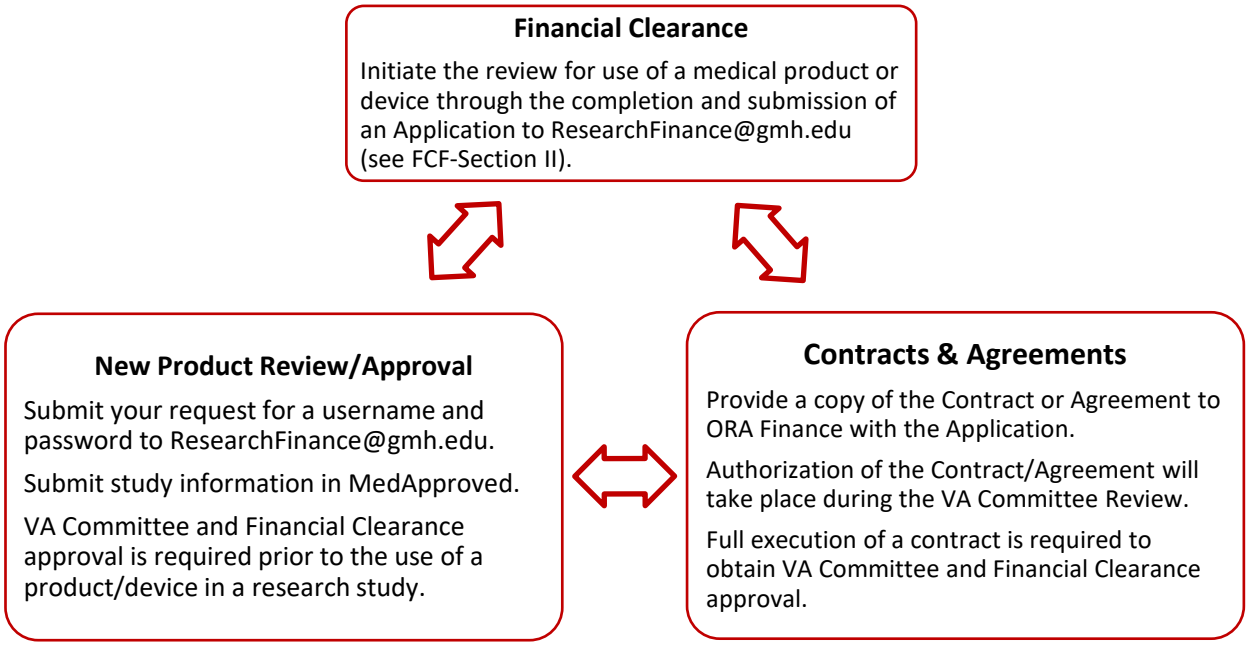
The process for obtaining approval at Grady for the use of a medical product or device in research is a collaborative effort between the Office of Research Administration (ORA) and Value Analysis (VA) Committee. The VA Committee is the reviewing body that ensures consistent consideration of products 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.). The VA Committee conducts its review using Grady's electronic submission platform, MedApproved.

Note: The VA Committee review is not related to Investigational Drug Use (IDS). To obtain approval for an IDS review the instructions for Investigational Drug Use in Section M of the ROC Application and Section IIIB of the Financial Clearance Form.

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 ORA Finance and the submission of a Financial Clearance Application Packet (Application).



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

- Email researchfinance@gmh.edu as soon as it is determined that the research study or trial proposes the use of a Non-Grady medical product or device (investigational or otherwise).
- When submitting a review request in MedApproved, identify the submission as "research". 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 the study will take place.
- Email questions regarding the VA Committee review process using the MedApproved Discussion.
- Email questions regarding the Financial Clearance process to researchfinance@gmh.edu.

Please Note:

Financial Clearance/ROC approval is required throughout the use of the approved medical device/product. If the scope of this study should change, regarding the use of these items, ORA should be notified, and an amended Financial Clearance will be issued.