**From:** Office of Research MB
**Subject:** Standardized presubmission assessment process
**Date:** Wednesday, June 18, 2025 3:09:41 PM

# MEMORANDUM

**From:** Office of Research
Tashanna Myers, M.D. Medical Director
Jennifer Sabbagh, Sr. Research Administrative Director
**To:** Research Community
**Date:** June 18, 2025
**Subject:** Standardized presubmission assessment process

Dear Research Community,

As you are aware, Baystate Health has maintained a **pause on initiating new clinical trials or new, non-NIH grants since May 2024** due to institutional restructuring, resource realignment and compliance concerns. We appreciate your patience and continued commitment to research excellence during this time.

As we begin to **recover and re-engage in research activities**, we are implementing a **standardized presubmission assessment process** for all new clinical trials and non-NIH grant submissions. This process is designed to ensure that new studies are feasible, mission-aligned, and appropriately resourced from the outset.

Before any study is submitted to the Office of Research, the following questions must be reviewed and approved by the Division Chief, Department Chair and Office of Research. Please attach with your request for exception.

1. Strategic Alignment
   - Does this study align with Baystate Health's mission, particularly in addressing high disease burden in our community? (eg. How many patients do you see with the target diagnosis in the next 12 months.)
   - How does this study enhance or complement your existing research portfolio? (eg. Are there competing studies in your portfolio, is this an area of high need @ Baystate)
2. Feasibility & Capacity
   - Do you have the time and capacity, support staff and sub-investigator support to successfully execute this study?
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What is your ability to accrue patients to this study?

- Will Clinical Trials Unit (CTU) resources be required? (Will you need provider, CRA, equipment support)

3. Experience & Oversight
    - What is your experience in running a trial of this size and through this funding mechanism?
    - Have there been any previous audit findings related to your research activities?
    - Is your current research portfolio up to date in our systems?
4. Financial Considerations
    - What is the funding stream?
    - If the study results in a financial deficit, will your department cover the shortfall?