

15 May 2024

Dear Members of the BH Research Community:

As you may know, we have instituted a temporary pause on activating any new clinical trials or submitting new, non-NIH grants. While we expect this hiatus to be relatively short-lived, probably several months, the precise duration is not yet known. We write this email to share the rationale for this decision.

The research enterprise at BH has grown >250% over the past 8 years thanks to your good work. However, such rapid growth has also been accompanied by commensurate expansions of administrative and regulatory demands and led to burgeoning audit and risk mitigation requirements, the latter including implementation of the OnCore Clinical Trials Management System (CTMS). Through these processes, several operational, regulatory, and finance challenges were revealed that led us to engage an external research consultant to help us more fully understand existing gaps to inform a corrective action plan.

Through the process of digesting the consultant's findings and recommendations, it has become clear that a temporary suspension of new clinical trial starts will have several salutary effects, including allowing our current processes to come into better compliance with our policies in the domains of research operations, research finance, and organizational risk mitigation. Exceptions to the pause will be limited and considered only on a case-by-case basis through written request to Dr. Friedmann. Such requests must include a detailed justification outlining mission-criticality, cost implications, and cost attribution.

We remain fully committed to advancing and growing BH's clinical research enterprise to support the strategic goals of BH. However, to do so requires a robust, effective research infrastructure. This brief research pause and subsequent operational improvements will provide BH with the firm foundation upon which to build impactful clinical research over the coming decades.

Sincerely,



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