Q & A Responses – May 6, 2026 – Clinical Research Town Hall

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Clinical Research Redesign

Q: How will the redesign provide opportunities for us to manage CTAs in a timelier way that aligns with federal sponsor budget periods and deadlines?

> **A:** We will be reviewing all current workflows to reduce or eliminate gaps and time delays. We understand that there are many areas that require looking into, so we appreciate all feedback as we progress.

Q: Can you further discuss what specific problems we are trying to solve through the restructure, and how will we know if these efforts are successful? What are the metrics of success? How are leadership teams defining success metrics for this redesign?

> **A:** The Clinical Research Redesign is guided by five priorities:
>
> 1. Enhance and promote cutting-edge clinical research at Weill Cornell Medicine
> 2. Reduce redundancies and administrative burden
> 3. Ensure compliance with all NIH and FDA regulations
> 4. Strengthen our strategic position with sponsors across academia, foundations, government, and industry through better tracking, greater efficiency, shorter turnaround times, and high quality
> 5. Ensure financial viability and support
>
> We will be further defining our Key Performance Indicators (KPIs) over the next couple of months but will include:
>
> - Reduction in time-to-activation of studies
> - Reduction in research billing compliance findings
> - Increase in clinical research portfolio

Q: With clinical research often operating at a deficit, can you comment on if/how the restructure will impact institutional support for clinical research? How will financial responsibility be allocated across investigators, departments, and the dean's office?

> **A:** We will be evaluating the current model for charging staff to studies and developing a sustainable workload model so that the portfolio remains cost-neutral or even profitable.

Q: Will there be reductions in staffing related to these changes?

> **A:** Although we do not foresee reductions at this time, we can never rule out that possibility.

Clinical Trials

Q: When will we be able to reliably and efficiently recruit patients for clinical research studies in Brooklyn?

> **A:** We are in the early stages of streamlining the Brooklyn Methodist Hospital (BMH) research submission process. We will continue to provide updates in future town halls. The goal is to have this resolved by the end of summer, if not sooner.

Q: The number of clinical trials across WCM has declined. What is the ideal number of trials for an institution our size? Is there a target?

> **A:** The ideal is not a number of trials but rather enabling an opportunity for more participants to be enrolled and more of our providers to participate as investigators in studies.

Collaborations

Q: Diversification of research revenues has been mentioned. What will be done to make WCM a more attractive collaborator for industry. In the past, factors such as delays in contracts over language etc has been a barrier to our ability to participate in industry sponsored-research optimally.

> **A:**: We plan to streamline the processes for budgets, contracts, and regulatory approvals.

CTSC

Q: Please provide an update on the CTSC.

A: Dr. Rainu Kaushal is leading the efforts for the new CTSA application as the new NOFO focuses heavily on data science. Many components are in progress to meet the September 2027 grant submission deadline. The new CTSA will align with the clinical research efforts for the supporting infrastructure.

Finance and Budget

Q: What is the expected Return on Investment (ROI) of outsourcing from a budget perspective? What is the cost associated with outsourcing on a study/department basis?

> **A:** The anticipated ROI is centered around a stronger negotiation position to get higher reimbursements. From a budget perspective, outsourcing on industry studies should remain relatively cost neutral as recoveries are expected from industry sponsors.

Q: How does this fit into Cornell Experience Modernization Initiative (CEMI)?

> **A:** The main area that Clinical Research will be impacted by CEMI is in the finance space for which we have representation on all appropriate committees.

IRB

Q: How do you suggest we regain the confidence of our industry partners that our IRB process is truly improved (with regard timeliness, etc) so that they will reengage with our institution?

> **A:** The IRB process has not been the sole reason for poor turn-around times (TAT) and time to activation. We learned this from the Human Research Protections (HRP) restructure and by reviewing parallel processes. To regain the confidence of industry partners, the entire process needs to be successfully streamlined through this restructuring.

Q: For IRB, can we assign individual business partners to the departments so there is actual person we can contact.

> **A:** Based on our recent assessments, this would lead to more delays. Having a cross-functional team with consistent manager engagement yields more immediate resolution.

JCTO (Joint Clinical Trials Office)

Q: Can you speak to the JCTO's ability to negotiate contacts when a research grant is involved?

> **A:** Federal awards are managed through OSRA. When a Clinical Trials Agreement (CTA) is required, the JCTO works closely with OSRA to ensure any flowdown terms from the grant are incorporated into the CTA.

Nursing

Q: Going forward, do you anticipate broader support for nursing research?

> **A:** As we progress further with our changes on the redesign efforts, we will be sharing these optimizations with NYP leadership. Perhaps some of the changes we are making will allow them to provide more dedicated time for research to their nursing staff.

Outsourcing

Q: Who owns Florence binder setup? Will departments lose certain admin functions? Will non-interventional studies need OnCore? How will IRB activation link with OnCore activation?

> **A:** The set-up for eBinders will be a combined effort between ITS and the JCTO. The implementation process will engage stakeholders from clinical research units as well.
>
> The security profiles within eBinders have not yet been stablished. This process will be managed by th implantation team.
>
> This response combines several questions: All studies that have an Intake form submitted in WRG-HS have a protocol automatically created in OnCore. Based on the responses to the Intake questions, all ancillary requirements are listed on the Study Activation Status Page (SASP). The JCTO Clinical Trials Management System (CTMS) team manages the study activation process and opening studies in OnCore. The team notifies the PI and study team at the time of Initial IRB approval of any pending items that are required to activate the study. OnCore Financials, including subject visit tracking, will be required for all studies (interventional and non-interventional) where the JCTO managed the contracts and finance review. This process ensures all study visits, protocol-related events and invoiceables are captures and invoiced to the Sponsor/funder. Additional process are being developed to capture accounts receivable and increase transparency for financial activity.

Q: Email states "Florence eBinders™ has been selected as the institutional electronic binder platform for all clinical research." - so will we no longer be using ORB?

> **A:** ORB will be decommissioned. Pre-work is being done to evaluate the process of transitioning active studies into eBinders and provide a platform for storage of studies that are no longer active.

Q: How will using external vendors impact the departments? Do departments have the option to opt out of this service?

> **A:** Departments should not be negatively impacted by the outsourcing at all. The communications with our outsourcing partners will all be handled centrally through the OCR. Functions that have been identified to be outsourced and/or centralized will mitigate current risks and eliminate compliance gaps while at the same time

allowing for the highest possible reimbursements from sponsors. There will be no ability to opt-out.

Q: Would bringing in external vendors for coverage analysis and budgets increase the overhead the departments would have to incur?

A: The vendor costs for outsourcing the coverage analysis and budgets will be incorporated into the industry budgets and paid by the Sponsor.