Q & A Responses – July 10, 2026 – Clinical Research Town Hall

Link to recording: https://weillcornell.hosted.panopto.com/Panopto/Pages/Viewer.aspx?id=d0b97fe0-a501-4aa9-83e7-b483012cc6a1

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AI

Q1: *Can AI be used to translate long forms?*

A1: No, but we are happy to talk through ideas. Guidance for translation requirements is available. We have developed a certification tool and form for users to complete to certify a form that is equivalent and can be accepted.

Q2: *Is WCM developing guidance or an SOP for studies using AI tools that outlines the required regulatory reviews (e.g., Privacy, Information Security, etc.) and provides a clear review pathway for emerging technologies?*

A2: The HRP (Human Resources Protections) office is developing an HRP specific AI policy, supplemental form for IRB applications, decision tree, ICF (Informed Consent Form) template language, and a guidance document to assist the research community. Updated documents currently are under review and should be available soon.

Clinical Research Redesign

Q1: *How are health services researchers engaged to learn about their needs for conducting health services research at WCM? The needs are very different for drug trials.*

A1: Initially with the clinical research redesign efforts, we have prioritized interventional clinical research / clinical trials. We will later include observational clinical research and health services research.

Q2: *I am very concerned about the resources from departments becoming centralized, as it took me 3 years to revamp clinical research and make it successful. would appreciate a discussion on what the plan is.*

A2: We're pleased that some departmental clinical research units are successful. Our goal with the clinical research redesign is to expand success to all parts of WCM. We plan to centralize and standardize budgets and contracts to provide a uniform approach which should help everyone.

Q3: *I wanted to ask whether there are any ongoing efforts to improve our research screening capabilities. Specifically, has there been any discussion about allowing SlicerDicer users, such as research coordinators, to obtain access to Workbench?*

From my understanding, Workbench would allow us to convert the patient populations identified in SlicerDicer into patient lists that can be further organized and manipulated. This would make screening significantly more efficient by allowing us to customize columns, track potential participants more effectively, and conduct outreach to patients who have consented to be contacted for research opportunities.

I recently discussed this with an IT specialist at Duke University while working on a collaborative study. He explained that their system allows this type of workflow and noted that it can actually be a more secure and efficient way to manage research recruitment. He also mentioned that he would be happy to share information about how their process works.

A3: We are always looking into opportunities to improve research recruitment. Ultimately, we would like to provide access to all patients that qualify for a study. Whenever we utilize new tools, especially those that are cloud-based, ITS will need to be engaged early on for security vetting and management. Please reach out to Travis Gossey and Tom Campion to discuss current and future solutions using Epic and other ARCH tools and services as well as Lynnea Lau and Chuck Mazer to schedule a meeting to begin the process.

Q4: *How is the proposed restructuring expected to affect current staff and management, including existing roles, responsibilities, reporting relationships, and staffing levels? Additionally, what transition processes will be used to move employees into the new structure, and how and when will*

affect individuals to receive information regarding their assignments, expectations, and available support?

A4: We are in the early stages of designing the Office of Clinical Research (OCR) and will provide more information about restructuring and transition in the future.

Q5: *(a) Confusion surrounding departmental resources. What is the actual plan for departments that are performing well? Will resources be pulled into centralization? (b) How will it work for smaller companies that are starting?*

A5: Coverage Analysis development, budget development, and budget negotiations centralization will create one standard fee structure and a unified approach for these processes across the organization. We are looking to expand our success. Departmental resources may be impacted with centralization, however there will be communication with appropriate contacts within departments who may be impacted as the process is rolled out. (b) Part of the fee schedule that will apply across the board. Will share and request feedback before implementation.

Q6: *Is there institutional support (internal or outsourced) for Investigator's Brochure preparation and maintenance? If not currently available, is this something being considered, given the regulatory writing burden on individual study teams?*

A6: This is not currently a resource the institution offers. However, it is currently under consideration.

Q7: *New investigators preparing IND (Investigational New Drug) submissions often struggle to know what preclinical data package the FDA will consider adequate (pharm/tox, ADME (Ab sorption, Distribution, Metabolism, and Excretion), stability, etc.). Is there centralized institutional guidance or a consult service for this, or is it left for each team to figure out independently?*

A7: We are exploring forming a centralized IND team who would help with initial submissions and monitoring over time – more to come.

Q8: *One of our bidirectional MTA (Materials Transfer Agreement) / DUAs (Data Usage Agreements) has been stuck for over a year. What's the escalation process, and who's the right contact to push it forward?*

A8: In an effort to resolve situations where either the negotiating department (OSRA or JCTO) or the escalation path is unclear, we will be creating new criteria to define a single workflow and escalation for all clinical research contracts.

Clinical Trials

Q1: *Concern from faculty for sponsored trial. Faculty PI brings in sponsor; it should contribute to faculty salary. They are not currently seeing that.*

A1: There is always a percentage of effort included for PI and sub investigators as well as key people working on a study. The faculty department would determine the salary incorporation.

Attendee Comments (submitted post event):

Feedback on Translations: Translating only portions of a clinical trial consent form, while relying on pre-translated non-study-specific language, creates significant operational and compliance concerns. Translation vendors generally will not certify or assume responsibility for language translated by another vendor. As a result, there may be no single translator who can certify that the complete consent form is accurate, internally consistent, and equivalent to the IRB-approved English version.

In addition, if only the study-specific sections are translated, WCM staff who do not speak or read the language may not be able to reliably determine where each translated section should be inserted into the pre-translated template. This creates a risk that text could be placed in the wrong section, omitted, duplicated, or presented out of sequence. It may also result in inconsistent terminology, formatting, readability, or meaning across the document.

For these reasons, the safer and more reliable approach is to have the complete, final, IRB-approved consent form translated and certified as one document by a qualified translation vendor.

General Feedback: This was a helpful town hall! Thanks for organizing it! Will the recording and slides be shared afterwards?

A1: Yes, the recording of this Clinical Research Town Hall can be found at the top of the file. All slides are visible in the recording.

Finance and Budget

Q1: *Any plans to increase PI visibility into trial finances/invoicing? PI effort translating to salary support?*

A1: The PI of study should be involved with study financials. Salary support is managed within each department. We are seeking to standardize the process and simplify it.

Q2: *NYP needs to be heavily involved in contract negotiations with sponsors.*

A2: Clinical care and research are separate but sometimes intersect. We plan WCM/NYP interaction with a feedback loop to the outsourcing vendor, WCG, to discuss rates and workflows. We do not anticipate any slowdown in the budgeting or contracting process.

Q3*: Will these changes result in increased expenses for the departments?*

A3: There should not be increased expenses for departments. The fee schedules are being reviewed to address the costs of using the outsourcing vendor. Vendor has experience and knows what sponsors will accept.

IRB

Q1: *How does implementation of the new IRB policies impact protocols that were already reviewed? Do people need to resubmit or amend it?*

A1: If an amendment or update of some kind is required, the IRB will be reaching out to the study team directly to rectify.

Q2: *Are the IRB updates currently active? If not, when do they come into effect?*

A2: Yes, all are active.

Q3: *Is there institutional support (internal or outsourced) for Investigator's Brochure preparation and maintenance? If not currently available, is this something being considered, given the regulatory writing burden on individual study teams?*

A3: Please refer to the *Clinical Research Redesign* section for response.

Q4: *New investigators preparing IND submissions often struggle to know what preclinical data package the FDA will consider adequate (pharm/tox, ADME, stability, etc.). Is there centralized institutional guidance or a consult service for this, or is it left to each team to figure out independently?*

A4: Please refer to the *Clinical Research Redesign* section for response.

Q5: *Can you shed a bit more light on .118 request form and short forms?*

A5: Sure! The .118 request form is an IRB application used to obtain certification under 45 CFR [Code of Federal Regulations] 46.118. It is to be used in place of an IRA on an initial IRB application when requesting a .118 determination. You can find this form and related guidance here. Additionally, you may reach out to the office at irb@med.cornell.edu or schedule a consultation.

Q6: *For studies opening at both WCM and CUMC (Columbia University Medical Center) (both retrospective and prospective) navigating single IRB (sIRB) reliance has been challenging. Is there an institutional update on streamlining the sIRB process for WCM/CUMC collaborations, and are there plans to simplify this for cross-institutional studies going forward?*

A6: We have a master agreement in place when reliance is warranted, but this will only be applicable when required (non-exempt, federally funded). When not required, collaboration protocols are submitted to both sites' IRBs for the approval of activities at that corresponding site. Setting up a reliance when one is not required is possible; however, it can be time-consuming and delay initiation. Historically, we had a Qualtrics from in place for CUMC and WCM collaborative

research, but the quickest path is to reach out to the HRP (Human Resources Protections) office early in the process so we can ensure the most efficient path.

JCTO

Q1: *What will happen to JCTO, CCTO, and OSRA?*

A1: We are planning to bring some of the functions together into the in OCR; while some will remain with specific offices/units based on function. Budgets and contracts are planned to be centralized, and others will be left to specific centers/institutes etc.

NIH

Q1: *Please acknowledge the NIH Public Access Policy issue and how it affects publication. IE PRMC/IRB "require" REDCap for PHI (Protected Health Information); however, using REDCap makes us subject to NIH Public Access Policy which is a barrier ($) to many journals/publications. Could avoid if we could save PHI on OneDrive for research studies.*

A1: WCM policy requires use of approved tools (i.e., REDCap) for manual chart reviews. Additionally, the NIH Public Access Policy states, "If, during the course of the publication process, an author is asked to pay a fee for submission of the Author Accepted Manuscript to PubMed Central, such costs are not allowable." WCM investigators should continue to use REDCap, which receives financial support through the NIH CTSA grant, in compliance with the NIH Public Access Policy without additional fees to journals or publishers.

We acknowledge the concern regarding the NIH Public Access Policy and its impact on publication costs. However, the NIH Public Access Policy is triggered by NIH-funded research and the resulting peer-reviewed publications, not by the use of REDCap itself. REDCap is required by WCM for studies involving PHI because it provides an approved, secure environment with appropriate access controls, audit trails, and regulatory safeguards.

While publication fees associated with compliance with the NIH Public Access Policy can be a challenge, storing PHI in an alternative platform such as OneDrive would not remove NIH Public Access Policy requirements for NIH-funded research. The publication and public access obligations remain tied to the funding source and resulting manuscripts, regardless of where study data are stored.

Research teams should continue to use institutionally approved systems for PHI management and consult with the library, grants office, or research administration regarding publication strategies, journal selection, and available resources to support compliance with NIH public access requirements while minimizing publication costs.

Outsourcing

Q1: *When will the outsourcing commence and will it cost the department money.*

A1: Outsourcing includes multiple components, including DSMC (Data and Safety Monitoring Committee), budget development and negotiation, calendar builds, coverage analysis builds and potentially even contracts. We are in the process of finalizing Statement of Work Agreements for all, but some services will move faster than others.

- DSMC restricted to general studies only will be outsourced, and the plan is within the next few months. Membership is currently being established.
- Primer studies are being sent to WCG for both the budget development and negotiation component, and the coverage analysis component to evaluate the handoff and performance workflow.

As soon as we have a better timeframe, we will share that more specifically.

As for the cost, there will be a new standardized fee schedule that all departments will need to accommodate. Since the idea is to outsource industry research at least initially, the expectation is that the associated fees will be billable to the sponsors for reimbursement. Non-industry support is being further evaluated.

Q2: *What is the fee structure for outsourcing? What is the capacity? How will this affect existing staff?*

A2: As noted above, a new fee schedule will be shared. We have shared our current year-over-year capacity with the outsourcing vendors and that is what they are planning for so that there will not be any delays.

We will work individually with departments to discuss any impacted personnel including what functions will stay with the departments, what functions will be centralized, and what functions will be outsourced. There may be opportunities for positions within the OCR as well as opportunities for the individuals to remain within the departments based on what their role and expertise levels are.

Q3: *Will Florence include eSource for subject records as well? If we will not have eSource, what is the plan for a part 11 compliant subject binder system for the institution since ORB is noncompliant?*

A3: Florence includes participant binder.

Q4: *When will Florence be rolling out? I did hear that it will be tested with certain groups.*

A4: We are projecting a 4-month roll-out. Anticipated kick-off meeting at the end of July. Expected end of November/December if everything moves according to plan.

Q5: *Will the study team need to transfer the documents from ORB to Florence or will ITS do this?*

A5: There is an option for automated transition of documents from ORB to Florence. However, this needs to be evaluated further to understand the value of the cost. We will be working towards getting Florence up for new studies and studies that do not have any or minimal enrollment. All active studies will then be evaluated individually.

Q6: *Will outsourcing lead to layoffs? Or will impacted employees be assimilated into the new system in an altered role?*

A6: Our goal in outsourcing is not to lay off individuals but rather to bring consistency and optimize workflows. The Clinical Research Optimization initiative is bigger than outsourcing where there will be new workflows, functions, and services for which personnel will be needed. We will work with department administrators to evaluate opportunities. Although not the intent, we cannot say for certain at this point that there will not be any layoffs associated with this initiative.