Einstein-Montefiore ICTR External Advisory Committee Meeting
November 8th, 2024

Attendees:

UM1 External Advisory Committee	
Martin Zand, MD PhD, Chair	University of Rochester
Barry Coller, MD	Rockefeller University
Lori Carter-Edwards, PhD MPH	Kaiser Permanente Bernard J. Tyson School of Medicine
Rowena Dolor, MD MHS	Duke University
Jomol Mathew, PhD	University of Wisconsin
Sarah Ratcliffe, PhD	University of Virginia
Cath Kane, MPA	New York University
Devin Heyward, PhD	Bronx Community Research Review Board
Gallya Gannot	NCATS Program Officer

The virtual EAC meeting began with introductions which were followed by presentations from Dr. Yaron Tomer, the Marilyn and Stanley M Katz Dean of the Albert Einstein College of Medicine, and Dr. Marla Keller, Executive Dean of the Albert Einstein College of Medicine and past CTSA UM1 PI and Director of the Institute for Clinical and Translational Research (ICTR). Dr. Keller assumed her new role in July 2024. Dr. Tomer announced he had appointed Dr. Jessica Kahn as Senior Associate Dean for Clinical and Translational Research, CTSA UM1 PI and ICTR Director on October 21, 2024. The External Advisory Committee then heard presentations by several ICTR co-leaders and had interactive discussions with the ICTR team. There were three breakout sessions during lunch (Evaluation and CQI, Learning Health System (LHS) Research, and Clinical Research Resources). Each EAC member attended one of the three breakout sessions which involved discussion with ICTR faculty and staff about resources not presented formally. The EAC provided summary comments to Drs. Keller, Kim, and Kahn and Ms. Alfieri at the end of the meeting.

Summary

Under the exceptional and outstanding leadership of Drs. Marla Keller and Mimi Kim, the Einstein-Montefiore ICTR has made excellent progress in its second year towards realizing its vision to improve the health of the Bronx and other communities that disproportionately suffer from poor health by making advances in translational science (TS) and health equity (HE). There is a clear commitment operationally to improving the health of the Bronx community in a number of areas. The EAC was impressed by the Dean's support of the ICTR and clinical and translational research and appreciated the presentation of the strategic plan which demonstrates the alignment and integration of resources and initiatives to bolster the mission of the ICTR. The ICTR was responsive to EAC comments from last year; e.g. regarding the collaboration between Biostatistics, Epidemiology and Research Design BERD and the Health Informatics (HI) modules, de-identified datasets, and the biorepository among others. Having multiple module and core co-leads in the organizational structure increases diversity among ICTR leadership, provides for leadership succession planning, and enhances knowledge among the ICTR team. The EAC members were thrilled to see so many accomplishments, especially in the face of several leadership successions, and are looking forward to hearing about continued progress across all cores and programs in the next year. The many grants and collaborations with multiple outside institutions is an additional strength.

Overall Recommendations

Role of ICTR in new centers and institutes. The EAC would like to hear more next year about the relationship between the medical school's executive team and the CTSA. Einstein is in institutional flux with respect to standing up institutes, centers, etc. There are many good reasons for this, but it can result in overlapping missions and complexity and competition with the CTSA. It would be helpful to have a sense next year of the role of the ICTR in all of the new institutes and centers, and how these are integrated into the ICTR

strategic plan. It will be important to engage in strategic planning to assess any potential concerns and what the ICTR can do proactively. Team formation, collaborations, and synergies will be important across those institutes and centers. Providing meaningful effort for those in other institutes/centers will be important, so that they are truly dual faculty. The EAC would like to hear more about strategic relationships and strategic joint projects; e.g. what programs and collaborations the ICTR is leading versus engaging in as participant, etc.

Faculty recruitment. The EAC would like to stress the importance of institutional support for faculty recruitment to build learning healthcare system (LHR), health equity research, and data sciences in translational research and science. It is critical that adequate salary support be provided for those hired through the ICTR. The EAC suggests Einstein-Montefiore Leadership consider an annual collaborative fund that is directed toward partial support of faculty who are seriously engaged with the CTSA (e.g. >25% effort) to ensure that they are dual faculty.

Increased collaboration and engagement between modules. To complement the excellent progress in the individual modules, the EAC would like to hear more next year about increased collaboration and engagement between modules. While it is clear that there is integration across the modules, it is less evident how far and how deep it goes, and the cadence of interactions. The EAC is especially interested in how the CCC is integrating with other elements and modules.

Integrated strategy. Many interesting initiatives were described but the EAC would like to hear more about an integrated strategy in different elements and modules. For example, the CCC is making progress in individual initiatives but what is the integrated strategy, how will all the initiatives work together, and what is the rationale for prioritizing specific initiatives? In the Learning Healthcare System (LHS) work, it was not clear what the overall framework was, and the module appears to be project specific. In BERD, again many projects were described but it was not clear how they are integrated and what the strategic focus was.

Resources and prioritization. The volume of requests for BERD continues to rise and there may be a need for more prioritization, more resources to respond to requests, and strategic deployment of resources. Health Informatics was responsive to many of the suggestions from last year, but like BERD, there are many projects and a need to pay attention to prioritization and governance in terms of allocating resources and integrating with other cores. There will be a need to increase volume in the Clinical Research Center and to focus on sustainability.

Outcomes. There was a focus on progress toward implementing initiatives and processes across the modules, but less of a focus on metrics, milestones, formative and summative outcomes. For example, you have a strong centralized Logic Model. If you were to use it as a framing device in future presentations, which process and outcomes metrics would you choose in order to provide context and further ground our discussion of each highlighted initiative? Expected and measurable outcomes are of particular interest. For example, many of the HI projects were characterized in a way that they are an “end,” and there was less emphasis that these are a “means” to a translational science (TS) goal. HI has created synthetic datasets, but what are the mid and long-term outcomes of this activity? What are the ideal impact(s)? How does this specific resource relate to the overall goals of the ICTR and the institution?

Module and Element Specific Recommendations

The EAC offers the following module and element specific assessments and recommendations.

Keller/Kim: Overview

Assessment and Recommendations.

- *Translational Research and Science:* The ICTR leadership has taken a lead role in conceptualizing and encouraging the transition from translational research to translational science, and their proposed spectrum model rather than a binary distinction is a valuable contribution to the CTSA consortium and to NCATS. Given the basic science strength at Einstein, it may also be valuable to try to identify platform technologies that have been developed by Einstein investigators and scientific core leaders that are in use in other CTSA hubs and/or the broader scientific community.
- *Community Health:* The overall commitment operationally to improve the health of the Bronx community is impressive.

- *Collaboration with new Institutes at Einstein:* It will be important to consider how the new data science institute will align with and collaborate with the ICTR. As noted above, there was discussion of a potentially "over-matrixed" institution with the addition of centers and institutes. While there are important drivers of this trend, it can result in overlapping missions and complexity, and some will compete with the CTSA. The ICTR and Einstein leadership should engage in strategic planning to assess the potential concerns and what they can do proactively to address them, including team formation across those institutes.
- *Clarity of Mission:* The EAC encourages clarity on what is a CTSA-driven initiative, and what is a collaboration with other Einstein initiatives.
- Clinical billing is an unrecognized and true institutional barrier to TS and the EAC encourages continued work on this.
- *Biobank Sharing:* External sharing of biobank specimens is recommended with awareness of potential regulatory barriers.
- *Cross-Module Integration and Collaboration:* The EAC was interested in the CCC's integration efforts with the other ICTR Modules and Elements, and would like to know what efforts are ongoing to document those processes, including the community engagement tracker, so that they can be disseminated. The EAC encourages the module co-leads to write a paper on the processes.

Milman: CTS Pilot Module Program

Assessment and Recommendations

- *TS vs. TR education*: The ICTR is a trailblazer with respect to TS vs. TR education and has taken a bold approach with practical implementation of approaches to TS vs TR (e.g. community education, decrease in investigator burden). The EAC recommends regional collaborations around using checklist language, screening, and actual administrative tools used when working with pilot awardees and in town halls. It would be helpful to "join hands" across hubs and across administrators and faculty. The EAC also recommends considering a follow-up publication to the hub's TS challenges paper (2023).
- *Better impact metrics:* Understanding the outcomes of the TS educational initiatives would be helpful; e.g. town hall, seminar and consultation attendees (N), as well as increase in knowledge or other outcomes.
- *A model pilot application process:* The way that the Pilot Module Program has iterated the pilot grant application process is impressive. The EAC would be interested to see plans for evaluating in the coming year the differences between using the letter of interest vs. the pre-application meetings with the TS two-question approach. Is it possible to get qualitative data? A concern was raised that changing several variables at once may make it difficult to know what is working. Perhaps meet with those whose LOI looks promising but haven't articulated the TS component well. Dr. Kane mentioned collaboration on a paper about the ICTR experience, as her NYU team has also used the 2-question approach.
- *Basic science outreach:* Consider reaching out to basic scientists who are developing techniques and technology platforms that are generalizable, or to core facility leaders. They may not recognize that their activities are aligned with TS. The ICTR could encourage them to make the platforms more easily disseminated. Consider providing opportunities to foster team formation in this regard, improving how pilots may bring together T1 focused work with TS further along the translational spectrum (see next comment).
- *T1 focus of pilots and alignment with other Modules:* There was some concern about the pilot grants being T1 focused and how that fits into the rest of the ICTR. However, ICTR leadership noted that a newly funded pilot project is focused on using AI methods to address methodological challenges in health equity research using the EHR.

Chambers: Community Collaborative Core

Assessment and Recommendations.

- *Progress:* The CCC has made excellent progress, especially in Aim 2. The integration of TR/TS content across the hub is innovative. However, acceleration of CTS research through community engagement was not well-articulated. What would acceleration look like? The EAC would like to hear more about this next year.

- *Innovative community engagement tracker:* The EAC was intrigued by the community engagement tracker and would like to hear more about it next year. This is an initiative that would be valuable to disseminate. This is an opportunity to collaborate with the data science group and figure out how to use NLP to scan advertisements of and descriptions of events, to get them into the database so that we can cross-reference code words and standardize data entry. It will be important for each group that uses it to see the value of it. An assessment of what potential users may seek can not only drive program evaluation efforts, but translational research questions the database can answer.
- *Clarification of terminology* will be helpful. For example, defining for the community what health equity means will drive optimal collaboration across institutions and the community. Clarification as to whether the ICTR is working on the following will be helpful: community engaged research vs. patient-partnered research vs. community engagement vs. patient engagement vs. clinical advocacy engagement vs. organizational engagement, as would clarification of the definition of community. In addition, consider a social network analysis so that the breadth and depth of connectivity are clear.
- *Integration of CCC programs throughout the ICTR:* The EAC recommends increased integration of community engagement across all ICTR programs. More attention is needed toward an integrated strategy. The module is making progress in individual initiatives, but what is the integrated strategy, how do the initiatives align, and why have specific initiatives been chosen? What are the common elements across all of the different initiatives? An example is the pilot programs which are largely basic science. Consider funds for pilots that support community engagement. There is a wealth of research about the biological embedding of disparities. How can other modules access the CCC to work together? Integration of the CCC across different modules may need discussions among the relevant parties to develop.
- *CCC staffing adequacy:* The ICTR should assess whether the ICTR CCC is adequately staffed, especially with investigators who can mentor junior faculty. What is the pipeline for developing investigators and mentors? What metrics can be used to assess staffing and resource adequacy?
- *Potential for increasing investigator burden*: As the ICTR adds more requirements for research teams (e.g. TS, health equity, community engagement and partnership) the time from start-up to completion of projects may be increased, itself a TS barrier.
- *Recommendation to focus on metrics:* The EAC recommends focusing on metrics, measures and outcomes in the third year and the impact on community health. Some of these measures may need to be less focused on impact and more on the upstream progress measures such as capacity, connectivity, and trust. Many translational researchers will likely be more comfortable with patient engagement as an initial first step, with community engagement incorporated in later stages of translational research/science. Continued collaboration with the Office of Community and Population Health will help to extend reach and foster connection of researchers to community-based organizations.
- *Consider a systems analysis of communities to address TS barriers:* Healthcare systems have often failed to really understand that communities have their own systems. So CTSAs should consider how do communities, as systems, operate and to then merge those systems to ultimately improve the health holistically of an individual as well as a population.

Rinke: Learning Health System and Dissemination & Implementation Science

Assessment and Recommendations

- *New PCORI initiative:* The ICTR is the home to the new PCORI funded Health System Implementation Initiative, which received funding for capacity building and for a project to implement narrow spectrum antibiotics for acute respiratory tract infections across 75 pediatric ambulatory sites across the Montefiore Health System.
- *Clearer delineation of ICTR driven initiatives:* There are a number of good projects, but the module seems to be project-specific and focused on engagement in the projects of others instead of ICTR-driven initiatives. It was not clear where ICTR is the leader or initiator on these projects.
- *It was not clear what the overall framework was*: consider clarifying which LHS framework or frameworks serve as a guide or roadmap for this module. Consider a learning collaborative similar to the “NIH collaboratory.” The EAC encourages Drs. Rinke and Gong to collaborate with the CTSA implementation science working group on these issues.

- Challenges of implementation science: The EAC understands the challenge of participation in an implementation science working group and grand rounds and recommends crowdsourcing strategies to engage and generate ideas. A reference to consider is "The clinician crowdsourcing challenge: using participatory design to seed implementation strategies: (see https://implementationscience.biomedcentral.com/articles/10.1186/s13012-019-0914-2)
- *Meet with stakeholders:* Consider meeting with health system leaders to find out what their priorities are, using existing meetings. Including the community to see how the research process works, especially through the CCC, could help support involvement and engagement.

Fazzari: BERD

Assessment and Recommendations.

- *Excellent responsiveness to prior EAC suggestions:* The EAC is pleased to see the responsiveness to the EAC comments from last year, especially with respect to the collaboration between BERD and Informatics. Some consideration should be given to the approach for measuring the added utility of the joint BERD/Informatics support for EHR based projects.
- *Metrics for outcomes and impact:* The EAC notes that the ICTR spent the last year creating the metrics and collecting the utilization consistently across all services. We are pleased that the metrics are reviewed across all services monthly in a HIC status meeting to identify areas of need and training and collaboration. We would like to hear more about combined BERD and HE metrics next year.
- *Collaboration with CCC:* The EAC would be interested to see a collaboration between BERD and the Community Collaborative Core in EHR training. We would suggest incorporating DEI in training.
- In the coming year, many projects are planned and the EAC did not have a good sense of how they were going to be integrated into the total operational work. What is the strategic focus?
- *Adequacy of resources:* The EAC perceived that a primary challenge for the BERD was the volume of requests and prioritization. Consider whether more resources are needed to respond to those requests and how those will be deployed strategically. Additional funding for the future Institute for Data Science may be helpful for BERD. Translating BERD consulting requests into training opportunities may also help to alleviate biostatistical bottlenecks.
- *Incorporating DEI and HE into training:* Incorporation of HE issues into EHR training would a great opportunity to collaborate with the Community Collaborative Core. The EAC noted that a new TS pilot project was just awarded to senior BERD statisticians on this topic, and would like to hear more about this in a year.

Mirhaji: Health Informatics

Assessment and Recommendations.

- *The EAC has seen some progress* since the last meeting, but substantial improvement is still needed. Several suggestions from last year's EAC have been implemented, including the HI modules and de-identified data sets. A number of generative AI models appear to be under development. However, a large number of individual projects were presented, and it was not clear how they are prioritized. The EAC had difficulty discerning the HI governance structure, and how the HI leadership prioritizes resources and integration with other cores.
- *Integration of HI projects into a cohesive set of goals:* A significant concern of the EAC is that many of the projects were characterized in the way that they are an "end" – with less emphasis that these are a "means" to a TS goal; e.g. to improving outcomes. For example, the HI core created synthetic datasets, but it was unclear if researchers are using them and what was their impact. Of more concern was that it was unclear from leadership which ICTR and institutional goals the HI activities and projects aligned with. This suggests that there is much work to be done yet, and the EAC would strongly suggest a discussion between the HI leadership and the ICTR Directors regarding these points. There is a case to be made for leading indicators, and articulation of intentions about where those are headed for the HI core.
- *Access to HI cohort discovery tools:* The EAC perceives a need for improved governance and prioritization for HI projects, including access to data collection tools other than ATLAS (e.g. EPIC Cosmos, TriNetX). Again, these do not seem to be integrated into larger ICTR goals.

- *AI education and research:* While HI has made progress over the past year with AI models, we would encourage more thought on how such models can be applied to TS, and consideration of collaboration with the Pilot Funding Program. While the TS emphasis is a major component of the UL1, it was unclear from the presentation how the HI leadership has integrated efforts into the TS framework.
- *Incorporation of health equity issues into training:* Given the overall ICTR focus on HE, the EAC felt that much greater clarity was needed into how HE was incorporated into HI training and projects. For example, algorithmic bias was addressed by a talk by Dr. Fazzari on AI/ML to Einstein alumni, but formal training materials or courses were not evident. This is a growth opportunity, and should be addressed for the next year.
- *Collaboration with CCC:* The EAC strongly encourages the HI to collaborate more with the CCC, and to expand on how community data (e.g. social determinants of health, geospatial data, etc.) can be used to advance CCC projects.

Bonuck: CTSA Element E Research Project, *Disability as Diversity: Reducing Researcher Roadblocks (D2/R3)*

Assessment and Recommendations.

- *National impact:* The Element E project is important and has the potential to have national impact. The work appears well on its way towards achieving this goal.
- *Accomplishments:* The EAC is happy to see so much has been accomplished in the last year and we are looking to continued progress in the next year. We are delighted to see integration and support for this project across all cores, especially from clinical research resources and the community collaborative core.
- *Defining next steps:* The module has elucidated much with intellectual and developmental disability (IDD) framing, which is complex. The EAC would like to know where the most immediate next step is, whether in the EHR, in design intervention in general, or other areas for advancing the work.
- *Integration of work across the cores:* The EAC suggests the module leaders think about how to integrate this where appropriate across the cores, and what is the story they want to tell that demonstrates the importance of this work and how it has the potential to affect delivery of health care, health equity, and awareness. This is perhaps something to talk about with the Alan Alda Institute.
- *Integration of various frameworks:* While several frameworks for this Element were discussed, integration or domains where they are being applied was less clear. There was a discussion of FRAME (body of images https://positiveexposure.org/), and branding (as an example (e.g. “Hey doc – how are my kidneys?” was trademarked by UNC to empower people to take charge of their kidney disease) – so the patient is in the driver’s seat. Could this concept be applied to this project? "No Research About Us without Us," the Disability Rights slogan, was borrowed (acknowledged) by the Bronx Community Research Review Board.

McGinn: Workforce Development
Assessment and Recommendations.

The CTSA EAC is once again extremely impressed with the range and breadth of the educational offerings and the commitment to diversifying the workforce.

- *The mentor training program* was noted to be particularly impactful, with over 100 faculty members having been trained.
- *Scientific communication training:* The engagement of the Alan Alda Center from Stony Brook for training in scientific communication is a unique and much needed project.
- *The Pathway Programs* have remarkably broad reach, from middle school through post-doctoral training, and include a number of partner institutions.
- *Career tracking data:* The EAC strongly supports the recommendation of the K12 EAC to track the careers of graduates from each of the programs, and for the ICTR to present those data at future meetings. In addition, the EAC would like to know what methods are used to assess each offering on a yearly basis. If participants fill out surveys, how have the data been used to make adjustments in the

programs? Are any survey questions designed as institutional climate assessments to assess whether trainees feel that Einstein provides an inclusive environment?

- *TS career development:* The EAC is happy to see that the core is introducing the concepts of translational science into the career development and pathway programs but cautions against training scholars to become "translational scientists" who focus on understanding and improving the translational process as a career as there is currently no path to an R grant in translational science.
- *The coordinator resources* are tremendous as is the curriculum. EAC would like to see metrics on coordinator recruitment/retention/career ladder.

Fishman: CQI and Evaluation

Assessment and Recommendations.

- *The EAC thinks that this module is outstanding* and is off to an excellent start – we liked the example of the highlighted logic module that shows which of the pieces of the logic module were associated with CQI.
- *Staffing burden of CQI evaluations:* The EAC would like the module to consider whether the addition of CQI on top of regular evaluation is creating challenges with respect to staffing and bandwidth.
- *Collaboration or connection between modules via CQI:* The EAC would like to see the impact of CQI connecting different modules across the ICTR and groups across the institution.

Abramowitz: Clinical Research Resources

Assessment and Recommendations.

- *Biorepository.* Dr. Keller explained the activities taken to expand the use of the sophisticated biorepository that Einstein has developed, allowing for internal institutional sharing. The EAC fully supports this action to enhance the utilization of this valuable resource, recognizing the administrative complexity involved in addressing all of the regulatory and IRB-mandated requirements. Extending the sharing to external users would likely further enhance utilization and provide a firmer base for justifying the significant fixed expenses for maintaining the biorepository. Similarly, offering space in the biorepository to scientists in other institutions could provide additional financial support.
- *Clinical Research Center.* The Einstein Biorepository is an outstanding potential research resource, but it is crucial to demonstrate its research value and develop a credible sustainability plan. The EAC recommends using the Clinical Research Center as an internal CQI project to find ways to increase utilization. The Research Participant Perception Survey developed by Dr. Rhonda Kost is designed for this purpose. In this vein, the EAC supports CRC collaboration with the cancer program to do phase 1 investigator-initiated clinical trials and increasing industry studies.
- *Sustainability:* We support ongoing discussions with institutional leadership about sustainability and subsidies. The Clinical Research Center serves 40 PIs with 53 active studies and 1,488 study visits last year. This is only about one-half of the pre-COVID volume and reflects the challenges of rebuilding clinical studies after the shutdown. The CRC should consider trying to obtain outcome data by surveying the research participants.
- *Additional economic challenges:* The EAC recognizes the economic challenges involved in having fixed costs for the CRC and reduced utilization. The EAC recommends both a careful analysis of potential money-saving actions that can still support the existing volume, as well as outreach to stimulate utilization, including providing assistance to investigators in developing protocols. Senior ICTR leadership may also want to consider meeting with basic science faculty to ascertain their interest in conducting human subjects research if provided with appropriate medical support.