

Executive Committee Meeting Minutes July 15, 2025

Present: Davey Smith, Colin Depp, Kathryn Gold, Mark Wallace, Mike Hogarth, Adriana Tremoulet, Liz Johnson, Christina Chambers, Sam Ward, Borsika Rabin, Paul Watson, Stephanie Farrell, Raul Lizarraga, Shane Crotty, Amertah Perman, Suzanne Page

Absent: John Ayers, David Boyle, Eric Mah, Jamison Langguth

Guests: Su-Yin Chang, Katie Fisch, Brin Rosenthal, Dan Kaufman, Karole Ignacio, Maryam Gholami, Gretchen Bandoli, Blanca Melendrez, Len Lazaro, Bekah Yohe, Bernadette Cale

Recorder: Nancy Giordanengo

| Agenda Item | Notes | Action Items, Comments |
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| Call to Order | Davey called the meeting to order at 2:30pm | |
| Opening remarks (Davey Smith) | Davey welcomed the committee members and guests. | |
| Approval of May 20 Meeting Minutes (Liz Johnson) | The committee approved the May meeting minutes by consensus. | |
| Presentation: Center for Computational Biology and Bioinformatics Updates (Katie Fisch and Brin Rosenthal) | <p>Katie presented an overview of the Center for Computational Biology and Bioinformatics (CCBB) which focuses on analyzing high-dimensional genomics data, including transcriptomics, epigenomics, and single-cell RNA sequencing. CCBB has been active since 2014, collaborating on over 100 unique projects annually with around 50 labs, and providing numerous consultations. She highlighted that CCCB staff are co-authors on about 20 publications per year, emphasizing their role as active collaborators rather than just service providers.</p> <p>Brin presented several research projects highlighting significant findings and therapeutic targets across different diseases by way of the ACTRI voucher program which provided funding for junior investigators' projects. Key projects included identifying ancestry-specific immune genes in severe preeclampsia, Clic1 as a novel anti-obesity therapeutic target, RNA editing for acute lymphoblastic leukemia relapse, Variant STAT4 and response in an autoinflammatory syndrome, and a high-impact publication on a genome sequencing study of 511 Meniere's disease.</p> | |

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| <p>Presentation: Advanced Cell Therapy Laboratory (Dan Kaufman)</p> | <p>Dan shared details about the Advanced Cell Therapy Laboratory (ACTL), which was established in 2016 and is now part of the Sanford Advanced Therapy Center: Sanford Stem Cell Institute. The facility includes a 2,000-square-foot area and additional space for process development.</p> <p>ACTL supports early-stage clinical trials for conditions like epilepsy, Parkinson's disease, and cancer. Many projects involve virus-activated lymphocytes, and NK cells, with a focus on neural stem cell therapies to improve patient treatments.</p> <p>The ACTL offers services like consultation, process development, GMP storage (cryostorage of cell banks and cell products) and final formulation/fill.</p> <p>Dan proposed developing GMP manufacturing space for gene therapy trials at UCSD. This initiative would help UCSD lead in this area, benefiting both the university and the community. One focus would be on lentivirus-based virus-like particles. Dan mentioned the plateau in cell therapy patient numbers at UCSD but noted rapid growth in gene therapy. Expansion of facilities could increase patient volume.</p> | |
| <p>Update on the status of the CTSA UM1 & K12 grants (Davey Smith)</p> | <p>Davey provided updates on the grants. The team worked to meet a tight deadline to submit JIT (Just-In-Time) documents in preparation for the notice of award.</p> <p>A recent federal court decision (<i>Massachusetts v. Kennedy</i>, No. 1:25-cv-10814-WGY) allows NIH and other agencies to proceed with standard funding decisions in 16 states—California included—without needing to remove or revise DEI components in grant applications. This effectively gives NIH the legal clearance to fund our awards as originally submitted, at least for now.</p> <p>There is currently a NCE on the UL1, 5UL1TR001442, until 4/30/2026. The UM1 and the UL1 cannot overlap by more than 2 months as they have overlapping aims. If funded, the earliest start date for an award would be 8/1/2025.</p> | |
| <p>Biomedical Informatics Updates (Mike Hogarth)</p> | <p>Mike presented updates on Velos. The latest version is called Velos 13 (Velos+) which was upgraded in October 2024 and the interface was implemented in April 2025. It allows new functionality to integrate coverage analysis and transfer to Epic, streamlining processes and reducing backlogs. Moores Cancer Center (MCC) is being trained to input their own coverage analysis and calendars, essentially handing it off to them by September 2025. When we are finished supporting MCC directly, there will be more capacity to serve others.</p> <p>Mike also discussed Epic CTMS, a new clinical trial management system being developed by Epic, which will include features like trial management, recruitment, budgeting, AI assisted study</p> | |

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| | <p>screening, and e-consenting, with a planned implementation by 2026.</p> <p>Mike encouraged interest in participating in Epic's immersion trip in October 2025 at UCSD to influence future system developments and mentioned the potential for electronic recruitment services through BMI/BIDS.</p> | <p>Contact Mike if you are interested in the immersion session.</p> |
| Center for Clinical Research updates (Mark Wallace) | <p>The Linda Vista clinic has had only 17 visits and 6 active studies. We are strategizing how to increase these numbers. A few factors are staffing challenges and Rady coordinator credentialing issues. We are considering dual RN roles.</p> <p>The La Jolla clinic has been very busy and, on our way, to exceed annual visits this year as compared to 2024:</p> <p>Active studies = 260 Phase 1 studies = 9 Active PIs = 96 Annual visits: Year 2024 = 8677. Year 2025 = 4566 Staffing is stable but we need three new RNs as the overnight studies are increasing. We currently have 18 staff.</p> <p>The L2 expanded clinical space had its official opening today. It will backfill the L1 clinic very quickly and wait times will decrease.</p> <p>IDS hazardous compounding is still on hold due to pharmacy hood and negative pressure affecting 5-6 current studies and putting a hold on future studies. The IBC has applied stricter compounding regulation on the BSL-1 agents than used in the health system. The fan has been delivered and tentative completion date is mid-December. The ventilation system will move air from inside the clinic to the outside of the building which will reduce future problems. One study will use MCC for support. Future limited slot availability will prioritize federally funded studies. Industry studies are put on hold.</p> <p>Mark provided updates on the initiatives to address investigator concerns:</p> <ul style="list-style-type: none"> • The Faculty Advisory Committee is being reorganized to the Faculty Advisory Council. The current chair, Jeremy Pettus, MD., will continue. A draft council charter has been created and is being finalized. It will be presented at the upcoming council meeting next week. The council will be re-organized to reduce the number faculty but have representatives from 5-6 main areas of research. The council will meet monthly. • Quarterly PI forum listening sessions are being organized to gather feedback and provide updates to the investigators and coordinators. | Dr. Smith, Dr. Wallace, Ji Sun, Dr. Daniels and investigators to meet with IBC to discuss lifting restrictions on BSL-I agents. |

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| | <ul style="list-style-type: none"> • Implementing a survey for users of the clinic, Clinical Trial Support Service, and CRC services . Results will be presented at both the quarterly PI and CRC listening sessions/forums. • ACTRI study start up process roles and expectations have been clarified as previously there was some misunderstanding. A new service level agreement was sent to all the PIs with concerns from only one PI. • Developing a 60-day implementation roadmap for any new ACTRI services or resource changes. • ACTRI team to train coordinators and users on the incident reporting process for protocol deviations. • Post high-level operational performance metrics on the CCR web page. • Implement a customer satisfaction survey for when studies close or transition phases occur. | |
| Next steps and announcements (Davey Smith) | We are working on an ACTRI grants accelerator in collaborator with BRAID, which a consortium of all CTSA hubs within the UC System. It will be housed at UCSD and is for faculty members interested in big grants like P30s, P01s (depending on the bandwidth) and U grants. It will be on a re-charge basis depending on needs. A formal presentation will be shared with the executive committee once the CTSA notice of award is received. | |
| Next meeting August 19, 2:30-4:00 | | |