

Curriculum Vitae

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I. EDUCATION

Johns Hopkins University Ph.D. in Chemical & Biomolecular Engineering, 2003-2007
Cornell University B.S. in Chemical & Biomolecular Engineering, 2000-2003

II. PROFESSIONAL EXPERIENCE

2010 – Now Full Professor (2021 – Now)
Associate Professor (2016 – 2021)
Assistant Professor (2010 – 2016)
Division of Pharmacoengineering & Molecular Pharmaceutics
Eshelman School of Pharmacy

Joint Appointments: Department of Biomedical Engineering, Department of
Microbiology & Immunology; Biophysics; Oral Biology (School of Dentistry)

Director, E(I) Lab Program (<http://eilab.unc.edu/>) (2015 – 2020)
Director, Young Innovators Program (<https://unceeii.org/programs/young-innovators-program/>) (2017 – 2020)
Assistant Director, Eshelman Institute of Innovation (2018 – 2020)

Core Faculty, Center for Nanotechnology in Drug Delivery
Member, Center for Infectious Disease
Member, Lineberger Comprehensive Cancer Center
Associate Member, Center for Gastrointestinal Biology & Disease

University of North Carolina at Chapel Hill

Founder & Interim CEO, Polyon Pharmaceutical (2023 – Now)
Founder & CSO, Inhalon Biopharma, Inc (2018 – Now)
Founder & Interim CEO, Mucommune, LLC (2016 – Now)

2008 - 2010 Research Assistant Professor
Department of Chemical & Biomolecular Engineering, Johns Hopkins University

2007 - 2008 Postdoctoral Fellow; Advisor: Justin Hanes
Department of Chemical & Biomolecular Engineering, Johns Hopkins University

2003 - 2007 Graduate Research Assistant; Advisor: Justin Hanes
Department of Chemical & Biomolecular Engineering, Johns Hopkins University

III. HONORS & AWARDS

2013 Packard Fellowship in Science and Engineering

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2013	IBM Junior Faculty Development Award, University of North Carolina – Chapel Hill
2012	CAREER Award, National Science Foundation
2010	New Faculty Research Award, American Association of Colleges of Pharmacy
2008	2 nd Place, AIChE Graduate Student Award (Bionanotechnology)
2008-2009	Croucher Foundation Postdoctoral Fellowship
2005-2007	Predocotrual Fellowship, Natural Sciences & Engineering Research Council of Canada
2003	Cornell Theory Center (IBM Computational Biology) Fellow
2003	Alumni Research Scholar, Cornell University
2000-2003	John McMullen Dean's Scholar, Cornell University

IV. PUBLICATIONS

Peer-Reviewed Articles (>100 total)

*Co-first author; ‡ Co-corresponding author; § Corresponding author.

[Impact factor of journal]; {Number of times cited}

Total citations: >13,500; h-index: 50; Number of Articles with over 100 citations: 33

Associated with lab research at UNC-CH:

72. Li Z, Ma A, Miller I, Starnes R, Talkington A, Stone CA, Phillips EJ, Choudhary SK, Commins SP, Lai SK[§]. (2023) Development of anti-PEG IgG/IgM/IgE ELISA assays for profiling anti-PEG immunoglobulin response in PEG-sensitized individuals and patients with alpha-gal allergy. **J Controlled Release**. 366:342-348 [Impact 11.5]
71. Shen L, Li Z, Ma A, Talkington A, Shipley S, Lai SK[§]. (2023) Free PEG suppresses anaphylaxis to PEGylated nanomedicine in swine. **ACS Nano**. *Accepted*. [Impact 15.6]
70. Shen L, Tiruthani K, Wolf W, Schaefer AM, Lai SK[§]. (2023) Siglec15-TGF- β bispecific antibody mediates synergistic anti-tumor response against 4T1 triple negative breast cancer in mice. **Bioengineering & Translational Medicine**. *Accepted* [Impact 10.6]
69. Tiruthani K*, Cruz-Teran C*, Chan JFW, Ma A, McSweeney M, Wolf W, Yuan SF, Poon VKM, Chan CCS, Botta L, Farrer B, Stewart I, Schaefer A, Edelstein J, Kumar PA, Auror H, Hutchins JT, Hickey A, Yuen KY, Lai SK[§]. (2023) Engineering a “muco-trapping” ACE2-immunoglobulin hybrid with picomolar affinity as an inhaled, pan-variant immunotherapy for COVID-19. **Bioengineering & Translational Medicine**. *Accepted* [Impact 10.6]
68. McSweeney M*, Alhajjar S*, Schaefer A*, Richardson Z, Wolf W, Stewart I, Sriboonyapirat P, McCallen J, Farmer E, Farrer B, Nzati B, Lord S, Farrer B, Moench TR, Kumar PA, Arora H, Pickles RJ, Hickey A, Ackermann M, Lai SK[§]. (2023) Inhaled “muco-trapping” monoclonal antibody for effective therapy against respiratory syncytial virus (RSV) infections. **Advanced Science**. *Accepted* [Impact 15.6]
67. Moench TR[‡], Botta L, Farrer B, Lickliter JD, Kang H, Park Y, Kim C, Hoke M, Brennan M, McSweeney MD, Richardson Z, Whelan JB, Cho JM, Lee SY, Faurot F, Hutchins J, Lai SK[‡]. (2022) A randomized, double-blind, Phase 1 study of IN-006, an inhaled antibody treatment for COVID-19. *Resubmitted to eBioMedicine*. [Impact 11.2]
<https://www.medrxiv.org/content/10.1101/2022.08.17.22278748v1>
66. Khalid MB, Zektser E, Chu E, Li J, Chatman L, Utoh J, Ryan P, Raza H, Loving H, Harb R, Kattappuram R, Komarow H, Feener EP, Lai SK, Le Q, Schwartz LB, Hartono S, Etienne E, Sun GP, Lyons JJ, Pao M, Laky K, Holland S, Brittain E, Frischmeyer-Guerrero PA. (2023) Placebo-Controlled Randomized Trial to Assess Recurrent Systemic Allergic Reactions Following COVID-19 mRNA Vaccination. *Submitted*.

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65. Li Z*, Shen L*, Ma A, Talkington A, Li Z, Nyborg AC, Bowers MS, LaMoreaux B, Livingston EW, Frank JE, Yuan H, Lai SK[§]. (2023) Addition of high MW polyethylene glycol to pegloticase effectively reduces PEG-immunogenicity and restores prolonged pegloticase circulation in mouse. **Acta Biomaterialia**. 170:250-259. [Impact 10.6]
64. Schaefer A, Yang B, Schroeder H, Harit D, Humphry MS, Ravel J, Lai SK[§]. (2023) Broadly neutralizing antibodies consistently trap HIV-1 in fresh cervicovaginal mucus from select individuals. **Acta Biomaterialia**. 169:387-397. [Impact 10.6]
63. Zierden HC, Delong K, Zulfiqar F, Ortiz JO, Laney V, Bensouda S, Hernández N, Hoang TM, Lai SK, Hanes J, Burke AE and Ensign L. (2023) Cervicovaginal mucus barrier properties during pregnancy are impacted by the vaginal microbiome. **Frontiers in Cellular & Infection Microbiology**. 13:1015625 [Impact 6.1]
62. Pearson J, Wessler T, Chen A, Boucher RC, Freeman R, Lai SK, Pickles R, Forest MG. (2023) Modeling identifies variability in SARS-CoV-2 uptake and eclipse phase by infected cells as principal drivers of extreme variability in nasal viral load in the 48 h post infection. **J Theor Biol**. 565:111470 [Impact 2.7]
61. Fritz M*, Edelstein J*, Lai SK[§]. (2022) Challenges and opportunities in gene editing of B-cells. **Biochemical Pharmacology**. 206: 115285. [Impact 6.1]
60. McSweeney M*, Stewart I*, Richardson Z*, Kang H, Park Y, Kim C, Tiruthani K, Wolf W, Schaefer A, Kumar PA, Aurora H, Hutchins J, Cho J, Hickey A, Lee SY, Lai SK[§]. (2022) Stable nebulization and muco-trapping properties of Regdanvimab/IN-006 supports its development as a potent, dose-saving inhaled therapy for COVID-19. **Bioengineering and Translational Medicine** 8(1):e10391. [Impact 10.2]
[Note: This work served as the foundation of inhaled mAb treatment for COVID that has completed Phase 1 clinical trial, and is now undergoing Phase 1B clinical trial.](#)
59. Shen L, Li J, Liu Q, Das M, Song W, Zhang X, Tiruthani K, Dorosheva O, Hu H, Lai SK, Liu R, Huang L. (2022) Nano-trapping C-X-C motif chemokine ligand 13 Reduces Regulatory B cells in Tumor Microenvironment and Inhibits Desmoplastic Tumor Growth. **J Controlled Release**. 343:303-313. [Impact 11.5]
58. Talkington A, McSweeney MD, Wessler T, Rath MK, Li Z, Zhang T, Yuan H, Frank JE, Forest MG, Lai SK[§]. (2022) A PBPK model that recapitulates anti-PEG antibody-mediated accelerated blood clearance of PEGylated nanomedicines in vivo. **Journal of Controlled Release**. 343:518-527 [Impact 11.5]
57. Chen A*, Wessler T*, Daftari K, Hinton K, Boucher RC, Pickles R, Freeman R, Lai SK, Forest MG. (2022) Modeling insights into SARS-CoV-2 respiratory tract infections 1 prior to immune protection. **Biophysical Journal**. 121(9):1619-1631 [Impact 3.7]
56. McSweeney MD, Mohan M, Commins S, Lai SK[§]. (2021) Anaphylaxis to Pfizer/BioNTech mRNA COVID-19 vaccine in a patient with clinically confirmed PEG allergy. **Frontiers Allergy**. 2:715844
55. Talkington A, Wessler T, Lai SK, Cao Y, Forest MG. (2021) Experimental data and PBPK modeling quantify antibody interference in PEGylated drug carrier delivery. **Bulletin of Mathematical Biology**. 83(12):123
54. Talkington A, McSweeney MD, Zhang T, Li Z, Nyborg A, Livingston EW, Frank JE, Yuan H, Lai SK[§]. (2021) High MW PEG restores prolonged circulation of Krystexxa in mice with anti-PEG antibodies. **Journal of Controlled Release**. 338:804-812 [Impact 11.5]
53. Huckaby JT*, Landoni E*, Jacobs TM, Savoldo B, Dotti G, Lai SK[§]. (2021) Bispecific Binder Redirected Lentiviral Vector Enables In Vivo Engineering of CAR-T Cells. **Journal of Immunotherapy of Cancer**. 9:e002737 [Impact 13.8]

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52. Shrestha B, Vincent K, Schaefer A, Yong Z, Vargas G, Motamedi M, Swope K, Morton J, Simpson C, Pham H, Brennan MB, Pauly MH, Zeitlin L, Bratcher B, Whaley K, Moench T, Lai SK[§]. (2021) Hexavalent sperm-binding IgG antibody released from vaginal film for development of potent on-demand nonhormonal female contraception. **PNAS** 118(48):e2107832118. [Impact 12.8]
Highlighted in GEN (<https://www.genengnews.com/topics/bioprocessing/bioprocessing-appears-on-track-to-creating-new-female-contraceptive/>), *Chemistry World* (<https://www.chemistryworld.com/news/engineered-antibody-that-snags-sperm-could-be-an-effective-non-hormonal-contraceptive/4014843.article>)
51. Schaefer A, Lai SK[§]. (2021) The biophysical principles underpinning muco-trapping functions of antibodies. **Human Vaccines & Immunotherapeutics**. 1-10
50. Shrestha B, Schaefer A, Zhu Y, Saada J, Jacobs TM, Chavez EC, Omsted SS, Cruz-Teran CA, Baldeon Vaca G, Vincent K, Moench TR, Lai SK[§]. (2021) Engineering sperm-binding IgG antibodies for the development of an effective nonhormonal female contraception. **Science Translational Medicine**. 13(606):eabd5219 [Impact 19.3]
Highlighted in The Scientist (<https://www.the-scientist.com/news-opinion/antibodies-stop-sperm-in-their-tracks-69079>), *Wired Magazine* (<https://www.wired.com/story/an-experimental-birth-control-attacks-sperm-like-a-virus/>), *MedScape* (<https://www.medscape.com/viewarticle/956627>), *WRAL TechWire* (<https://www.wraltechwire.com/2021/08/11/unc-scientists-discover-possible-new-birth-control-method-lab-made-proteins/>), and many others.
49. Cruz-Teran C*, Tiruthani K*, McSweeney MD*, Ma A, Pickles R Lai SK[§], (2021) Challenges and opportunities for antiviral monoclonal antibodies as COVID-19 therapy. **Advanced Drug Delivery Reviews**. 169:100-117. [Impact 17.9]
48. Lai SK[§], McSweeney MD, Pickles R (2021) Learning from past failures: challenges with monoclonal antibody therapies for COVID-19. **J Controlled Release**. 329:87-95 [Impact 11.5]
47. McSweeney MD, Shen L, DeWalle AC, Joiner JB, Ciociola EC, Macauley MS, Lai SK[§]. (2021) Pre-treatment with high molecular weight free PEG effectively suppresses anti-PEG antibody induction by PEG-liposomes in mice. **J Controlled Release**. 311-312: 138–146. [Impact 11.5]
46. Zhu Y, Saada J, Shrestha B, Lai SK, Villarreal P, Pyles R, Motamedi M, Vargas G, Moench T. Vincent KL. (2020) Surrogate post-coital testing for contraceptive efficacy against human sperm activity in the ovine vaginal model. **Biology of Reproduction**. 104(2):317-324 [Impact 4.2]
45. Anderson D, Politch JA, Cone R, Zeitlin L, Lai SK, Santangelo PJ, Moench MR, Whaley KJ. (2020) Engineering monoclonal antibody-based contraception and multipurpose prevention technologies. **Biology of Reproduction**. 103(2): 275–285. [Impact 4.2]
44. Shrestha B, Schaefer A, Chavez E, Kopp AJ, Jacobs TM, Moench TR, Lai SK[§]. (2020) Engineering tetravalent IgGs with enhanced agglutination potencies for trapping vigorously motile sperm in mucin matrix. **Acta Biomaterialia** 117:226-234 [Impact 10.6]
43. Huckaby J, Jacobs TM, Li Z, Perna RJ, Wang A, Nicely N, Lai SK[§]. (2020) Structure of an anti-PEG antibody reveals an open ring that captures highly flexible PEG polymers. **Communications Chemistry**. 3:124
42. Schiller JL, Lai SK[§]. (2020) Tuning Barrier Properties of Biological Hydrogels. **ACS Applied Bio Materials**. 3(5) 2875–2890.
41. Voorhees P, Cruz-Teran C, Edelstein J, Lai SK[§]. (2020) Challenges & Opportunities for Phage-based in situ Microbiome Engineering in the Gut. **J Controlled Release**. 326:106-119 [Impact 9.8]

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40. Hoang T, Toler E, DeLong K, Mafunda N, Bloom S, Sierden H, Moench T, Coleman JS, Hanes J, Kwon D, Lai SK, Cone R, Ensign LM. (2020) The cervicovaginal mucus barrier to HIV-1 is diminished in bacterial vaginosis. **PLoS Pathogens**. 16(1):e1008236. PMID: 31971984 [Impact 6.5] {Cited: 2}
39. Schroeder HA, Newby J, Schaefer A, Subramani B, Tubbs A, Forest MG, Miao E, Lai SK[§]. (2020) LPS-binding IgG arrests actively motile Salmonella Typhimurium in gastrointestinal mucus. **Mucosal Immunology**. <https://doi.org/10.1038/s41385-020-0267-9>. PMID: 32123309 [Impact 7.4]. {Cited: 3}
38. Parker CL, Jacobs TM, Huckaby J, Harit D, Lai SK[§]. (2020) Efficient and highly specific gene transfer using mutated lentiviral vectors redirected with bispecific antibodies. **mBio**. 11(1):e02990-1, PMID: 31964730 [Impact 6.5]
37. Schiller JL, Fogle MM, Bussey O, Kissner WJ, Hill DB, Lai SK[§]. (2019) Antibody-mediated trapping in biological hydrogels is governed by sugar-sugar hydrogen bonds. **Acta Biomaterialia**. 107:91-101, PMID: 32147470 [Impact 8.9] {Cited: 1}
36. Parker CL, McSweeney MD, Lucas AT, Jacobs TM, Wadsworth D, Zamboni WC, Lai SK[§]. (2019) Pretargeted delivery of PEG-coated drug carriers to breast tumors using multivalent, bispecific antibody against polyethylene glycol and HER2. **Nanomedicine**. 21:102076, PMID: 31394261 [Impact: 6.5] {Cited: 2}
35. Zhu F, Jay M, Schiller JL, Schroeder HA, Wessler T, Chen A, Forest MG[‡], Lai SK[‡]. (2019) Modeling barrier properties of intestinal mucus reinforced with IgG and secretory IgA against motile bacteria. **ACS Infectious Disease**. 5(9):1570-1580 [Impact: 4.3] {Cited: 5}
34. Patel KB, Mao ST, Forest MG, Lai SK, Newby JM. (2019) Limited processivity of single motors improves overall transport flux of self-assembled motor-cargo complexes. **Physical Review E**. 100: 022408, PMID: 31574716. [Impact: 2.4]
33. Edwards VL*, Smith SB*, McComb EJ, Tamarelle J, Ma B, Humphrys MS, Gajer P, Gwilliam K, Schaefer AM, Lai SK, Mark KS, Brotman RM, Bavoil P, Forney LJ, Ravel J. (2019) Cervicovaginal microbiota-host interaction modulates Chlamydia trachomatis infection. **mBio**. 10(4): e01548-19, PMID: 31409678. [Impact 6.7] {Cited: 12}
Highlighted in ScienceDaily: "How vaginal microbiome can elicit resistance to chlamydia"; Biospace: "New Research Identifies How Microbiome Can Increase Risk or Protection Against Sexually Transmitted Infections (STIs)"
32. McSweeney MD*, Price LSL*, Wessler T, Ciociola EC, Herity LB, Piscitelli JA, DeWalle AC, Harris TN, Chan A, Saw RS, Hu P, Jennette JC, Forest MG, Cao Y, Montgomery SA, Zamboni WC[‡], Lai SK[‡]. (2019) Overcoming anti-PEG antibody mediated accelerated blood clearance of PEGylated therapeutics by preinfusion with high molecular weight free PEG. **Journal of Controlled Release**. 311:138-146, PMID: 31454530 [Impact 9.8] {Cited: 4}
31. Schiller JL, Marvin A, McCallen JD, Lai SK[§]. (2019) Robust antigen-specific tuning of the nanoscale barrier properties of biogels using matrix-associating IgG and IgM antibodies. **Acta Biomaterialia**. 89:95-103, PMID: 30878451 [Impact 8.9] {Cited: 2}
30. Jensen MA, Wang YY, Lai SK, Forest MG, McKinley SA. (2019) Antibody-mediated immobilization of virions in mucus. **Bulletin of Mathematical Biology**. 81: 4069–4099, PMID: 31468263 [Impact 1.8]
29. McSweeney MD*, Wessler T*, Price LSL, Ciociola EC, Herity LB, Piscitelli JA, Zamboni WC, Forest MG, Cao Y[‡], Lai SK[‡]. (2018) A minimal physiologically based pharmacokinetic model that predicts anti-PEG antibody-mediated clearance of PEGylated drugs in human and mouse. **Journal of Controlled Release**. 284:171-178, PMID: 29879519 [Impact 9.8] {Cited: 9}

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28. Huckaby J, Parker CL, Jacobs T, Schaefer A, Wadsworth D, Nguyen A, Newby J, Lai SK[§]. (2019) Engineering polymer-binding bispecific antibodies for enhanced pretargeted delivery of nanoparticles to mucus-covered epithelium. **Angewandte Chemie**. 58(17):5604-5608, PMID: 30811861 [Impact 12.1]. {Cited: 3}
27. Newby J, Schaefer AM, Lee P, Forest MG[‡], Lai SK[‡]. (2018) Convolutional neural networks automate detection for tracking of submicron-scale particles in 2D and 3D. **PNAS**. 115(36): 9026-9031, PMID: 30135100, PMCID: PMC6130393 [Impact 9.7] {Cited: 46}
This Week in Machine Learning & AI Podcast (<https://twimlai.com/talk/179>; 200k listens/mo); WRAL TechWire "UNC-CH launches new company to commercialize particle tracking tech"; ScienceDaily "Better particle tracking software using artificial intelligence"; Phys.org
26. Schroeder HA, Nunn KL, Schaefer A, Henry CE, Lam F, Pauly MH, Whaley KJ, Zeitlin L, Humphrys MS, Ravel J, Lai SK[§]. (2018) Herpes simplex virus binding IgG traps HSV in human cervicovaginal mucus across the menstrual cycle and diverse vaginal microbial composition. **Mucosal Immunology**. 11:1477–1486, PMID: 29988116, PMCID: PMC6485947 [Impact 7.5] {Cited: 9}
25. Yang B, Schaefer A, Wang YY, McCallen JD, Lee P, Newby J, Arora H, Kumar PA, Zeitlin L, Whaley KJ, McKinley SA, Fischer W, Harit D[‡], Lai SK[‡]. (2018) ZMapp Reinforces the Airway Mucosal Barrier Against Ebola Virus. **Journal of Infectious Disease**. 218(6):901-910, PMID: 29688496 [Impact 5.2] {Cited: 11}
24. Fix SM, Nyankima AG, McSweeney MD, Tsuruta JK, Lai SK, Dayton PA. (2017) Accelerated clearance of ultrasound contrast agents containing polyethylene glycol (PEG) is associated with the generation of anti-PEG antibodies. **Ultrasound in Medicine and Biology**. 44(6):1266-1280. PMID: 29602540 [Impact 2.6] {Cited: 16}
23. McSweeney MD, Versfeld ZC, Carpenter DM, Lai SK[§]. (2017) Physician awareness of immune responses to polyethylene glycol-drug conjugates. **Clinical and Translational Science**. 11(2):162-165. PMID: 29383836 [Impact 2.0] {Cited: 16}
22. Newby J, Seim I, Lysy M, Ling Y, Huckaby J, Lai SK, Forest G. (2017) Technological strategies to estimate and control diffusive passage times through the airway mucus barrier in mucosal drug delivery. **Adv Drug Deliv Rev**. 124:64-81, PMID: 29246855 [Impact 15.6] {Cited: 12}
21. Huckaby J, Lai SK[§] (2017) PEGylation for enhancing nanoparticle diffusion in mucus. **Adv Drug Deliv Rev**. 124:125-139, PMID: 28882703 [Impact 15.6] {Cited: 92}
20. Parker CL, Yang Q, Yang B, McCallen JD, Park SI[‡], Lai SK[‡] (2017) Multivalent interactions between streptavidin-based pretargeting fusion proteins and cell receptors impede efficient internalization of biotinylated nanoparticles. **Acta Biomaterialia**. 63:181-189, PMID: 28870833 [Impact 8.9] {Cited 3}
19. McCallen J*, Prybylski J*, Yang Q, Lai SK[§]. (2017) Cross-reactivity of anti-PEG antibodies to other polymers containing C-C-O backbone. **ACS Biomaterials Science & Engineering**. 3(8):1605–1615. [Impact 4.4] {Cited 3}
18. Newby J*, Schiller J*, Wessler T, Edelstein J, Forest MG[‡], Lai SK[‡]. (2017) A blueprint for robust crosslinking of mobile species in biogels using third-party molecular anchors with short-lived anchor-matrix bonds. **Nature Communications**. 8(1):833, PMID: 29018239 PMCID: PMC5635012, [Impact 12.4] {Cited 13}
17. Yang Q, Parker CL, Lin Y, Press OW, Park SI[‡], Lai SK[‡]. (2017) Pretargeting with bispecific fusion proteins facilitates delivery of nanoparticles to tumor cells with distinct surface antigens. **J Controlled Release** 255:73-80. PMID: 28363519 [Impact 9.8] {Cited 11}

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16. Wang YY*, Harit D*, Subramani DB, Arora H, Kumar P, Lai SK[§]. (2017) Influenza-binding antibodies immobilise influenza viruses in fresh human airway mucus. **European Respiratory Journal** 49:1601709. PMID: 28122865 [Impact 12.2] {Cited 21}
15. McCallen JD*, Schaefer AM*, Lee P*, Hing L, Lai SK[§]. (2016) Stereolithography-based 3D printed "pillar plates" that minimizes fluid transfers during enzyme linked immunosorbent assays. **Annals of Biomedical Engineering** 45(4):982-989. PMID: 27913951 [Impact 3.4] {Cited 2}
14. Yang Q, Jacobs TM, McCallen JD, Moore DT, Huckaby JT, Edelstein JN, Lai SK[§]. (2016) Analysis of pre-existing IgG and IgM antibodies against polyethylene glycol (PEG) in the general population. **Analytical Chemistry** 88(23):11804-11812. PMID: 27804292 DOI: 10.1021/acs.analchem.6b03437. [Impact 6.0] {Cited 61}
13. Lei M, Newby J, Lin C, Zhang L, Xu F, Kim W, Forest MG, Lai SK, Milowsky M, Wobker S, Huang L. (2016) The Binding Site Barrier Elicited by Tumor Associated Fibroblasts Interferes Disposition of Nanoparticles in Stroma-Vessel Type Tumors. **ACS Nano** 10(10): 9243–9258. PMID: 27666558 [Impact 13.7] {Cited 83}
12. Henry C, Wang YY, Yang Q, Hoang T, Hoen T, Ensign L, Nunn KL, Schroeder H, McCallen J, Moench T, Cone R, Roffler S, Lai SK[§]. (2016) Anti-PEG antibodies alter the mobility and biodistribution of densely PEGylated nanoparticles in mucus. **Acta Biomaterialia** 43:61-70 PMID: 27424083, [Impact 8.9] {Cited 17}
11. Wang YY, Schroeder H, Nunn KL, Woods K, Anderson DJ, Lai SK[‡], Cone RA[‡]. (2016) Diffusion of Immunoglobulin G in shed vaginal epithelial cells and in cell-1 free regions of human cervicovaginal mucus. **PLoS ONE**. 11(6): e0158338. PMCID: PMC4928780. [Impact 2.8] {Cited 15}
10. Wessler T, Chen A, McKinley SA, Cone R, Forest MG[‡], Lai SK[‡]. (2015) Using computational modeling to optimize the design of antibodies that trap viruses in mucus. **ACS Infectious Disease**. 2(1):82-92 PMCID: PMC4707974 [Impact 4.3] {Cited 21}
9. Yang Q*, Parker C*, McCallen J, Lai SK[§]. (2015) Addressing challenges of heterogeneous tumor treatment using bispecific protein-mediated pretargeted drug delivery. **J Controlled Release**. 220(Pt B):715-26 PMCID: PMC4688191 [Impact 9.8] {Cited 12}
8. Wang YY, Nunn KL, McKinley S, Lai SK[§]. (2015) Minimizing biases associated with tracking analysis of submicron particles in heterogeneous biological fluids. **J Controlled Release**. 220(Pt A):37-43. PMCID: PMC4688199 [Impact 9.8] {Cited 16}
7. Nunn KL, Wang YY, Harit D, Humphrys M, Ma B, Cone R, Ravel J, Lai SK[§]. (2015) Enhanced trapping of HIV-1 by human cervicovaginal mucus is associated with *Lactobacillus crispatus*-dominant microbiota. **mBio**. 6(5):e01084-1 PMCID: PMC4611035 [Impact: 6.8] {Cited 94} *Highlighted in Witkin SS, Linhares IM. 2015. mBio 6(5):e01485-15. mBiosphere: "Lactobacilli present in cervicovaginal mucus alter its protective properties" Press Release by American Society for Microbiology, "Vaginal microbes influence whether mucus can trap HIV virus". Covered by numerous other media outlet, including International Business Times and Slate Magazine.*
6. Chen A, McKinley SA, Shi F, Wang S, Mucha PJ, Harit D, Forest MG, Lai SK[§]. (2015) Modeling of Virion Collisions in Cervicovaginal Mucus Reveals Limits on Agglutination as the Protective Mechanism of Secretory Immunoglobulin A. **PLoS ONE**. 10(7):e0131351 PMCID: PMC4488843 [Impact 3.2] {Cited 12}
5. Yang Q, Lai SK[§]. (2015) Emergence, characteristics and unaddressed questions about anti-PEG immunity. **WIREs Nanomedicine & Nanobiotechnology** (Invited Review). 7(5):655-77. PMCID: PMC4515207 [Impact 6.4] {Cited 243}

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4. McKinley SA[‡], Chen A, Shi F, Wang S, Mucha P, Forest MG, Lai SK[‡]. (2014) Modeling neutralization kinetics of HIV-1 by broadly neutralizing monoclonal antibodies in genital secretions coating the cervicovaginal mucosa. **PLoS ONE**. 9(6):e100598 PMID: PMC4072659 [Impact 3.2] {Cited 24}
3. Chen A, McKinley SA, Shi F, Wang S, Mucha P, Forest MG[‡], Lai SK[‡]. (2014) Transient antibody-mucin interactions produce a dynamic molecular shield against viral invasion. **Biophysical Journal**. 106(9):2028-2036. PMID: PMC4017286 [Impact 3.5] {Cited 42}
2. Yang Q, Jones SW, Parker C, Zamboni WC, Jear JE, Lai SK[§]. (2014) Evading immune cell uptake and clearance requires PEG grafting at densities markedly exceeding the minimum for brush conformation. **Molecular Pharmaceutics**. 11(4):1250-8 PMID: 24521246 [Impact 4.6] {Cited 143}
1. Wang YY*, Kannan A*, Nunn KL, Murphy M, Subramani DB, Moench TM, Cone RA, Lai SK[§]. (2014) IgG in cervicovaginal mucus traps HSV and prevents vaginal Herpes infections. **Mucosal Immunology**. 7(5):1036-44 PMID: PMC4122653 [Impact 7.4] {Cited 70}

Associated with lab research at Johns Hopkins & earlier: 35

35. Yu T, Chisholm J, Choi WJ, Anonuevo A, Pulicare S, Zhong W, Chen M, Fridley C, Lai SK, Ensign LM, Suk JS, Hanes J. (2016) Mucus-Penetrating Nanosuspensions for Enhanced Delivery of Poorly Soluble Drugs to Mucosal Surfaces. **Advanced Healthcare Materials**. 5(21):2745-2750 PMID: 27717163 [Impact 5.6] {Cited 7}
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31. Suk JS, Kim AJ, Trehan K, Schneider CS, Cebotaru L, Woodward OM, Boylan NJ, Boyle MP, Lai SK, Guggino WB, Hanes J. (2014) Lung gene therapy with highly compacted DNA nanoparticles that overcome the mucus barrier. **J Control Release**. 178:8-17. PMID: PMC3951606 [Impact 9.8] {Cited 138}
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29. Wang YY, Lai SK, Ensign LM, Zhong W, Cone R, Hanes J. (2013) The Microstructure and Bulk Rheology of Human Cervicovaginal Mucus Are Remarkably Resistant to Changes in pH. **Biomacromolecules**. 14(12):4429-35. PMID: PMC3918948 [Impact 5.7] {Cited 41}
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 18. Yang M*, Lai SK*, Wang YY, Zhong W, Happe C, Zhang M, Fu J, Hanes J. (2011) Biodegradable Nanoparticles Composed Entirely of Safe Materials that Rapidly Penetrate Human Mucus. **Angew Chem Int Ed Engl.** 50(11):2597-600. PMID: PMC3100893 [Impact 12.0] {Cited 198} *Listed by Wiley-VCH in "Hot Topics: Drug Delivery"; "Polymer coat helps nanoparticles penetrate mucus", Royal Society of Chemistry.*
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3. Suh J, Choy KL, Lai SK, Suk JS, Tang B, Prabhu S, Hanes J. (2007) PEGylation of nanoparticles improves their cytoplasmic transport. **Int J Nanomedicine**. 2(4):735-41. PMID: PMC2676827. [Impact 5.0] {Cited 146}
2. Suk JS, Suh J, Choy K, Lai SK, Fu J, and Hanes J. (2006) Gene delivery to differentiated neurotypic cells with RGD and HIV Tat peptide functionalized polymeric nanoparticles. **Biomaterials**. 27(29):5143-5150. PMID: 16769110 [Impact 8.8] {Cited 166}
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Associated with education research at UNC-CH:

2. McLaughlin JE, Bush AA, Friedman AD, Lai SK. (2020) Immersive Research Experiences for High School Students to Promote Diversity and Visibility in Pharmacy Education. **American Journal of Pharmaceutical Education**. 84(3):ajpe7589, PMID: 32313287
1. Friedman AD, Bush AA, Melendez CR, Lai SK, McLaughlin JE. (2017) The Young Innovators Program at the Eshelman Institute for Innovation: A Case Study Examining the Role of a Professional Pharmacy School in Enhancing STEM Pursuits Among Secondary School Students. **International Journal of STEM Education**. 4(1):17, PMID: 30631673 {Cited: 4}

Book Chapters

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Others

What's Snot to Like? – A middle school lesson plan that explores the respiratory and immune systems through mucus. Principal Developers: Nicholas Hoffmann, Amber Vogel. Additional Contributors: Crystal Harden Adams, Samuel K. Lai, Cathy P. Oakes.

What's Snot to Like? was developed by Morehead Planetarium and Science Center's DREAMS Initiative with support from the National Science Foundation CAREER Award to Dr. Samuel Lai (Fed. Grant DMR-1151477), and support from the State of North Carolina to Morehead Planetarium and Science Center.

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V. PATENTS

Johns Hopkins

1. Hanes J, Lai SK. (2008) Compositions and methods for enhancing transport through mucus. *Awarded*: WO2008030557A2; EP20070837876 (Issued); JP2014256264A (Issued); CA 2663003 (Issued); DE200760012559 (Issued); ES07837876T (Issued)
2. Lai SK, Wang YY, Cone RC, Hanes J. (2009) Compositions and methods for reducing particle penetration through mucus. WO2009089070A2
3. Lai SK, Yang M, Wang YY, Mert O, Ensign L, Hanes J. Compositions and methods relating to reduced mucoadhesion. WO2012061703A1; US15065017 (Pending); EP20110838873 (Pending); CA 2816977 (Pending)
4. Popov A, Enlow EM, Bourassa J, Gardner CR, Chen HM, Ensign LM, Lai SK, Yu T, Hanes J, Yang M. Nanocrystals, compositions, and methods that aid particle transport in mucus. WO2013166385A1; US13886493 (Issued); US14731921 (Issued); US14731972 (Issued); US15187552 (Issued); US15354704 (Issued); EP20130724670 (Pending); JP2015510480A (Issued); KR20147033571A; CA 2871778 (Pending)
5. McDonnell PJ, Khan YA, Lai SK, Kashiwabuchi RT, Behrens A, Hanes J. Sustained delivery of therapeutic agents to an eye compartment. WO2011106702A2; US13581454 (Issued); US14521904 (Issued); US15138132 (Issued); US15884158 (Pending); EP20110748181 (Pending); CA 2791278 (Issued); [Cited: 97]

UNC – Chapel Hill

Issued Patents: ; Pending Patents:

6. Lai SK, Wang YY, Kannan A, Nunn KL, Subramani B, Cone R. (2012) Compositions and Methods for Inhibiting Pathogen Infections. WO2014070786A1: **US 10,100,102 B2 (Issued)**; **EP2912060B1 (Issued)**; **US 10,829,543 B2 (Issued)**; EP3666285A3 (Pending); US17/066,874 (Pending)
7. Lai SK, Yang Q. (2013) Polymer coated particles and methods thereof. WO2014205000A1; **US14898652 (Issued)**
8. Lai SK, Henry CE, Wessler T, Chen A, Shiller J, Forest MG. (2016) Optimized Crosslinkers for Trapping a Target on a Substrate. WO2017083681A1: **US 10,793,623 B2 (Issued)**, US17/698,645 (Pending)
9. Lai SK, McSweeney M. (2017) Use of High Molecular Weight Polyethylene Glycol Compositions to Restore the Efficacy of Pegylated Therapeutic Compositions. **US 11,813,333 B2 (Issued)**
10. Lai SK, Yang B, McCallen J. (2018) Composition and Methods for Inhibiting Pathogen Infection in the Lung. Provisional US 62/646,200. Combined with #6 as **US 2019/0023769A1 (Issued)**
11. Newby J, Forest G, Lai SK. (2018) Methods, Systems, and Computer Readable Media for Using Synthetically Trained Deep Neural Networks for Automated Tracking of Particles in Diverse Video Microscopy Data Sets. **US 10,664,978 B2 (Issued)**
12. Lai SK, Shrestha B, Schaefer A, Jacobs T, Moench T. (2018). Anti-sperm Antibodies and Use Thereof.
13. Lai SK, Parker C, Huckaby J, Jacobs T. (2019) Gene Transfer Systems. WO2021119335A1
14. Lai SK, Tiruthani K, Cruz-Teran C. (2020) Binding Proteins Useful Against ACE2-targeted viruses. PCT Application: US 17/914,000
15. Lai SK, Kushiro K, Moench TR. (2022) Methods and Apparatuses for Delivery of an Agent to the Lungs and Nasal Passages. PCT Application: US 17/889,141
16. Lai SK, Moench TR, Hutchins JT. (2022) Compositions and methods for inhalable therapeutics. WO2023230486A2
17. Lai SK, Shen L, Schaefer AS, Tiruthani K. (2023) Bispecific antibodies for Cancer Therapy. Provisional 63/466,518.

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18. Lai SK, Zhao JY, Fritz M, Shen L. (2023) Compositions and methods relating to viral therapeutics. Provisional.
19. Lai SK, Shen L, Li Z. (2023) PEG suppression of anaphylaxis. Provisional

Patents Family #1, #3 and #4 are licensed by Kala Pharmaceuticals. # 1 & #4 formed the basis of Kala Pharmaceuticals, which secured Series A financing in 2010, completed successful Phase II and III trials in 2015, completed IPO in 2017, and received FDA-approval of its first drug (Inveltys) in 2018.
Patent Family #5 is licensed by Graybug, LLC, which completed Series A financing in 2015, Series B financing in 2016, filed IND in 2017, and advanced the technology through Phase 2b clinical trials.
Patent Family #6, #8, #12 has been licensed to Mucommune. #6 formed the basis of Mucommune, LLC, which has received >\$11M in non-dilutive federal contracts to date. IND for lead product targeted for 2024.
Patent Family #6, #8, #10, #14 & #15 has been licensed to Inhalon Biopharma. #6 formed the basis of Inhalon Biopharma, which has received >\$43M in funding to date. Inhalon is a clinical stage company with multiple products in its pipeline.
Patent Family #11 formed the basis of AI Tracking Solutions, LLC. AITS has received ~\$500K in non-dilutive federal contracts. AITS was wind down in 2022.
Patent Family #9 formed the basis of Polyon Pharmaceutical, INC. Polyon is launched in 2023. Polyon has received ~\$600k in non-dilutive funding to date.

VI. GRANTS

Notes: (1) Listed funding total represents total of direct and indirect costs unless otherwise indicated
(2) For grants I am not PI, only total costs to Lai Lab is listed.

Current Research Support (Total: ~\$10M)

R21AI180822 (Lai, PI) National Institute of Allergy and Infectious Disease <i>Title: In vivo engineering of chimeric antibody reprogrammed (CAR) B cells with fully tunable antibody response</i>	1/2024 – 12/2025	\$404,300
Tier 2 Development Award (Lai, PI) LCCC <i>Title: Engineering Bispecific Binders against Siglec-15 and TGF-β for Enhanced Therapy and Prevention of Metastasis in Triple Negative Breast Cancers</i>	7/2023 – 6/2025	\$150,000 (0% indirect)
FY23ITN622 (Lai, PI) Benaroya Research Institute (NIAID) <i>Title: Measurement of anti-PEG antibodies in COVID-19-004 clinical trial biospecimens</i>	2/2023 – 1/2024	\$333,170
R01AI165853-01 (Lai/Pickles, MPI) National Institute of Allergy and Infectious Disease <i>Title: Engineering “muco-trapping” antibodies for inhaled therapy of parainfluenza and human metapneumovirus infections</i>	9/2022 – 7/2027	\$3,076,249
BAPP_012 (Lai/Hutchins, MPI) NC Policy Collaboratory <i>Title: Developing IN-007 as an Inhaled Treatment Against Pathogens Utilizing Human ACE2 for Viral Attachment and Entry</i>	10/2022 – 10/2024	\$1,999,667 (0% indirect)

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Note: \$333k to UNC.

R21CA273983 (Lai, PI) National Cancer Institute <i>Title: Engineering Siglec15/TGF-beta targeted bispecific antibodies that modulate the tumor microenvironment and enhances T-cell immunotherapy against pancreatic cancer</i>	4/2023 – 3/2025	\$420,769
1R01HD101344-01 (Baum/Lai, MPI) Eunice Kennedy Shriver National Institute of Child Health and Human Development <i>Title: Next Generation Multipurpose Prevention Technology: An Intravaginal Ring for HIV Prevention and Nonhormonal Contraception</i>	12/2019 – 11/2024	\$1,449,006 (Lai Lab)
1R01HD101562-01 (Lai, PI) Eunice Kennedy Shriver National Institute of Child Health and Human Development <i>Title: Engineering bispecific antibodies for non-hormonal contraception</i>	4/2020 – 3/2024	\$2,089,046
R44AI141054-01A1 (Cone, PI; Lai, Consortium-PI) Phase 2 awarded 5/2021 National Institute of Allergy and Infectious Disease <i>Title: Development of RespiraClear for targeted mucosal treatment of RSV infections</i>	2/2019 – 4/2024	\$130,928
<u>Completed Support (Total: >\$10M)</u>		
OPP1024615 (Lai, PI) Bill and Melinda Gates Foundation, Grand Challenges Round 5 Title: Mucosal vaccines based on trapping pathogens in mucus.	11/2010 - 5/2012	\$100,000 (0% IDC)
U19AI096398 (Anderson, PI; Lai, Project 3 co-PI) National Institute of Allergy and Infectious Diseases Title: Optimizing plantibodies for trapping HIV and HSV in cervicovaginal mucus.	7/2011-6/2016	\$864,320
ID 1031734 (Hope, PI; Lai, co-investigator) Bill and Melinda Gates Foundation, Collaboration for AIDS Vaccine Discovery Title: Harnessing antibody-mucus interactions to prevent HIV transmission.	8/2011-5/2012	\$137,500 (10% IDC)
New Faculty Research Award (Lai, PI) American Association of Colleges of Pharmacy Title: Engineering lymphocyte- and macrophage- inert nanoparticles for lymphatic drug delivery.	1/2011-1/2012	\$10,000 (0% IDC)
P30 DK34987 (Lai, PI) UNC Center for Gastrointestinal Biology & Disease Pilot Feasibility Award, NIH Title: Antibody-mediated trapping of pathogens in gastrointestinal mucus.	7/2011-1/2013	\$30,000 (0% IDC)
U54CA151652 (DeSimone, PI; Lai, Pilot Proj. PI) NIH/NCI Center for Cancer Nanotechnology Excellence (CCNE) Title: Immune-inert nanoparticles for lymphatic drug delivery	11/2011-10/2012	\$50,000 (0% IDC)
P30 AI50410 (Lai, PI) UNC CFAR Developmental Award, NIH Title: Mobility of HIV in cervicovaginal mucus from women with bacterial vaginosis.	6/2011-5/2012	\$18,000 (0% IDC)
R21AI093242 (Lai, PI) National Institute of Allergy and Infectious Diseases	1/2011 – 12/2013	\$407,000

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Title: Trapping HIV in mucus with IgG antibodies.

R21AI090507 (Lai, PI) 7/2011 – 6/2014 \$403,182
National Institute of Allergy and Infectious Diseases

Title: Diffusion of viruses across human airway mucus and trapping by antibodies.

R21EB017938 (Lai, PI) 10/2014 – 9/2016 \$412,696
National Institute of Biomedical Imaging and Bioengineering

Title: Prevalence and characteristics of anti-PEG antibodies in humans

550KR91409 (Lai, PI) 1/2015 – 12/2016 \$50,000 (0% IDC)
NC TraCS

Title: Reinforcing mucosal defense against Ebola transmission

(Lai, PI) 10/2015 – 9/2016 \$50,000 (0% IDC)
Eshelman Institute for Innovation

Title: Shoebox-sized plasmapheresis machine for cheap & rapid generation of convalescent serum in Africa

13426-15 (Lai, PI) 10/2015 – 12/2017 \$32,500 (0% IDC)
Venture Well Foundation

Title: Carolina E(I) Lab: A Multidisciplinary, Entrepreneurial Experience in Transforming Bold Ideas into Successful Ventures.

ID 1151477 (Lai, PI) 4/2012-3/2018 \$400,000
National Science Foundation

Title: CAREER: Biophysical investigations of immune-mediated pathogen trapping in mucus

(Lai, Project 1 PI) 7/2015 – 6/2018 \$480,000 (0% IDC)
NC General Assembly – Research Opportunities Initiative

Title: Research Program in Immunoengineering

R41 AI122472-01 (Moench, PI; Lai, Consortium PI) 2/2016 – 1/2018 \$65,434 (0% IDC)
National Institute of Allergy and Infectious Diseases

Title: STTR: Delivery of pathogen-trapping antibodies for vaginal protection

(Lai, PI) 7/2016 – 6/2018 \$200,000 (0% IDC)
Eshelman Institute for Innovation

Title: Engineered bispecific fusion proteins (BFP) for targeted delivery of therapeutic nanoparticles and viral vectors

RX03512419 (Lai, PI) 10/2015 – 9/2018 \$660,203 (0% IDC)
Eshelman Institute for Innovation

Title: Engineered antibodies with carefully tuned mucin-affinity for enhanced mucosal protection

(Lai, PI) 7/2016 – NCE \$50,000 (0% IDC)
Eshelman Institute for Innovation

Title: "Hijacking Vaccines": Durable immunity via genetic editing of B cells by CRISPR/Cas9

R41 GM123897 (Lai, PI) 4/2017 – NCE \$79,891 (0% IDC)
National Institute of General Medical Sciences

Title: STTR: Artificial neural networks for high performance, fully automated particle tracking analysis even at low signal-to-noise regimes

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R56HD095629-01 (Lai, PI) 8/2017 – 7/2019 \$356,000
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
Title: Development of novel sperm-binding antibodies

(Lai, PI) 10/2015 – 2/2020 \$195,000 (0% IDC)
 Eshelman Institute for Innovation
Title: Carolina E(I) Lab: A Multidisciplinary, Entrepreneurial Experience in Transforming Bold Ideas into Successful Ventures.

(Lai, PI) 9/2019 – 3/2020 \$49,952
 Kimberly-Clark Corp
 Kimberly-Clark Expert Service Agreement / Industry service agreement

R43AI138726-01A1 (Cone, PI; Lai, Consortium PI) 7/2018 – 6/2020 (NCE) \$61,235 (0% indirect)
 National Institute of Allergy and Infectious Disease
Title: SBIR: Sustained vaginal delivery of monoclonal antibodies for preventing HIV transmission

R43HD094454-01A1 (Cone, PI; Lai, Consortium PI) 7/2018 – 6/2020 (NCE) \$67,303 (0% IDC)
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
Title: SBIR: Development of a biologic for non-hormonal contraception

R41GM130202-01 (Lai, PI) 7/2018 – 6/2020 (NCE) \$85,241 (0% IDC)
 National Institute of General Medical Sciences
Title: An integrated neural network analysis and video microscopy platform for fully automated particle tracking

U54HD096957-01 (Anderson, PI; Lai, Project 2 co-I) 9/2018 – 8/2020 \$299,797
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
Title: Antibody-based Contraceptive MPTs: Preclinical and Clinical Research

R21AI144631 (Lazear, PI; Lai, co-I) 4/2019 – 3/2021 \$85,892
 National Institute of Allergy and Infectious Disease
Title: Protective Immune Mechanisms against Zika Virus Infection in the Female Reproductive Tract

DMS- 2028758 (Forest, PI; Lai, co-PI) 5/2020 – 4/2021 \$25,000
 National Science Foundation
Title: RAPID: A Lung Mucus Strategy for COVID-19 Viral Protection

RX03912416 (Lai, PI) 6/2019 – 5/2021 \$200,000 (0% IDC)
 Eshelman Institute for Innovation
Title: Durable and molecularly precise immunity against HIV through B-cell reprogramming

1017727 (Lai, PI) 6/2018 – 5/2021 \$180,000 (0% IDC)
 Burroughs Wellcome Foundation
Title: Young Innovators Program: an immersive research experiential program at the UNC Eshelman School of Pharmacy

RX03202404 (Lai, PI) 3/2020 – 6/2021 \$50,000 (0% IDC)
 Eshelman Institute for Innovation
Title: Development of novel "muco-trapping" mAb constructs for COVID19

C192014 (Lai, PI; Hickey, co-PI). 7/2020 – 6/2021 \$60,000 (0% IDC)

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NC TraCS, NIH

Title: Nebulization characterization of antibodies for inhaled therapy of COVID-19

NC Policy Collaboratory Project (Lai, PI) 6/2020 – 12/2020 \$798,352 (0% IDC)

University of North Carolina – Chapel Hill

Title: Preclinical Development of a potent, muco-trapping antibody against SARS-CoV-2

2013-39274 (Lai, PI) 12/2013 – 11/2020 (NCE) \$875,000 (10% IDC)

Packard Foundation

Title: Harnessing antibody-mucin interactions to control microbial communities in the gut

RX03812424 (Lai, PI) 6/2018 – NCE \$483,025 (0% indirect)

Eshelman Institute for Innovation

Title: In Vivo Engineering of T-cells for CAR-T-based Therapy

RX03912411 (Lai, PI) 6/2019 – 12/2021 \$100,000 (0% IDC)

Eshelman Institute for Innovation

Title: Dose finding study of high MW free PEG to reduce anti-PEG antibody mediated pseudoallergic response in swine

1R43AI149894-01 (Cone, PI; Lai, Consortium-PI) 7/2020 - NCE \$74,250 (0% IDC)

Title: SBIR: Aerosol immunotherapy for treatment of human metapneumovirus infection

R44AI157661 (Cone, PI; Lai, Consortium-PI) 06/2021 - NCE \$97,064 (0% IDC)

Title: SBIR: In vivo validation and IND-enabling development of MM004, a bispecific inhaled immunotherapy for RSV and MPV

1810168 (Lai, PI) 6/2018 – 5/2022 \$501,654

National Science Foundation

Title: Dynamic tuning of barrier properties of hydrogels using weakly adhesive third-party crosslinkers

R44HD097063-01 (Cone, PI; Lai, Consortium PI) 7/2018 – 3/2023 \$219,901

Phase 2 awarded 4/2021

National Institute of Allergy and Infectious Disease

Title: Fast-Track SBIR: Capsule-intravaginal ring for sustained release of antibodies for non-hormonal contraception and vaginal protection against HIV

FY21ITN452 (Pedan, PI; Lai, Subcontract PI) 4/2021 – NCE \$747,154

Benaroya Research Institute (NIAID)

Title: Systemic Allergic Reactions to COVID mRNA vaccines

R01HL141934-01 (Lai/Zamboni, MPI) 4/2018 – 3/2023 \$2,658,464

National Heart, Lung and Blood Institute

Title: Overcoming anti-PEG immunity to restore prolonged circulation and efficacy of PEGylated therapeutics

P30AI50410 (Lai, Pilot Project PI) 9/2022 – 5/2023 \$50,000 (0% indirect)

National Institute of Allergy and Infectious Disease

Title: Engineering bispecific antibodies for simultaneous non-hormonal contraception and prevention of HIV transmission

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VII. INVITED TALKS

[§]International Meetings; [†]University Seminars; * Public Presentation; # International University Seminars

- 71 [§] Engineering ‘muco-trapping’ mAbs for treatment of acute respiratory infections. Antibodies for Infectious Disease, **Festival of Biologics USA**. San Diego, CA. Apr 15-17, 2024. [The Festival of Biologics USA meeting brings together over 2,000 attendees from pharma, biotech, academia, and regulatory bodies.](#)
- 70 [§] Engineering CAR-T and CAR-B cells *in situ*. Innovations in CAR T Therapy, **PEGS Europe**. Lisbon, Portugal. Nov 10, 2023.
- 69 [§] Nebulization of mAb for treatment of acute respiratory infections. Inhalation and Nasal Communities, **AAPS**. *Virtual*. Aug 10, 2023.
- 68 [§] Viral Vectors for in vivo Engineering of B and T Cells. Next-Generation Immunotherapies, **PEGS Boston**. Boston, MA. May 19, 2023.
- 67 [§] Preclinical Data and Phase 1 Study of Inhaled Muco-trapping Antibodies for Treatment of Acute Respiratory Infections. Emerging Indications for Therapeutic Antibodies, **PEGS Boston**. Boston, MA. May 16, 2023.
- 66 [§] PEG-specific antibody response to COVID mRNA vaccines and methods to overcome anti-PEG antibodies. **Mechanisms and Barriers in Nanomedicine**. Golden, CO. May 4-6, 2023.
- 65 [§] Inhaled muco-trapping monoclonal antibody for effective therapy against respiratory syncytial virus infections in lambs. **International Society for Influenza and other Respiratory Virus Diseases (ISIRV)**. Seattle, WA. May 3-5, 2023.
- 64 [§] Phase 1 clinical trial of IN-006 demonstrates stable nebulization of antiviral monoclonal antibodies enables safe and effective delivery to the upper and lower respiratory tracts. **Inhaled Biologics: Challenges and Future Directions** (Organized by AstraZeneca). Gaithersburg, MD. Apr 14, 2023.
- 63 [§] Engineering mucosal biologics based on “muco-trapping” antibodies. **Pharmaceutical & BioScience Society International (PBSS) Symposium**. *Virtual*. Feb 6, 2023.
- 62 [§] Elucidating The Protective Functions Of IgG Antibodies In The Respiratory Mucosa. **Chemical and Biological Defense Science & Technology (CBD S&T) Conference**. San Francisco. Dec 10, 2022.
- 61 [§] Phase 1 Safety Findings, Pharmacokinetics, and Nebulization Stability of IN-006 Support its Development as a Potent, Dose-Sparing Inhaled Therapy for COVID-19. **Vaccine Summit 2022**. Washington, DC. Oct 12, 2022.
- 60 [†] Advancing muco-trapping antibodies for inhaled therapy of respiratory infections from bench to clinic. Seminars in Respiratory Biology, **Marsico Lung Institute**, University of North Carolina at Chapel Hill. Dec 17, 2021.
- 59 [†] Anti-PEG antibodies (APA): origins, methods to quantify APA response, and implications in the clinic. Carolina Center for Nanotechnology Training Program. **University of North Carolina at Chapel Hill**. Nov 29, 2021.
- 58 [#] Advancing muco-trapping antibodies for inhaled therapy of respiratory infections from bench to clinic. LabEx MabImprove. Research Centre for Respiratory Diseases, **INSERM - CEPR Faculté de Médecine**, Paris, France. Nov 18, 2021.
- 57 [†] Taking the road less traveled: a look under the hood of my ongoing journey to move inventions from the bench to patients. **Bizzell Business of Health Care Pharmacy Lecture Series**. Eshelman School of Pharmacy. University of North Carolina at Chapel Hill Oct 12, 2021
- 56 ^{*} Nebulized delivery of antibodies for inhaled treatment of acute respiratory infections. Office of New Drug Product, **U.S. Federal Drug Administration**. Sep 8, 2021.
- 55 ^{*} Anti-PEG antibodies (APA): origins, methods to quantify APA response, and implications in the clinic. Office of New Drug Product, **U.S. Federal Drug Administration**. Sep 8, 2021.
- 54 [†] Engineering and translational development of “muco-trapping” antibodies for respiratory and female reproductive health. Department of Pharmaceutics, and Center for Pharmaceutical Engineering and Sciences. School of Pharmacy, **Virginia Commonwealth University**. Mar 12, 2021.

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- 53 † Pioneering “muco-trapping” antibodies to reinforce the mucosal defense, and elucidating adaptive immunity to synthetic polymers. Department of Chemical and Biomolecular Engineering, **University of Tennessee, Knoxville**. Feb 23, 2021.
- 52 # TBD. Invitation, Distinguished Speaker Seminar Series “Mittwochs-Kolloquium” (MiKo). **Max Planck Institute**. Tuebingen, Germany. October 2020.
- 51 † Elucidating the design of antibodies as third-party crosslinkers that reinforces the barrier properties of biological hydrogels through computational modeling. **Department of Bioinformatics and Computational Biology, UNC School of Medicine**, Chapel Hill, NC. Oct 21, 2019.
- 50 * **Inhaled Immunotherapy for Acute Respiratory Infections**. Innovation Symposium, **Eshelman Institute of Innovation**, Chapel Hill, NC. Oct 10, 2019.
- 49 † Characterizing and overcoming the adaptive immune response to synthetic materials. Targeted Delivery to the Tumor Microenvironment Workshop, Center for Nanotechnology and Drug Delivery, Chapel Hill, NC. Oct 9, 2019.
- 48 § Engineering mucosal biologics based on “muco-trapping” antibodies. 4th Annual Bioengineering and Translational Medicine Conference, Durham, NC. Oct 7, 2019.
- 47 † Engineering phages for gene therapy of the microbiome. Transdisciplinary Research on the Microbiome, UNC School of Medicine, Chapel Hill, NC. Oct 4, 2019.
- 46 † Engineering “muco-trapping” antibodies to reinforce the mucosal defense in the respiratory and female reproductive tracts. Department of Immunology and Microbiology, University of Hong Kong, Hong Kong. Jul 29, 2019.
- 45 § Fortifying Mucus Membranes Using IgG Antibodies That Crosslink Pathogens to Mucins. Antibody Engineering, San Diego, CA. Dec 13, 2018.
- 44 † Engineering broadly transducing lysogenic phages against Clostridium for in situ production of biologic therapies. Center for Gastrointestinal Biology & Disease, Chapel Hill, NC. October 15, 2018.
- 43 Development of Multimeric anti-sperm sperm mAb. NICHD, Minneapolis, MN. Sep 24, 2018.
- 42 A Biological Velcro Fortifying the Mucosal Defense Against Foreign Invaders. Packard Foundation 30th Annual Meeting, San Diego, CA. Sep 9, 2018.
- 41 † Trapping pathogens, saturating (anti-drug) antibodies, modifying bugs. Chapel Hill PharmSci Conference, Chapel Hill, NC. Apr 19, 2018.
- 40 * Trapping Bugs and Tracking Drugs. Innovation Symposium, Eshelman Institute of Innovation, Chapel Hill, NC. Apr 19, 2018.
- 39 † Creating a biological Velcro to reinforce the mucosal barriers against pathogens, Department of Bioengineering, Rice University, Houston, TX. Oct 3, 2017.
- 38 † Creating a biological Velcro to reinforce the mucosal barriers against pathogens, Department of Immunology & Microbiology, Chapel Hill, NC. Jun 21, 2017.
- 37 † Casting a Biological Net Against Pathogens. Guest speaker at the Igniting Innovation Symposium, Eshelman Institute for Innovation, Chapel Hill, NC. Apr 26, 2017.
- 36 † Harnessing weakly adhesive antibodies to reinforce the mucosal defense against pathogens. Center for Gastrointestinal Biology & Disease, Chapel Hill, NC. Mar 30, 2017.
- 35 † Elucidating the biophysical and molecular interactions of pathogens and polymers with the immune system. School of Pharmacy, University of Georgia, Athens, GA. Jan 25, 2017.
- 34 † The cost of indecision. What’s Next America, Frank Hawkins Kenan Institute of Private Enterprise, UNC Kenan Flagler Business School, Chapel Hill, NC. Sep 20, 2016.
- 33 † Elucidating the biophysical and molecular interactions of pathogens and polymers with the immune system. Virginia Commonwealth University, Richmond, VA. Sep 20, 2016.
- 32 § Properties and Mechanisms of the Innate and Adaptive Mucus Barrier Against Pathogens. Antimicrobial Activity and Defense Strategies at the Mucosal Surface, Albufeira, Portugal. April 16, 2016.
- 31 § Immunoengineering. Plenary Lecture. Annual Meeting for American Institute of Chemical Engineers, Salt Lake City, UT. November 9 2015.

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- 30 § A research program at the interface of immunology and engineering. PharmAlliance Pharm Sci Symposium. Chapel Hill, NC. Oct 30, 2015.
- 29 † Elucidating the biophysical and molecular interactions of pathogens and polymers with the immune system, Boston University, Boston, MA. Aug 13, 2015.
- 28 § Properties and mechanisms of innate and adaptive mucus barrier against pathogens. 13th International Workshop on Carcinoma-associated Mucins, Cambridge, U.K. Jul 21, 2015.
- 27 § Homing Nanoparticles to Molecularly Heterogenous Targets via Bispecific Fusion Proteins. Gordon Research Conference on Cancer Nanotechnology, West Dover, VT. Jun 19, 2015.
- 26 † Elucidating the biophysical and molecular interactions of pathogens and polymers with the immune system, University of Washington, Seattle, WA. Feb 25, 2015.
- 25 † Properties and mechanisms of innate and adaptive mucus barrier against pathogens. Department of Immunology and Microbiology, University of Hong Kong, Hong Kong. Jan 12, 2015.
- 24 § Elucidating Mucosal Immunity against Pathogens and Particles Based on Antibody-Mucin Interactions. Chapel Hill PharmSci Conference, Chapel Hill, NC. May 29, 2014.
- 23 § Influence of Vaginal Microbiota on the Diffusional Barrier Properties of Cervicovaginal Mucus against HIV. Keystone Symposium in HIV Pathogenesis – Virus vs. Host, Banff, Canada. Mar 10, 2014.
- 22 † Role of secreted antibodies in reinforcing the genital mucus barrier. IPCP Annual Investigator's Meeting, Boston University, Boston, MA. Oct 17, 2013.
- 21 † The role of secreted antibodies in reinforcing the mucus barrier against pathogens. Cystic Fibrosis Center, University of North Carolina, Chapel Hill. Oct 11, 2013.
- 20 § Mucosal immunity based on antibody-mucin crosslinking. Keystone Symposium in B Cell Development and Function (X1) and HIV Vaccine (X2), Keystone, CO. Feb 12, 2013.
- 19 † Mucosal immunity based on antibody-mucin crosslinking. Department of Immunology and Microbiology, University of Hong Kong, Hong Kong. Jan 14, 2013.
- 18 § Mucosal immunity mediated by antibody-mucin crosslinking. American Society for Matrix Biology /Society for Functional Glycomics Joint Annual Meeting, San Diego, CA. Nov 13, 2012.
- 17 † Vaginal mucosal immunity mediated by IgG Fc-mucin affinity. IPCP Annual Investigator's Meeting, Boston University, Boston, MA. Oct 11, 2012.
- 16 † Mucosal immunity: Antibody-mediated trapping of pathogens in mucus. Center for Computer Integrated Systems for Microscopy and Manipulation, University of North Carolina, Chapel Hill. Oct 10, 2012.
- 15 § PEG coatings, and their interactions with immune cells and antibodies. GRC Drug Carriers in Medicine & Biology, Waterville Valley, NH. Aug 15 2012.
- 14 † Antibody-mediated trapping of pathogens in GI mucus. Center for Gastrointestinal Biology & Disease Annual Symposium, University of North Carolina, Chapel Hill. Jun 25 2012.
- 13 † Closing the Gate to Viruses at their Portals of Entry. Department of Molecular and Cellular Biophysics, University of North Carolina, Chapel Hill. Jan 19, 2012.
- 12 † Biophysical properties of the mucus barrier against viruses. ID/CFAR Seminar, University of North Carolina, Chapel Hill. May 19, 2011.
- 11 † Biophysical properties of the mucus barrier against viruses. The Virtual Lung Project Group, University of North Carolina, Chapel Hill. NC. Apr 26, 2011.
- 10 † Permeation of HIV across Human Cervicovaginal Mucus. CFAR Day, University of North Carolina, Chapel Hill. NC. Dec 1, 2010.
- 9 † The mucus barrier and mucosal drug delivery from the perspective of virus-mimicking nanoparticles. Northwestern University, IL. Sep 23, 2010.
- 8 † The mucus barrier and mucosal drug delivery from the perspective of virus-mimicking nanoparticles. Queen Mary Hospital, Hong Kong. Jun 14, 2010.
- 7 † The mucus barrier and mucosal drug delivery from the perspective of virus-mimicking nanoparticles. University of North Carolina, Chapel Hill. NC. Apr 12, 2010.
- 6 † The mucus barrier and mucosal drug delivery from the perspective of virus-mimicking nanoparticles. University of Maryland, Baltimore County, MD. Apr 5, 2010.

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- 5 † The mucus barrier and mucosal drug delivery from the perspective of virus-mimicking nanoparticles. Columbia University, NY. Jan 27, 2010.
- 4 § Real-Time Tracking of Biomaterial-Based Nanoparticle Behavior in Biological Barriers. American Institute for Chemical Engineers (AIChE), Nashville, TN. Nov 2009.
- 3 § The Mucus Barrier to Aerosol Therapy for CF. International Society for Aerosols in Medicine (ISAM), Monterey, CA. May 2009.
- 2 † Mucus-Penetrating Particles for Transmucosal Drug Delivery and Biophysical Characterization of the Mucus Barrier. Hong Kong University of Science & Technology, Hong Kong. Jan 9, 2009.
- 1 † Therapeutic Nanosystems to Mucosal Tissues. Chinese University of Hong Kong, Hong Kong. Jan 7, 2008.

VIII. COURSES TAUGHT AT UNC

Semester	Course Title (Number, Credit Hours)	Enrollment	Lectures
Fall 2010	Nanomedicine (NANO 738, 3 cr)	~20	1
Fall 2011	Advanced Drug Delivery (MOPH 864, 3 cr)	~20	1
Fall 2012	Basic Pharmaceutics I (PHCY 410, 3 cr)	170+	8
Fall 2013	Basic Pharmaceutics I (PHCY 410, 3 cr)	170+	8
Fall 2013	Advanced Drug Delivery (MOPH 864, 3 cr)	~20	2
Spring 2014	Mathematical Modeling II (Math 769, 3 c)	~20	1
Fall 2014	Basic Pharmaceutics I (PHCY 410, 3 cr)	170+	6
Fall 2014	Nanomedicine (NANO 738, 3 cr)	~20	1
Fall 2015	Advanced Drug Delivery (MOPH 864, 3 cr)	~20	2
Fall 2015	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	~45	9
Spring 2016	Basic Pharmaceutics I (PHCY 512, 3 cr)	170+	2
Spring 2016	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	~45	9
Spring 2016	Advanced Drug Delivery Systems (BMME 590, 3 cr)	~20	1
Fall 2016	Advanced Drug Delivery (MOPH 864, 3 cr)	~20	3
Fall 2016	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	~45	9
Spring 2017	Basic Pharmaceutics I (PHCY 512, 3 cr)	170+	2
Spring 2017	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	~45	9
Spring 2017	Particle Tracking in Biological Fluids (MATH 891, 1 cr)	~20	1
Fall 2017	Advanced Drug Delivery (MOPH 864, 3 cr)	~20	3
Fall 2017	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	26	9
Fall 2017	Immunology (MCRO 614, 3 cr)	16	1
Spring 2018	Basic Pharmaceutics I (PHCY 512, 3 cr)	170+	2
Spring 2018	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	25	9
Spring 2018	Advanced Drug Delivery Systems (BMME 590, 3 cr)	~20	1
Spring 2018	Particle Tracking in Biological Fluids (MATH 891, 1 cr)	7	1
Fall 2018	Immunology (MCRO 614, 3 cr)	19	1
Fall 2018	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	26	4
Spring 2019	Nanomedicine (DPMP 738, 3 cr)	7	3
Spring 2019	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	26	4
Spring 2019	Particle Tracking in Biological Fluids (MATH 891, 1 cr)	3	1
Fall 2019	Advanced Drug Delivery (DPMP 864, 6 cr)	10	3
Fall 2019	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	27	4
Fall 2019	Immunology (MCRO 614, 3 cr)	23	1
Spring 2020	Nanomedicine (DPMP 738, 3 cr)	14	
Spring 2020	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	22	4
Spring 2020	Particle Tracking in Biological Fluids (MATH 891, 1 cr)	2	1
Fall 2020	Advanced Drug Delivery (DPMP 864, 6 cr)	8	3
Fall 2020	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	25	4
Fall 2020	Immunology (MCRO 614, 3 cr)	31	1

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Fall 2020	Science & Public Policy: The Social, Economic, and Political Context of Science and Innovation (PLCY 575, 3 cr)	26	1
Spring 2021	Nanomedicine (NANO 738, 3 cr)	13	1
Spring 2021	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	23	4
Fall 2021	Advanced Drug Delivery (DPMP 864, 6 cr)	8	4
Fall 2021	Immunology (MCRO 614, 3 cr)	30	1
Fall 2021	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)	27	4
Fall 2021	Pharmaceutics & Drug Delivery Systems I (PHCY 512, 2 cr)		4
Spring 2022	Nanomedicine (NANO 738, 3 cr)		1
Spring 2022	Pharmaceutics & Drug Delivery Systems II (PHCY 514, 2 cr) "Worthy of Recognition"		2
Spring 2022	Seminars in Pharmaceutical Sciences (PHRS 899, 1 cr)		4
Fall 2022	Advanced Drug Delivery (DPMP 864, 6 cr) "Worthy of Recognition"	12	4
Fall 2022	Immunology (MCRO 614, 3 cr)	22	1
Fall 2022	Advanced Physical Pharmacy		1
Spring 2023	Nanomedicine (NANO 738, 3 cr) "Worthy of Recognition"	9	12
Spring 2023	Pharmaceutics II (PCHY 514) "Worthy of Recognition"	136	3
Fall 2023	Advanced Drug Delivery (DPMP 864, 6 cr) "Worthy of Recognition"	15	4
Fall 2023	Advanced Physical Pharmacy		1
Fall 2023	Immunology (MCRO 614, 3 cr)	30	1

IX. PRODUCTS OF INTERDISCIPLINARY SCHOLARSHIP & ENTREPRENEURSHIP

Founder & Director, Carolina E(I) Lab Program. The program, conceptualized, designed and currently directed by Lai, is an eight-month long experiential program that will bring together graduate students, professional students and postdocs from diverse disciplines across UNC to conceive, develop and test innovative solutions to unmet needs in healthcare. The program is designed for ~6-8 teams of 6-10 members per team each year over the first 3 years. Teams will be given generous financial support to develop the necessary prototypes, become inventors on patents, and be trained in various aspects of entrepreneurship and innovation, and the top teams will receive monetary prizes. Example problems in Year 1 include a rapid serum antibiotics concentration measurement device and a re-engineered IV delivery system for pediatric patients. Through this process, participants will gain invaluable multidisciplinary teamwork experience, and be trained in leading methodologies for startup and entrepreneurship including Lean LaunchPad, Business Model Canvas, Customer Discovery, Intellectual Properties and startup financing. According to VentureWell Foundation (previously National Collegiate Inventors and Innovators Alliance, or NCIIA), a foundation focused on promoting innovation and entrepreneurship in higher education institutions, this program will be the first of its kind in the country. The program is currently supported by 3 separate grants/awards (see Section G for details).

Website: <http://eilab.unc.edu/>

Founder, Mucommune, LLC. Mucommune, LLC was launched in 2016 to harness Lai's pioneering discovery in antibody-mucin interactions for female reproductive health. Mucommune has secured over \$11M in federal contracts to date. Lai serves as the Founder and interim CEO.

Founder, Inhalon Biopharma, Inc. was launched in late 2018 to harness Lai's pioneering discovery in antibody-mucin interactions to develop therapeutic interventions against respiratory infections. Inhalon completed an oversubscribed Series Seed financing in 2020 and Series A financing in 2022, and received over \$25M in non-dilutive federal contracts as of May 2023. Inhalon became clinical stage company in 2022. Lai serves as the Founder, CSO, and Board of Directors.

Co-Founder, AI Tracking Solutions, LLC. AITS was launched in 2017, based on proprietary software algorithms developed based on machine learning and convolution neural networks for

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tracking submicron objects at exceptionally poor signal-to-noise ratios. AITS has received two STTR to date, and launched its first product in Jan 2019. <http://www.aitracker.net>
AITS has wind down its operation in 2022.

Founder, Polyon Pharmaceutical, Inc. Polyon was launched in 2023 to harness Lai's invention on methods to mitigate induction of anti-PEG antibodies as well as overcome pre-existing anti-PEG antibodies, a type of anti-drug antibodies common to many PEG-modified therapeutics. Polyon received a Kickstart Award in 2023, and will receive its first SBIR award in 2023.

Advisor, Blackstone Entrepreneurship Network 2016 -

Kala Pharmaceutical was launched based on key IP developed by Lai. See Section V above. The lead product (Invelsys) was approved by the FDA in 2018, with a second drug (Eysuvis) approved in 2020. Kala completed its IPO in 2017.

Graybug Vision was launched based on a portfolio of IP including IP developed by Lai. See Section V above. Graybug completed its IPO in 2020, and its lead product was advanced through Phase IIb clinical trials.

X. SUPERVISION & MENTORING EXPERIENCE

Advisees

Current Ph.D. Students:

Stephen Szpak, Pharm Sci, 2024 –
Jingyu Zhao, BBSP (Genetic Medicine), 2022 –
Zhongbo Li, BBSP (Pharm Sci), 2020 –
Marshall Fritz, Pharm Sci, 2020 –
Peter Voorhees, BBSP (Pharm Sci), 2019 –
Alison Schaefer, Biomedical Engineering, 2018 –

Current Postdoc:

Previous Graduate Students:

Alice Ma, Biomedical Engineering, 2018 – 2021. Next: NIBIB
Jasmine Edelstein, Biomedical Engineering, 2015 – 2021. Next: BE Biopharma
Anne Talkington, Computational Biology, 2019 – 2021. Next: Postdoc, University of Virginia
Bhawana Shrestha, BBSP (Immunology), 2017 – 2021. Next: BioAgilytix
Justin Huckaby, Biomedical Engineering, 2015 – 2021. Next: Atsena Therapeutics
Morgan McSweeney, BBSP (Pharm Sci), 2016 – 2019. Next: Mucommune/Inhalon Biopharma.
Jennifer Schiller, BBSP (Pharm Sci), 2014 – 2019. Next: BioAgilytix
Christina Parker, BBSP (Pharm Sci), 2013 – 2019. Next: Eli Lilly
Holly Schroeder, Molecular Pharmaceutics, 2013 – 2018. Next: Asklepios BioPharmaceutical
Angela Yang, Molecular Pharmaceutics, Ph.D. 2011 – 2017. Next: Regeneron
Tim Wessler, Applied Mathematics, Ph.D. 2016 (co-advised with Greg Forest) Next: Postdoc Fellow,
U Michigan
Kenetta L. Nunn, M.S. 2014 Current: Postdoc, U Michigan
Arthi Kannan, M.S. 2013

Year	2017	2018	2019	2020	2021	2022			
Ph.D. Graduated	1	1	3	0	4	0			

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Previous Postdocs:

Limei Shen, Ph.D. 2018 –2021. Next: Research Associate, Lai Lab, UNC

Karthik Tiruthani, Ph.D. 2018 –2021. Next: Istari Oncology

Carlos Cruz-Teran, Ph.D. 2017 –2021. Next: Locus Biosciences

Jay Newby, Ph.D. 2015-2018 (co-advised with Greg Forest). Next: Assistant Professor, U Alberta at Edmonton

Tim Jacobs, Ph.D. 2015-2018 Next: CTO, Duologics

Feifei Zhu, Ph.D., 2016-2017 (co-advised with Greg Forest). Next: Google

Ying-Ying Wang, Ph.D., 2011-2014 (co-advised with Richard Cone). Next: Genentech.

Alex Chen, Ph.D. 2012-2014 (co-advised with Greg Forest). Current: Assistant Professor, California State University-Dominguez Hills

Mohammed Shukoor, Ph.D., 2013-2014

Durai B. Subramani, Ph.D. 2011-2014

Michael Murphy, Ph.D., 2011

Student/Postdoc Awards

Year	Student (Degree)	Award
2012	Kenetta Nunn (M.S.)	NIH Diversity Supplement Fellowship, 2012-2014
	Ying-Ying Wang (Postdoc)	NIH NRSA F32 Postdoctoral Fellowship
2013	Angela Yang (Ph.D.)	PhRMA Foundation Graduate Fellowship, 2013-2014
	Kenetta Nunn (M.S.)	President's Scholar Award for Under-Represented Minority Scientists, International Congress for Mucosal Immunology
2015	Christina Parker (Ph.D)	NSF Graduate Research Fellowship
	Angela Yang (Ph.D)	Dissertation Completion Fellowship, UNC – Chapel Hill
	Felix Lam (Pharm.D)	Joe Hollingsworth Memorial Scholarship
2016	Morgan McSweeney (Ph.D.)	NSF Graduate Research Fellowship
	Jasmine Edelstein (Ph.D.)	NSF Graduate Research Fellowship
	Justin Huckaby (Ph.D.)	NSF Graduate Research Fellowship
	Tim Jacobs (Postdoc)	NIH NRSA F32 Postdoctoral Fellowship
	Jasmine Edelstein (Ph.D.)	Royster Fellowship
2017	Jen Schiller (Ph.D.)	PhRMA Foundation Graduate Fellowship, 2017-2018
	Holly Schroeder (Ph.D.)	Dissertation Completion Fellowship, UNC – Chapel Hill
	Carlos Cruz-Teran (Postdoc)	Pfizer-NCBC Postdoctoral Fellowship in AAV Gene Therapy
2018	Christina Parker (Ph.D.)	GSK Graduate Fellowship
2019	Bhawana Shrestha (Ph.D.)	NICHD Annual Meeting Top Student Talk
	Jasmine Edelstein (Ph.D.)	Frank Porter Graham Honor Society
2020	Bhawana Shrestha (Ph.D.)	PhRMA Foundation Fellow
	Justin Huckaby (Ph.D.)	Dissertation Completion Fellowship, UNC – Chapel Hill
	Jasmine Edelstein (Ph.D.)	Dissertation Completion Fellowship, UNC – Chapel Hill
	Justin Huckaby (Ph.D.)	BME Department Achievement Award
2021	Bhawana Shrestha (Ph.D.)	Gordon Sharp Graduate Innovator Award
	Anne Talkington (Ph.D.)	PEO Scholar Award
	Bhawana Shrestha (Ph.D.)	Graduate Education Advancement Board Impact Award
2022	Limei Shen (Ph.D.)	Lung Cancer Institute Vicky Amidon Innovation Award

Graduate Thesis Committee

Year	Student (Degree)	Division / Department	Thesis Advisor	Thesis Title
2012	Jing Xu (PhD)	Chemistry	Joseph Desimone	
2013	Chester Corales (PhD)	MOPH	Dhiren Thakker	

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	Yuan Zhang (PhD)	MOPH	Leaf Huang
2014	Tammy Shen (PhD)	MOPH	Joseph Desimone
	Lei Peng (PhD)	BBSP/MOPH	Russell Mumper
2015	John Mellnik	BBSP/Comp Sci	Greg Forest
	Kevin Reuter	Chemistry	Joseph Desimone
	Sarah Claypool	CBMC	Rihe Liu
2016	Ashley Johnson	Chemistry	Joseph Desimone
	Andrew Satterlee	BME	Leaf Huang
2017	Matthew Haynes	DPMP	Leaf Huang
	Junghyun Kim	DPMP	Michael Jay
	Cameron Bloomquist	DPMP	Joseph Desimone
	Cassie Caudill	DPMP	Joseph Desimone
	Tyler Goodwin	DPMP	Leaf Huang
2018	Samantha Fix	DPMP	Paul Dayton
	Suzanne Lynch	BBSP/Biophysics	Richard Superfine
2019	Youn Gee Seo	DPMP	Sasha Kabanov
	John Prybylski	DPMP	Michael Jay
TBD	Phil Durham	DPMP	Paul Dayton
	Jimmy Fay	Biophysics	Sasha Kabanov
	Randy Qian	DPMP	Xiao Xiao
	Cesar Lopez	Immunology	Helen Lazear
	Kunyu Qiu	DPMP	Aaron Anselmo
	Ava Vargason	DPMP	Aaron Anselmo
	Amelia Mccue	Biophysics	Brian Kuhlman

XI. SERVICE TO THE PROFESSION

Advisory Panel

- 2012 – 2015 Scientific Advisor, Morehead Planetarium and Science Center,
"Addressing the Science of Really Gross Things: Engaging Young Learners in
Biomedical Science Through a Fulldome Show and Supporting Curricula." NIH-SEPA
R25OD010522
- 2020 Scientific Advisory Board for safety profile of Takeda's Adynovi.

Meeting/Conference Organizer

- Nov 2012 Co-Chair, *Frontiers in Chemistry and Medicine Symposium*,
American Chemical Society Southeast Regional Meeting, Raleigh, NC.
- Oct 2013 Co-Chair, Bionanotechnology for Gene and Drug Delivery
Annual Meeting of American Institute of Chemical Engineers (AIChE), San Francisco,
CA
- May 2014 Chair & Organizer, 8th Annual Chapel Hill Pharmaceutical Sciences Conference,
Chapel Hill, NC
Total Participants: ~140 people spanning academia & industry, with 24 speakers.
Successfully obtained the following sponsorship: \$5,500 grant from NC Biotech Center,
\$5,000 from CCNE, \$10,000 from Novartis Vaccines
- Nov 2015 Co-Chair, Bionanotechnology for Gene and Drug Delivery
Annual Meeting of American Institute of Chemical Engineers (AIChE), Salt Lake City,
UT
- Dec 2017 Session Chair, International Conference on CRISPR Technologies, Raleigh, NC
- May 2018 Co-Chair & Co-Organizer, 12th Annual Chapel Hill Pharmaceutical Sciences
Conference, Chapel Hill, NC

Curriculum Vitae

Reviewer for the following journals

ACS Nano, Acta Biomaterialia, Advanced Materials, Advanced Materials Interfaces, AIDS Research and Human Retroviruses, Annals of Biomedical Engineering, Biomacromolecules, Biophys J, Expert Opinion on Drug Delivery, Journal of Biomaterials Science: Polymer Edition, J Combinatorial Chemistry, J Controlled Release, J Drug Targeting, Langmuir, Molecular Pharmaceutics, Molecular Therapy, Mucosal Immunology, Nature Communications, Nature Nanotechnology, PLoS Pathogens, PLoS One, Science Advances, Scientific Reports, Small

Reviewer for grants

Defense Threat Reduction Agency (JSTO-CBD), Italian Cystic Fibrosis Foundation, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) DDK-C, NSF Biomaterials Program (BMAT), Smithsonian Institute,

Professional society memberships

American Chemical Society, American Institute of Chemical Engineers, American Society for Gene Therapy, Biomedical Engineering Society, Controlled Release Society, International Society for Aerosol Medicine

XII. SERVICE TO UNC & ESHELMAN SCHOOL OF PHARMACY

AAPS Student Chapter Faculty Advisor (2010 – 2018) • Chapel Hill Pharmaceutical Sciences Committee (2012 – Now) • Curriculum Committee (2010 – 2012) • Dean of Pharmacy Search Committee (2019) • Global Engagement Committee (2015 – Now) • Graduate Admissions Committee, Biomedical Engineering (2013 – Now) • HHMI International Student Research Fellowship UNC Internal Review Committee (2012 – Now) • Infoporte User Committee (2011 – 2012) • Packard Fellowships in Science and Engineering UNC Internal Review Committee (2014 – Now) • Pharmacoengineering Committee (2010 – 2013) • Faculty Panel, UNC Industry Partnership Summit (2015)