

Curriculum Vitae

Samuel K. Lai, Ph.D.

UNC Eshelman School of Pharmacy,
Division of Molecular Pharmaceutics
University of North Carolina, Chapel Hill
Campus box 7362, Chapel Hill, NC 27599-7360
Email: lai@unc.edu Phone: (919) 966-3024

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 & CSO, Inhalon Biopharma, Inc (2018 – Now)
Co-Founder, AI Tracking Solutions, Llc (2017 – Now)
Founder & 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

Curriculum Vitae

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	Predoctoral 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 (>85 total)

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

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

Total citations: >10,000; h-index: 44; Number of Articles with over 100 citations: 20

Citations 2021: 1439

Associated with lab research at UNC-CH:

69. Fritz M*, Edelstein J*, Lai SK§. (2022) Methods of B-cell immunoengineering. *In preparation*.
68. Li Z, Ma A, Talkington A, Lai SK§. (2022) Development of quantitative anti-PEG IgE ELISA. *In preparation*.
67. McSweeney M*, Stewart I*, Richardson Z*, Kumar P, Hickey A, Hutchins J, Lai SK§. (2022) Nebulization and muco-trapping of Regdanvimab. *In preparation*.
66. McSweeney M*, Richardson Z*, Alnajjar S*, Schaefer A, Stewart I, McCallen J, Wolf W, Kumar P, Hickey A, Ackermann M, Lai SK§. (2022) Inhaled “muco-trapping” monoclonal antibodies potently treats respiratory syncytial virus infections in lambs. *In preparation*.
65. Tiruthani K, Pickles R§, Wolf W, Ma A, Lai SK§. (2022) Apical infection and spread of human metapneumovirus in well differentiated human airway epithelial cells defines the route of antibody dosing. *In preparation*.
64. Shen L, Li Z, Talkington A, Ma A, Li Z, Zhang T, Yuan H, Frank JE, Lai SK§. (2022) Reformulation of pegloticase that evades clearance by anti-PEG antibodies. *In preparation*.
63. Tiruthani K, Cruz-Teran C, Chan J, Ma A, Wolf W, Stewart I, Schaefer A, Edelstein J, Kumar P, Hickey A, Yuen KY, Lai SK§. (2022) Engineering a “muco-trapping” ACE2-immunoglobulin hybrid with picomolar affinity for topical immunotherapy against SARS-CoV-2. *In preparation*.
62. Shen L, Li Z, Massoud N, Talkington A, Ma A, Shipley S, Lai SK§. (2022) Free PEG infusion mitigates PEG-mediated anaphylaxis in swine. *In preparation*.
61. Shen L, Li J, Liu Q, Das M, Song W, Zhang X, Tiruthani K, Dorosheva O, Hu H, Lai SK, Liu R, Huang L. (2021) Nano-trapping C-X-C motif chemokine ligand 13 Reduces Regulatory B cells in Tumor Microenvironment and Inhibits Desmoplastic Tumor Growth. **J Controlled Release**. *Accepted*.
60. 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

Curriculum Vitae

59. 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 9.8]
57. Talkington A, McSweeney MD, Wessler T, Rath MK, Li Z, Zhang T, Yuan H, Frank JE, Forest MG, Lai SK[§]. (2021) A PBPK model that recapitulates anti-PEG antibody-mediated accelerated blood clearance of PEGylated nanomedicines in vivo. **Journal of Controlled Release**. *Accepted*. [Impact 9.8]
56. 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
55. Chen A*, Wessler T*, Daftari K, Hinton K, Boucher RC, Pickles R, Freeman R, Lai SK, Forest MG. (2021) Modeling insights into SARS-CoV-2 respiratory tract infections 1 prior to immune protection. **Biophysical Journal**. *Accepted*.
54. 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]
53. 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 11.2]
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>)
52. Schaefer A, Yang B, Schroeder H, Lai SK[§]. (2021) HIV-binding antibodies immobilizes HIV in human cervicovaginal mucus. *Submitted*.
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 18.0]
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[§], (2020) Challenges and opportunities for antiviral monoclonal antibodies as COVID-19 therapy. **Advanced Drug Delivery Reviews**. 169:100-117. [Impact 15.5]
48. Lai SK[§], McSweeney MD, Pickles R (2020) Learning from past failures: challenges with monoclonal antibody therapies for COVID-19. **J Controlled Release**. 329:87-95 [Impact 9.8]
47. 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]

Curriculum Vitae

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 3.3]
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 3.3]
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 8.9]
43. Huckaby J, Tiruthani K, Jacobs TM, Nicely N, Lai SK[§]. (2020) Structural basis for binding of polyethylene glycol by anti-PEG antibody. **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. McSweeney MD, Shen L, DeWalle AC, Joiner JB, Ciociola EC, Macauley MS, Lai SK[§]. (2020) 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 9.8]
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. 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}
37. Parker CL, Jacobs TM, Huckaby J, Harit D, Lai SK[§]. (2019) Efficient and highly specific gene transfer using mutated lentiviral vectors redirected with bispecific antibodies. **mBio**. 11(1):e02990-1, PMID: 31964730 [Impact 6.5]
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”;

Curriculum Vitae

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}
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}

Curriculum Vitae

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}
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}

Curriculum Vitae

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 PMID: 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 PMID: 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. PMID: PMC4515207 [Impact 6.4] {Cited 243}
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}
34. Ensign LM, Lai SK, Wang YY, Yang M, Mert O, Hanes J, Cone R. (2014) Pretreatment of Human Cervicovaginal Mucus with Pluronic F127 Enhances Nanoparticle Penetration without Compromising Mucus Barrier Properties to Herpes Simplex Virus. **Biomacromolecules**. 15(12):4403-9 PMID: PMC4261994 [Impact 5.7] {Cited 22}
33. Yang M*, Lai SK*, Yu T*, Wang YY, Happe C, Zhong W, Zhang M, Anonuevo A, Fridley C, Hung A, Fu J, Hanes J. (2014) Nanoparticle penetration of human cervicovaginal mucus: The effect of polyvinyl alcohol. **J Control Release**. 192:202-8. PMID: PMC4194208 [Impact 9.8] {Cited 73}
32. Yang M, Yu T, Wood J, Wang YY, Tang BC, Zeng Q, Simons BW, Fu J, Chuang CM, Lai SK, Wu TC, Hung CF, Hanes J. (2014) Intraperitoneal delivery of paclitaxel by poly(ether-anhydride) microspheres effectively suppresses tumor growth in a murine metastatic ovarian cancer model. **Drug Deliv Transl Res**. 4(2):203-209. PMID: PMC3956079. [Impact 3.4] {Cited 11}

Curriculum Vitae

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}
30. Yang M*, Yu T*, Wang YY, Lai SK, Zeng Q, Miao B, Tang BC, Simons BW, Ensign LM, Liu G, Chan K W Y, Juang CY, Mert O, Wood J, Fu J, McMahon MT, Wu TC, Hung CF, Hanes J. (2014) Vaginal delivery of paclitaxel via nanoparticles with non-mucoadhesive surfaces suppresses cervical tumor growth. **Advanced Healthcare Materials**, 3(7):1044-52. PMID: PMC4059793 [Impact 5.6] {Cited 72}
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}
28. Yu T, Wang YY, Yang M, Zhong W, Pulicare S, Choi WJ, Mert O, Fu J, Lai SK, Hanes J. (2012) Biodegradable mucus-penetrating nanoparticles composed of diblock copolymers of polyethylene glycol and poly(lactic-co-glycolic acid). **Drug Deliv. Transl. Res.** 2 (2), 124-128. PMID: PMC3818113 [Impact 3.4] {Cited 60}
27. Boylan NJ*, Kim AJ*, Suk JS, Adstamongkonkul P, Simons BW, Lai SK, Hanes J. (2012) Enhancement of Airway Gene Transfer by DNA Nanoparticles Using A pH-Responsive Block Copolymers of Polyethylene glycol and Poly-L-lysine. **Biomaterials**. 33:2361-2371 PMID: PMC3259202 [Impact 8.8] {Cited 50}
26. Kim AJ, Boylan NJ, Suk JS, Lai SK, Hanes J. (2012) Non-degradative Intracellular Trafficking of Highly Compacted Polymeric DNA Nanoparticles. **J Control Release**. 158(1):102-7. PMID: PMC3294172 [Impact 9.8] {Cited 36}
25. Boylan NJ, Suk JS, Lai SK, Jelinek R, Boyle MP, Cooper MJ, Hanes J. (2012) Highly compacted DNA nanoparticles with low MW PEG coatings: In vitro, ex vivo and in vivo evaluation. **J Control Release**. 157:72-79. PMID: PMC3245330 [Impact 9.8] {Cited 77}
24. Mert O*, Lai SK*, Ensign L, Yang M, Wang YY, Wood J, Hanes J. (2011) A poly(ethylene glycol)-based surfactant for formulation of drug-loaded mucus penetrating particles. **J Control Release**. 157(3):455-60. PMID: PMC3246104 [Impact 9.8] {Cited 69}
23. Suk JS, Boylan NJ, Trehan K, Tang BC, Schneider CS, Lin JM, Boyle MP, Zeitlin PL, Lai SK, Cooper MJ, Hanes J. (2011) N-acetylcysteine Enhances Cystic Fibrosis Sputum Penetration and Airway Gene Transfer by Highly Compacted DNA Nanoparticles. **Molecular Therapy**. 19(11): 1981–1989. PMID: PMC3222526 [Impact 7.0] {Cited 68}
22. Jachak A, Lai SK, Suk JS, Biswal S, Breyse P, Hanes J. (2011) Transport of Metal Oxide Nanoparticles and Single-walled Carbon Nanotubes across Human Mucus. **Nanotoxicology**. 6(6):614-22. PMID: PMC4696010 [Impact 5.8] {Cited 45}
21. Wang YY, Lai SK, So C, Schneider C, Cone R, Hanes J. (2011) Mucoadhesive nanoparticles may disrupt the protective human mucus barrier by altering its microstructure.. **PLoS ONE**. 6(6): e21547. PMID: PMC3126822 [Impact 4.4] {Cited 104}
20. Lai SK, Suk JS, Pace A, Wang YY, Yang M, Mert O, Chen J, Kim J, Hanes J. (2011) Drug carrier nanoparticles that penetrate human chronic rhinosinusitis mucus. **Biomaterials**. 32(26): 6285-6290. PMID: PMC3130096 [Impact 7.9] {Cited 112}
19. Hida K, Lai SK, Suk JS, Won SY, Boyle MP, Hanes J. (2011) Common gene therapy viral vectors do not efficiently penetrate sputum from cystic fibrosis patients. **PLoS ONE**. 6(5):e19919. PMID: PMC3103503 [Impact 4.4] {Cited 54}

Curriculum Vitae

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.*
17. Suk JS, Lai SK, Boylan NJ, Dawson MR, Boyle MP, Hanes J. (2011) Rapid Transport of Muco-inert Nanoparticles in Cystic Fibrosis Sputum Treated with N-acetyl Cysteine. **Nanomedicine (Lond).** 6(2):365-75 PMID: PMC3102009 [Impact 5.0] {Cited 125}
16. Lai SK, Wang YY, Hida K, Cone R, Hanes J. (2010) Nanoparticles reveal that human cervicovaginal mucus is riddled with pores larger than viruses. **Proc Natl Acad Sci U S A.** 107(2):598-603 PMID: PMC2818964 [Impact 9.7] {Cited 309} *Selected for Faculty of 1000 Biology.*
15. Tang BT, Dawson M, Lai SK, Wang YY, Suk JS, Yang M, Zeitlin PL, Boyle MP, Fu J, Hanes J. (2009) Biodegradable polymer nanoparticles that rapidly penetrate the human mucus barrier. **Proc Natl Acad Sci U S A.** 106(46):19268-73. PMID: PMC2780804 [Impact 9.7] {Cited 399} *In this issue, "Mucus is no match for coated nanoparticles", PNAS; "Biodegradable Particles Can Bypass Mucus, Release Drugs Over Time", Science Daily; selected for Faculty of 1000 Biology.*
14. Lai SK*, Hida K*, Shukair S, Wang YY, Cone R, Hope TJ, Hanes J. (2009) Human immunodeficiency virus type 1 is trapped by acidic but not by neutralized human cervicovaginal mucus. **J Virology.** 83:11196-11200. PMID: PMC2772788 [Impact 5.8] {Cited 259}
13. Suk JS*, Lai SK*, Wang YY, Boyle MP, Hanes J (2009). The Penetration of Fresh Undiluted Sputum Expecterated by Cystic Fibrosis Patients by Non-adhesive Polymer Nanoparticles. **Biomaterials.** 30(13):2591-2597. PMID: PMC2661768 [Impact 8.8] {Cited 272}
12. Lai SK*, Wang YY*, Cone R, Wirtz D, Hanes J (2009). Altering mucus rheology to "solidify" human mucus at the nanoscale. **PLoS ONE.** 4(1): e4294. PMID: PMC2627937 [Impact 4.4] {Cited 122} *"A Better Mesh: Researchers 'Tighten' Body's Protective Coating", Science Daily; featured in over 10 other science/medical news outlets.*
11. Lai SK[‡], Wang YY, Hanes J[‡]. (2009) Mucus-penetrating nanoparticles for drug and gene delivery to mucosal tissues. **Adv Drug Deliv Rev.** 61(2):158-171. PMID: PMC2667119 [Impact 15.6] **{Cited 1359}** *Featured on the Cover*
10. Lai SK, Wang YY, Wirtz D, Hanes J. (2009) Micro- and macrorheology of mucus. **Adv Drug Deliv Rev.** 61(2):86-100. PMID: PMC2736374 [Impact 15.6] {Cited 749}
9. Wang YY*, Lai SK*, Suk JS, Pace A, Cone R, Hanes J. (2008) Addressing the PEG Muco-adhesivity Paradox to Engineer Nanoparticles that "Slip" through the Human Mucus Barrier. **Angew Chem Int Ed Engl.** 47(50):9726-9729. PMID: PMC2666733 [Impact 12.0] {Cited 470} *News & Views: "Drug delivery: Stealth particles give mucus the slip", Nature Materials (2009) 8: 11 - 13; News Blog: "Breaking the mucus barrier", The Scientist (2008); also featured in over 20 other science/medical news outlets.*
8. Lai SK, Hida K, Chen C, Hanes J. (2008) Characterization of the intracellular dynamics of a non-degradative pathway accessed by polymer nanoparticles. **J Control Release.** 125(2):107-111. PMID: PMC2220013 [Impact 9.8] {Cited 82}
7. Lai SK, Hida K, Man ST, Chen C, Machamer C, Schroer TA, Hanes J. (2007) Privileged delivery of polymer nanoparticles to the perinuclear region of live cells via a non-clathrin, non-degradative pathway. **Biomaterials.** 28(18): 2876-2884. PMID: 17363053 [Impact 8.8] {Cited 283} *Editor's choice, Drug Discovery Today (2007).*

Curriculum Vitae

6. Lai SK, O'Hanlon ED, Harrold S, Man ST, Wang YY, Cone R, Hanes J. (2007) Rapid transport of large polymeric nanoparticles in fresh undiluted human mucus. **Proc Natl Acad Sci U S A.** 104(5):1482-1487. PMID: PMC1785284 [Impact 9.7] {Cited 905}
Research highlights include: "Nanoparticles: Against the flow", Nature Nanotechnology (2007); "Nanoparticles and mucus", Journal of American Medical Association (2007) 297(9):941; "Coated Nanoparticles Solve Sticky Drug-Delivery Problem", National Cancer Institute, Alliance for Nanotechnology in Cancer Newsletter.
5. Suk JS, Suh J, Lai SK, Hanes J. (2007) Quantifying the intracellular transport of viral and nonviral gene vectors in primary neurons. **Exp Biol Med (Maywood).** 232(3): 461-9. PMID: 17327481 [Impact 2.4] {Cited 81}
Society of Experimental Biology & Medicine Best Paper Award for 2007, Basic Biology Section.
4. Castellanos M, Kushihiro K, Lai SK, Shuler ML. (2007) A genomically/chemically complete module for synthesis of lipid membrane in a minimal cell. **Biotechnol Bioeng.** 97(2):397-409. PMID: 17149771 [Impact 3.3] {Cited 18}
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}
Listed in 2006 by Science Direct as a "Top 25 Hottest Article" in the area of Biomaterials (based on times downloaded).
1. Lai SK, Batra A, Cohen C. (2005) Characterization of polydimethylsiloxane elastomer degradation via cross-linker hydrolysis. **Polymer.** 46: 4204-4211. [Impact 1.5] {Cited 28}

Associated with education research at UNC-CH:

2. McLaughlin JE, Bush AA, Friedman AD, Lai SK. (2019) 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

4. Schaefer A, Lai SK. (2018). Innate and Adaptive Barrier Properties of Airway Mucus. In Inhalation Aerosols, Physical and Biological Basis for Therapy, AJ Hickey and HM Mansoor (Ed.) 3rd Ed. CRC Press.
3. Yang Q, Lai SK. (2016) Engineering well-characterized PEG-coated nanoparticles for elucidating biological barriers to drug delivery. In Cancer Nanotechnology, Methods and Protocols, R Zeineldin (Ed.) Springer. (Methods Mol Biol. 2017; 1530:125-137) {Cited 6}

Curriculum Vitae

2. Kim MS, Lai SK. (2011) Mucosal Barriers to Drug- and Gene- Loaded Nanoparticles. In Mass Transport and Biological Barriers to Nanotherapeutics (Chapter 8). R Serda (Ed.) Pan Stanford Publishing, Singapore. {Cited: 2}
1. Lai SK, Hanes J. (2007) Real time multiple particle tracking of gene nanocarriers in complex biological environments. In Gene Therapy Protocol, J Ledoux (Ed.), 3rd Ed. The Humana Press, Totowa. (Methods Mol Biol. 2008;434:81-97.) {Cited 22}

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.

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 2019/0023769A1 (Issued)**; EP3666285A3 (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: **US2018/0258160A1 (Issued)**
9. Lai SK, McSweeney M. (2017) Use of High Molecular Weight Polyethylene Glycol Compositions to Restore the Efficacy of Pegylated Therapeutic Compositions. PCT/US18/48126

Curriculum Vitae

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 and issued as **US 2019/0023769A1**
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. Provisional US 62/655,006
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.
14. Lai SK, Tiruthani K, Cruz-Teran C. (2020) Novel inhaled immunotherapy against acute respiratory infections
15. Lai SK, Tiruthani K. (2020) Development of highly potent neutralizing mAb against SARS-like coronaviruses

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 currently in Phase 2 clinical trials.

Patent Family #6, #8, #12 has been licensed to Mucommune. #6 formed the basis of Mucommune, LLC, which has received >\$5.5M in non-dilutive federal contracts to date. First IND targeted for early 2022.

Patent Family #6, #8, #10, #14 & #15 has been licensed to Inhalon Biopharma. #6 formed the basis of Inhalon Biopharma, which has received >\$5M in funding to date, with first IND targeted for late 2020.

Patent Family #11 formed the basis of AI Tracking Solutions, LLC. AITS has received ~\$500K in non-dilutive federal contracts 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: >\$9.4M)

R01HL141934-01 (PI: Lai; co-PI: Zamboni) 4/2018 – 3/2022 \$2,658,464

National Heart, Lung and Blood Institute

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

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

1R01HD101344-01 (MPI: Baum/Lai) 12/2019 – 11/2024 \$1,449,006 (Lai Lab)

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Title: Next Generation Multipurpose Prevention Technology: An Intravaginal Ring for HIV Prevention and Nonhormonal Contraception

1R01HD101562-01 (Lai, PI) 4/2020 – 3/2024 \$2,089,046

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Title: Engineering bispecific antibodies for non-hormonal contraception

Curriculum Vitae

1R43AI149894-01 (Cone, PI; Lai, Consortium-PI) 7/2020 - NCE \$74,250 (0% IDC)
Title: SBIR: Aerosol immunotherapy for treatment of human metapneumovirus infection

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

R44AI141054-01A1 (Cone, PI; Lai, Consortium-PI) 2/2019 – 1/2023 \$130,928
Phase 2 awarded 5/2021
National Institute of Allergy and Infectious Disease
Title: Development of RespiraClear for targeted mucosal treatment of RSV infections

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

FY21ITN452 (Pedan, PI; Lai, Subcontract PI) 4/2021 – 7/2022 \$716,154
Benaroya Research Institute (NIAID)
Title: Systemic Allergic Reactions to COVID mRNA vaccines

Pending/Submitted

R01AI165853-01 (MPI: Lai/Pickles) 9/2021 – 8/2026 \$3,013,086
Title: Engineering “muco-trapping” antibodies for inhaled therapy of parainfluenza and human metapneumovirus infections
Impact Score: 37 (Percentile: 24); to be resubmitted March 2022

R01AI169257-01 (MPI: Lai/Pickles) 4/2022 – 3/2027 \$2,799,659
Title: Engineering improved bivalent binding antibodies for more potent treatment against RSV and MPV infections

R01AI165989-01A1 (PI: Lai) 7/2022 – 6/2025 \$2,152,956
Quantitative assessment of magnitude and temporal dynamics of anti-PEG immunity in vaccinees receiving COVID mRNA vaccines
Resubmission; previous Impact Score: 33 (Percentile: 18)

R21CA273983-01 (PI: Lai) 7/2022 – 6/2024 \$420,769
Title: Engineering Siglec15-targeted bispecific antibodies that modulate the tumor microenvironment and enhances T-cell immunotherapy

R21AI171726-01 (PI: Lai) 7/2022 – 6/2024 \$417,391
Title: Engineering multivalent IgG antibodies for more effective binding and neutralization against influenza

(PI: Kushiro; Consortium PI: Lai) 7/2022 – 6/2023 \$84,907
Title: SBIR: Dose finding and optimization for MM010, a PEG-specific intervention that blocks hypersensitivity to PEGylated medicines

(PI: Hutchins; Consortium PI: Lai) 4/2022 – 3/2024 \$106,539

Curriculum Vitae

Title: SBIR: IND-enabling development of IN-007, an inhaled muco-trapping immunotherapy for COVID19 and other ACE2-targeted infections

Impact Score: 29 (2021 Payline: 29)

Completed Support (Total: >\$5M)

OPP1024615 (Lai, PI) 11/2010 - 5/2012 \$100,000 (0% IDC)

Bill and Melinda Gates Foundation, Grand Challenges Round 5

Title: Mucosal vaccines based on trapping pathogens in mucus.

U19AI096398 (Anderson, PI; Lai, Project 3 co-PI) 7/2011-6/2016 \$864,320

National Institute of Allergy and Infectious Diseases

Title: Optimizing plantibodies for trapping HIV and HSV in cervicovaginal mucus.

ID 1031734 (Hope, PI; Lai, co-investigator) 8/2011-5/2012 \$137,500 (10% IDC)

Bill and Melinda Gates Foundation, Collaboration for AIDS Vaccine Discovery

Title: Harnessing antibody-mucus interactions to prevent HIV transmission.

New Faculty Research Award (Lai, PI) 1/2011-1/2012 \$10,000 (0% IDC)

American Association of Colleges of Pharmacy

Title: Engineering lymphocyte- and macrophage- inert nanoparticles for lymphatic drug delivery.

P30 DK34987 (Lai, PI) 7/2011-1/2013 \$30,000 (0% IDC)

UNC Center for Gastrointestinal Biology & Disease Pilot Feasibility Award, NIH

Title: Antibody-mediated trapping of pathogens in gastrointestinal mucus.

U54CA151652 (DeSimone, PI; Lai, Pilot Proj. PI) 11/2011-10/2012 \$50,000 (0% IDC)

NIH/NCI Center for Cancer Nanotechnology Excellence (CCNE)

Title: Immune-inert nanoparticles for lymphatic drug delivery

P30 AI50410 (Lai, PI) 6/2011-5/2012 \$18,000 (0% IDC)

UNC CFAR Developmental Award, NIH

Title: Mobility of HIV in cervicovaginal mucus from women with bacterial vaginosis.

R21AI093242 (Lai, PI) 1/2011 – 12/2013 \$407,000

National Institute of Allergy and Infectious Diseases

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

Curriculum Vitae

<p>13426-15 (Lai, PI) Venture Well Foundation Title: Carolina E(I) Lab: A Multidisciplinary, Entrepreneurial Experience in Transforming Bold Ideas into Successful Ventures.</p>	<p>10/2015 – 12/2017</p>	<p>\$32,500 (0% IDC)</p>
<p>ID 1151477 (Lai, PI) National Science Foundation Title: CAREER: Biophysical investigations of immune-mediated pathogen trapping in mucus</p>	<p>4/2012-3/2018</p>	<p>\$400,000</p>
<p>(Lai, Project 1 PI) NC General Assembly – Research Opportunities Initiative Title: Research Program in Immunoengineering</p>	<p>7/2015 – 6/2018</p>	<p>\$480,000 (0% IDC)</p>
<p>R41 AI122472-01 (Moench, PI; Lai, Consortium PI) National Institute of Allergy and Infectious Diseases Title: STTR: Delivery of pathogen-trapping antibodies for vaginal protection</p>	<p>2/2016 – 1/2018</p>	<p>\$65,434 (0% IDC)</p>
<p>(Lai, PI) Eshelman Institute for Innovation <i>Title: Engineered bispecific fusion proteins (BFP) for targeted delivery of therapeutic nanoparticles and viral vectors</i></p>	<p>7/2016 – 6/2018</p>	<p>\$200,000 (0% IDC)</p>
<p>RX03512419 (Lai, PI) Eshelman Institute for Innovation <i>Title: Engineered antibodies with carefully tuned mucin-affinity for enhanced mucosal protection</i></p>	<p>10/2015 – 9/2018</p>	<p>\$660,203 (0% IDC)</p>
<p>(Lai, PI) Eshelman Institute for Innovation <i>Title: "Hijacking Vaccines": Durable immunity via genetic editing of B cells by CRISPR/Cas9</i></p>	<p>7/2016 – NCE</p>	<p>\$50,000 (0% IDC)</p>
<p>R41 GM123897 (Lai, PI) National Institute of General Medical Sciences <i>Title: STTR: Artificial neural networks for high performance, fully automated particle tracking analysis even at low signal-to-noise regimes</i></p>	<p>4/2017 – NCE</p>	<p>\$79,891 (0% IDC)</p>
<p>R56HD095629-01 (Lai, PI) Eunice Kennedy Shriver National Institute of Child Health and Human Development <i>Title: Development of novel sperm-binding antibodies</i></p>	<p>8/2017 – 7/2019</p>	<p>\$356,000</p>
<p>(Lai, PI) Eshelman Institute for Innovation <i>Title: Carolina E(I) Lab: A Multidisciplinary, Entrepreneurial Experience in Transforming Bold Ideas into Successful Ventures.</i></p>	<p>10/2015 – 2/2020</p>	<p>\$195,000 (0% IDC)</p>
<p>(Lai, PI) Kimberly-Clark Corp Kimberly-Clark Expert Service Agreement / Industry service agreement</p>	<p>9/2019 – 3/2020</p>	<p>\$49,952</p>
<p>R43AI138726-01A1 (Cone, PI; Lai, Consortium PI) National Institute of Allergy and Infectious Disease <i>Title: SBIR: Sustained vaginal delivery of monoclonal antibodies for preventing HIV transmission</i></p>	<p>7/2018 – 6/2020 (NCE)</p>	<p>\$61,235 (0% indirect)</p>

Curriculum Vitae

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)
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

Curriculum Vitae

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

VII. INVITED TALKS

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

- 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 MablImprove. 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.
- 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.

Curriculum Vitae

- 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.
- 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.

Curriculum Vitae

- 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.
- 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

Curriculum Vitae

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
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

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

Curriculum Vitae

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 \$8M in federal contracts to date. Lai serves as the Founder, CEO, and Chair of the Board of Directors.

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, as well as over \$13M in federal contracts. Lai serves as the Founder, CSO, and Chair of the 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 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>

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.

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 is currently in Phase II clinical trials.

X. SUPERVISION & MENTORING EXPERIENCE

Advisees

Current Ph.D. Students:

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:
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

Curriculum Vitae

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				

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

Curriculum Vitae

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	
	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	
2020	Phil Durham	DPMP	Paul Dayton	
	Jimmy Fay	Biophysics	Sasha Kabanov	
	Randy Qian	DPMP	Xiao Xiao	
	Cesar Lopez	Immunology	Helen Lazear	
2021	Kunyu Qiu	DPMP	Aaron Anselmo	
	Phil Durham	DPMP	Paul Dayton	
	Amelia Mccue	Biophysics	Brian Kuhlman	
	Zhiyuan Yao	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.

Curriculum Vitae

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

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 in 2021 (~80-90 hrs):

~3 articles/mo: Advanced Science, Biomaterials, Contemporary Clinical Trials, Infectious Disease & Therapy, J Controlled Release, J Materials Chemistry, Lancet Respiratory Medicine, Nature Communications, Nature Nanotechnology, Science Advances, Science Translational Medicine,

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,

Reviewer in 2021 (~140 hrs):

NSF BMAT, NIH EBIT, ACS Petroleum Research Fund, Italian CF Foundation, Georgetown University CFAR

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

Unpaid Scientific Advisor to Media/Press in 2021 (~10 hrs):

Missouri Independent, National Geographic, Science, SF Chronicle, Wallstreet Journal

XII. SERVICE TO UNC & ESHELMAN SCHOOL OF PHARMACY

AAPS Student Chapter Faculty Advisor (2010 – 2018) • Chapel Hill Pharmaceutical Sciences Committee (2012 – 2018) • Curriculum Committee (2010 – 2012) • Dean of Pharmacy Search Committee (2019) • Full Professor Committee (2021 – NOW) • Global Engagement Committee (2015 – 2021) • Graduate Admissions Committee, Biomedical Engineering (2013 – Now) • HHMI International Student Research Fellowship UNC Internal Review Committee (2012 – 2020) • 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)