University of Miami Curriculum Vitae

1. Date: June 06, 2022

I. PERSONAL

2. Name: Isildinha M. Reis, Dr.PH

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4. Office address: University of Miami School of Medicine, Dept. of Public Health Sciences

Clinical Research Building (R669)

1120 NW 14th Street 10th Floor, Room 1045

Miami, FL 33136, USA

5. Current Academic Rank: Professor5A. Current Track of Appointment: Research Track

6. Primary Department: Public Health Sciences (Formerly "Epidemiology and Public Health",

name change date 3/29/2013.)

7. Secondary or Joint Departmental Appointments: NA

II. HIGHER EDUCATION

8. Institutional:

University of California at Los Angeles School of Public Health	DrPH in Biostatistics	03/1996
University of São Paulo, Brazil		
School of Public Health	Lato sensu M.S in Public Health	12/1991
Institute of Mathematics and Statistics	M.S. in Statistics	11/1989
Institute of Mathematics and Statistics	B.S. in Statistics	02/1981

9. Non-Institutional:

Statistics in Health. Summer course of the University of Reading Statistical Service Centre, Reading, United Kingdom.	07-09/1989
Variance Estimation in Complex Surveys. Short-course promoted by the International Association of Survey Statisticians, Paris, France.	08/1989

10. Certification, licensure:

Institutional Review Board Educational Seminar.

Accreditation required for performing research on human subjects.

University of Miami School of Medicine, Human Subjects Office. 11/2000

III. EXPERIENCE

11. Academic:

Research Professor Research Associate Professor Research Assistant Professor Department of Public Health Sciences Leonard M. Miller School of Medicine, University of Miami	06/2017 - present 06/2006 - 05/2017 04/1999 - 05/2006
Faculty Biostatistician Sylvester Biostatistics and Bioinformatics Shared Core Resource Sylvester Comprehensive Cancer Center Leonard M. Miller School of Medicine, University of Miami	04/1999 - present
Director Interim co-Director Interim co-Director Division of Biostatistics, Sylvester Biostatistics and Bioinformatics Shared Core Resource Sylvester Comprehensive Cancer Center Leonard M. Miller School of Medicine, University of Miami	04/2012 - 06/2015 04/2008 - 11/2008 07/2004 - 12/2006
Professora Doutora (Assistant Professor) Assistente (Assistant) Auxiliar de Ensino (Lecturer) Department of Epidemiology School of Public Health, University of São Paulo, Brazil	03/1996 - 01/1999 04/1989 - 03/1996 07/1985 - 04/1989

12. Hospital Appointments: N/A

13. Non-Academic:

Research Assistant Section of Public Health Dentistry School of Dentistry, University of California at Los Angeles	08/1993 - 06/1995
Junior Systems Analyst Department of Nutrition, School of Public Health, University of São Paulo, Brazil	12/1983 - 06/1985

Statistical consultant 1984 -1985

Department of Nutrition, School of Public Health, University of São Paulo, Brazil.

- Study 1: "Nutrition and health conditions of the children in the city of São Paulo" Principal Investigator: Carlos Augusto Monteiro, MD
- Study 2: "Prevalence of anemia in health centers of São Paulo state" Principal Investigator: Sophia Cornbluth Szarfac
- Study 3: "The use of vitamin C to combat anemia"
 Principal Investigator: Sophia Cornbluth Szarfac

Biostatistician 12/1981 - 11/1983

Indústrias Farmacêuticas [Pharmaceutical Industry] Fontoura-Wyeth S.A., São Paulo, Brazil

14. Military: N/A

IV. PUBLICATIONS

- 15. Books and monographs published: None
- **16.** Juried or refereed journal articles and exhibitions: (127 publications)
- 1. Saul EE, Alderuccio J, Reis IM, Zhao W, Iyer SG, Rodriguez G, Desai A, Chapman JR, Markoe AM, Isrow DM, Lossos I. Long-term outcomes of patients with conjunctival extranodal marginal zone lymphoma. Am J Hematol., 2022 May 21. doi: 10.1002/ajh.26591.Online ahead of print. PMID: 35560252. Impact Factor 10.05.
- Venkatramani V, Reis IM, Gonzalgo ML, Castle EP, Woods ME, Svatek RS, Weizer AZ, Konety BR, Tollefson M, Krupski TL, Smith ND, Shabsigh A, Barocas DA, Quek ML, Dash A, Parekh DJ. Comparison of Robot-Assisted and Open Radical Cystectomy in Recovery of Patient-Reported and Performance-Related Measures of Independence A Secondary Analysis of a Randomized Clinical Trial. JAMA Network Open. 2022 Feb 1;5(2):e2148329. doi:10.1001/jamanetworkopen.2021.48329 Online ahead of print. PMID: 35171260. Impact Factor 8.483.
- Alderuccio JP, Kuker RA, Barreto-Coelho P, Martinez BM, Miao F, Kwon D, Beitinjaneh A, Wang TP, Reis IM, Lossos IS, Moskowitz CH. Prognostic value of presalvage metabolic tumor volume in patients with relapsed/refractory diffuse large B-cell lymphoma. Leuk Lymphoma. 2022 Jan;63(1):43-53. doi: 10.1080/10428194.2021.1966786. Epub 2021 Aug 17. PMID: 34414842. Impact Factor 2.891.
- 4. Jiang X, Lu X, Gentles A, Zhao D, Wander S, Zhang Y, Natkunam Y, Slingerland J, **Reis IM**, Rabinovich B, Abdulreda M, Moy V, Lossos I. HGAL inhibits lymphoma dissemination by interacting with multiple Cytoskeletal proteins. Blood Advances. 2021 Dec 14; 5(23):5072-5085. doi: 10.1182/bloodadvances.2021004304. PMID: 34543391. **Impact Factor 6.799.**
- 5. Smith DH, Raslan S, **Reis IM**, Al-Awady A, Buitron I, Perez M, Liu H, Halgowich J, Gordon C, Webb Hooper M, Barengo NC, Franzmann EJ. Decreased Levels of Soluble CD44 in a High-Risk Population following a Smoking Cessation Program. Int J Environ Res Public Health. 2021 Dec 14;18(24):13174. doi: 10.3390/ijerph182413174.PMID: 34948786. . Impact Factor 3.39.
- 6. Florindez JA, Alderuccio JP, **Reis IM**, Lossos IS. Primary thyroid lymphoma: survival analysis of SEER database (1995-2016). Leuk Lymphoma. 2021 Nov; 62(11):2796-2799. doi: 10.1080/10428194.2021.1933479. Epub 2021 May 27.PMID: 34039243. **Impact Factor 3.093.**
- 7. Kwon D, Reddy RRS, **Reis IM**. ABCMETAapp: R shiny application for simulation-based estimation of mean and standard deviation for meta-analysis via approximate Bayesian computation. Res Synth Methods. 2021 Jun 20. doi: 10.1002/jrsm.1505. Online ahead of print. PMID: 34148300. **Impact Factor 5.273.**
- 8. Alderuccio JP, Florindez JA, Reis IM, Zhao W, Izidore S Lossos IS. Treatments and Outcomes in Stage I Extranodal Marginal Zone Lymphoma in the United States. Cancers. 2021 Apr 9;13(8):1803. PMID: 3391880, PMCID: PMC8069638. DOI: 10.3390/cancers13081803. Impact Factor 6.126.
- 9. Horodyski L, Ball B, Emile C, Rhodes A, Miao F, **Reis IM**, Carasquillo M, Livingstone J, Matadial C, Ritch CR, Deane LA. Safe transition to opioid-free pathway after robotic-assisted laparoscopic prostatectomy. J Robot Surg. 2021 Apr 15. doi: 10.1007/s11701-021-01237-0. Online ahead of print. PMID: 33855681. **Impact Factor 2.**

- 10. Alderuccio JP, Saul EE, Iyer SG, **Reis IM**, Alencar AJ, Rosenblatt JD, Lossos IS. R-MACLO-IVAM regimen followed by maintenance therapy induces durable remissions in untreated mantle cell lymphoma long term follow up results. Am J Hematol. 2021 Mar 18. doi: 10.1002/ajh.26163. PMID: 33735476. **Impact Factor 6.973.**
- 11. Bell EB, **Reis IM**, Cohen ER, Almuhaimid T, Smith DH, Alotaibi F, Gordon C, Gomez-Fernandez C, Goodwin WJ, Goodwin WJ, and Franzmann EJ. Green salad intake is associated with improved oral cancer survival and lower soluble CD44 levels. Nutrients. 2021 Feb; 13(2): 372. Published online 2021 Jan 26. doi: 10.3390/nu13020372. PMID: 33530399. **Impact Factor 4.546.**
- 12. Martos MP, Katz JE, Parmar M, Jain A, Soodana-Prakash NP, Punnen S, Gonzalgo ML, **Reis IM**, Smith NA, Shah HN. Impact of peri-operative factors on nadir serum prostate-specific antigen levels after holmium laser enucleation of prostate. BJUI Compass 2020, WJUR-D-20-01750 Submission Notification to co-author) **Impact Factor 5.588.**
- 13. Martin L, Ossin D, Schachar J, Devakumar H, Alas A, Davila GW, **Reis IM**, Miao F, Hurtado E. Comparison of methods to identify stress urinary incontinence in women with pelvic organ prolapse. Female Pelvic Med Reconstr Surg. 2021 Jan 1; 27(1):e127-e132. doi: 10.1097/SPV.00000000000000858. PMID: 33369965. **Impact Factor 1.503.**
- 14. Punnen S, Stoyanova R, Kwon D, **Reis IM**, Soodana-Prakash N, Ritch CR, Nahar Bm Gonzalgo ML, Kava B, Liu Y, Arora H, Gaston SM, Castillo RP, DalPra A, Abramowitz M, Kryvewnko ON, Davicioni E, Pollack A, Parekh D. Heterogeneity in genomic risk assessment from tissue based prognostic signatures used in the biopsy setting and the impact of MRI targeted biopsy. J Urol. 2020, JU-20-2188. PMID: 33356482. **Impact Factor 5.925.**
- 15. Florindez JA, Alderuccio JP, **Reis IM**, Lossos IS. Survival analysis in treated plasmablastic lymphoma patients: a population-based study. Am. J. of Haematol.2020;95(11):1344-1351, doi: 10.1002/ajh.25955. PMID: 32777103. **Impact Factor 5.020.**
- 16. Florindez JA, Alderuccio JP, **Reis IM**, Lossos IS. Splenic marginal zone lymphoma: A US population-based survival analysis (1999-2016). Cancer. 2020 Nov 1; 126(21):4706-4716. doi: 10.1002/cncr.33117. PMID: 32767702. **Impact Factor 5.742.**
- 17. Lossos IS, **Reis IM**, Rosenblatt JD, Alderuccio JP. Long-term outcomes of frontline ⁹⁰Y-ibritumomab tiuxetan in marginal zone lymphoma. Leuk Lymphoma. Leuk Lymphoma. 2020 Dec; 61(13):3234-3238. doi:10.1080/10428194.2020.1802449. PMID: 32755329. **Impact Factor 3.093.**
- 18. Johnson, AL., Medina H, **Reis IM**, Schlumbrecht M, Pinheiro, PS. The Role of Histology on Endometrial Cancer Survival Disparities in Diverse Florida. Accepted for publication in PLOS ONE (PONE-D-19-33494R2, email 7/8/2020). **Impact Factor 2.870**
- 19. Liu J, Medina H, **Reis IM**, Sussman DA, Pinheiro, PS. Disadvantages for non-Hispanic Whites in gastric carcinoma survival in Florida. Cancer Causes Control. 2020 Sep;31(9):815-826. doi: 10.1007/s10552-020-01320-1. PMID: 32462560. **Impact Factor 2.300.**
- 20. Cohen ER, **Reis IM**, Gomez-Fernandez C, Smith D, Pereira L, Freiser ME, Marotta G, Thomas GR, Sargi ZB, Franzmann EJ. CD44 and associated markers in oral rinses and tissues from oral and oropharyngeal cancer patients. Oral Oncol. 2020 Jul;106:104720. doi: 10.1016 /j.oraloncology.2020.104720. PMID: 32325304. **Impact Factor 3.98.**
- 21. Husnain M, Kuker R, **Reis IM**, Iyer SG, Zhao W, Chapman JR, Vega F, Lossos IS, Alderuccio JP. Clinical and radiological characteristics of patients with pulmonary marginal zone lymphoma: A single center analysis. Cancer Med. 2020 Jul;9(14):5051-5064. doi: 10.1002/cam4.3096. PMID: 32452658;PMCID: PMC7367627. **Impact Factor 3.362.**

- 22. Ramasamy R, Masterson TA, Best J, Bitran J, Ibrahim E, Molina M, Kaiser U, Miao F, **Reis IM**. Effect of Natesto on Reproductive Hormones, Semen Parameters and Hypogonadal Symptoms: A single-center, open-label, single-arm trial. J Urol. 2020 Sep; 204(3):557-563. doi: 10.1097/JU.000000000001078. PMID: 32294396. **Impact Factor 5.925.**
 - Reply by Authors. Ramasamy R, Masterson TA, Best JC, Bitran J, Ibrahim E, Molina M, Kaiser UB, Miao F, Reis IM. J Urol. 2020 Sep;204(3):563. doi: 10.1097/JU.0000000000001078.03. PMID: 32574104.
- 23. Becerra MF, Venkatramani V, **Reis IM**, Soodana-Prakash N, Punnen S, Gonzalgo ML, Raolji S, Castle EP, Woods ME, Svatek RS, Weizer AZ, Konety BR, Tollefson M, Krupski TL, Smith ND, Shabsigh A, Barocas DA, Quek ML, Dash A, Parekh DJ. Health-Related Quality of Life of Patients with Bladder Cancer in the RAZOR Trial A Multi-Institutional Randomized Trial Comparing Robot versus Open Radical Cystectomy. J Urol. 2020 Sep;204(3):450-459. doi: 10.1097/JU.0000000000001029. PMID: 32271690. **Impact Factor 5.925.**
- 24. Patel P, Katz J, Lokeshwar SD, Molina M, **Reis IM**, Clavijo R, Ramasamy R. Phase II Randomized, Clinical Trial Evaluating 2 Schedules of Low-Intensity Shockwave Therapy for the Treatment of Erectile Dysfunction. Sex Med. 2020 Jun;8(2):214-222. doi: 10.1016/j.esxm.2020.01.010. PMID: 32184082; PMCID: PMC7261672. **Impact Factor 3.151.**
- 25. Nahar B, Bhat A, **Reis IM**, Soodana-Prakash N, Becerra MF, Lopategui D, Venkatramani V, Patel R, Madhusoodanan V, Kryvenko ON, Ritch CR, Gonzalgo ML, Punnen S, Parekh DJ. Prospective Evaluation of Focal High-Intensity Focused Ultrasound (HIFU) for Patients with Localized Prostate Cancer. J Urol. 2020 Sep;204(3):483-489. doi: 10.1097/JU.000000000001015. PMID: 32167866. Impact Factor 5.925.
- 26. Alderuccio JP, Isrow D, **Reis IM**, Iyer SG, Meshman JJ, Zhao W, Vega F, Chapman JR, Markoe AM, Lossos IS. Diagnostic bone marrow biopsy in patients with stage I EMZL treated with radiation therapy: needed or not? Blood. 2020 Apr 9;135(15):1299-1302. doi: 10.1182/blood.2019003236. PMID: 31978219; PMCID: PMC7265788. **Impact Factor 16.601.**
- 27. Pollack A, Chinea FM, Bossart E, Kwon D, Abramowitz MC, Lynne C, Jorda M, Marples B, Patel VN, Wu X, Reis I, Studenski MT, Casillas J, Stoyanova R. Phase I Trial of MRI-Guided Prostate Cancer Lattice Extreme Ablative Dose (LEAD) Boost Radiation Therapy, Int J Radiat Oncol Biol Phys, (Feb 2020), doi: 10.1016/j.ijrobp.2020.01.052. PMID: 32084522. Impact Factor 6.203.
- 28. Alghamdi SA, Krishnamurthy K, Garces Narvaez SA, Algashaamy KJ, Aoun J, **Reis IM**, Recine MA, Jorda M, Poppiti RJ, Gomez-Fernandez CR. Low-grade ductal carcinoma in situ: Improving Interobserver Reproducibility on the Path to Surveillance Strategies. Am J Clin Pathol., 2020 Feb 8;153(3):360-367. doi: 10.1093/ajcp/agz179. PMID:31769792. **Impact Factor 2.413.**
- 29. Venkatramani V, Reis IM, Castle EP, Gonzalgo ML, Woods ME, Svatek RS, Weizer AZ, Konety BR, Tollefson M, Krupski TL, Smith ND, Shabsigh A, Barocas DA, Quek ML, Dash A, Kibel AS, Pruthi RS, Montgomery JS, Weight CJ, Sharp DS, Chang SS, Cookson MS, Gupta GN, Gorbonos A, Uchio EM, Skinner E, Soodana-Prakash N, Becerra MF, Swain S, Kendrick K, Smith JA Jr, Thompson IM, Parekh DJ. Predictors of recurrence, progression-free and overall survival following open versus robotic radical cystectomy: Analysis from the RAZOR trial with a 3-year follow-up. J Urol. 2020 Mar; 203(3):522-529. doi: 10.1097/JU.00000000000000565. PMID: 31549935; PMCID: PMC7487279. Impact Factor 5.647.
- 30. Soodana-Prakash N, Castillo RP, **Reis IM**, Stoyanova R, Kwon D, Velasquez MC, Nahar B, Kannabur P, Johnson TA, Swain SK, Ben-Yakar N, Venkatramani V, Ritch C, Satyanarayana

- R, Gonzalgo ML, Parekh DJ, Bittencourt L, Punnen S. Validation of dominant and secondary sequence utilization in PI-RADS v2 for classifying prostatic lesions. Can J Urol. 2019 Jun; 26(3):9763-9768. PMID: 31180306. **Impact Factor 5.157.**
- 31. Weed DT, Zilio S, **Reis IM**, Sargi Z, Abouyared M, Gomez CR, Civantos FJ, Rodriguez CP, Serafini P. The reversal of immune exclusion mediated by Tadalafil and an anti-tumor vaccine also induces PDL1 upregulation in recurrent head and neck squamous cell carcinoma: interim analysis of a phase I clinical trial. Frontiers in Immunology 2019 May; 10:1206-1204. PMID: 31214178. **Impact Factor 6.429.**
- 32. Lee E, Nelson OL, Puyana C, Takita C, Wright JL, Zhao W, **Reis IM**, Lin RY, Hlaing WM, Bakalar JL; Yang GR, Hu JJ. Association between C-reactive protein and radiotherapy- related pain in a tri-racial/ethnic population of breast cancer patients: A prospective cohort study. Breast Cancer Research 2019 May 28;21(1):70. PMID: 31138314. **Impact Factor 6.142.**
- 33. Birnbaum MD, Zhao N, Moorthy BT, Patel DM, Kryvenko ON, Heidman L, Kumar A, Morgan WM, Ban Y, **Reis IM**, Chen X, Gonzalo ML, Jorda M, Burnstein KL, Zhang F. Reduced Arginyltransferase 1 is a driver and a potential prognostic indicator of prostate cancer metastasis. Oncogene 2019 Feb;38(6):838-851. PMID: 30177837. **Impact Factor 40.137.**
- 34. Alderuccio JC, **Reis IM**, Zhao W, Lossos IS. Short survival and frequent transformation in extranodal marginal zone lymphoma with multiple mucosal sites presentation. Am J Hematol. 2019 May;94(5):585-596. PMID: 30784098. **Impact Factor 5.303.**
- 35. Rich BJ, Perlow H, Kodiyan J, Portelance L, **Reis IM**, Pearson JM, Slomovitz B, Wolfson A. Impact of Greater than Three Cycles of Adjuvant Chemotherapy plus Vaginal Brachytherapy on Outcome of Patients with At-Risk Stage I-II Endometrial Carcinoma. Annals of Clinical Oncology 2019;1(1):1-7 (doi:10.31487/j.ACO.2018.01.005). **Impact Factor 14.196**
- 36. de la Fuente MI, Alderuccio JC, Reis, IM, Omuro A, Markoe A, Echegaray JJ, Davis JL, Harbour JW, Lossos IS. Bilateral radiation therapy followed by methotrexate-based chemotherapy for primary vitreoretinal lymphoma. Am J Hematol. 2019;94:455-460. PMID: 30663807. **Impact Factor 5.303**.
- 37. Alderuccio, J, Zhao, W, Desai A, Gallastegui N, Ramdial J, Kimble E, de la Fuente MI,Rosenblatt JD, Chapman JR, Vega F, Reis IM, Lossos, I. Risk factors for transformation to higher grade lymphoma and its impact on survival in a large cohort of patients with marginal zone lymphoma from a single institution. J Clin Oncol. 2018 Oct 12. [Epub ahead of print] PMID: 30312133. Impact Factor 26.303.
- 38. Ramey SJ, Yechieli R, Zhao W, Kodiyan J, Asher D, Chinea FM, Patel V, **Reis IM**, Wang L, Wilky BA, Subhawong T, Trent JC 2nd. Limb-sparing surgery plus radiotherapy results in superior survival: an analysis of patients with high-grade, extremity soft-tissue sarcoma from the NCDB and SEER. Cancer Med. 2018 Sep;7(9):4228-4239.PMID:30030882. **Impact Factor 3.362.**
- 39. Kwon D, **Reis IM**, Breto AL, Tschudi Y, Gautney N, Zavala-Romero O, Lopez C, Ford JC, Punnen S, Pollack A, Stoyanova R. Classification of Suspicions Lesions on Prostate multiparametric MRI using Machine Learning. J Med Imaging (Bellingham). 2018 Jul;5(3):034502. PMID: 30840719. Impact Factor NA.
- 40. Stoyanova R, Chinea F, Kwon D, **Reis IM**, Tschudi Y, Parra NA, Breto AL, Padgett KR, Pra AD, Abramowitz MC, Kryvenko ON, Punnen S, Pollack A. An Automated Multiparametric MRI Quantitative Imaging Prostate Habitat Risk Scoring System for Defining External Beam

- Radiotherapy Boost Volumes. Int J Radiat Oncol Biol Phys. 2018 Nov 15;102(4):821-829. PMID: 29908220. Impact Factor 5.133.
- 41. Parekh D, Reis IM, et al. Effect of robot-assisted radical cystectomy versus open radical cystectomy on progression-free survival in patients with bladder cancer: the RAZOR (Randomized Open versus Robotic Cystectomy) clinical trial. The Lancet 2018 Jun; 391: 2525–2536. PMID: 29976469. Impact Factor 44.002.
- 42. Malpica L, Pimentel A, Reis IM, Gotuzzo E, Lekakis L, Komanduri K, Harrington T, Barber GN, Ramos JC. Epidemiology, clinical features, and outcome of HTLV-1-related ATLL in an area of prevalence in the United States. Blood Adv, 2018, 2(6), 607-620. PMID: 29545256. **Impact Factor ~10**.
- 43. Palacio S, Hosein PJ, **Reis I**, Akunyili II, Ernani V, Pollack T, Macintyre J, Restrepo MH, Merchan JR, Rocha Lima CM. The nab-paclitaxel/gemcitabine regimen for patients with refractory advanced pancreatic adenocarcinoma. J Gastrointest Oncol. 2018 Feb;9(1):135-139. PMID: 29564179. Impact Factor NA.
- 44. Mahmoud O, **Reis IM**, Samuels MM, Elsayyad N, Bossart E, Both J, ELGhoneimy E, Moustafa M, AbdAllah M, Takita C. Prospective Pilot Study Comparing the Need for Adaptive Radiotherapy in Unresected Bulky Disease and in Postoperative Patients With Head and Neck Cancer. Technol Cancer Res Treat. 2017;16(6):1014-1021,PMID: 28671024. **Impact Factor 2.204**
- 45. Cohen E, **Reis IM**, Perez A, Gomez C, Pereira L, Frazier ME, Hoosien G, Franzmann EJ. Immunohistochemistry Analysis of CD44, EGFR, and p16 in Oral Cavity and Oropharyngeal Squamous Cell Carcinoma. Otolaryngology—Head and Neck Surgery, 2017:157(2):239-251. PMID: 28397583. **Impact Factor 2.276.**
- 46. Greer S, Han T, Dieguez C, McLean N, Saer R, **Reis I**, Levi J, Marquez VE. Enzyme-driven chemo- and radiation-therapy with 12 pyrimidine nucleoside analogs not yet in the clinic. Anticancer Agents Med Chem. 2017;17(2):250-264. PMID: 27745548. **Impact Factor 2.722**.
- 47. Wright JL, Saigal K, **Reis I**, Zhao W, Takita C, Ambros T, Saeed AM, Sujoy V, Hurley J. Locoregional and overall recurrence after neoadjuvant endocrine therapy versus chemotherapy in post-menopausal women with estrogen receptor positive HER2 negative breast cancer. *Am J Clin Oncol.* 2017; 490-497. PMID:26017482. **Impact Factor 2.61.**
- 48. Gomez-Arteaga A, DeGennaro V, George S, **Reis IM**, Santamaria E, Westin GFF, Gabriel D, Hurley JD. Presentation, treatment and outcomes of Haitian women with breast cancer in Miami and Haiti: Disparities in breast cancer. A retrospective cohort study. Journal of Global Oncology, 2016;3(4):389-399. PMID: 28831447. **Impact Factor NA.**
- 49. Wu ES, Park JY, Zeitouni JA, Gomez CR, **Reis IM**, Zhao W, Kwon D, Lee E, Nelson OL, Lin HY, Franzmann EJ, Savell J, McCaffrey TV, Goodwin WJ, Hu JJ. Effect of actionable somatic mutations on racial/ethnic disparities in head and neck prognosis. Head & Neck 2016; 38(8):1234-41. PMID:27028310. **Impact Factor 2.641.**
- 50. Pereira LHM, **Reis IM**, Reategui EP, Gordon C, Saint-Victor S, Duncan R, Gomez C, Bayers S, Fisher P, Perez A, Goodwin WJ, Hu JJ, Franzmann EJ. Risk stratification system for oral cancer screening. *Cancer Prevention Research* 2016; 9(6):445-55. PMID: 27020654. **Impact Factor** 4.444.
- 51. Wolfson AH, **Reis IM**, Portelance L, Diaz DA, Zhao W, Gibb RK. Prognostic impact of clinical tumor size on overall survival for subclassifying stages I and II vaginal cancer: A SEER analysis. *Gynecologic Oncology* 2016; 141(2):255-9. PMID:26970567. **Impact Factor 3.774.**

- 52. Fan YS, Casas CE, Peng J, Watkins M, Fan L, Chapman J, Ikpatt OF, Gomez C, Zhao W, **Reis IM**. HER2 FISH classification of equivocal HER2 IHC breast cancers with use of the 2013 ASCO/CAP practice guideline. *Breast Cancer Research and Treatment* 2016; 155:457-462. PMID: 26895325. **Impact Factor 3.94.**
- 53. Lee E, Takita C, Wright JL, **Reis IM**, Zhao W, Nelson OL, Hu JJ. Characterization of risk factors for adjuvant radiotherapy-associated pain in a tri-racial/ethnic breast cancer population. *Pain* 2016; 157(5): 1122-1131. PMID: 26780493. **Impact Factor 5.21.**
- 54. Wright JL, Takita C, **Reis IM**, Zhao W, Lee E, Nelson OL, Hu JJ. Prospective evaluation of radiation-induced skin toxicity in a race/ethnically diverse breast cancer population. *Cancer Med* 2016; 5(3):454-64. PMID: 26763411. **Impact Factor 2.5.**
- 55. Kallingal GJS, Weinberg JM, **Reis IM**, Nehra A, Venkatachalam MA, Parekh DJ. Long-term response to renal ischemia in the human kidney after partial nephrectomy: results from a prospective clinical trial. *BJU International*. 2016; 117(5):766-74. PMID:26053785. **Impact Factor 3.533**.
- 56. Diaz DA, **Reis IM**, Weed DT, Elsayyad N, Samuels M, Abramowitz MC. Head and neck second primary cancer rates in the HPV era: A population based analysis. *Head & Neck* 2016; 38(Suppl 1): E873-83. PMID: 25966421. **Impact Factor 3.0.**
- 57. Kwon D, **Reis IM**. Simulation-based estimation of mean and standard deviation for metaanalysis via Approximate Bayesian Computation (ABC). *BMC Med Res Methodol*. 2015;15:1-12. PMID: 26264850. **Impact Factor 2.27.**
- 58. Arsenault D, Hurley J, Takita C, **Reis IM**, Zhao W, Rodgers S, Wright JL. Predictors of locoregional outcome in HER2-overexpressing breast cancer treated with neoadjuvant chemotherapy. *Am J Clin Oncol.* 2015; 38(4):348-352. PMID: 23799288. **Impact Factor 2.206.**
- 59. **Reis IM**, Ramachandran K, Speer C, Gordian E, Singal R. Serum GADD45a methylation is a useful biomarker to distinguish benign versus malignant prostate disease. *British Journal of Cancer* 2015; 113(3):460-468. PMID:26171936. **Impact Factor 4.82.**
- 60. Weed DT, Vella JL, **Reis IM**, De La Fuente AC, Gomez C, Sargi Z, Nazarian R, Califano J, Borello I, Serafini P. Tadalafil reduces myeloid derived suppressor cells and regulatory T cells and promotes tumor immunity in patients with head and neck squamous cell carcinoma. *Clin Cancer Res.* 2015; 21(1):39-48. PMID: 25320361. **Impact Factor 8.193.**
- 61. Diaz, DA, Pollack A, **Reis I**, Mahmoud O, Gonzalgo MA, Ishkanian A, Fernandez G, Manoharan M, Abramowitz MC. Neoadjuvant radiotherapy improves survival in patients with T2b/T3 bladder cancer: a population based analysis. *Clin Genitourin Cancer*. 2015; 13(4):378-384. PMID: 25907230. **Impact Factor 2.322.**
- 62. Hosein PJ, Sandoval-Sus JD, Goodman D, Gomez-Arteaga A, **Reis I**, Hoffman J, Stefanovic A, Rosenblatt JD, Lossos IS. Updated survival analysis of two sequential prospective trials of R-MACLO-IVAM followed by maintenance for newly diagnosed mantle cell lymphoma. *Am J Hematol.* 2015; 90(6):E111-E116. PMID: 25737247. **Impact Factor 3.477.**
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17. Other works, publications, and abstracts:

18a. Patent submitted

Franzmann E, Pereira L, **Reis IM**, Duncan RC. "Methods for detecting human papillomavirus and providing prognosis for head and neck squamous cell carcinoma." University of Miami patent, publication number US 20150219656 A1, application number US 14/688,221, publication date 2015/08/06 http://www.google.com/patents/US20150219656 (co-inventor).

18b. Letters to the Editor

Lebrão ML, Silva NN, **Reis IM**. Latorre MRO, Hamerly I. Sistema Nacional de Informações de Demanda Ambulatorial. [National health care information system.] *Rev. Saúde Pública* 1988; 22:344-45.

18c. Technical reports

Reis IM, Singer JM. Uso do SOC para ajuste de modelos log-lineares a dados categorizados. [The use of SOC software to fit log-linear models for categorical data.] EMBRAPA/ NTIA, CT-NTIA-8904, Campinas, 1989. (Technical Report)

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18d. Abstracts of Oral or Poster Presentations (165)

Abbreviations:

AACR: American Association for Cancer Research ASCO: American Society of Clinical Oncology

AAO-HNSF: American Academy of Otolaryngology-Head and Neck Surgery Foundation

AHNS: American Head and Neck Society

ASTRO: American Society for Radiation Oncology

ASA: American Statistical Association

ARS: American Radium Society

ASH: American Society of Hematology AUA: American Urological Association

COSM: Combined Otolaryngology Spring Meetings

ECHNO: European Congress on Head and Neck Oncology

ENAR: Eastern North American Region of the Biometrics Society ISMRM: International Society for Magnetic resonance in Medicine NAACCR: North American Association of Central Cancer Registries

SESAUA: Southeastern Section of the AUA SABCS: San Antonio Breast Cancer Symposium

SUO: Society of Urologic Oncology

USCAP: United States and Canadian Academy of Pathology

- Atluri VS, Zucker I, Reis IM, Kwon D, Soodana-Prakash N, Tewari A, Patel V, Wagaskar V, Konety B, Kasraeian A, Czarniecki S, Thoreson G, Kim E, and Punnen S. MRI, Biomarker, or both? Results from a large multi-institutional study of 1111 men with 4Kscore, multiparametric MRI and prostate biopsy. AUA Meeting. Las Vegas, NV, Sept 10-13, 2021. (Abstract submission #).
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- 3. Almeida R, Soodana-Prakash N, Kwon D, **Reis IM**, Castilho RP, Kryvenko O, Stoyanova R, Pollack A, Nahar B, Gonzalgo M, Ritch C, Parekh DJ, and Punnen S. The performance of mpMRI and the 4Kscore for predicting progression on Active Surveillance; results from a single-institution prospective study AUA Meeting. Las Vegas, NV, Sept 10-13, 2021. (Abstract submission #).
- 4. Buitron E, Smith DH, **Reis IM**, Liu H, Halgowich J, Gordon C, Franzmann EJ. Family history of cancer does not influence a change of CD44 levels in oral rinses. AHNS Annual Meeting. 2021 AHNS Annual Meeting at COSM April 7–11, 2021 | Virtual; or AHNS 10th International Conference on Head and Neck CancerJuly 22-25, 2021 | Chicago, Illinois.
- 5. Smith DH, Raslan S, **Reis IM**, Liu H, Halgowich J, Gordon C, Franzmann EJ. 12-month smoking cessation program lowers soluble CD44 levels in a high-risk population. AHNS Annual Meeting. 2021 AHNS Annual Meeting at COSM April 7–11, 2021 | Virtual; or AHNS 10th International Conference on Head and Neck CancerJuly 22-25, 2021 | Chicago, Illinois.
- 6. Weed DT, Zilio S, **Reis IM**, Sargi Z, Abouyared M, Gomez CR, Civantos FJ, Rodriguez CP, Serafini P. The reversal of immune exclusion mediated by tadalafil and an anti-tumor vaccine also induces PDL1 up regulation in recurrent head and neck squamous cell carcinoma: final analysis including clinical outcomes of a phase I clinical trial. AHNS Annual Meeting. 2021 AHNS Annual Meeting at COSM April 7–11, 2021 | Virtual; or AHNS 10th International Conference on Head and Neck CancerJuly 22-25, 2021 | Chicago, Illinois.
- 7. Alderuccio JP, Kuker RA, Barreto-Coelho P, Martinez BM, Miao F, Beitinjaneh A, Wang TP, **Reis IM**, Lossos IS, Moskowitz CH. Prognostic Value of PET/CT Metrics in Patients with Relapsed and Refractory (r/r) Diffuse Large B-Cell Lymphoma (DLBCL) Treated with Platinum-Based

- Chemotherapy: An Intent-to-Treat Analysis. 62nd ASH Annual Meeting. San Diego, California, December 5-8, 2020 will be presented as **an all-virtual event**, given the continuing threat of the COVID-19 pandemic. Virtual Poster Publication Number: 1209, Submission ID: 141098.
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- 9. Takita C, Kesmodel S, Marples B, Stoyanova R, Gomez C, Net J, Yepes M, **Reis IM**. Phase I Study to Evaluate the Safety and Feasibility of Preoperative Ablative Radiotherapy (SABER) for Selected Early Stage Breast Cancer. 2020 San Antonio Breast Cancer Symposium®, December 8-12, 2020. Poster presentation, Abstract #1330.
- 10. Wang K, Hu JJ, Reis IM, Zhao W, Yang GR, Herna S. Breast Cancer Survival Disparities by Insurance Status or Race/Ethnicity in Specific Patient Populations. AACR Virtual conference: 13th AACR Conference on The Science Of Cancer Health Disparities In Racial/Ethnic Minorities And The Medically Underserved. Oct 2-4, 2020. Control/Tracking Number: xxx-AACR.
- 11. Wang K, Hu JJ, **Reis IM**, Zhao W, Yang GR, Herna S. Predicting Breast Cancer Survival Outcomes in a Tri-Racial/Ethnic Population. AACR Virtual conference: 13th AACR Conference on The Science Of Cancer Health Disparities In Racial/Ethnic Minorities And The Medically Underserved. Oct 2-4, 2020. Control/Tracking Number: xxx-AACR.
- 12. Liu, J, Medina HN, Reis IM, Pinheiro, PS. Disadvantages for non-Hispanic Whites in Gastric Carcinoma survival in Florida. NAACCR 2020 Conference in Philadelphia, PA June 21 26, 2020. Abstract # 109.
- 13. Johnson, AL, Medina HN, Reis IM, Schlumbrecht M, Pinheiro, PS. The role of histology on endometrial cancer survival disparities in diverse Florida. NAACCR 2020 Conference in Philadelphia, PA June 21 26, 2020. Abstract # 106.
- 14. Weed DT, Zilio S, **Reis IM**, Sargi Z, Abouyared M, Gomez CR, Civantos FJ, Rodriguez CP, Serafini P. The reversal of immune exclusion mediated by tadalafil and an anti-tumor vaccine also induces PDL1 up regulation in recurrent head and neck squamous cell carcinoma: final analysis including clinical outcomes of a phase I clinical trial. AHNS Annual Meeting. Chicago, IL, Jul 18, 2020.
- 15. Bell EB, Almuhaimid T, Cohen ER, Alotaibi F, Gordon C, **Reis IM**, Gomez C, Goodwin WJ, and Franzmann EJ. Green Salad Intake is Associated with Improved Oral Cancer Survival and Lower Soluble CD44 Levels. AHNS Annual Meeting. Chucago, IL, Jul 18, 2020.
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- 17. Mihyu MM, **Reis IM**, Takita C, Wright JL, Lee E, Nelson OL, Yang GR, Bakalar JL, Hu JJ. Association between DNA Oxidative Damage and Radiotherapy-Induced Skin Toxicities in Breast Cancer Patients. AACR Annual Meeting. April 24-29, 2020; San Diego, CA. Control/Tracking Number: 20-A-6581-AACR.
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- 19. Venkatramani V, Reis IM, Soodana-Prakash N, Becerra MF, Gonzalgo ML, Castle EP, Woods ME, Svatek RS, Weizer AZ, Konety BR, Tollefson M, Krupski TL, Smith ND, Shabsigh A, Barocas DL, Quek ML, Dash A, Parekh DJ. Urologic complications after robotic and open radical cystectomy: An analysis from the RAZOR trial. AUA Meeting. Wahingtom, DC, May 15-18, 2020. (Abstract submission #20-8154).
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- 23. Meshman J, Farnia B, Stoyanova R, **Reis I**, Abramowitz M, Dal Pra A, Horwitz E, Pollack A. Biopsy positivity in prostate cancer patients undergoing mpMRI-targeted radiation dose escalation. 102nd American Radium Society (ARS) National Meeting; May 2020; Scottsdale, Arizona. (Oral Presentation).
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- 27. Alderuccio JP, Yeir SG, **Reis IM**, Alencar AJ, Rosenblatt JD, Lossos IS. R-MACLO-IVAM Is an Effective Regimen to Induce Long Term Remission in Untreated Mantle Cell Lymphoma. ASH Meeting. Orlando, FL, December 7-10, 2019. (ASH abstract submission #125004).
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- 32. Slingerland JM, Lippman ME, Hurley, J, Net JM, Collado-Mesa F, **Reis, IM**, Noriega-Esquives BS, Pegram M, Yepes, MM, Avisar, E, Jorda M, Aoun J. Results of a randomized double blind trial of neoadjuvant anastrozole plus placebo vs anastrozole plus saracatinib for ER+ postmenopausal breast cancer. 2018 SABCS, San Antonio, TX, Dec 4-8, 2018. " Poster presentation #. Abstract # 1556.
- 33. Pollack A, Chinea FM, Bossart E, Kwon D, Abramowitz MC, Lynne C, Jorda M, Marples B, Patel V, Wu X, Reis IM, Studenski M, Casillas V, Stoyanova R. Dosimetry and Toxicity of a Phase I Clinical Trial of Men Treated for Prostate Cancer with Lattice Extreme Ablative Dose (LEAD) Radiotherapy. ASTRO Annual Meeting. San Antonio, TX, Oct 21-24, 2018. Poster#: SU_32_2316 Abstract xx.
- 34. Takita C, **Reis IM**, Yakoub D, Panthaki Z, Boneti C, Kassira W, Moller M, Samuels S, Freedman L, Ahamad A, Kesmodel S, Avisar E. Final Results of Phase I Study of Prophylactic Nipple-Areola Complex (NAC) Radiotherapy after Nipple Sparing Mastectomy (NSM) and Immediate Reconstruction for Breast Cancer or DCIS Patients not Initially Eligible for NSM. ASTRO Annual Meeting. San Antonio, TX, Oct 21-24, 2018. Poster Discussion Session, Oral Presentation # 1144. Abstract xx.
- 35. Alderuccio JP, Desai A, Crestani NG, Ramdial J, Kimble E, De La Fuente MI, Chapman J, Vega F, Zhao W, **Reis IM**, Lossos IS. Outcomes in Patients with Marginal Zone Lymphomas Undergoing Transformation to High-Grade Lymphomas. ASCO Annual Meeting. Chicago, IL, Jun 1-5, 2018. Abstract 217525.
- 36. Kwon D, Jung J, **Reis IM**. Non-inferiority test for clustered matched-pair binary data using hierarchical Bayesian method. ASA Joint Statistical Meeting (JSM). Vancouver, BC, Canada, Jul 28-Aug 2, 2018. Abstract # 327129.
- 37. Stoyanova R., Abramowitz MC, Chinea FM, Kwon D, **Reis IM**, Padgett KR, Punnen S, Kryvenko ON, Pollack A. An Automated Multiparametric MRI Quantitative Imaging Prostate Habitat Risk Scoring System for Defining External Beam Radiotherapy Boost Volumes. Joint Annual Meeting ISMRM-ESMRMB, Paris, France, June 16-21 2018. Abstract 6092.
- 38. Castillo LEM, Pimentel A, **Reis IM**, Gotuzzo E, Lekakis LJ, Komanduri K, Harrington TJ, Barber GN, Ramos JC. Epidemiology, clinical features, and outcome of HTLV-1 related Adult T-cell Leukemia-lymphoma in a Prevalent Area in the U.S." ASH Annual meeting. Atlanta, GA, Dec 9-12, 2017. Abstract 373.

- 39. Barboza MP, Prakash NS, **Reis IM**, Miao F, Velasquez MC, Castillo R, Ritch CR, Gonzalgo ML, Kava B, Satyanarayana R, Parekh DJ, and Punnen S. Does MPMRI Perform Differently in Men Undergoing Targeted Biopsy for Evaluation of Prostate Cancer versus those on Active Surveillance? SUO Annual Meeting. Washington, DC, Nov29-Dec1, 2017. Poster 211.
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- 42. Vosoughi A, **Reis IM**, Jorda M. Rater aggreement of urine cytology characteristics by Cyto Atyp Paris. USCAP Annual Meeting. Charleston, SC. Jan 14-16, 2017. Abstract xxx.
- 43. Kwon D, Jung J, **Reis IM**. Hierarchical Bayesian Method for Dealing with Uncertainty of Dose-Response Relationship Estimation in Meta-Analysis. ENAR Spring meeting. Washington, DC, Mar 12-15, 2017. (Presenter)
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- 45. **Reis IM**, Perez A, Pereira L, Freizer M, Cohen E, Hoosien G, Franzmann EJ. Immuno-histochemistry analysis of CD44, EGFR and p16 in oral and oropharyngeal squamous cell carcinomas. ECHNO 2016 Annual Meeting. Budapest-Hungary, Sep 7-10, 2016.
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- 48. Cohen ER, A Perez A, Pereira LH, Reategui E, **Reis IM**, Gomez, C, Freiser ME, Franzmann EJ. CD44 and associated markers in oral rinses and tissues from oral cancer patients. AHNS 9th International Conference on Head and Neck Cancer. Seattle, WA, Jul 16-20, 2016. (*Oral presentation*)
- 49. Kwon D, **Reis IM**. Simulation-based estimation of mean and standard deviation for metaanalysis using Approximate Bayesian Computation (ABC) coupled with model averaging method. ENAR Spring meeting. Austin, TX, Mar 6-9, 2016. (Presenter)
- 50. Pereira LHM, Reis IM, Reategui EP, Gordon C, Saint-Victor S, Duncan R, Gomez C, Bayers S, Fisher P, Perez A, Goodwin WJ, Hu JJ, Franzmann EJ. Risk stratification system for oral screening. Poster presentation. Global Oral Cancer Forum. New York, NY, Mar 4-5, 2016.

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- 53. Wright JL, Takita C, Lee E, **Reis I**, Zhao W, Nelson O, Hu JJ. Predictors of radiation-induced skin toxicity in a prospective study of tri-racial/ethnic breast cancer patient population. ASTRO Annual Meeting. San Antonio, TX, Oct 18-21, 2015. Abstract 2134.
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- 55. Nelson OL, Wu ES, Park JY, Zeitouni J, Gomez CR, **Reis IM**, Zhao W, Lee E, Lin H-L, Franzman EJ, Savell J, McCaffrey TV, Goodwin WJ, Hu JJ. Actionable somatic mutations in head and neck cancer prognosis. AACR Annual Meeting. April 18-22, 2015; Philadelphia, PA. *Cancer Res.* 2015;75: 3876.
- 56. Wu ES, Park JY, Gomez CR, **Reis IM**, Zhao W, Lee EY, Nelson OL, Franzmann EJ, Goodwin WJ, Hu JJ. Racial/ethnic-specific somatic mutations in head and neck cancer prognosis. 2015 Miami Winter Symposium "Towards Personalized Cancer Medicine". University of Miami Miller School of Medicine and Sylvester Cancer Center; Miami, FL, Jan 18-21, 2015.
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- 60. Cnossen NR, Orman AG, Kwon D, Ritch C, Gonzalgo M, Ishkanian A, Reis I, Pollack A, Abramowitz M. A meta-analysis of health-related quality of life after primary treatment for prostate cancer as measured by the Expanded Prostate Index Composite. ASCO Genitourinary Cancers Symposium. Orlando, FL, Feb 26-28, 2015. J Clin Oncol 2015;33(7): abstract 39.
- 61. Palacios S, Akunyili II, Ernani V, Macintyre J, Merchan JR, Pollack T, **Reis I**, Restrepo MH, Rocha-Lima CMS, Hosein PJ. Gemcitabine (Gem) and nab-Paclitaxel (nab-P) in patients (pts) with refractory advanced pancreatic cancer. ASCO Gastrointestinal Cancers Symposium. San Francisco, CA, Jan 15-17, 2015. J Clin Oncol 2015; suppl 3; abstr 413.
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- 78. Wright JL, Takita C, **Reis IM**, Zhao W, Poitevien M, and Hu JJ. Racial/ethnic disparities in breast cancer radiosensitivity. AACR Annual Meeting, Chicago, IL, Mar 31- Apr 4, 2012.
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18e. Received Acknowledgement

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- 8. Michielin F, Cols. Avaliação clínica comparativa entre indoramina e metildopa: Estudo multicêntrico. F. Méd. (BR), 1983; 87:247-52.
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19. Other works accepted for publications

19a. Manuscripts under revision or submitted for publication

V. PROFESSIONAL

20. Funded Research Performed:

20a. CURRENT GRANTS

1. THE SYLVESTER CANCER CENTER SUPPORT

Principal Investigator: Nimer, Stephen

Role in Project: Biostatistical Co-Investigator, 5%

Grant #: 1P30CA240139

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), P30

Project Period: 07/01/2019 - 06/30/2024

Total Award: \$12,133,751

Summary: The major goal of this proposal is for The Sylvester Comprehensive Cancer Center at the University of Miami to seek National Cancer Institute designation to support its mission to reduce the human burden from cancer through research, education, prevention, and the delivery of quality patient care.

2. EPIGENETIC TARGETING OF AFRO-CARIBBEAN VARIANT OF HTLV-1 RELATED ADULT T-CELL LEUKEMIA-LYMPHOMA

Principal Investigator: Ramos, Juan Carlos Role in Project: Co-Investigator, 3% Grant #: 1R01CA223232-01

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), R01

Project Period: 01/01/18-12/31/22

Total Award: \$ 1,721,736

Summary/Aims: This project revolves around a novel clinical approach to treat ATLL, and the study of the biological effects of a new class of drugs in this type of cancer in order to advance the treatment and cure of a fatal neglected disease affecting a U.S. population group. Specific Aim 1: To conduct a clinical trial using a potent HDAC inhibitor in combination with AZT-based maintenance therapy to eradicate ATLL. Specific Aim 2: To investigate the molecular basis of HDAC inhibitors in ATLL.

3. MRI IMAGING AND BIOMARKERS FOR EARLY DETECTION OF AGGRESSIVE PROSTATE CANCER

Principal Investigator: Pollack, Allan

Role in Project: Co-Investigator, 4%

Grant #: U01CA239141

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), U01

Project Period: 09/19/19-08/31/22

Total Award: \$ 2,977,709

4. IMPACT OF PRECISION INTERVENTION ON REDUCING BREAST CANCER DISPARITIES

Principal Investigator: Hu, JJ

Role in Project: Co-Investigator, 5%

Grant #: FP6831 (submitted 02/18/2022)

Funding Source: Florida Breast Cancer Foundation (FL-BCF)

Project Period: 12 months 06/01/2022- 05/31/2023

Total Award: \$ 100,000

20b. PENDING GRANTS (12)

1. DEVELOPMENT OF AN EFFECTIVE, LOW-COST, POINT-OF-CARE EARLY DETECTION TEST FOR ORAL CANCER IN LOW RESOURCE SETTINGS

Principal Investigator: Franzmann, EJ
Role in Project: Co-Investigator,
Grant #: (submitted 02/2022)

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), STTR

Project Period: ?

Total Award: \$400,000

2. ORAL CANCER EARLY DETECTION IN FLORIDA CITY

Principal Investigator: Franzmann, EJ
Role in Project: Co-Investigator 2%
Grant #: (submitted 04/05/2022)?

Funding Source: SCCC CTA
Project Period: 4/21-4/24
Total Award: \$50,000

3. TUMOR MUTATION BURDEN AND IMMUNE SIGNATURES IN PREDICTING BREAST CANCER PRECISION INTERVENTIONS

Principal Investigator: Hu, Jennifer

Role in Project: Co-Investigator 5%

Grant #: Submitted 9/2021 FP5544

Funding Source: FDOH

Project Period: 7/1/22-6/30/27 Total Award: \$ 1,499,466

4. TRANSFORMATIVE RESEARCH TO ADVANCE PRECISION INTERVENTION OF BREAST CANCER.

Principal Investigator: Hu, Jennifer

Role in Project: Co-Investigator (\$5,000 for BBSR)

Grant #: Submitted 8/2021 FP5250

Funding Source: NIH

Project Period: 04/1/22- 3/30/27 Total Award: \$3,660,177

5. MOLECULAR DETERMINANTS OF BREAST CANCER DISPARITIES IN TRANSFORMING PRECISION INTERVENTION

Principal Investigator: Hu, Jennifer Role in Project: Co-Investigator

Grant #: Submitted 2/2021 FP3652

Funding Source: Florida Breast Cancer Foundation (FL-BCF)

Project Period: 07/1/21- 6/30/22

Total Award: \$ 100,000

6. EFFECT OF COVID-19 INFECTION ON MALE REPRODUCTION

Principal Investigator: Ramasamy, Ranjith & Zhang, Fangliang

Role in Project: Co-Investigator, 5%

Grant #: 1R01HD110510-01 (submitted 02/2022)

Funding Source: National Institutes of Health (NIH), National Institute of Child Health and

Human Development (NICHD), R01

Project Period: 07/01/21- 06/30/26

Total Award: \$3,834,700.00 (Total Cost)

7. OVARIAN CANCER HEALTH DISPARITIES – ROLE OF HRD IN HIGH GRADE SEROUS CARCINOMA.

Principal Investigator: George, Sophia & Schlumbrecht, Matthew

Role in Project: Co-Investigator, 5% Grant #: (submitted 11/2020)

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), R01

Project Period: 07/01/21- 06/30/26
Total Award: \$ 2,618,600 (Total Cost)

Summary/Aims: Aim 1: Determine the genomic variant landscape and association with clinicopathologic features in Black women with high-grade serous ovarian cancer; Aim 2: Define early genomic events in pre-neoplastic lesions in Black women; Aim 3: Develop neoplastic models of HGSC in Black women.

8. STING-dependent Adjuvants (STAVs) Cell based Therapy for Aggressive Leukemias

Principal Investigator: Ramos, Juan Carlos Role in Project: Co-Investigator, 3% (Submitted 10/2020)

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), R01

Project Period: 07/01/21- 06/30/26 Total Award: \$ 3,837,501 (Total Cost)

Summary/Aims: We aim to evaluate whether STAVs could be useful immunotherapy in combination with DC vaccine for the treatment of aggressive incurable leukemias. Our strategy provides a new therapeutic approach for the treatment this cancer.

9. A PHASE 1 TRIAL OF COMBINED MEK, STAT3 AND PD-1 INHIBITION IN METASTATIC PANCREATIC DUCTAL ADENOCARCINOMA

Principal Investigator: Merchant, Nipun Role in Project: Co-Investigator, 3%

Grant #: NA (Submitted 09/27/2019)
Funding Source: The ASCO Foundation
Project Period: 07/01/20 – 06/30/23

Total Award: \$ 1.938.975

10. UNRAVELING THE INTEGRATIVE EFFECTS OF NEOADJUVANT CHEMOTHERAPY AND IMMUNOTHERAPY ON OVARIAN CANCER TUMOR BIOLOGY

Principal Investigator: Huang, Marilyn Role in Project: Co-Investigator, 3%

Grant #: NA (Submission: 09/27/2019)

Funding Source: The ASCO Foundation Project Period: 07/01/20 – 06/30/23

Total Award: \$?

11. GENETIC DETERMINANTS OF NEUROCOGNITIVE AND PSYCHOSOCIAL FUNCTIONING IN LATINO AND NON-LATINO PATIENTS UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION.

Principal Investigator: Rueda-Lara, Maria & Penedo, Frank

Co-Investigator (\$5,000 for BBSR) (Submitted 10/2019) Sylvester 01/01/20- 12/30/22 Role in Project:

Grant #:

Funding Source:

Project Period:

\$ 71, 000 Total Award:

20c. COMPLETED/ENDED GRANTS (29)

1. DOES SEX MATTER? TARGETING SEX DIFFERENCES IN AGE-RELATED LUNG DISEASE

Principal Investigator: Elliot, Sharon J

Role in Project: Co-Investigator, Biostatistician, 3%

Grant #: 1 R21 AG060338-01

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), R21

Project Period: 02/15/19-12/31/20

Total Award: \$ 275,000

Summary/Aims: The research goal is to detect sex-specific differential pathways. *Aim1*: Determine the activational effects of gonadal hormones/respective receptors and subsequent downstream signaling that contribute to age-associated lung disease. We will compare gonadectomize (GDX) aging male and female BLM-treated mice to determine if estrogens are protective and androgens harmful to lung fibrosis. We will determine the contribution of AR and ER in the development of lung fibrosis using myofibroblasts isolated from lungs of male and female patients with IPF. *Aim 2*: Determine whether sex chromosomes contribute to sex differences in age-associated lung disease using the four core genotypes mouse model. This model separates the effects of gonadal sex (ovaries versus testes) from the sex chromosome complement (XX vs. XY) by producing XX and XY gonadal males and XX and XY gonadal females.

2. METABOLOMICS: NOVEL STRATEGIES TO IMPROVE BREAST CANCER

RADIOTHERAPY RESPONSES
Principal Investigator: Hu, Jennifer J.

Role in Project: Co-Investigator/Biostatistician, 5%

Grant #: 1R21 CA234880-01

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI), R21

Project Period: 07/01/19-06/30/21 Total Award: \$ 437,029 (Total Cost)

Summary/Aims: Aim1: To evaluate global metabolomics-driven models in predicting RT-induced EASRs/pain. Our pilot data support the working hypothesis that at least 7 metabolic pathways contribute to worse RT-induced EASRs/pain; the alanine, aspartate and glutamate metabolism pathway has the highest impact. We will test 240 pre-RT urine samples (120 high and 120 low EASRs/pain) for 712 metabolites in building a prediction model of RT-induced EASRs/pain after adjusting for potential confounders in multivariable logistic regression models. Aim 2: To validate/quantitate significant metabolites/pathways (pilot and Aim 1) in predicting RT-induced EASRs/pain after adjusting for confounders in multivariable logistic regression models. The working hypothesis is that pre-RT metabolomics can predict an individual's risk for RT-induced EASRs/pain. We will target significant metabolites/pathways using another 240 samples (120 high and 120 low EASRs/pain) for validation/quantitation. Aim 3: To evaluate the performance metabolites/pathways in clinical application. We will compare the performance of metabolites/pathways (Aim 2) and patient/clinic characteristics in predicting RT-induced EASRs/pain using Receiver Operating Characteristic (ROC) curves. Milestone: The comprehensive models with patient/clinic characteristics and metabolomics will accurately predict RT-induced EASRs/pain and impact clinical practice.

3. THE ROLE OF ATE1-MEDIATED DEGRADATION OF CYCLIN D1 IN BREAST CANCER PROGRESSION

Principal Investigator: Zhang, Fangliang Role in Project: Co-Investigator, 2%

Grant #:

Funding Source: Florida Breast Cancer Foundation (FL-BCF)

Project Period: 7/01/19 - 06/30/20

Total Award: \$ 100,000

Summary/Aims: While our hypothesized mechanism likely operates in all stages of BC, a reduction of Ate1 appears to be more prevalent in ER-negative cells. We will carried out three independent aims covering biochemical, cell-based, and human tissue-based angles. Aim 1. How does Ate1 regulate the half-life of cyclin D1? Aim 2. Is tumor growth or metastasis of BC cells affected by Ate1-dependent degradation of cyclin D1? Aim 3. What is the correlation between Ate1 and cyclin D1 levels in relation to BC malignancy in patients?

IMPACT OF ETIOLOGY-DRIVEN PRECISION MEDICINE ON REDUCING BREAST CANCER DISPARITIES

Principal Investigator: Hu, Jennifer J.

Role in Project: Co-Investigator/Biostatistician, 5%

Grant #: 5BC04

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 05/15/15-05/15/18

Total Award: \$ 1,290,000

Summary/Aims: The goal is to build a paradigm-shift model system to translate etiology to precision medicine in breast cancer. The study will test the working hypothesis that genetic polymorphisms, dietary factors, metabolomics, and somatic mutations are associated with more aggressive triple negative breast cancer (TNBC) and worse survival. The Specific Aims are: (1) To evaluate genegene and gene-diet interaction in TNBC risk utilizing a new OncoArray panel of 250,000 genetic polymorphisms and food frequency questionnaire; (2) To determine metabolomic signatures of TNBC by utilizing a high-throughput technology for >478 metabolites; (3) To investigate impact of gene-gene, gene-diet interactions and metabolomics on somatic mutations.

5. AN UNKNOWN ROLE OF ARGINYLATION IN PROSTATE CANCER

Principal Investigator: Zhang, Fangliang

Role in Project: Co-Investigator, 3% (3rd year fiscal year)

Grant #: PC140622

Funding Source: Department of Defense (DOD)

Project Period: 10/01/15 – 08/30/18

Total Award: \$ 225,000

Summary/Aims: We hypothesize that Ate1/arginylation is an essential regulator for the physiological responses to oxidative stress, and that the down-regulation of Ate1 in PC cells allow them to metastasize. Therefore, a lower level of Ate1 in the primary tumor of prostate cancer is a predictive sign for future metastasis. Specific Aims: (1) Testing whether down-regulation of Ate1 promotes the metastasis of prostate cancer cells. (2) Testing the association between the level of Ate1 in primary tumors and clinical outcomes. (3) Identification of targets of arginylation related to its anti-cancer role in response to oxidative stress.

6. METHYLATION PROFILING IN FREE CIRCULATING DNA AS A BIOMARKER FOR RISK STRATIFICATION OF PROSTATE CANCER

Principal Investigator: Singal, Rakesh

Role in Project: Biostatistician, 10% (Year 2)

Grant #: 4BB18

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 12/1/15-11/30/18

Total Award: \$400,000

Summary/Aims: (1) Identification of methylation markers of aggressive prostate cancer; (2) Determination of methylation of selected genes in plasma of patients prior to radical prostatectomy (RP); (3) Correlation of methylation levels of candidate genes with pathological stage of disease and GS of patients undergoing RP.

7. OPTICAL IMAGING OF A CD44 BASED ORAL RINSE WITH FLORESCENT DETECTION TO VISUALIZE ORAL CANCER

Principal Investigator: Reis, Isildinha M (PI-UM) & Franzmann, Elizabeth J (PI-Vigilant)

Role in Project: PI-UM, 10% Grant #: 1R43DE025797-01

Funding Source: Vigilant Biosciences / National Institutes of Health (NIH) Small Business

Innovation Research (SBIR)

Project Period: 02/05/2016 - 10/30/2017

Total Award: \$ 191,538 (UM \$ 63,432) Year 1 \$ 27,916 (UM 16,588) Year 2

Summary/Aims: The goal is this study is to develop an imaging device that will involve a simple rinse and spit solution with an anti-CD44 probe bound to non-absorbable, fluorescent microspheres that will bind to cells expressing abnormally high levels of CD44. Specific Aim#1: Test an in-vitro model for detecting CD44 elevated cells using fluorescent probes on membranes. To do this, we will culture well-characterized cell lines that have been engineered to overexpress or underexpress CD44. Specific Aim #2: Test the system in tumor explants from humans. In this Aim, we will determine how well the conjugate identifies carcinogenesis in humans. We will analyze at least ten (10) oral squamous cell cancer tissues with surrounding normal margin from patients who are going to the operating room (OR) for surgical removal of an oral squamous cell cancer of moderate to severe dysplasia or invasive cancer and at least 10 patient tissues that were excised for benign conditions (chronic tonsillitis) using the anti-CD44 fluorescently labeled beads.

8. EARLY DETECTION FOR SMOKING-ASSOCIATED HEAD AND NECK CANCER

Principal Investigator: Franzmann, Elizabeth J.

Role in Project: Co-Investigator/Biostatistician, 10%

Grant #: 4BB20

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 12/1/13 – 11/30/15 Total Award: \$347,826 (DC)

Summary/Aims: The overall goal is to determine variations in solCD44 and total protein levels over time in high-risk participants from a health clinic in Liberty City, Miami, Florida. The specific aims are: (1) To evaluate variations in solCD44 and total protein level over time in 150 high-risk participants from Liberty City. The goal was to follow a previous study cohort of 150 patients annually with oral exam, oral rinse collection and risk assessments. Quantitate changes in individual participant's marker levels were analyzed to determine normal and abnormal variations and associations with risk behavior changes. We determined whether patients with significantly increasing levels developed pre-malignancy or malignancy and cross-checked data with the Florida Cancer Data System (FCDS). (2) To determine whether oral rinse solCD44 and protein marker levels decrease

with smoking cessation. We collected oral rinse and saliva samples in 150 subjects from Liberty City and other regions of South Florida who are newly enrolled in smoking cessation programs. We measured solCD44 and protein. We confirmed smoking cessation using saliva cotinine levels. We compared marker levels before, 3 months and 1 year after completion of smoking cessation in quitters and non-quitters. (3) To examine whether solCD44 and protein levels in oral rinses from HNSCC correlate with disease burden. In this aim, we evaluated 30 cases enrolled in the first 18 months and collected oral rinses before and after treatment to determine if marker levels would drop with decreased tumor burden.

9. METHYLATION PROFILING IN CELL-FREE DNA AS A TEST FOR PROSTATE CANCER DIAGNOSIS

Principal Investigator: Singal, Rakesh

Role in Project: Co-Investigator/Biostatistician, 2%

Grant #: NA

Funding Source: Woman's Cancer Association (WCA)

Project Period: 05/1/14 - 5/31/2015 Total Award: \$50,000 (Total cost)

Summary/Aims: To study whole genome methylation patterns in blood of patients who underwent prostate biopsy to identify methylation signatures as biomarkers for detection of prostate cancer.

10. GENOMIC PREDICTION MODELS OF LUNG CANCER SURVIVAL AND TREATMENT RESPONSE

Principal Investigator: Lally, Brian

Role in Project: Biostatistician, 10%

Grant #: M1200762

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 7/1/12-6/30/15 Total Award: \$675,000 (Total DC)

Summary/Aims: Prospective multicenter study design recruiting a tri-racial/ethnic cohort of about 600 (200 AA, 200 HW, 200 NHW) newly diagnosed NSCLC patients at 3 VA medical centers within the Veterans Integrated Service Network 8. Specific aims: (1) To evaluate the impact of mental health, physical fitness, and smoking history/status on treatment response and survival in NSCLC. (2) To explore how mental health, smoking history/status, and physical fitness contribute to treatment delays and treatment-associated toxicity in NSCLC. (3) To develop and validate genomic biomarkers in predicting clinical outcomes of NSCLC.

11. HOST DEFENSE REGULATION AND VIRAL ONCOGENESIS (Administration Core (Core A))

Principal Investigator: Barber, Glen

Role in Project: Biostatistician, 15% (10% in 2014)

Grant #: 1P01CA12811501-A5

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 8/14/09-7/31/14

Total Award: \$5,562,927 (Total Cost)

Summary/Aims: The overall objective of this P01 was to understand the basic mechanisms by which different oncogenic viruses evade host innate immunity leading to infection and ultimately cancers. It was composed by the following three strong and interactive research projects: Project 1: Mechanisms of host defense and regulation by oncoviral encoded gene products; Project 2: Host Defense Regulation by HTLV-I; Project 3: Disruption of antiviral signaling pathways by HTLV-I Tax. The P01 was supported by three core facilities: Administrative Core, Tissue & Pathology Core, and Molecular Core. The Administration Core provided the structure that

integrates the various components of the PO1 including organizational, administrative, accounting, biostatistics, informatics, and clinical research support functions. The specific aim of the Biostatistics subcomponent of the Administrative Core was to provide the following biostatistical support: i. Collaborate with investigators in the design and conduct of clinical studies. ii. Consult with investigators on statistical aspects of laboratory experiments. iii. Determine sample size needed to test specific hypotheses at appropriate levels of significance and power. iv. Prepare descriptive summaries and statistical analyses (estimation, testing, and model building) of data obtained from clinical or laboratory investigations.

12. IMPACT OF GENOMICS ON DISPARITIES IN BREAST CANCER RADIOSENSITIVITY

Principal Investigator: Hu, Jennifer J

Role in Project: Biostatistician, 10% (5% in 2014)

Grant #: 1R01CA135288-05

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 1/1/10-12/31/14 Total Award: \$2,125,641 (Total DC)

Summary/Aims: It is expected that the findings would enhance the understanding of the genetic susceptibility and molecular mechanisms of EASRs, thus leading to improved preventive strategies. Specific aims: Aim 1. To develop polygenic models of RT-induced EASRs with a comprehensive evaluation of genome-wide nonsynonymous single nucleotide polymorphisms. Aim 2. To evaluate the association between RT-induced EASRs and three functional phenotypes:

(1) the Comet assay for DNA damage, (2) the ionizing radiation (IR)-induced H2AX phosphorylation assay for DNA damage signal transduction, (3) the IR-induced cell cycle G2 delay. Aim 3. To explore polygenic models of genome-wide nsSNPs in predicting RT-induced late side effects (> 4 years) and/or locoregional recurrence in 850 breast cancer patients with a median follow up of 8 years (range 4-12 years).

13. IMPACT OF MOLECULAR GENETICS ON DISPARITIES OF BREAST CANCER RISK AND PREVENTION

Principal Investigator: Hu, Jennifer J. Role in Project: Biostatistician, 10%

Grant #: 1BG04 (EProst 20090481)

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 7/1/10 - 6/30/15 (Ended 12/31/13)

Total Award: \$ 1,500,000 (Total Cost)

Summary/Aims: We hypothesized that breast cancer with worse diagnosis occurs most frequently in underserved minorities due to (1) genetic defects in DNA repair, (2) elevated DNA damage, and (3) gene-environment interactions. The goal was to test a new paradigm that genetic and nongenetic regulation of DNA damage/repair contributes to breast cancer disparities in tumor phenotypes and treatment response. Specific aims were: Aim 1: To investigate racial/ethnic specific polygenic models of DNA damage signaling and repair responses in breast cancer risk with a comprehensive evaluation of tagging single nucleotide polymorphisms in 169 genes of 5 candidate pathways. Aim 2: To evaluate whether racial/ethnic-specific breast cancer risk is associated with 3 DNA damage/repair functional phenotypes: (1) BER: oxidative DNA damage,

(2) DSBR: ionizing radiation-induced H2AX phosphorylation, (3) NER: plasmid-based DNA-repair capacity. Aim 3: To elucidate the racial/ethnic specific molecular mechanisms of genetic (i.e., SNPs) and non-genetic (i.e., alcohol, dietary nutrient deficiencies, and/or smoking exposure) regulations of DNA damage/repair functional phenotypes contributing to breast cancer diagnosis and progression.

14. EARLY DETECTION MARKERS FOR SMOKING-INDUCED HNSCC

Principal Investigator: Franzmann, Elizabeth J.

Role in Project: Biostatistician, 10% (5% in 2013)

Grant #: 10BG02

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 7/1/10 - 6/30/15 (Ended 12/31/13)
Total Award: \$ 1,043,478 (Revised Total DC)

Summary/Aims: Aim 1: To determine the levels of solCD44 and protein in oral rinses from subjects enrolled in a Liberty City head and neck screening clinic and examine a) how they vary with demographic and risk factors and b) how they change over time. Aim 2: to determine changes in oral rinse solCD44 and protein marker status with smoking cessation. In Aim 3: To evaluate perceived acceptability of the test and its likelihood to influence smoking cessation in the population.

15. RESTORING ER EXPRESSION AND ANTI-ESTROGEN RESPONSE IN ER-NEGATIVE BREAST CANCER

Principal Investigator: El-Ashry, Dorraya Role in Project: El-Ashry, Dorraya Biostatistician, 5%

Grant #: 09BW04

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 1/1/10 - 12/31/12 Total Award: \$ 566,798 (Total DC)

Summary/Aims: The overall goals of this project were (1) to determine if restoration of ER expression and responses to antiestrogen therapies was possible in ERalpha-negative breast cancer in humans and (2) to identify genotypic and/or phospho-proteomic determinants of that subset of ER- breast cancers in which this was possible. Successful completion of this work would lead to a clinical trial testing combination therapy of a MEK inhibitor and an anti-estrogen in ERalpha-negative breast cancer patients.

16. TARGETING OF EBV LATENCY IN BURKITT LYMPHOMA

Principal Investigator: Ramos, Juan Carlos
Role in Project: Biostatistician, 5%
Grant #: 5-R01-CA-112217-01-05

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 09/22/06 - 07/31/12

Total Award: \$ 937,334 (Total DC, no cost extension)

Summary/Aims: Specific Aim 1: To study EBV viral load in patients with BL enrolled on a therapeutic protocol of chemo/antiviral (AZT, hydrea) therapy. Under this aim, we aimed to determine the following: A) If there was an early phase of EBV reactivation upon initiation of chemotherapy in patients with EBV+ BL. B) If changes in EBV viral load during chemotherapy correlated with response to therapy. C) If EBV viral load could be used as a marker for relapse in patients who achieve remission. Specific Aim 2: To investigate the mechanism of NF-κB activation (canonical vs. non-canonical) and the type of viral latency (I, II, or III) in which each occurs in BL. It was hypothesized that inhibition of NF-κB in BL disrupts EBV latency and results in apoptosis. Primary tumors linked to the aforementioned clinical trial were utilized to determine the following: A) If type I latency was associated with a lack of the canonical NF-κB (p65) activation pathway. B) If a lytic gene expression of EBV was present in primary BL. C) Whether AZT inhibited NF-κB and activated EBV in primary BL cells and if this occurred in type I latency tumors. D) If AZT mediated apoptosis in EBV associated lymphoma was potentiated by the addition of hydroxyurea. Specific Aim 3: To conduct a clinical trial of chemo/antiviral (AZT) therapy for patients with poor prognosis (relapsed, chemo resistant) EBV+ BL. It was

hypothesized that reactivation of EBV induced by conventional chemotherapy would potentiate the unique anti-tumor properties of AZT.

17. A NEOADJUVANT TRIAL OF ANASTRAZOLE AND A NOVEL SRC INHIBITOR, AZD0530, FOR LABC.

Principal Investigator: Pegram, Mark D
Role in Project: Biostatistician, 10%
Grant #: 1-R21-CA-147163-02

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 6/1/09 - 5/31/12 Total Award: \$ 274,555 (Total DC)

Summary/Aims: This grant supported a clinical trial that combined for the first time a novel molecular Scr oncogene, with the antiestrogen anastrazole for women with breast cancer. This was a Phase I/randomized Phase II clinical trial of the Src inhibitor, AZD0530, together with anastrozole. The Phase I part of study was carried out in postmenopausal women with ER positive metastatic disease receiving combined neoadjuvant treatment with anastrozole plus AZD0530. In the phase II part of study, ER+/PgR+ postmenopausal women with locally advanced breast cancer were randomized to either neoadjuvant treatment with anastrozole alone or in combination with AZD0530. Specific aims: (1) To test if Src inhibition can delay or inhibit resistance to aromatase inhibition in ER+ post-menopausal breast cancer. (2) To test the ability of serial MRI to evaluate changes in tumor volume and blood flow as a more reliable clinical measure of response to neoadjuvant hormonal therapy. (3) To define biologic endpoints or predictors of treatment response that may assist in patient selection for subsequent studies. To this end, we conducted assays in molecular targets and upstream regulators of Src using protein and gene expression profiles and quantitate tumor initiating cells in diagnostic samples, tumor biopsies at 12 weeks and resected cancers at mastectomy or lumpectomy after 4-6 months of treatment with anastrozole alone or anastrozole and AZD0530.

18. A SIMPLE TEST FOR PROSTATE CANCER DIAGNOSIS

Principal Investigator: Singal, Rakesh
Role in Project: Biostatistician, 2%
Grant #: PROPOSALM1101848

Funding Source: Woman's Cancer Association (WCA)

Project Period: 6/1/11- 5/31/12 Total Award: \$ 50,000 (Total DC)

Summary/Aims: This grant proposed to compare spectrophotometric and fluorescence- based

quantitation of total fcDNA to that of amplifiable DNA levels determined by qPCR.

19. TARGETED THERAPY FOR BURKITT LYMPHOMA IN RESOURCE POOR SETTINGS

Principal Investigator: Barber, Glen
Role in Project: Biostatistician, 5%
Grant #: 5-R01-CA-121935-05

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 09/22/06 - 07/31/11 Total Award: \$982,630 (Total DC)

Summary/Aims: The goals of this project were to investigate the molecular epidemiology and pathogenesis of primary tumors and prospectively analyze lymphomas derived from patients with EBV+ forms of BL in resource poor settings. This proposal was an opportunity to develop and innovative model of collaboration between diverse organizations to achieve better awareness and access. The hypothesis was that in primary BL, NF-κB activation (and sensitivity to antiviral mediated apoptosis) is dependent upon the form of latency of EBV. We prospectively analyzed

lymphomas derived from Brazilian patients with EBV+ (endemic and HIV associated) forms of BL. Specific aims: (1) To determine the pathway for activation of NF- κ B (canonical vs. non canonical) and the context of EBV latency in which each occurs. (2) To determine the transcription profile of EBV+ BLs and to test the hypothesis that some primary EBV+ BLs display viral lytic transcripts including vTK, in the absence of intermediate culture or non-specific amplification. (3) Using primary tumor specimens, to test the hypothesis that inhibition of NF- κ B leads to disruption of EBV latency and apoptosis; and to determine the sensitivity of primary EBV positive BLs to AZT alone or in combination with inducers of the viral lytic program and inhibitors of NF- κ B.

20. SALIVARY SOLUBLE MARKERS IN HEAD AND NECK CANCER

Principal Investigator: Franzmann, Elizabeth J. Role in Project: Biostatistician, 5% 5-R01-CA-118584-03

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 6/4/07 - 5/31/11

Total Award: \$1, 299,409 (Total DC)

Summary/Aims: Our long-term goal is to design and perform a definitive screening trial with the outcomes of early detection and most definitely, survival. Specific Aim 1. To determine whether solCD44, HA and HAase levels in oral rinses distinguishes between patients with invasive HNSCC and high-risk controls with favorable sensitivity and specificity. Specific Aim 2. To assess short-term variability of solCD44, HA, and HAase levels in oral rinses from control and HNSCC patients.

21. REVERSAL OF 5-FU RESISTANCE BY ARSENIC TRIOXIDE IN COLORECTAL CARCINOMA

Principal Investigator: Ardalan, Bach
Role in Project: Biostatistician, 10%
Grant #: 5-R21-CA-117116-02

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 6/4/07 - 5/31/10 Total Award: \$ 379,896 (Total DC)

Summary/Aims: The overall goal of this R21 proposal was to conduct a phase I/II to examine whether concurrent administration of low dose ATO would down regulate thymidylate synthase expression and reverse clinical 5-FU resistance in CRC patients. Aim 1: Determine in the Phase I component of a Phase I/II clinical trial the dose of 5-FU/Leucovorin in combination with a fixed dose of ATO that can be safely administered for the treatment of 5-FU-resistant relapsed/refractory colorectal cancer patients. Aim 2: Determine if ATO administration down regulates the expression of thymidylate synthase in tumor and normal tissue (PBMC, oral mucosal epithelium), and correlate expression between intratumoral and normal tissue levels as well as to clinical parameters.

22. MOLECULAR EPIDEMIOLOGY AND PREVENTION OF BREAST CANCER

Principal Investigator: Hu, Jennifer J.
Role in Project: Biostatistician, 10%
Grant #: 5-R01-CA-073629-11

Funding Source: National Institutes of Health (NIH), National Cancer Institute (NCI)

Project Period: 7/1/06 - 6/30/10.

Total Award: \$1,300,000 (Total Cost)

Summary/Aims: Aim 1: To investigate polygenic models of DNA damage signaling and repair responses in breast cancer risk with a comprehensive evaluation of haplotype tagging single nucleotide polymorphisms and non-synonymous SNPs in 189 genes of multiple candidate pathways. Aim 2: To evaluate the association between breast cancer risk and three functional

phenotypes: (1) the ionizing radiation (IR)-induced H2AX phosphorylation assay for DNA damage signal transduction, (2) the IR-induced cell cycle G2 delay, and (3) the Comet assay for DNA damage. Aim 3: To apply a candidate-pathway approach in assessing genetic (i.e., SNPs) and non-genetic (i.e., alcohol, dietary deficiencies, and/or smoking exposure) regulations of DNA damage/repair functional phenotypes in driving breast carcinogenesis and progression.

23. PPARGAMMA: BIOMARKER FOR BREAST CANCER IN OLDER WOMEN

Principal Investigator: Pearl, Seo

Role in Project: Biostatistician, 5% Grant #: 7-K08-AG-026744-03

Funding Source: National Institutes of Health (NIH), National Institute on Aging (NIA)

Project Period: 08/15/07-06/30/10 Total Award: \$481,351 (Total DC).

Summary/Aims: The goal of this project was to determine whether the aberrant methylation of selected genes in serum DNA is associated with the presence of breast cancer and whether this association is influenced by age, family history and breast cancer risk factors. Specific aims: (1a) To determine if methylation of five genes (RASSF1A, APC, GSTP1, RARb and Twist) in plasma correlate with methylation of these genes in tumor tissue of women with breast cancer (cases). (1b) To compare methylation of these five genes measured in plasma between breast cancer cases and controls (women without breast cancer). (1c) To determine if methylation of these five genes measured in plasma and in tumor tissue of breast cancer cases and in plasma of controls vary by potential breast cancer prognostic factors, such as age, menopause status, family history, and smoking history. (2) To develop a test using methylation expression of the five pre-selected genes (RASSF1A, APC, GSTP1, RARb and Twist) in plasma to predict the presence of breast cancer.

24. RESISTANCE TO INTERFERON-BASED THERAPY IN ADULT T-CELL LEUKEMIA

Principal Investigator: Ramos, Juan Carlos Role in Project: Biostatistician, 5%

Grant #: 3707

Funding Source: Damon Runyon Cancer Research Foundation

Project Period: 07/01/07-06/30/10 Total Award: \$450,000 (Total DC)

Summary/Aims: The overall goal of this proposal was to investigate the role of IRF-4 in primary ATLL focusing on mechanisms involved in IFN resistance. These studies would clarify the mechanisms of antiviral therapy in this unique viral associated malignancy and help identify the subset of patients most likely to benefit from this treatment. Ultimately this work would have great potential to define the molecular processes contributing to the neoplastic growth of ATLL. Specific Aims: Aim 1: We studied the role IRF-4 plays in interferon resistance in Adult T-cell leukemia. To accomplish this, we studied whether a) IRF-4 suppression by RNA interference restores sensitivity to IFN-based therapy in an established ATLL NOD/SCID mouse model and b) whether targeting of NF-kB with pharmacologic inhibitors (bortezomib) restores IFN- α sensitivity. Aim 2: We conducted a clinical trial to test the hypotheses that a) weekly peg-IFN- α is an effective alternative to daily dosing in ATLL, b) whether specific molecular markers (IRF-4, c-Rel) are predictive of antiviral response and, c) whether IRF-4 expression, alterations in NF-kB, or other molecular events common in ATLL such as defective tumor suppressors, are associated with disease progression or recurrence after treatment.

25. PATHOGENESIS AND THERAPY OF VIRAL RELATED LYMPHOMAS

(Administration, Core A of this pre-SPORE grant)

Principal Investigator: Lossos, Izidoros Role in Project: Biostatistician, 10%

Grant #: 07BR01

Funding Source: FL Biomedical Research, Bankhead-Coley (BHC)

Project Period: 7/1/07-6/30/10 Total Award: \$925,924 (Total DC)

Summary/Aims: The main goal of this project was to host activities that would serve as unique platforms for training of young investigators in both clinical and basic aspects of AIDS oncology and to promote collaborative efforts in anticipation of submission of an NCI SPORE application.

26. ABERRANT PROMOTER METHYLATION IN SERUM DNA AS A BIOMARKER FOR PROSTATE CANCER.

Principal Investigator: Singal, Rakesh Role in Project: Co-PI, 5%

Grant #: W81XWH-04-1-0241

Funding Source: Department of Defense (DOD)

Project Period: 5/1/04-5/31/09

Total Award: \$ 354,637 (Total DC)

Summary/Aims: The main objective of this study was to develop a serum-based test for prostate cancer using DNA methylation of one or more candidate genes to improve the predictive value of prostate screening.

27. CYTOCHLOR/ CYTOFLUOR: NEW TUMOR TARGETED RADIOSENSITIZERS

Principal Investigator: Abdel-Wahab, May Role in Project: Biostatistician, 5% Grant #: 5R42CA079272-03

Funding Source: National Institutes of Health (NIH), NCI-SBIR-STTR

Project Period: 7/10/04-5/31/07 Total Award: \$110,391 (Total DC)

Summary/Aims: The specific aims were as follows: (1) To determine the levels of the critical enzymes, dCK and dCMP in tumors and associated normal tissue, (2) to simplify the protocol from 3 biomodulators to 1, (3) the determination of the % of cells of human tumors growing in nude mice incorporating 5-chlorouracil in their DNA, (4) the determination of the dose enhancement ratio utilizing human tumors growing in nude mice (PC-3 prostate), (5) to compare CldC + H4U vs. IdU as a radiosensitizer of human tumors in nude mice, and (6) to determine the minimal effective dose of CldC as a radiosensitizer.

28. ARSENIC TRIOXIDE + ASCORBIC ACID FOR MULTIPLE MYELOMA.

Principal Investigator: Kelvin Lee

Role in Project: Biostatistician, 5% Grant #: 5R01CA97243-05

Funding Source: National Institutes of Health (NIH)

Project Period: 7/1/99-9/28/06

Total Award: \$1,698,731 (Total DC)

Summary/Aims: Aims: To conduct a phase II clinical trial of arsenic + ascorbic acid for

refractory/relapsed multiple myeloma and develop correlates of response and toxicity.

29. PROSTATE CANCER AND VITAMIN D: RECEPTORS, RESPONSE AND RACE

Principal Investigator: Schwartz, Gary G Role in Project: Biostatistician, 20% Grant #: R01 CA-94-028

Funding Source: National Institutes of Health (NIH)

Project Period: 07/01/99 - 06/30/00 Total Award: \$112,265 (Total DC)

Summary/Aims: The ultimate goal of this study in prostate cancer was to understand the roles played by vitamin D and calcium and how these factors could be manipulated to develop preventive and therapeutic strategies.

20d. STATISTICIAN in clinical trials, letters of intent (LOIs), and other research studies conducted at UM/Sylvester (84 studies, including 10 LOIs)

- 1. EPROST 2021xxxx: A phase 1 trial of combined MEK, STAT3 and PD-1 inhibition in metastatic pancreatic ductal adenocarcinoma. PI: Peter Hosein.
- 2. EPROST 2021xxxx: A multicenter, Phase Ib/II study that combines Luspatercept and Lenalidomide (L2) in lower-risk, non-del(5q) MDS Patients. PI: Mikkael A. Sekeres
- 3. EPROST 2021xxxx: Phase 1 Clinical Trial of Lenvatinib, Pembrolizumab and Hypofractionated Pelvic Radiation Therapy for pMMR/MSS Recurrent/Unresectable Endometrial Carcinoma. PI Aaron Wolfson / Marilyn Huang.
- 4. EPROST 2021xxxx: A Phase 3, Randomized, Comparative Effectiveness Clinical Trial of Early Continence comparing Continence Hood (CH) versus Retzius Sparing (RS) Robot-Assisted Radical Prostatectomy (RALP) for patient with localized prostate cancer (Hood-RS Trial). Pl: Bruno Nahar.
- 5. EPROST 2021xxxx: A phase 1/2 study of zanubrutinib and tafasitamab in mantle cell lymphoma. PI: Alvaro Alencar.
- 6. EPROST 2021xxxx: A Randomized Phase 2 Study of Neoadjuvant mFOLFIRINOX and IL-1 Inhibition with or without Immune Checkpoint Inhibition in Resectable Pancreatic Cancer. PI: Nipun B. Merchant.
- 7. Phase 1b/2 trial of AMG 900 in combination with docetaxel for patients with previously treated, metastatic, histologically documented gastric and gastroesophageal junction (GEJ) cancers. Pl: Nkiruka, Ezenwajiaku / Albert Craig Lockhart.
- 8. LOI 2021-03: A phase 2, open-label, study evaluating safety and efficacy of the Lenalidomide in relapsed extranodal marginal zone lymphoma. PI: Izidore Lossos.
- 9. EPROST 2021xxxx: A phase 2, open-label, study evaluating safety and efficacy of the loncastuximab in relapsed/refractory marginal zone lymphoma. PI: Izidore Lossos.
- 10. EPROST 2021xxxx: PET/CT-based prognostication in patients with relapsed and refractory diffuse large B cell lymphoma treated with loncastuximab tesirine PI: Juan Alderuccio.
- 11. EProst 2020xxxx: Single-arm, open-label Phase 2 study of loncastuximab tesirine in combination with rituximab in patients with advanced stage follicular lymphoma. PI: Juan Alderuccio.
- 12. EProst 2020xxxx: Phase 2 Single Agent Dostarlimab in Chemoresistant Gestational Trophoblastic Neoplasia (GTN). Pl: Marilyn Huang.
- 13. EProst 2020xxxx: A Randomized Phase 2 Study of Neoadjuvant mFOLFIRINOX and IL-1 Inhibition with or without Immune Checkpoint Inhibition in Resectable Pancreatic Cancer. PI: Nipun B. Merchant.
- 14. EProst 2020xxxx: A Pilot Safety Trial of STING-dependent Adjuvants (STAVs) and Stimulated Dendritic Cells for Aggressive Relapsed/Refractory Leukemias. PI: Juan Carlos Ramos.
- 15. LOI 2020-May: Phase 2 study of RAMIRI plus Checkpoint Inhibition in Patients with Metastatic Gastroesophageal Cancers. PI: Craig Lochart.
- 16. LOI 2020-Feb: A Randomized Phase 2 Study of Neoadjuvant mFOLFIRINOX and IL-1 Inhibition with or without Immune Checkpoint Inhibition in Resectable Pancreatic Cancer. PI: Nipun B. Merchant.

- 17. EProst 20200543: Phase II Trial of Maintenance Cemiplimab-rwlc after Concurrent Chemoradiotherapy (CRT) in Intermediate and High-Risk Head and Neck Squamous Cell Carcinoma (HNSCC). PI: Cesar A. Perez.
- 18. LOI 2020-02: A phase 2, open-label, study evaluating safety and efficacy of the combination of Lenalidomide and Tafasitamab (MOR208) in untreated extranodal marginal zone lymphoma. PI: Izidore Lossos.
- 19. LOI 2020-08: Phase 1/2 Study of R-CHOP (Rituximab-Cyclophosphamide-Adriamycin-Vincristine-Prednisone) with Olaparib (Ola-R-CHOP) in patients with untreated Diffuse Large B-Cell Lymphoma (DLBCL) expressing high LMO2. PI: Izidore Lossos.
- 20. LOI 2020-06: Phase 1 Study of R-CHOP (Rituximab-Cyclophosphamide-adriamycin-vincristine-prednisone) with Pamiparib (Pami-R-ICE) in patients with untreated Diffuse Large B-Cell Lymphoma (DLBCL) PI: Izidore Lossos.
- 21. LOI 2019-2020: Phase 2 Trial of Pembrolizumab and Hypofractionated Pelvic Radiation Therapy for Patients with Recurrent/Unresectable Endometrial Carcinoma. PI: Aaron H Wolfson.
- 22. LOI 2019: Simple-arm, Phase 2 study of Loncastuximab tesirine in combination with rituximab in untreated patients with follicular lymphoma and marginal zone lymphoma. PI: Crag Moskowitz & Juan Alderuccio.
- 23. LOI 2019: A Phase 2, open-label, study evaluating safety and efficacy of the combination of duvelisib and Ibrutinib in relapsed and refractory marginal zone lymphoma. PI: Izidore Lossos & Juan Alderuccio.
- 24. LOI 2019: Phase 1/2 Study of R-ICE (Rituximab-Ifosfamide-Carboplatin-Etoposide) with Olaparib (Ola-R-ICE) in Patients with First-Relapse/Primary Refractory Diffuse Large B-Cell Lymphoma (DLBCL). PI: Izidore Lossos & Juan Alderuccio.
- 25. EProst 20190283: "Phase I Study to Evaluate the Safety and Feasibility of Preoperative Ablative Breast Radiotherapy (SABER) for Selected Early Stage Breast Cancer". PI: Cristiane Takita.
- 26. EProst 2018xxxx: "An exploratory phase II, randomized, controlled, open label, study of tadalafil, a PDE5 inhibitor, with nivolumab, a check point inhibitor, and the enhanced antitumor MUC1 vaccine for the treatment of recurrent head and neck squamous cell cancer (HNSCC)". PI: Donald Weed.
- 27. EProst 2018xxxx: "A randomized, open-label, phase II study of FOLFIRINOX versus FLOT chemotherapies for previously untreated advanced gastric, gastro-esophageal junction, and esophageal tumors". PI: A. Craig Lockhart.
- 28. EProst 2018xxxx: "A phase II study of neoadjuvant therapy with 5-FU, leucovorin, oxaliplatin and docetaxel (FLOT) concurrent with radiation therapy (RT) in patients with resectable esophageal cancer". PI: A. Craig Lockhart.
- 29. Eprost 20150952: "Miami Membrane for Potency (MMeP) Trial to Assess the Impact of Dehydrated Human Amnion Membrane Allograft Placement during Robotic Radical Prostatectomy on Early Return of Erectile Function." PI: Sanoj Punnen.
- 30. EProst 2017xxxx: "A phase I, open-label, dose-escalation, study of trabectedin [T] in combination with doxorubicin [D] and olaratumab [O] in patients with metastatic or recurrent leiomyosarcoma". PI: Marilyn Huang.

- 31. 2017 LOI: "Combination of daratumumab and bendamustine in non-transplant eligible patients with relapse/refractory multiple myeloma." PI: James Hoffman.
- 32. 2016 LOI: "A phase II open-label study to assess the efficacy of first line ibrutinib in newly diagnosed patients with marginal zone lymphoma of the ocular adnexa." PI: Izidore Lossos.
- 33. 2016 LOI: "Single-center phase I study of intratumoral talimogene laherparepvec in combination with low-dose irradiation in patients with pancreatic adenocarcinoma." PI: Nicolas Acquavella.
- 34. EProst 20160653: "Proof of concept study of vorinostat, a histone deacetylase inhibitor, in patients with class 2 high risk uveal melanoma." PI: Lynn Feun (prior PI: Nicolas Acquavella).
- 35. EProst 20170846: "Phase II Single Arm Study of Combination Pembrolizumab, Chemotherapy and Bevacizumab in Patients with Recurrent, Persistent, or Metastatic Cervical Cancer." PI: Marilyn Huang.
- 36. EProst 20160477: "Phase II single arm study of combination pembrolizumab, paclitaxel, and carboplatin in patients with advanced stage ovarian, fallopian tube, or peritoneal carcinoma receiving neoadjuvant chemotherapy". PI: Marilyn Huang.
- 37. EProst 20151012: "The validity of sentinel lymph node dissection (SLND) in patients with apparent early stage endometrial cancer (EC)". PI: Brian Slomovitz.
- 38. EProst 20150989: "DePICT: Defining Platforms for Individualized Cancer Treatment." Pl: Jonathan Trent.
- 39. EProst 20150567: "A Phase II trial of Belinostat as consolidation therapy with zidovudine for adult T-cell leukemia-lymphoma (ATLL)." PI: Juan Carlos Ramos.
- 40. 2014 LOI: "An open-label single-arm phase 2 study of azacitidine plus pembrolizumab (MK-3475) in patients with high-risk myeloid malignancies who are unfit for intensive chemotherapy ". PI: Justin Watts.
- 41. EProst 20140960: "PDE5 Inhibition via tadalafil (Cialis®) to enhance anti-tumor MUC1 vaccine efficacy in patients with resectable, and recurrent or second primary head and neck squamous cell carcinoma (HNSCC): A phase I/II clinical trial". PI: Donald Weed.
- 42. EProst 2014x: "Overcoming 5-FU resistance with arsenical trioxide: A single-arm phase II trial in metastatic colon cancer". PI: Bach Ardalan.
- 43. EProst 2014x: "A Randomized, Open-label, phase I trial of continuous, intermittent, and pulsatile selumetinib (AZD6244) plus nab-paclitaxel as second-line treatment for stage IIIB or IV non-small cell lung cancer (NSCLC)". PI: Khaled Tolba.
- 44. EProst 20140460: "Phase I trial of intratumoral administration of recombinant vesicular stomatitis virus expressing human interferon beta (VSV-hIFN-β) in patients with recurrent/metastatic squamous cell carcinoma of the head and neck". PI: Jaime Merchan.
- 45. EProst 20130200: "Overcoming 5-FU resistance with arsenical trioxide: phase II, colon cancer trial". PI: Bach Ardalan.
- 46. EProst 20110069: "Phase II study to evaluate fenofibrate therapy in patients with relapsed/refractory multiple myeloma who have failed at least two prior therapies". PI: Denise Pereira & Theodore J Lampidis. (active)
- 47. LOI 2010: "Treatment of multiple myeloma with fenofibrate". PI: Denise Pereira.
- 48. EProst 20100389 "A Phase I Trial of MRI-guided lattice extreme ablative dose radiotherapy for prostate cancer." (LEAD study) PI: Allan Pollack. (active)

- 49. EProst 20100153: "A phase I study of nelfinavir added to cisplatin chemotherapy concurrent with pelvic radiation for locally advanced cervical cancer (II-IVA)". PI: Matt Pearson (previously Fiona Simpkins).(active)
- 50. EProst 20100252: "Evaluation of the use of AZD6244 to induce increased ER expression and anti-estrogen response in ER-negative/low breast cancer". PI: Mark Pegram & Dorraya El-Ashry.
- 51. EProst 20100156: "Mechanisms and control of head and neck (HN) cancer". PI: Elizabeth Franzmann.
- 52. LOI Jul/Aug 2009 for Bill and Melissa Gates Foundation: "Use of N-acetyl cysteine for the treatment of Kaposi's Sarcoma in Sub-Saharan Africa". Pls: Pascal J. Goldschmidt-Clermont, MD and Enrique Mesri, PhD. (In collaboration with Bob Duncan, I developed statistical considerations -- study design, sample size justification and methods of analysis -- for this grant LOI.)
- 53. LOI Jul 2009: "Phase I/II study of cetuximab-irinotecan-panobinostat combination in patients with metastatic colorectal adenocarcinoma who failed at least one line of systemic chemotherapy". PI: Caio Max Rocha-Lima.
- 54. LOI Jan 2009: "Clinical evaluation of docetaxel in combination with platinum salts as neoadjuvant therapy for triple negative breast cancer". PI: Judith Hurley.
- 55. EProst 20090462: "Phase II clinical trial of bortezomib (VelcadeTM) in combination with tamoxifen in the treatment of patients with metastatic triple negative breast cancer previously treated with chemotherapy". PI: Stefan Gluck.
- 56. LOI Nov 2008: "A phase II study of temsirolimus in patients with advanced urothelial carcinoma". PI: Rakesh Singal.
- 57. EProst 20090229: "A phase I trial assessing the safety and feasibility of prophylactic nipple-areola complex (NAC) irradiation after nipple-sparing mastectomy and immediate reconstruction in patients with in-situ or invasive breast cancer." PI: Cristiane Takita.
- 58. SCCC 2009003: "A Phase I/II study of combination of gemcitabine, oxaliplatin, and sorafenib (GEMOX-Sorafenib) in patients with advanced biliary tract cancer. " PI: Caio M Rocha-Lima.
- 59. LOI for SCCC 2009003: "A Phase I/II study of combination of gemcitabine, oxaliplatin, and sorafenib (GEMOX-Sorafenib) in patients with advanced biliary tract cancer". PI: Caio M Rocha-Lima.
- 60. Eprost 20090166, SCCC 2009002: "Phase II study of chemotherapy (doxorubicin, methotrexate and leucovorin) in combination with antiviral-based therapy (zidovudine + hydroxyurea) for relapsed Epstein Barr virus associated non-Hodgkin's lymphoma". PI: Juan Carlos Ramos.
- 61. IRB 20080130: "Pathologic and molecular prognostic factors in adult renal cell carcinoma". Pl: Merce Jorda.
- 62. 2008: "Comparison of two visual examinations (white light v. Velscope enhanced) for early detection of SCCA of the head and neck. New protocol amended to project SCCC 2006117 "Salivary soluble markers in head and neck cancer". PI: Elizabeth Franzmann.
- 63. IRB 20080325 (SCCC 2008002, IND 102,186): "A phase I pharmacokinetic and randomized phase II trial of neoadjuvant treatment with anastrozole plus AZD0530 in postmenopausal patients with hormone receptor positive breast cancer". PI: Joyce Slingerland.

- 64. SCCC 2008077: "Phase II trial of PET-guided neoadjuvant chemotherapy with FLOD in the management of previously untreated advanced esophago-gastric carcinoma" PI: Dr. Ardalan.
- 65. LOI for SCCC 2008077: "Phase II trial of PET-guided neoadjuvant chemotherapy with FLOD in the management of previously untreated advanced esophago-gastric carcinoma" PI: Dr. Ardalan.
- 66. SCCC 2008017: "A phase II trial of photodynamic therapy with gemcitabine and oxaliplatinum in nonresectable biliary tract cancer". PI: Afonso Ribeiro.
- 67. 2007: "Pilot study of dietary intervention in indigent breast cancer patients". Pl: Judith Hurley.
- 68. 2007: "Are circulating tumor cells (CTCs) predictive of pCR, DFS, PFS, and OS in locally advanced breast cancer". PI: Orlando Silva.
- 69. 2007: "Retrospective study of correlation between MRI and pathology in breast cancer patients". PI: Stefan Gluck & Maria Manzanares. (Retrospective chart review.)
- 70. 2007: "The effect of HAART on cervical cancer outcomes in HIV-infected women with cervical cancer as compared to non-infected women". PI: Nathalie Dauphin-McKenzie and Joseph Lucci. (Retrospective chart review.)
- 71. SCCC 2007096: "Phase II trial of Abraxane® in the treatment of patients with pancreatic cancer who failed first-line treatment with Gemcitabine-based therapy". PI: Caio Max Rocha- Lima & Gilberto Lopez.
- 72. SCCC 2007079: "Predictors of response and resistance to neoadjuvant therapy in breast cancer". Pl: Judith Hurley. (Retrospective chart review.)
- 73. EProst 20070805, SCCC 2007055 "Prospective study of the molecular characteristics of sensitive and resistant disease in patients with HTLV-I associated adult T cell leukemia treated with zidovudine (AZT) plus interferon alpha-2B". Pl: Juan Carlos Ramos. (Part of a Damon Runyon grant.)
- 74. SCCC 2006987: Racial disparities in acute toxicities of adjuvant chemotherapy with FEC 100 and their impact on the outcomes of patients with breast cancer". PI: Stefan Glück.
- 75. SCCC 2006081: "A Phase II Study of gemcitabine, abraxane and bevacizumab for first line metastatic breast cancer". PI: Stefan Glück.
- 76. SCCC 2006080: "A Phase I/II Study of azacitidine (Vidaza®), docetaxel and prednisone for patients with metastatic hormone refractory metastatic prostate cancer. PI: Rakesh Singal.
- 77. SCCC 2004162 (2006 amendment): "A Phase I Study of 5-FU (plus leucovorin) and arsenic trioxide for patients with refractory/relapsed metastatic colorectal carcinoma". Pl: Bach Ardalan.
- 78. SCCC 2006059: "Phase II randomized double-blind study of hectoral in patients undergoing salvage or post-operative ionizing radiation (IR) for localized prostate cancer after prostatectomy". PI: May Abdel-Wahab. (Updated version, April 2006 -- "Phase II randomized double-blind study of Cholecalciferol, in conjunction with ionizing radiation (IR) post-prostatectomy or salvage therapy for prostate cancer".)
- 79. SCCC 2006049: "Phase II study of antiviral-based therapy (zidovudine + hydroxyurea) in combination with chemotherapy (doxorubin, methotrexate, and leucovorin) for relapsed endemic Burkitt lymphoma". PI: William Harrington.
- 80. SCCC 2005155: "An open-label study of the efficacy and safety of oral CEP-701 (80mg BID) for the treatment of patients with advanced melanoma". Pl: Oluwatoyin Shonukan.

- 81. SCCC 2005145: "Phase II study of avastin, irinotecan, high dose 24 hour continuous intravenous infusion of floxuridine and leucovorin in patients with previously untreated metastatic colorectal cancer". PI: Bach Ardalan.
- 82. SCCC 2005097: "Translational Phase I trial of escalating doses of 5-chloro-2'-deoxycytidine (CldC) with a fixed dose of tetrahydrouridine combined with external beam brain radiation for metastatic carcinoma to the brain". PI: May Abdel-Wahab.
- 83. SCCC 2005030: "Phase II clinical trial of Thalidomide + arsenic trioxide + liposomal doxorubicin + ascorbic acid (ThAD-C) consolidation followed by arsenic trioxide + prednisone maintenance post high-dose chemotherapy/stem cell transplantation for multiple myeloma". PI: Kelvin Lee.
- 84. SCCC 2004066: "Evaluation of genetic risk in Bahamian women with breast/ovarian cancer". PI: Judith Hurley.
- 85. SCCC 2004162: "A phase I/II study of 5-FU, arsenic trioxide, and leucovorin for patients with refractory/relapsed metastatic colorectal carcinoma". (PI: Bach Ardalan)
- 86. SCCC 2004064: "Phase II study of dose dense carboplatin, taxotere, and herceptin as primary systemic therapy in breast cancer". PI: Judith Hurley.
- 87. SCCC 2004035: "A pilot study to assess vaginal quality and psychosexual function with the use of vaginal estrogen therapy in women undergoing pelvic irradiation for cervical cancer". Pl: Nicholas Lambrou.
- 88. SCCC 2004136: "Pharmacogenomics approach to chemotherapy response in NSCLC". PI: Luis Raez.
- 89. SCCC 2003160: "An open-label phase II study of capecitabine, docetaxel and herceptin as first line treatment for patients with metastatic breast cancer whose tumors overexpress Her-2/neu". PI: Shou-Ching Tang.
- 90. SCCC 2003151: "A non-randomized Phase II study: Feasibility and outcome of neo-adjuvant chemotherapy with oxaliplatin, flurordeoxyuridine (FudR), taxotere and leucovorin in the treatment of previously untreated advanced esophago-gastric carcinoma". PI: Dr Ardalan Bach.
- 91. SCCC 2003149: "Phase II Study of oxaliplatin, high-dose 24-hour continuous intravenous infusion of floxuridine, and leucovorin in patients with previously untreated advanced metastatic colorectal cancer". PI: Dr Ardalan Bach.
- 92. SCCC 2003083: "Open label phase II trial of docetaxel, epirubicin and cycloplosphamide (TEC) in HER2/neu-negative metastatic breast cancer (GIA# 11224)". PI: Shou-Ching Tang.
- 93. SCCC 2003053: "Phase II Trial of docetaxel and capecitabine in the treatment of HER2/neunegative metastatic breast cancer (GIA# 11203)". .PIs: Orlando Silva.
- 94. SCCC 2003041: "A Phase II Study of neoadjuvant Docetaxel and estramustine in high-risk prostate cancer". .PI: Gustavo Fernandez.
- 95. SCCC 2002076: "Phase II study of high-dose, 24-hour continuous intravenous infusion of floxuridine, camptosar and leucovorin for advanced previously untreated colorectal cancer". .PI: Bach Ardalan.
- 96. SCCC 2002053: "Phase II Trial of docetaxel and capecitabine in the treatment of HE2/neunegative metastatic breast cancer (GIA# 11203)". PI: Orlando Silva.

- 97. SCCC 2002033: "Translational phase I trial of escalating dose of 5-chloro-2'-deoxycytidine (CldC) with a fixed dose of tetrahydrouridine combined with a fixed dose of 3240 cGy external radiation in once a day fractionation, followed by only external radiation with concomitant boost in patient with advanced squamous cell carcinoma of the oral cavity and oropharynx". Supporting Agency: NCI, Division of Cancer Treatment and Diagnosis. .PIs: Luis Raez, May Wahab.
- 98. SCCC 2001071: "Combination chemotherapy with docetaxel and captosar for patients with newly diagnosed or relapsed, locally advanced or metastatic non-small cell lung cancer". PI: Luis Raez.
- 99. SCCC 2001040: "Phase II trial of hepatic intra-arterial cisplatinum chemotherapy with systemic octreotide for unresectable hepatocellular carcinoma (HCC)" PI: Luis Raez.
- 100. SCCC 2001032: "Phase II study of arsenic trioxide and ascorbic acid therapy in metastatic colorectal cancer refractory to chemotherapy. PI: Bach Ardalan.
- 101. SCCC 2001013: "Phase II trial of neoadjuvant carboplatinum and taxotere in the treatment of locally advanced and inflammatory breast cancers that do not overexpress Her-2". PI: Judith Hurley.
- 102. SCCC 2000082: "Phase I trial of hycamtin, adriamycin and oncovin in advanced non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC)". PI: Kasi Sridhar.
- 103. SCCC 2000010: "Phase I/II trial of arsenic trioxide (As2O3) with ascorbic acid in the treatment of relapsed/refractory multiple myeloma". Supporting Agency: NIH/NCI, Division of Cancer Treatment. PI: Kevin Lee.
- 104. SCCC 2000: "Phase I study of topotecan in combination with fixed doses of doxorubicin and vincristine in patients with advanced NSCLC or advanced SCLC". PI: Kasi Sridhar.
- 105. SCCC 1999064: "A phase II study of lipiodol chemoembolization therapy with cisplatin and thiotepa followed by oral thalidomide for primary liver cancer and liver metastases". PI: Lynn Feun.
- 106. SCCC 1999056: "Phase II trial of neoadjuvant herceptin, taxotere and cisplatinum in the treatment of locally advanced and inflammatory breast cancer". PI: Judith Hurley.
- 107. SCCC 1999022: "Phase I study of oral eniluracil/5-FU with cisplatin in patients with locally recurrent or metastatic carcinomas of the aerodigestive tract (head and neck, lung or esophagus)". Pls: Lini Bartlett-Pandite, Kasi Sridhar.
- 108. SCCC 1999009: "Elicitation of a cellular immune response in non-small cell lung cancer (NSCLC) patients by immunogenic tumor cell vaccination: a phase I/II study". Pls: Eckhard R. Podack, Kasi Sridhar, Peter A. Cassileth.

21. Editorial responsibilities:

PLOS ONE 2015-present BMC Medical Research Methodology 2015-present

22. Professional and Honorary Organizations:

Member of the following organizations:

Member of the American Statistics Association (ASA)	1984-present
Member of the Brazilian Statistics Association [Associação Brasileira de Estatística (ABE)]	1989-1999
Member of the International Association of Survey Statisticians (IASS)	1984-1999
Member of the Delta Omega Society, Iota Chapter of the Delta Omega Society at UCLA	1995-1999
Member of the Delta Omega Society	1995-1999
Member of the lota Chapter of the Delta Omega Society at UCLA	1995-1999

23. Honors and Awards:

Excellence in Teaching, University of Miami, Miami, FL 2008

One-year Dissertation fellowship award, University of California at Los Angeles.

09/1995-03/1996

Elected a member of the Iota Chapter of The Delta Omega Society at UCLA and a member of the National Society.

1995

Master program fellowship.
CNPq - Conselho Nacional de Desenvolvimento Científico e Tecnológico,

1984-1985

08/1991-08/1995

Brazilian Ministry of Science and Technology

Fellowship for summer course Statistics in Health,

07-09/1989

Statistical Service Centre, University of Reading, Reading, United Kingdom. WHO/PAHO - World Health Organization / Pan American Health Organization.

24. Post-Doctoral Fellowships: N/A

Doctoral program fellowship.

25. Other Professional Activities:

25a. Service on National Scientific Review Panels, Study Section, Committees

Member of scientific review panels at the National Institutes of Health (NIH):

PAR-11-151: "Strategic Partnering to Evaluate Cancer Signatures [SPECS III] (U01)"

10/2011

The emphasis of PAR-11-151 was on the late translational stage of existing signatures (DNA, RNA, protein etc.), moving them forward to potential clinical usefulness. If along the way, additional signatures were discovered this would be fine. Thus, an application which was focuses only on discovery or technology development would not be deemed responsive to this RFA (request for applications) targeting multidisciplinary research groups. A total of 40 U01 applications were evaluated.

PAR-10-126: "Strategic Partnering to Evaluate Cancer Signatures [SPECS II] (U01)"

11/2010

A total of 44 U01 applications were evaluated for the potential clinical usefulness of molecular signatures (DNA, RNA, protein etc.) that have already been developed. The emphasis was on the late translational stage into the potential clinical trial rather than a focus on discovery. The goal was the confirmation and evaluation of clinically useful multi-analyte molecular signatures. Applications were from multidisciplinary groups and featured analytical technologies, oncology, pathology, assay development, biostatistics and bioinformatics.

PAR-06-294: "Small Grants Program for Cancer Epidemiology (R03)"

11/2007

PAR-06-313: "Cancer Prevention Research Small Grants Program (R03)"

11/2007

Small Business Innovation Research (SBIR) Topic 214 "Systems to Enhance Data Collection and Medication Compliance in Clinical Trials"

03/2005

RFA-CA-04-015: "Strategic Partnering to Evaluate Cancer Signatures [SPECS I] (U01)"

11/2004

The grant funding mechanism was a multi-institutional award *U01 Research Project - Cooperative Agreements*. NCI invited investigators to form strategic partnerships that would bring together the multidisciplinary expertise and resources needed to determine how the information derived from comprehensive molecular analyses can be used to improve patient care and ultimately, patient outcomes. The applications addressed the potential usefulness for clinical decision making of molecular signatures that were already developed, focusing on the gap between initial signature molecule discovery and the integration into clinical practice. In response to NCI, applications submitted addressed well-defined clinical needs such as identification of sub-stages in a tumor's development, risk of progression, differential responses to target therapies or prediction of responses to selected therapies.

25b. Seminars, lectures, workshops.

UM SCCC Annual Zubrod Memorial Lecture and Poster Session at UM SCCC, Miami, FL. (Attendance and poster presentations)	1999-2021
2018 Joint Statistical Meetings (JSM) of the American Statistical Association Vancouver, BC, Canada (<i>Poster presentation</i>)	(ASA) 07/28-08/02/2018
2017 Spring Meeting of the Eastern North America Region (ENAR) of the International Biometrics Society (IBS), Washington, DC (Poster presentation)	03/12-15/2017
2016 Spring Meeting of the Eastern North America Region (ENAR) of the International Biometrics Society (IBS), Austin, Texas (Poster presentation)	03/06-09/2016
2015 Spring Meeting of the Eastern North America Region (ENAR) of the International Biometrics Society (IBS), Miami, FL (Poster presentation)	03/15-18/2015
2011 Spring Meeting of the Eastern North America Region (ENAR) of the International Biometrics Society (IBS), Miami, FL (Attend and provided support as volunteer.)	03/20-23/2011
Regular attendance to the UM/Sylvester Distinguished Lecture Seminar Seri	es. 1999-present
Regular attendance to seminars at the department of Public Health Sciences	1999-present
Attend VIII Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lectures", at UM SCCC, Miami, FL.	01/22/2010
Attend VII Annual Landon Foundation-America Association for "Cancer Research (AACR) Awards Lectures", at UM SCCC, Miami, FL.	01/23/2009
Attend Second annual meeting on Molecular Markers in Cancer, ASCO, NCI, and EORTC. Hollywood, FL.	10/30 & 11/1/2008
Attend VI Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lectures, at UM SCCC, Miami, FL.	01/18/2008
2007 Annual Meeting of the American Society of Clinical Oncology (ASCO) Chicago, IL. (Attendance and poster presentation)	05/1-5/2007
Attend Cancer Biology of the Eye Workshop Bascom Palmer Eye Institute and Sylvester Comprehensive Cancer Center.	02/15/2007
Attend V Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lectures", at UM SCCC, Miami, FL.	01/19/2007

2006 Annual Meeting of the American Society of Clinical Oncology (ASCO) Atlanta, GA. (Attendance and poster presentation)	06/2-6/2006
Attend IV Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lectures", at UM SCCC, Miami, FL.	01/20/2006
Attend III Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lectures", at UM SCCC, Miami, FL.	01/19/2005
Attend Second Annual Landon Foundation - America Association for "Cancer Research (AACR) Awards Lecture", at UM SCCC.	01/16/2004
Attend Novel Therapeutic Approaches in the Treatment of Multiple Myeloma, sponsored by IM SCCC and Multiple Myeloma Research Foundation.	02/2003
Participation on Workshop Workshop "Operational Research for the Control of Tropical Diseases" Pan American Group of Health, Program of Communicable Diseases, Brazilian Ministry of Health, SENEPE e DNDS. Goiânia, Brazil.	Jul-Aug/1997
Invited lecturer "Analysis of contingency tables " In biostatistics course offered by the Federal University of Goiás, Institute of Tropical Pathology and Public Health, Department of Community Health; Goiânia, Goiás, Brazil.	06/1990

VI. TEACHING

26. Teaching Awards Received:

Certificate of Appreciation for outstanding service to the Public Health Student Association as Faculty Advisor.

08/2010

The University of Miami Miller School of Medicine Public Health Student Association.

Fall 2008 "Lecturer of the Semester"

12/2008

The University of Miami Miller School of Medicine, Public Health Student Association.

27. Teaching Specialization:

EPH 751: Survival Analysis in Clinical Trials (former EPH651)

2017-22, 2010-2015

2000-2008

Department of Public Health Sciences University of Miami School of Medicine

Developed during 1999-2000. A three-credit course offered yearly for graduate students in epidemiology, and biostatistics and also allowing students of other department of the University of Miami. Students learn statistical methods for analysis and interpretation of time to event data. The topics covered in ten lectures of 3 hours duration are: survival curves (functions of survival time, relationships among the several survival functions), estimation of the survival curve by the Kaplan-Meier method, parametric models for estimating survival, comparison of two survival curves (log-rank or Mantel-Haenszel test), estimation of sample size for survival studies, Cox's proportional-hazards models (variable selection, inclusion of interactions, assessment of model fit and diagnostics for the proportional hazards assumption), development of prognostic indices, and time-dependent variables. Students are expected to participate actively in classroom discussions, complete written reports for assigned exercises, make classroom presentations of assigned exercises, and complete a final term assignment involving survival data analysis.

Lecture on Biostatistics Multidisciplinary Clinical Research Symposium

Nov 15, 2019

Hematology Oncology Fellowship Training Program at the

Sylvester Comprehensive Cancer Center and Jackson Memorial Hospital, University of Miami School of Medicine

Biostatistics in Clinical Research Radiation Oncology Lecture Series 2019

Aug 26 & 30, Sep 3& 4, 2019

Residency Program of the Department of Radiation Oncology,

Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

Biostatistics in Clinical Research

2015-2019

Didactic Lecture for the Division of Hematology/Oncology, Core Curriculum, Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

Survival Analysis 2015, 2016

Didactic Lecture for the Division of Hematology/Oncology, Core Curriculum, Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

Biostatistics for Clinical Research

Apr 9, 2013

Didactic Lecture for Residents in the

Residency Program of the Department of Radiation Oncology,

Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

Biostatistics in Clinical Research

Feb 21, 2013

Didactic Lecture for the Division of Hematology/Oncology, Core Curriculum, Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

Biostatistics for Clinical Research Workshop

2001-2008

UM/Sylvester Biostatistics Core Resource (BCR),

Sylvester Comprehensive Cancer Center, University of Miami School of Medicine

The objective of this workshop was to familiarize oncology residents and fellows in oncology programs of the SCCC with statistical methods commonly found in the research literature and applicable to their future research activities in the area of clinical oncology studies. The lectures were taught by members of the UM/Sylvester Biostatistics Core Resource (BCR). My participation was to give lectures on survival analysis in cancer studies, and on clinical trials.

Categorical data analysis applied to epidemiologic studies

1997

University of São Paulo, School of Public Health

Course developed to be offered to epidemiology or other public health graduate programs.

Biostatistics 1985-1991, 1997-1998

University of São Paulo, School of Public Health

A required course in the several programs of specialization in public health.

Biostatistics 1987-1989

University of São Paulo, School of School of Nutrition

A four-credit course for students in graduate programs.

Biostatistics 08/1987

Rondônia Federal University Foundation; Porto Velho, Rondônia, Brazil.

Biostatistics 07/1988

Rondônia Federal University Foundation; Porto Velho, Rondônia, Brazil.

Biostatistics 12/1989

Brazilian Health Ministry, Department of Especial Health Programs,

National Division of Sexually Transmitted Diseases and AIDS, Brasilia, Brazil.

Biostatistics 04/1997

Federal University of Goiás, Institute of Tropical Pathology and Public Health, Department of Community Health; Goiânia, Goiás, Brazil.

28. Thesis and Dissertation Advising/Post-doctoral Student Supervision

28a. Thesis or Dissertation Advisor

George Ruochen Yang: Doctoral degree in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Dissertation Tentative Title: "MOLECULAR MECHANISMS OF BREAST CANCER PROGNOSIS". Dissertation Defense: 10/2021. (Committee member, Faculty advisor jointly with Dr Jenifer J. Hu).

Xiaozhuang Hu: Master of Science in Public Health (MSPH) at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis Title: Immune-cell profiling among female breast cancer patients with different clinical characteristics. 11/20/2020. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Hankun Xie: Master of Science in Public Health (MSPH) at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis Title: Combined effects of transforming growth factor-beta and C-reactive protein on radiotherapy-induced skin toxicities in breast cancer patients. 08/03/2020. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Caroline Ripat: Master of Science in Public Health (MSPH) at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis Title: Evaluation of risk factors associated with in-hospital pediatric acute moderate-to-severe pain and pain management. 06/20/2019. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Kaichen Wang: Master of Public Health (MPH) at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Capstone project Title: Breast cancer survival disparities in a tri-race/ethnic populations. May 2019. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Yindi Li: Master of Science in Public Health (MSPH) at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: Metabolomics Analyses and RT-induced Skin Toxicity among Breast Cancer Patients. 07/27/2018. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Mohamed Mihyu, MD: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: Association between DNA Oxidative Damage Biomarker 8-hydroxy-2-deoxyguanosine (8-OHdG) and Radiotherapy-Induced Early Adverse Skin Reactions in a Multiracial/Ethnic Breast Cancer Population. 07/18/2018. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Chaonan Wang: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: Racial/Ethnic Disparities in Breast Cancer Survival. Thesis defense: 12/05/2016. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Abzal Zhumagaliuly, MD: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: Radiotherapy-Induced Immune Cell Type Changes in Breast Cancer Patients. Thesis defense: 07/04/2017. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Nurila Aryntayeva, MD: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: "Immune-Cell Profiling In Breast Cancer Risk". Thesis defense: 06/04/2017. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Saltanat Sapargaliyeva, MD: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: Transforming Growth Factor-Beta (Tgf-B) in Radiation Therapy-Induced Early Skin Toxicity in Breast Cancer Patients. Thesis defense: 05/14/2017. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Raed Jannadi, MD: Master of Science in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Thesis title: "Racial/ethnic disparities in lung cancer survival". Thesis defense: 08/15/2016. (Faculty advisor jointly with Dr Jennifer J. Hu, Ph.D.)

Eunkyung (Muriel) Lee: Doctoral degree in Public Health at University of Miami, Miller School of Medicine, Department of Public Health Sciences. Dissertation Title: "**G**enetic/molecular biomarkers of cancer pain in breast cancer patients undergoing radiation therapy". Dissertation Defense: 02/2017. (Committee member).

Julie Kornfeld: Doctoral degree in Public Health at University of Miami, Miller School of Medicine, Department of Epidemiology and Public Health. Dissertation Title: "Factors that are associated with acceptance of Human Papillomavirus Vaccines: A Study of Spanish Information Seekers". Dissertation Defense: 11/2009. (Committee member)

Nicole Cook: Doctoral degree in Public Health at University of Miami, Miller School of Medicine, Department of Epidemiology and Public Health. Dissertation Title: "A multi-level approach to understanding Pap smear compliance at Community Health Centers including patient, provider and organizational variables". Dissertation Defense: 102008. (Committee member)

Kimberly Nhu-Mai Hoang: Bachelor's thesis submitted in partial fulfillment of requirements for the distinction of *summa cum laude* at University of Miami, Miller School of Medicine. Thesis title: "Genetic polymorphisms of multiple DNA-repair pathways and breast cancer risk". Thesis date: 05/2008. (Committee member)

Hermes Flores: Doctoral degree in Public Health at University of Miami, Miller School of Medicine, Department of Epidemiology and Public Health. Dissertation Title: "Genetic polymorphisms associated with dyslipidemia and subclinical inflammation in subjects with the metabolic syndrome: A case control study in South Florida". Dissertation Defense: 04/2006. (Committee member)

Guillermo Prado: Doctoral degree in Epidemiology at University of Miami, Miller School of Medicine, Department of Epidemiology and Public Health. Dissertation Title: "The efficacy of three interventions to prevent substance use and sexual behavior in subgroups of Hispanic adolescents". Dissertation Defense: --4/2005. (Committee member)

Helena dos Santos: Doctoral degree in Public Health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "Prevalência, distribuição e determinantes do retardo do crescimento infantil na população urbana do estado do Pará, Brasil". Dissertation Defense: 04/1998. (Committee member)

Denise Costa Coitinho: Doctoral degree in Public Health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "A influência da história reprodutiva no Índice de massa corporal de mulheres brasileiras". Dissertation Defense: 03/1998. (Committee member)

Adriana Souza de Toledo Piza: Master of Science in Public health – Epidemiology, University of São Paulo School of Public Health. Dissertation Title: "Adaptação do método imunoenzimático (ELISA) para detecção de anticorpos anti-rábicos neutralizantes em soros humanos. Comparação com a prova de soroneutralização em cultura celular". Dissertation Defense: 06/1997. (Committee member)

Fátima Cristina Minari: Master of Science in Public health – Epidemiology, University of São Paulo School of Public Health. Dissertation Title: "Morbidade: um estudo conceitual e empírico". Dissertation Defense: 01/1997. (Committee member)

Lenise Mondini: Doctoral degree in Public Health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "Desnutrição e obesidade no Brasil: relevância epidemiológica e padrões de distribuição intra-familiar em diferentes estratos econômicos e regionais". Dissertation Defense: 12/1996. (Committee member)

28b. Committee Member ONLY for Qualifying Exam of Master/Doctoral students

Wander Ricardo Mingardi: candidate for a master's degree in Public health – Epidemiology, University of São Paulo School of Public Health. Dissertation Title: "Prevalência de carie e fatores de risco: estudo realizado entre escolares de 12 anos da região administrativa do Ipiranga, município de São Paulo, 1998". Qualifying exam: 03/1998. (Committee member)

Miguel Veses Cataluña: candidate for a doctoral degree in Public Health - Epidemiology, University of Caxias do Sul and University of São Paulo School of Public Health. Dissertation Title: "Duração da vida segundo a relação da ocupação com o mercado de trabalho". Qualifying exam: 12/1997. (Committee member)

Maria Teresa Cera Sanches: candidate for a master's degree in Public health – Maternal-Infant, University of São Paulo School of Public Health. Dissertation Title: "Disfunções motoras-orais e suas repercussões no aleitamento materno". Qualifying exam: 11/1997. (Committee member)

Ligia Beatriz Bento Franz: candidate for a master's degree in Public health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "Bioimpedância Elétrica como método de avaliação da composição corporal de indivíduos adultos e idosos". Qualifying exam: 11/1996. (Committee member)

Nélida Antonia Schmid de Fornés: candidate for a doctoral degree in Public Health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "Padrões alimentares e fatores de risco para doenças cardiovasculares ateroscleróticas em população da área metropolitana na região sudeste do Brasil". Qualifying exam: 10/1996. (Committee member)

Ana Lúcia Medeiros de Souza: candidate for a master's degree in Public health - Nutrition, University of São Paulo School of Public Health. Dissertation Title: "Estratificação social e obesidade no Brasil" [Social class and obesity in Brazil]. Qualifying exam: 10/1996. (Committee member)

28c. Academic Advisor

Department of Epidemiology and Public Health University of Miami, Miller School of Medicine MPH (Master in Public Health)

Diego Perilla	2008 - 1010
Brad Coyle	2005 - 2007
Angel Loor	2005 - 2010
Jeffrey Simmons	2004 - 2007
Daniel Torres	2001 - 2002
Enrique Molina	2001 - 2002

28d. Mentor of PhD student

Department of Public Health Sciences University of Miami, Miller School of Medicine

 Evan Wu
 2013 - 2014

 Eric M Hecht
 2015 – 2016

 George Ruochen Yang
 2019 - present

28e. Mentor of Young Investigators and Medical Residents or Fellows in specific training programs at UM Sylvester.

Guide and teach trainees in their research projects with respect to research methods, biostatistics, presentations and interpretation of results for manuscripts and oral/poster presentations in scientific meetings.

Azad A. Jabiev, M.D.	Division of Endocrine surgery, UMSOM
Gil Ascunce, M.D.	Division of Gastroenterology
Alexandra Gomez	Resident, Division of Internal Medicine, University of Miami /Jackson Memorial Hospital.
Agustin Pimentel, M.D. Carmen Calfa, M.D. Christopher Lobo, M.D. Gilberto de Lima Lopes, M.D. Hyo Sook Han, M.D. Juan Pablo Alderuccio, M.D. Nizar J. Bahlis, M.D. Partha M. Das, M.D. Peter J Hosein, M.D. Tadeu Ambros, M.D.	Department of Medicine, Division of Hematology and Oncology
Jennifer McCafferty-Grad, Ph.D.	Department of Microbiology and Immunology
Fiona Simpkins, M.D. J. Matthew Pearson, M.D. Joseph De La Garza, M.D. Nathalie Dauphin-McKenzie, M.D.	Department of Obstetrics and Gynecology
Erin R. Cohen, M.D. Gia Hoosien, M.D. Joyson Kodiyan, M.D.	Department of Otolaryngology

Turki M. AlMohimmed, M.D. Drew. H Smith, M.D. Shahm Raslan, MD. Claudia P. Rojas, M.D. Loren Herrera, M.D.	Department of Pathology
Yasir, Saba M.D.	
Faisal FM Alotaibi, M.D. Saltanat Sapargaliyeva, MD	Department of Public Health Sciences
Daniel Arsenault, M.D. Dayssy Alexandra Diaz, M.D. Joseph E Panoff, M.D. Kelly La Favre, M.D. Kunal Saigal, M.D. Omar Mahmoud, M.D. Nicholas R Cnossen, M.D. Benjamin James Rich	Department of Radiation Oncology
George JS Kallingal, M.D. Murugesan Manoharan, M.D.	Department of Urology

28f. Statistical consultant on master/doctoral dissertations School of Public Health, University of São Paulo, Brazil.

1982-1990, 1996-1998

11/2007-2010

VII. SERVICE

29. University of Miami Committee and Administrative Responsibilities:

29a. Administrative responsibilities

 Director
 04/2012 - 06/2015

 Interim co-Director
 04/2008 - 11/2008

 Interim co-Director
 07/2004 - 12/2006

Division of Biostatistics,

Sylvester Biostatistics and Bioinformatics Shared Resource

Sylvester Comprehensive Cancer Center

Leonard M. Miller School of Medicine, University of Miami

Member of the Curriculum Committee for MPH and Ph.D. Programs,

29b. Standing Committees

Member of the UM/Sylvester Data and Safety Monitoring Committee 2013 - present

Alternate member of the UM/Sylvester Data and Safety Monitoring Committee 2004– 2012

Alternative member of the UM/Sylvester Protocol Review Committee 2012– 2018

Member of the UM/Sylvester Protocol Review Committee 1999 – 2012

Department of Epidemiology and Public Health.

Affiliated member of the UM/Sylvester Biobehavioral Oncology and Cancer Epidemiology (BOCE) research program 2007-2009, 2011-present

Affiliated member of the UM/Sylvester

2013-present

Cancer Epidemiology and Prevention (CEP) research program

29c. Ad Hoc Committees

Participation in the 2017 accreditation of the Epidemiology Doctoral **Program of the Department of Public Health Sciences (PHS)**

2017

Participated as a faculty member and course instructor.

Participation in the 2014 accreditation of the academic programs of the Department of Public Health Sciences (PHS) Participated as a faculty member and course instructor.

2013/2014

Faculty Advisor for the Public Heath Student Association

2010 - 2011

Department of Epidemiology and Public Health

Reviewer Committee Member of grant applications to the

11/2010

"2010 Sylvester Pap Corps Cancer Health Disparities Pilot Grants Competition" Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine

Participation in the 2006 accreditation of the academic programs of the Department of Epidemiology and Public Health

2006

Participated as a faculty member and course instructor.

Faculty Peer Evaluations

2004, 2006, 2009, 2010

Department of Epidemiology and Public Health (DEPH)

Member, Committee for Ph.D. Biostatistics Comprehensive Exam

2005-09, 2011-2019

Department of Public Health Sciences (PHS)

Member, **Search Committee** for Chief of Biostatistics Division Department of Epidemiology and Public Health (DEPH)

2004-2005

Member, MPH and Ph.D. Curriculum Committee Department of Epidemiology and Public Health (DEPH) 2000-2002

Member. Information and Technology Committee

2000-2003

Department of Epidemiology and Public Health (DEPH)

30. Community Activities: Participant of activities in the following organizations

Fraternidade PAX Universal (Brotherhood for Universal Peace) 1996-present A non-profit, metaphysical organization in São Paulo, Brazil, that exists for 22 years to gather people to meditate for Universal Peace and Healing, with the objective of awakening people's consciousness for the Third Millennium.

Theosophical Society, member at large Miami-Dade Blavatsky Theosophical Lodge (http://www.logiablavatsky.com)

2000-present 2002-present

The Theosophical Society, founded in 1875, is a worldwide body whose primary object is "Universal Brotherhood based on the realization that life, and all its diverse forms, human and non-human, is indivisibly One". The Society imposes no belief on its members, who are united by a common search for Truth and desire to learn the meaning and purpose of existence through study, reflection, self-responsibility and loving service. Theosophy is the wisdom underlying all religions when they are stripped of accretions and superstitions. It offers a philosophy which renders life intelligible and demonstrates that justice and love guide the cosmos. Its teachings aid the unfoldment of the latent spiritual nature in the human being, without dependence. The Society is composed of students belonging to any religion or to none. Its members are united by their approval of the Society's Three Objects, by their wish to remove religious antagonisms and to draw together people of goodwill whatsoever their religious opinions, and by their desire to study religious truths and to share the results of their studies with others. Theosophists respect the different beliefs. They see each religion as an expression of the Divine Wisdom, adapted to the needs of a particular time and place.

Headquarters: Chennai, Madras, India (<u>www.ts-adyar.org</u>); In USA: The Theosophical Society in America (<u>http://www.theosophical.org</u>).