2025 Summer Student Research Program
Project Description

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PROJECT TITLE (200 Characters max):

Long-Term Cohort Project Studying Drug Users and Related Groups

HYPOTHESIS:

1) ***Our long-term cohort project is uniquely suited to examining patterns of drug use and long-term outcomes (such as cancer and end stage liver disease), as well as the dynamics of the HIV and HCV epidemics, among adult drug users, using subject-level data.***
2) ***These baseline data, such as medical and behavioral factors and biomarkers, as well as new biomarker and genomic data, are predictive of specific health and vital status outcomes.***
3) ***Over 1800 persons (>18%) were studied on two or more occasions using comparable questionnaires, enabling assessment of changes over time in the factors ascertained, etc.***

PROJECT DESCRIPTION **(Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)**

Clients enrolled in drug treatment programs (including medication-assisted treatment programs) suffer from a variety of disadvantages and medical issues, including access to care, complications from infectious agents, and drug-related problems such as overdoses. We have developed an expanding interdisciplinary team of faculty co-investigators, both within and outside of Rutgers, and senior drug treatment program staff to embark on a set of endeavors. Our past cohort studies included systematic administered interviews of treatment program clients using an extensive structured interview we developed asking about their demographics; behaviors; patterns of drug abuse, including opioids, cannabis, other classes of drugs, alcohol and tobacco; and sexual behavior. In study subsets, issues such as drug overdose and treatment of hepatitis C virus (HCV) and of HIV have been explored in detail. We have documented high rates of infection with hepatitis C. Beyond the epidemiology, the health policy and system implications are being explored.

In 2020, we received an R01 grant from the National Institute on Drug Abuse, which we anticipate will extend through at least June 2026, to obtain and analyze a large amount of additional outcomes data on these cohorts. Our analytic framework has also expanded to include genomic data derived from stored specimens from our biorepository.

Current novel findings from our past studies include the association of specific drugs such as tobacco and cannabis with lung cancer; a picture of long-term mortality due to liver failure; the epidemiology and impact of infection with HCV and HIV, occurrence of overdoses, and health issues among male and female drug users with a focus on chronic diseases such as cancer, including hepatocellular carcinoma and lung cancer.

From 2016-2019 we enrolled 325 drug users (308 of whom had not been enrolled in our previous sub-studies) to examine in detail some highly relevant current issues, methadone dosage over a prolonged period of time, their use of opioids during and out of treatment, racial/ethnic disparities including patterns of drug use and ages of initiation, and comorbidities such as type II diabetes mellitus and obesity, measures of social vulnerability, and hepatitis C virus infection. This study is helping to

provide the basis for our initial exploration of some of the new types of data we have been acquiring through our registry matching efforts.

We have also engaged with the drug treatment programs on developing innovative ways to access their detailed treatment records over time. For example, we have been able to ascertain serial methadone dose — in some people over a period exceeding a decade. We have also been examining their use of various prescription controlled substances in recent years. Some of the structuring and analysis of these data involves programming using such tools as Python, SQL and SAS. Other software that has proven useful at times has included Excel, REDCap, Qualtrics, R, and OpenEpi. For the most part, we have relied upon expert collaborators regarding the use of genomic software.

This project complements and builds upon the national prospective cohort project that Dr. Weiss designed in the mid 1980's while he was at the National Cancer Institute (NCI), plus more recent studies, which totaled about 11,400 enrollments from over 10,100 persons nationally, of whom 9,800 had opioid use disorder, and >2,600 were from NJ. The overall study now has over 192,400 person-years of follow-up, with over 50,600 person-years among the NJ subjects. He joined the NJMS faculty in 1987. The project has substantial accumulated medical, laboratory and questionnaire data, plus a linked biospecimen repository of about 100,000 vials. The follow-up periods for these initial studies now exceed 30 to 40 years, with extensive baseline databases. These constitute the only large cohort study of adults with high rates of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infection within New Jersey, and furthermore included both men and women and a diverse racial/ethnic mix from the start. In September 2012, in the largest material transfer from NIH in the history of UMDNJ (RBHS's predecessor as a separate institution), the majority of the biospecimen repository, that is, 82,962 vials, were transferred from NCI to Dr. Weiss, supplementing other specimens already held here. Linkage and personal identifying data are known to us. Collaborations have been renewed with many of the original treatment programs and with the NJ Department of Health and the NJ State Cancer Registry, with administrative approvals obtained to repeat various types of registry matching studies to ascertain long-term outcomes.

The National Institute on Drug Abuse (NIDA) and we are collaborating on a broad array of studies of diseases and conditions, including various chronic diseases and cancers, drug addiction, tobacco use, etc., and effective therapeutic dose of opioid agonists (e.g., methadone) and partial agonists (e.g., buprenorphine). Our colleagues are already involved in analyses with us both using GWAS approaches (as part of the NIDA Genetics Consortium, of which Dr. Weiss is an active member) and the use of artificial intelligence algorithms on supercomputing platforms to examine more sophisticated approaches. Due to the complexity of the genomics work, we do not anticipate that any student will be directly involved in those analyses at this juncture; however, they may assist us in developing carefully vetted datasets on specific outcomes for exploratory analysis, risk factor analyses, and collaboration with our genetic epidemiologists.

To ascertain outcomes through linkages to existing databases, we have completed a match to the National Death Index-Plus (NDI-Plus), and are collaborating with the NJ State Cancer Registry (NJSCR) and the Virtual Pooled Registry Cancer Linkage System (VPR-CLS, a new nationally designed consortium of state cancer registries) to ascertain all incident cancers. As part of our review and exploration of matches, we routinely obtain supplemental information from the SSDI through Ancestry.com to obtain or verify vital status updates and explore selected subject characteristics. Renewed matching is also anticipated to occur soon again to the NJDOH state-wide New Jersey HIV/AIDS registry. Relevant analyses are ongoing. Our matching to the NDI is likely to be updated.

No student will be involved with any wet laboratory work. Nevertheless, by way of background, technology has been evolving over the decades, with laboratory analyses becoming possible on minute

amounts of stored material. Genomic tests have been validated on our stored samples, including serum, plasma, and lymphocytes. Other lab analyses need to be validated on our samples prior to embarking on large-scale studies. Multiple laboratory-based investigators have expressed interest, and opportunities to do laboratory-based work and related analyses will be evolving in future years. For example, a possible future initiative could be studying metabolomics using our biospecimens, which might include ~4000 compounds such as cannabinoid and nicotine metabolites, either collaboratively or if additional grant resources are obtained.

Most members of these cohorts have a history of injection drug use, so the rates of HIV, HTLV-II, and hepatitis C virus (HCV) infection among them are all quite high. Thus, these data have the potential to be a rich resource for finding predictors of mortality due to these infectious agents – such as hepatocellular carcinoma, HCV-associated liver failure and HIV-associated issues. The prevalence of use of tobacco and cannabis, among other drugs, is also very high. Among our most frequent causes of death are lung cancer and overdoses.

Dr. Weiss was responsible for first detecting and demonstrating an epidemic of HTLV-II in drug users. He also demonstrated immunologic abnormalities associated with HTLV-II, and played an integral role in the FDA's decision to screen blood donors for HTLV-II. The long-term medical effects of HTLV-II, if any, remain to be determined. These cohorts will provide new epidemiologic information about HTLV-II as well as many other infectious agents.

Data were assembled over the last 40+ years from this study using questionnaires and other data collection forms designed by Dr. Weiss and his collaborators. In the approximately four decades since these studies were initiated, advances and standardization of data elements and their design have occurred to facilitate inter-institutional laboratory studies.

In general, a major focus for research activity will be preparation, management, and analysis of both existing and newly acquired outcomes data, especially vital status, patterns and causes of mortality, and cancer, in our cohort studies. The status of the various matches noted above will play a role. Our expectation is that the major foci of work on this cohort project in the 2025 SSRP will be on (1) continued adjudication of matched data received from registries, an endeavor that requires understanding, combining, and critical assessment of data from several sources, (2) analysis of outcomes data from these cohorts, and (3) assisting us in the development of manuscripts publishable in peer-reviewed journals. The detailed specific summer project based upon our many initiatives and very long-term prospective cohort study, with an appropriate timeline for summer research, will be developed with the student based upon her/his past experience, training, and interests.

Dr. Daniel M. Rosenblum, Assistant Professor, will also provide key mentorship on the project, and has been working full time with Dr. Weiss for over 20 years. Depending on the student's interests and project specifics, Dr. Jill A. Rabinowitz, Assistant Professor, Department of Psychiatry, Robert Wood Johnson Medical School, may provide additional mentorship or oversight. There are also many collaborators from the NJSCR, Rutgers Cancer Institute, the Rutgers Addiction Research Center, and other Rutgers faculty, and several outside collaborators who are integral to current initiatives, who may assist with mentorship as appropriate.

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SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

Journal Publications (selected):

- ***Saxena J, Chilakapati R (NJMS Class of 2024), Attia P (NJMS Class of 2026), Rosenblum DM, Weiss SH. Body Mass Index Trends among a Cohort of Subjects Enrolled in Medication Assisted Treatment Programmes for Opioid Use Disorder: Racial/Ethnic, Gender, and Age Differences. Journal of Food Nutrition and Metabolism (ISSN 2674-2411) 5(1). 2022. PMID 38370009. PMCID PMC10871669. doi: http://dx.doi.org/10.31487/j.JFNM.2022.01.01.***
- ***Garvin MR, Rosenblum DM, Kainer D, Bergen AW, Climer S, Goedert JJ, Attia PJ, Sullivan K, Gaddis NC, Johnson EO, Jacobson DA, Weiss SH. Genetic Loci Associated with Cocaine Use Identified using Novel Approach to Detect Epistasis.***
- ***Attia PJ, Bergen AW, Rosenblum DM, Rabinowitz JA, Weiss SH. Identification of Optimal Methadone Dose in Patients Receiving Medication Assisted Treatment in New Jersey Based Programs. In preparation for submission to Journal of Substance Use and Addiction Treatment***
- ***Agrawal R (NJMS Class of 2023), Rosenblum DM, Attia PJ (NJMS Class of 2026), Pyrsopoulos NT, Weiss SH. Hepatitis C Virus (HCV) in Non-Injection Drug Users. (Under review, 2024).***
- ***Several other manuscripts are expected to be submitted shortly.***
- ***Weiss SH, Ahuja Sonali (NJMS Class of 2022): F1000Prime Recommendation of [Shover CL et al., Proc Natl Acad Sci USA 2019 116(26):12624-12626]. In F1000Prime, 07 Aug 2019;* DOI 10.3410/f.735955392.793563337 *. Commentary on: Association between medical cannabis laws and opioid overdose mortality has reversed over time.***
- ***Weiss SH, Skurnick J, Zhao C, Henrard D. Mortality due to hepatic failure among a cohort of injection drug users: a preliminary report from the United States. Workshop on viral hepatitis and HIV infections. Anales de Medicina Interna Octubre:57-58, 1995.***
- ***Hisada M, Chatterjee N, Kalaylioglu Z, Battjes RJ, Goedert JJ. Hepatitis C virus load and survival among injection drug users in the United States. Hepatology 42:1446-1452, 2005.***
- ***Hisada M, Chatterjee N, Zhang M, Battjes RJ, Goedert JJ. Increased Hepatitis C Virus load among injection drug users infected with Human Immunodeficiency Virus and Human T Lymphotropic Virus Type II. The Journal of Infectious Diseases 188:891–7, 2003.***
- ***Goedert JJ, Fung MW, Felton S, Battjes RJ, Engels EA. Cause-specific mortality associated with HIV and HTLV-II infections among injecting drug users in the USA. AIDS 15:1295-1302, 2001.***
- ***Briggs NC, Battjes RJ, Cantor KP, Blattner WA, Yelin FM, Wilson S, Ritz AL, Weiss SH, Goedert JJ. Seroprevalence of human T cell lymphotropic virus type II infection, with or without human immunodeficiency virus type 1 coinfection, among US intravenous drug users. The Journal of Infectious Diseases 172:51-58, 1995.***
- ***Cantor KP, Weiss SH, Goedert JJ, Battjes RJ. HTLV-I/II seroprevalence and HIV/HTLV coinfection among U.S. intravenous drug users. Journal of the Acquired Immune Deficiency Syndromes 4:460-467, 1991.***
- ***Wiktor SZ, Jacobson S, Weiss SH, Shaw GM, Reuben JS, Shorty VJ, McFarlin DE, Blattner WA. Spontaneous lymphocyte proliferation in HTLV-II infection. Lancet 337:327-328, 1991.***
- ***Wang RY-H, Grandinetti T, Shih JW-K, Weiss SH, Haley CL-D, Hayes MM, Lo S-C. Mycoplasma genitalium infection and host antibody immune response in patients infected by HIV, patients attending sexually transmitted diseases (STD) clinics and in healthy blood donors. FEMS Immunology and Medical Microbiology 19:237-245, 1997.***
- ***Caussy D, Weiss SH, Blattner WA, French J, Cantor KP, Ginzburg H, Altman R, Goedert JJ. Exposure factors for HIV-1 infection among heterosexual drug abusers in New Jersey treatment programs. AIDS Research and Human Retroviruses 6:1459-1467, 1990.***
- ***Beretta A, Weiss SH, Rappocciolo G, Mayur R, Cosma A, De Santis C, Quirinale J, Robboni P, Shearer GM, Berzofsky JA, Villa ML, Siccardi AG, Clerici M. Seronegative intravenous drug users at risk for HIV exposure exhibit antibodies to HLA class I antigens and T-cells specific for HIV envelope. The Journal of Infectious Diseases 173(2):472-476, 1996. (Cited in April 29, 1996 issues of Blood Weekly and of Vaccine Weekly.)***
- ***Heredia A, Joshi B, Weiss SH, Lee SF, Muller J, Poffenberger KL, Quirinale J, Epstein JS, Hewlett IK. Absence of evidence of retrovirus infection in intravenous drug users with idiopathic CD4+ lymphocytopenia. The Journal of Infectious Diseases 170:748-749, 1994.***

- ***Weiss SH, Klein CW, Mayur RK, Besra J, Denny TN. Idiopathic CD4+ T-lymphocytopenia. Lancet 340:608-609, 1992.***
- ***Weiss SH, Goedert JJ, Sarngadharan MG, The AIDS Seroepidemiology Collaborative Working Group, Gallo RC, Blattner WA. Screening test for HTLV-III (AIDS agent) antibodies: specificity, sensitivity and applications. The Journal of the American Medical Association 253:221-225, 1985.***
- ***Weiss SH, Cowan EP. Laboratory detection of human retroviruses. In: AIDS and Other Manifestations of HIV Infection, 4th edition, ed. Gary P. Wormser, Elsevier Science, London. Chapter 8, pp. 147-183, 2004.***
- ***Robert-Guroff M, Weiss SH, Giron J, Jennings AM, Ginzburg HM, Margolis I, Blattner WA, Gallo RC. Prevalence of antibodies to HTLV-I, -II, and -III in intravenous drug abusers from an AIDS endemic region. The Journal of the American Medical Association 255:3133-3137, 1986.***

Recent Abstracts:

- ***Garvin MR, Rosenblum DM, Kainer D, Bergen AW, Climer S, Goedert JJ, Attia PJ, Sullivan K, Gaddis NC, Johnson EO, Jacobson DA, Weiss SH. Genetic Loci Associated with Cocaine Use Identified Using Novel Approach to Detect Epistasis. Presented at the NIDA Genetics and Epigenetics Cross-Cutting Research Team Meeting, May 23-24, 2024, NIH Campus, Bethesda, MD.***
- ***Attia PJ, Bergen AW, Rosenblum DM, Rabinowitz JA, Weiss SH. Demographic and Social Determinants of Methadone Dose and Treatment Outcomes Among Patients Receiving Medication Assisted Treatment in New Jersey Based Programs. Accepted for presentation as poster at the NIDA Genetics and Epigenetics Cross-Cutting Research Team Meeting, March 2025, NIH Campus, Bethesda, MD.***
- ***Garvin MR, Rosenblum DM, Bergen AW, Weiss SH. Long-read sequencing identifies CYP2D6 haplotype associated with frequent cocaine use. Accepted for presentation as poster at the NIDA Genetics and Epigenetics Cross-Cutting Research Team Meeting, March 2025, NIH Campus, Bethesda, MD.***
- ***Garvin MR, Rosenblum DM, Bergen AW, Kainer D, Climer S, Rabinowitz JA, Goedert JJ, Sullivan KA, Gaddis NC, Giamberardino S, Johnson EO, Jacobson DA, Weiss SH. Biologically-driven epistasis - an innovative new approach for genetic analyses of addiction. Accepted for presentation as poster at the NIDA Genetics and Epigenetics Cross-Cutting Research Team Meeting, March 2025, NIH Campus, Bethesda, MD.***
- ***Bergen AW, Attia PJ, Rosenblum DM, Rabinowitz JA, Weiss SH. Stable Methadone Dose, Toxicology & Treatment Retention in New Jersey Medication-Assisted Treatment Programs. Submitted for presentation at the NIDA Genetics and Epigenetics Cross-Cutting Research Team Meeting, May 23-24, 2024, NIH Campus, Bethesda, MD.***
- ***M O'Shaughnessy, R Chilakapati, J Goedert, N Pyrsopoulos, DM Rosenblum, SH Weiss, Hepatocellular Carcinoma: Long Latency and Short Survival among Persons Who Inject Drugs in a Large, Long-Term Prospective Cohort, American Public Health Association 2020 Annual Meeting and Exposition (Epidemiology program), Virtual (Session 2057.0, Cancer Epidemiology), October 2020.***
- ***SH Weiss, DM Rosenblum, A Brooks, C Bixby, C Hevi, EO Johnson. Successful Illumina Array Genotyping on Serum Stored For Three Decades. 2020 NIDA Genetics Consortium Meeting at NIDA headquarters, 6001 Executive Blvd, Rockville, MD, January 13-14, 2020.***
- ***MN Fahmy, DM Rosenblum, SH Weiss. Drug Use Patterns by Education and Employment Status among New Jersey Methadone Maintenance Clients. American Public Health Association 2019 Annual Meeting and Exposition (Alcohol, Tobacco and Other Drugs Section program), Philadelphia, PA (Session 3327.1, Opioid Use Disorders: A Roundtable of Compelling, Conversations).***
- ***DM Rosenblum, N Pyrsopoulos, R Wolferz, B Biondi, A Kurland, J Connor, SH Weiss. Is curative therapy for infection with hepatitis C virus (HCV) reaching infected drug users? American Public***

Health Association 2017 Annual Meeting and Exposition (Epidemiology program), Atlanta, GA, Nov 8, 2017 (oral).

- ***R Wolferz, A Kurland, DM Rosenblum, A Mittal, M Pulaski, E Bahrami, J Lomuti, M Fahmy, E Zerbo, M Jaker, SH Weiss. Are current drug treatment programs successful in preventing drug overdoses? American Public Health Association 2017 Annual Meeting and Exposition (Epidemiology program), Atlanta, GA, Nov 8, 2017 (oral).***
- ***R Wolferz, DM Rosenblum, N Pyrsopoulos, A Kurland, M Pulaski, SH Weiss. A minority of drug users infected with the hepatitis C virus have received curative treatment. American Public Health Association 2017 Annual Meeting and Exposition (Medical Care section), Atlanta, GA, Nov 6, 2017.***
- ***NT Pyrsopoulos, DM Rosenblum, J Connor, R Wolferz, A Kurland, M Pulaski, P Patel, SH Weiss. HCV-infected persons in the USA: Identification, current treatment needs, and obstacles to care. American Association for the Study of Liver Diseases (AASLD), The Liver Meeting®, Washington, DC, Oct 20-24, 2017.***
- ***Savan Kabaria, Jessica Connor, Breanne E. Biondi, Matt Pulaski, Daniel M. Rosenblum, Stanley H. Weiss. Human T-Cell Lymphotropic Virus Type II Infection Is Associated with Increased Medical Mortality in a National Long-term Cohort of Injection Drug Users. 14th Annual AMA Research Symposium – Medical Student Section. Walt Disney World Swan and Dolphin Resort, Orlando, Fla. Nov 11, 2016. (Mr. Kabaria is NJMS Class 2019.)***
- ***SH Weiss, BE Biondi, Antoinette Stroup, Sumathy Vasanthan, Karen Pawlish, Daniel M. Rosenblum. Hepatocellular carcinoma in a 30-year prospective cohort study of 2200 HCV-infected adults. Abstract #362311. 144th American Public Health Association Annual Meeting & Expo, Denver, Oct. 29 - Nov. 2, 2016.***
- ***Breanne E. Biondi, Sumathy Vasanthan, Anita Thomas, Karen Pawlish, Daniel M. Rosenblum, Arjun Gupta, Antoinette Stroup, Stanley H. Weiss. Methodological issues in matching cohorts to registry data: results from a large, long-term, prospective study. 4th Epidemiology Congress of the Americas, Miami, FL, June 21-24, 2016.***

Past Relevant Student Summer Projects:

- ***Gurrala A (NJMS 2027), Breast Cancer Disparities in a 40-Year Prospective Cohort of Persons with Opioid Use Disorder (OUD) from New Jersey, 2024***
- ***Gurrala A (NJMS 2027), Prostate Cancer Disparities in a 40-Year Prospective Cohort of Persons with Opioid Use Disorder (OUD) from New Jersey, 2024***
- ***Vaydovsky BR (NJMS 2027), Lung Cancer Disparities in a 40-Year Prospective Cohort of Persons with Opioid Use Disorder (OUD) from New Jersey, 2024***
- ***Allen WE (NJMS 2025), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2021***
- ***Patel S (NJMS 2025), Long-Term Cohort Studies of Drug Users and Related Groups, 2021***
- ***Berkowitz DP (NJMS 2024), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2021***
- ***Choi JH (NJMS 2024), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2021***
- ***Parikh P (NJMS 2024), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2021***
- ***Randhawa A (NJMS 2024), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2020***
- ***Truong TM (NJMS 2023) , Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2020***
- ***Agrawal R (NJMS 2023) , Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2020***
- ***Adedipe OO (NJMS 2023) , Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2020***

- ***Chilakapati R (NJMS 2024), Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs, 2020***
- ***O'Shaughnessy MG (NJMS 2022). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Ahuja S (NJMS 2022). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Karajgikar RM (TCNJ/NJMS 2022/2025). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Agrawal PV (NJIT/NJMS 2022/2025). Cohort Studies of Drug Users and Related Groups 2019.***
- ***Tang NC (TCNJ/NJMS 2022/2025). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Chen K (TCNJ/NJMS 2022/2025). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Patel R (TCNJ 2021). Cohort Studies of Drug Users and Related Groups. 2019***
- ***Patel SM (NJMS 2021). Studies of Drug Users and Related Groups. 2018***
- ***Chilakapati R (TCNJ/NJMS 2021/2024). Studies of Drug Users and Related Groups. 2018***
- ***Randhawa A (TCNJ/NJMS 2021/2024). Studies of Drug Users and Related Groups. 2018***
- ***Muenzen RM (NJMS 2020). Studies of Drug Users and Related Groups. 2017***
- ***George LC (NJMS 2020). Studies of Drug Users and Related Groups. 2017***
- ***Peddireddy S (TCNJ/NJMS 2020/2023). Studies of Drug Users and Related Groups. 2017***
- ***Patel J (TCNJ/NJMS 2020/2023). Studies of Drug Users and Related Groups. 2017***
- ***Kabaria S (NJMS 2019). Follow-up of Long-Term Prospective Cohort Studies of Injection Drug Users and Related Groups. 2016***
- ***Connor JA (NJMS 2019). Follow-up of Long-Term Prospective Cohort Studies of Injection Drug Users and Related Groups. 2016***
- ***Pulaski MR (NJMS 2019). Current issues among New Jersey drug users. 2016***
- ***Kaushal N (NJMS 2019). Cancer Outcomes in The Long-Term Prospective Weiss Cohort Studies: New Jersey Cohorts. 2015.***
- ***Eltoukhy H (NJMS 2015). Characterization of Two Prospective Cohorts for their Use in a Bio-Specimen Repository at NJMS. In: 2011 Summer Student Research Abstracts, New Jersey Medical School, pp. 13-17.***
- ***Knox KR (NJMS 2003). Comparison of Cancer Incidence in HIV+ and HIV- Injection Drug Users: 15-Year Follow Up of a Cohort Study. New Jersey Medical School Summer Student Research Abstracts 2001; Abstract # 35.***

THIS PROJECT IS: ☒**Clinical** ☒**Laboratory** ☒ **Behavioral** ☐ **Other**

THIS PROJECT IS CANCER-RELATED☒
Please explain Cancer relevance

- ***A major emphasis is currently on the detailed examination of our lung and liver cancer and other outcome data.***
- ***The ongoing follow-up in conjunction with the NJ State Cancer Registry and Virtual Pooled Registry Cancer Linkage System and matches to the NJ AIDS/HIV registry will enable us to assess risk factors for cancer and progression in these well-defined cohorts, and understand aspects of the AIDS epidemic over three decades.***
- ***Hepatitis C virus (HCV) infection (which a study drawn from these cohorts was the very first to demonstrate is highly prevalent in injection drug users) is a major cause of hepatocellular carcinoma with a latency on the order of decades. Better understanding of biomarkers in HCV-infected individuals that are correlated with occurrence of hepatocellular carcinoma can lead to more effective use of medical resources to prevent this cancer. Another key outcome is end stage liver failure.***
- ***HIV infection is linked with specific types of cancers.***

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED☒
Please explain Heart, Lung, Blood relevance

- ***A major emphasis is currently on the detailed examination of our lung cancer outcome data.***
- ***Specimens that have been collected and that could be examined for biomarkers include sera, plasma, urine, Ficoll-hypaque purified lymphocytes, and EBV-transformed cell lines, and viral isolates.***
- ***Data from these studies were instrumental in the decision by the US FDA that all blood products be screened for HTLV-II. The demonstration that these retroviruses were highly prevalent in these***

specimens helped lead to setting the early policies in the state of NJ concerning testing for HIV, and on the FDA's approach to test licensing. The results from this study will be relevant to U.S. screening practices of potential blood donors.

THIS PROJECT INVOLVE RADIOISOTOPES? ☐

THIS PROJECT INVOLVES THE USE OF ANIMALS ☐
PENDING ☐ **APPROVED** ☐ **IACUC PROTOCOL #**

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS? ☒
PENDING ☒ **APPROVED** ☒ **IRB PROTOCOL # Pro20150001314, Pro20160000704 (both approved)**

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS	☐	ENTERING FRESHMAN	☐
SOPHOMORES	☐	ALL STUDENTS	☒

THIS PROJECT IS WORK-STUDY: **Yes** ☒ **or** **No** ☐

THIS PROJECT WILL BE POSTED DURING ACADEMIC YEAR FOR INTERESTED VOLUNTEERS: **Yes** ☒ **or** **No** ☐

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

- ***Receive training in confidential study procedures.***
- ***How to critically assess medical records and outcomes data.***
- ***Learn how to function as part of an interdisciplinary research team.***
- ***Strategies for efficient use of health data.***
- ***How to approach the analysis of datasets.***
- ***How to design follow-up analyses in cohort studies, such as nested-case control designs.***
- ***How to develop and analyze statistical models for the epidemiologic analysis of outcomes.***
- ***How to perform critical and systematic assessment of methodologies, and their practical applications.***
- ***How critical assessment of findings can lead to changes in approach or implementation.***
- ***How to understand and utilize power calculations in setting project objectives and goals that appear feasible.***

CRITICAL PRIOR EXPERIENCE AND SKILLS

- *Prior experience in performing data analysis and in using data analysis software, especially SAS, is REQUIRED to perform independent analyses; there is insufficient time during the summer period to newly learn and become expert in SAS programming and to perform new data analyses on the considerable new data we are continually receiving. (In our experience, the time to become proficient in SAS requires too much effort to be tenable during a summer research experience.)*
- *Prior experience with software such as MS Excel and the Microsoft Office Suite is REQUIRED, and this software can be used to help compile and examine new data and perform limited analyses under direction, especially by those students without SAS expertise.*
- *A student with extensive experience in using and analyzing genomic data may be able to assist in other specialized ongoing analyses.*
- *Excellent written and communication skill is REQUIRED.*

- *Excellent interpersonal skills conducive to working in an interdisciplinary team environment, including an ability to be proactive in obtaining assistance.*
- *Human subjects protection training and certification through the Rutgers-specified CITI course for Social, Behavioral, and Epidemiologic Research Investigators. (See Collaborative Institutional Training Initiative (CITI) \| Rutgers Research for details.) Completion of training culminating in certification will be REQUIRED at least **6 weeks prior** to starting, to give adequate time to be added to our current IRB protocol(s).*

USEFUL ADDITIONAL RELEVANT PRIOR EXPERIENCE AND SKILLS

(Note: Only some of these skills are requisite for a specific project. However, some skill(s) are important to enable getting a jump-start.)

- *Prior experience working on a research team.*
- *Prior experience in interpreting research data.*