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PROJECT TITLE (200 Characters max):

Study of Drug Users Currently Enrolled in NJ Methadone Treatment Programs

HYPOTHESES:

- 1) Our new studies that were begun in summer 2016 will reveal community-level dynamics relevant to public policies.
- 2) We shall examine the genetics of methadone dose as well as of other drugs
- 3) The medical and behavioral factors and new biomarker data are predictive of specific health and vital status outcomes.

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

We received funding in 2018 from the National Institute on Drug Abuse (**NIDA**) to begin a new project investigating the association of genetic and other biological factors with methadone maintenance treatment dose. This complements our prior initiatives in this area.

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 and senior drug treatment program staff to embark on a set of endeavors. Current program clients will be interviewed at NJ drug treatment programs using an extensive structured interview we developed asking about their demographics, behaviors, and attitudes, with particular foci on: hepatitis C infection and the availability and barriers to treatment for hepatitis C; issues related to drug overdoses; patterns of drug abuse, including alcohol and tobacco; and nutrition. We have documented low rates of treatment for hepatitis C, in the face of continuing high rates of infection. Beyond the epidemiology, the health policy and system implications are being explored.

The above project complements and builds upon several national prospective cohort studies that Dr. Weiss designed in the mid 1980's while he was at the National Cancer Institute (NCI), which totaled about 11,084 enrollments from over ~10,000 different persons nationally, including ~2,500 from NJ. He joined the NJMS faculty in 1987. These studies have substantial accumulated medical, laboratory and questionnaire data, plus a linked biospecimen repository of over 100,000 vials. The follow-up period is >30 years, with an extensive baseline database. 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 legacy UMDNJ history, 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 are being renewed with many of the original treatment programs and with the NJ Department of Health and the NJ State Cancer Registry. Preliminary, detailed sample size calculations incorporating estimates of various outcome measures have

already been performed. Planning for the judicious use of these repository samples and data sets has begun.

NIDA has agreed to analyze biospecimens from our subjects, ascertaining the presence or absence of ~800,000 single nucleotide polymorphisms (**SNP**s, that is, genetic variants) that may affect risk for a broad array of diseases and conditions, including various chronic diseases and cancers, drug addiction, tobacco use, etc. We anticipate analyses both using GWAS approaches (as part of the NIDA Genetics Consortium, of which Dr. Weiss is a member) as well as creating polygenic risk models when examining disease outcomes.

Current novel findings from our past studies include a picture of long-term mortality due to liver failure, the association of specific drugs such as tobacco and cannabis with lung cancer, 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.

The detailed specific project based upon our new field initiatives, with an appropriate timeline for a summer project, will be developed with the student based upon her/his past experience, training, and interests. Dr. Daniel M. Rosenblum, Assistant Professor, will also provide mentorship on the project.

It is anticipated that the student will be trained so as to interview subjects in the field, assist with the ongoing study endeavors, and participate in data analyses.

SPONSOR'S PUBLICATIONS MOST RELEVANT TO THIS RESEARCH:

Recent Abstracts:

- 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). https://apha.confex.com/apha/2019/meetingapp.cgi/Paper/436532. November 4, 2019.
- 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? <u>American Public Health Association</u> 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? <u>American Public Health Association 2017 Annual Meeting and Exposition (Epidemiology program)</u>, 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. <u>American Public Health Association</u> 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. <u>American Association for the Study of Liver Diseases (AASLD), The Liver Meeting®</u>, 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. <u>14th Annual AMA Research Symposium Medical Student Section</u>. 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:

- 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.

Journal Publications (selected):

- 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 <u>F1000Prime</u>, 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. <u>Anales de Medicina Interna</u> 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. <u>Hepatology</u> 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. <u>The Journal of Infectious Diseases</u> 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. <u>AIDS</u> 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. <u>The Journal of Infectious Diseases</u> 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. <u>Journal of the Acquired Immune Deficiency Syndromes</u> 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. <u>Lancet</u> 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. <u>FEMS Immunology and Medical Microbiology</u> 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. <u>AIDS Research and Human Retroviruses</u> 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. <u>The Journal of Infectious Diseases</u> 170:748-749, 1994.
- Weiss SH, Klein CW, Mayur RK, Besra J, Denny TN. Idiopathic CD4+ T-lymphocytopenia. <u>Lancet</u> 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: <u>AIDS and Other Manifestations of HIV Infection</u>, 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.

IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS? Yes Or No (IF YES, PLEASE SUPPLY THE GRANTING AGENCY'S NAME) National Institute on Drug Abuse Grant 1R01DA044014-01								
THIS PROJECT IS:	⊠Clinical	⊠ Laboratory	⊠ Behavioral	☐ Other				
THIS PROJECT IS CANCER-RELATED Please explain Cancer relevance:								
THIS PROJECT IS HEART, LUNG & BLOOD- RELATED Please explain Heart, Lung, Blood relevance:								
THIS PROJECT EMPI THIS PROJECT INVO PENDING	LVES THE USE	E OF ANIMALS	ACUC PROTOCOL#					
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(both approved), & Pro2019002287 (pending).

THIS PROJECT IS SUITABLE FOR: UNDERGRADUATE STUDENTS SOPHMORES	ENTERING FRESHMAN 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.
- Receive training in conducting in-person interviews using a written questionnaire.
- Develop comfort working with staff and subjects in novel outpatient settings.
- How to design follow-up analyses in cohort studies, such as nested-case control designs.
- Strategies for efficient use of health data.
- How to approach the analysis of datasets.
- 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.
- For those who include a laboratory based component, how to conduct lab analyses and assess results.

USEFUL RELEVANT PRIOR EXPERIENCE AND SKILLS

(\underline{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 with data analysis and data analysis software such as MS Excel; knowledge of more advanced software, such as SAS, would permit participation in complex data analyses.
- Prior fieldwork experience in urban areas, including client interviewing and/or administration.
- Excellent written and communication skills.
- Prior experience working on a research team.
- If interested in a lab-associated component: prior relevant lab experience.
- Human subjects protection training and certification through the Rutgers-specified CITI course for Social, Behavioral, and Epidemiologic Research Investigators. (See <a href="https://orangle.com/o
- Car and driver's license extremely helpful for this project, since it involves access to community sites, or else pairing with another research assistant who has such access.