

Summer 2017 Student Research Program  
Project Description

**FACULTY SPONSOR'S NAME AND DEGREE:** *Stanley H. Weiss, MD*

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**PROJECT TITLE (200 Characters max):**

## *Studies of Drug Users and Related Groups*

### **HYPOTHESES:**

- 1) *Our new studies begun in summer 2016 will reveal community-level dynamics relevant to public policies.*
- 2) *Our long-term cohorts are uniquely suited to examining the dynamics of the HIV and HCV epidemics among adult drug users.*
- 3) *Baseline data, such as medical and behavioral factors and biomarkers, as well as 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)

*Clients enrolled in drug 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. In 2016 we enlisted a team of faculty co-investigators and senior drug treatment program staff to embark on a new set of endeavors. Current program clients are being interviewed at NJ drug treatment programs using a comprehensive survey we developed. 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 10,066 persons. He joined the NJMS faculty in 1987. These studies have substantial accumulated medical, laboratory and questionnaire data, plus a linked biospecimen repository. In September 2012, in the largest material transfer from NIH in legacy UMDNJ history, over 82,000 vials were transferred from NCI to Dr. Weiss, supplementing other specimens already held here. Linkage and personal identifying data are known to us.*

*Beginning in 2016, collaborations were renewed with many of the original treatment programs and with the NJ Department of Health and the NJ State Cancer Registry.*

*Utilizing our linkage information and follow-up data, beginning in 2015 we matched 2,254 persons enrolled from NJ to the NJ State Cancer Registry (NJSCR). Future matching will include national databases (such as the National Death Index and the Social Security Administration database), and other state-wide databases (such as the New Jersey HIV/AIDS, Hepatitis C and tuberculosis registries). Relevant analyses are ongoing.*

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

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*Technology has been evolving over the decades, with laboratory analyses becoming possible on minute amounts of stored material. These tests need to be validated on our stored 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.*

*Dr. Weiss was responsible for 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.*

*The detailed specific project based upon these very long-term prospective cohort studies, 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, as may collaborators from the NJSCR and the Cancer Institute of NJ, and other Rutgers faculty.*

### **SPONSOR'S PUBLICATIONS MOST RELEVANT TO THIS RESEARCH:**

#### **Recent Abstracts:**

- *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 Student Summer Projects:**

- *Kabaria S (NJMS 2019). Follow-up of Long-Term Prospective Cohort Studies of Injection Drug Users and Related Groups.*
- *Connor JA (NJMS 2019). Follow-up of Long-Term Prospective Cohort Studies of Injection Drug Users and Related Groups.*
- *Pulaski MR (NJMS 2019). Current issues among New Jersey drug users.*
- *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, 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.*

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- 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 I 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, 4<sup>th</sup> 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)**

*Although the project is not currently supported by extramural funds, extramural support for some of the infrastructure supporting a project exists.*

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

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### THIS PROJECT IS CANCER-RELATED

#### Please explain Cancer relevance:

- *The ongoing follow-up in conjunction with the NJ State Cancer Registry will enable us to assess risk factors for cancer and progression in these well-defined cohorts.*
- *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.*
- *HIV and HTLV-I infection are linked with specific types of cancers.*
- *Beyond immunologic abnormalities, a health impact of HTLV-II remains to be determined. This project is uniquely suited to examine this issue due to the high prevalence of HTLV-II, plus the study's size and longevity.*

### THIS PROJECT IS HEART, LUNG & BLOOD- RELATED

#### Please explain Heart, Lung, Blood relevance:

*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 EMPLOYS RADIOISOTOPES

### THIS PROJECT INVOLVES THE USE OF ANIMALS

PENDING

APPROVED

IACUC PROTOCOL #

### THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS

PENDING

APPROVED

IRB PROTOCOLS #'s Pro20150001314, Pro20160000704

Each of these studies is also protected by a Certificate of Confidentiality issued by the National Institute of Drug Abuse in 2016.

### THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS   
SOPHOMORES

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?

- *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.*

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### **USEFUL 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 with data analysis and data analysis software such as MS Excel and SAS.*
- *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 [orra.rutgers.edu/citi](http://orra.rutgers.edu/citi) for details.)*
- *Car and driver's license (for projects involving access to community sites).*