Name: James David Dziura PhD, MPH

Proposed for Promotion to: Professor, Department of Emergency Medicine Investigator Track, with Secondary Appointments in Public Health (Biostatistics) and Internal Medicine (Endocrinology).

**Term:** *Primary Appointment*: beginning July 1, 2016

*Secondary Appointment*: July 1, 2016

**School Assignment:** Yale University School of Medicine and Graduate School

Reason for Promotion: Dr. Dziura, currently an Associate Professor in the Investigator Track is being recommended for promotion to Professor based on his outstanding contributions to research, his dedication to teaching and his administrative leadership roles as the Deputy Director of both the Yale Center for Analytical Sciences (YCAS) and the Yale Data Coordinating Center (YDCC). Dr. Dziura plays an integral part in the scientific development and conduct of multiple research projects at Yale.

Dr. Dziura has a strong and voluminous history of research activity in team science as an epidemiologist and biostatistician; he has collaborated on 167 peer-reviewed articles with faculty in the Yale School of Medicine. He has organized data coordinating and biostatistical efforts to secure several federal center/consortium grants for Yale, including the General Clinical Research Center renewals, the CTSA award and competing renewals, the Diabetes Research Center, the Liver Center, and the Autism Biomarkers Consortium for Clinical Trials. He also has been an integral member of over 15 NIH funded research studies including Emergency Medicine (Co-I for: Post R01, Bernstein R18 and R01, Vaca R01), Pediatrics (Co-I for Caprio R01s: Metabolic markers and predictors of childhood obesity, Pathophysiology of Type 2 diabetes in youth), Cardiology (Lampert R01s: Exercise and Genetics in HCM and LQTS; T-wave alternans and emotion in daily life), Endocrinology (Co-I for Insogna R01: Impact of protein on bone mass), Immunology (Co-I for Herold R01: Phase II randomized trial of HOKT3y 1 in Type I Diabetes,) and Nursing (Co-I for Scahill R01s: Randomized trial of parent training for young children with Autism; Behavior Therapy for Adults with Tourette Syndrome; Guanfacine in PDD). Dr. Dziura has been vital to the design, conduct and analyses of these studies, serving as the lead biostatistician and overseeing data coordinating efforts.

Dr. Dziura has also been dedicated to the training of Yale investigators in the fundamentals of research design and biostatistics. He created a graduate school course “Introduction to Biostatistics in Clinical Research” offered annually through the Investigative Medicine program. Over its 13 year run under his direction, the course has been well-received, enrolling 65-85 students (junior faculty, staff, medical and graduate students) per year. As a core faculty member for the Yale-Drug Abuse, Addiction, and HIV Research Scholars (Yale-DAHRS), he provides one-on-one instruction and mentorship in study design and analysis. He also developed a directed reading course for statistical/design topics related to substance abuse research for the scholars. In addition to training non-statisticians, Dr. Dziura dedicates a significant portion of his time training and mentoring statisticians in collaborative science. He taught an Introduction to Clinical Trials (Bis540a –fall 2014) and helped to initiate a new course in the Fall of 2011, “Statistical Consulting” for the School of Public Health. Dr. Dziura also created the YCAS Internship Program giving doctoral and master’s students in quantitative sciences the opportunity to engage in the design, conduct and analysis of real research projects.

Dr. Dziura’s contributions to team science are exemplified by his role in the creation and expansion of both the YCAS and the YDCC. YCAS, which was created in January of 2010 as a collaboration between the Yale Center for Clinical Investigation and the School of Public Health, serves as a biostatistical and epidemiologic resource for the medical campus. During its inception, Dr. Dziura negotiated partnerships with clinical departments (Emergency Medicine, Internal Medicine-pulmonology, Anesthesiology, Surgery, OB/GYN, Psychiatry) as well as centers (Cancer Center, Diabetes Research Center and Liver Center) and individual investigators to expand YCAS to meet the analytic needs of the medical campus. The center has grown from a group of 4 to 41 faculty and staff and now includes the clinicaltrials.gov compliance unit which Dr. Dziura oversees. YCAS is involved with developing over 90 grant proposals, consulting with over 400 investigators and publishing over 100 manuscripts annually. The YDCC was created by Dr. Dziura during his sabbatical (Fall 2013) as a partnership between the YCAS, Emergency Medicine, the Yale Program on Aging (POA) and the Yale Center for Medical Informatics (YCMI). It is composed of faculty from the School of Medicine and School of Public Health with expertise in biostatistics, epidemiology, clinical trials and informatics along with a highly trained technical staff skilled in systems programming, data management, data analysis and statistical programming. The YDCC is a vital component to conducting large multi-site studies at Yale. It currently leads the data coordinating efforts for several nationwide multicenter clinical studies including STRIDE and the ABC-CT. Dr. Dziura currently serves as Deputy Director for both YCAS and YDCC.

In summary, Dr. Dziura is an impressive collaborative scientist with a proven record of successful collaborations and notable contributions to the research infrastructure at Yale.

### Education: BS Bates College May 1993 MPH Yale School of Public Health May 1998

PhD Yale Graduate School of Arts and Sciences May 2001

**Career/Academic Appointments:**

2001-2002 Post-Doctoral Associate, John B. Pierce Laboratory, New Haven, CT

2002-2006 Associate Research Scientist, Department of Internal Medicine, General Clinical Research Center, New Haven, CT

2006-2011 Research Scientist, Department of Internal Medicine, Yale Center for Clinical Investigation, New Haven, CT

2011-present Associate Professor, Department of Emergency Medicine, Yale School of Medicine New Haven, CT

2011-present Secondary Appointment, Department of Internal Medicine (Endocrinology), Yale School of Medicine New Haven, CT

2014-present Secondary Appointment, Department of Biostatistics, Yale School of Public Health

**Administrative Positions:**

2006-present Manager, Biostatistics Support Unit, Yale Center for Clinical Investigation, New Haven, CT

2010-present Deputy Director, Yale Center for Analytical Sciences (Epidemiology and Public Health), New Haven, CT

2013-present Director, Clinicaltrials.gov Compliance Unit, New Haven, CT

2014-present Deputy Director, Yale Data Coordinating Center, New Haven, CT

**Professional Honors or Recognition:**

March 2016. Outstanding Referee, Academic Emergency Medicine.

February 2015. Outstanding Referee, Academic Emergency Medicine.

May 2013. “A Rapid Assessment to Predict ED Revisits, Hospital Admissions or Death at 30 Days Following ED Discharge in Older Individuals” Selected as Honorable Mention Poster at 2013 Annual Society for Academic Emergency Medicine conference.

March 2002. Selected by IASO as a participant in the 1st annual Stock Conference to discuss and answer the question, "How much physical activity is enough to prevent weight gain?"

**Grant history for last 12 years:**

**Current:**

Agency: NIH/NICHD

I.D.#: U19 MH108206

Title: Autism Biomarkers Consortium for Clinical Trials (ABC-CT)

P.I.: James McPartland, PhD

Percent Effort: 0.15 FTE

Role on Project: Director – Data Coordinating Core

Direct costs per year: $5,329,527

Total costs for project period: $34,081,680

Project period: 07/01/2015-06/30/2019

Agency: NIH/NHLBI

I.D.#: R01 HL125587 - 01A1

Title: PTSD, Sleep & Blood Pressure

P.I.: Matthew Burg, PhD

Percent Effort: 0.10 FTE

Role on project: Co-Investigator

Direct Costs per year: $499,666

Project period: 07/01/2015-06/30/2020

Agency: NIH/NIDA

I.D.#: 1R01DA041067-01

Title: Working with HIV Clinics to Adopt Addiction Treatments Using Implementation

Facilitation

P.I.: David Fiellin, MD

Percent Effort: 0.10 FTE

Role on project: Co-investigator Biostatistician

Direct Costs/year:  $297,113

Project period: 12/01/2015-11/30/2020

Agency: NIH/NHLBI

I.D.#: RO1 HL125918-01

Title: Exercise and Genetic Cardiovascular Conditions

P.I.: Rachel Lampert, MD

Percent Effort: 0.05 FTE

Role on project: Co-Investigator - Biostatistician

Total costs for project period: $1,346,137

Project period: 01/02/2015-2020/01/31

Agency: NIH/NIDA

I.D.#: 1R01DA035775-01A1

Title: A network analytic model of adherence and abstinence

P.I.: Steven Bernstein, MD

Percent Effort: 0.10 FTE

Role on project: Co-Investigator - Biostatistician

Direct costs per year: $148,625

Project period: 07/01/14-06/30/16

Agency: NIH/NIAAA

I.D.#: 1R01AA022083

Title: Automated Bilingual Computerized Alcohol Screening and Intervention in Latinos

P.I.: Federico Vaca, MD

Percent Effort: 0.05 FTE Yr1-5

Role on project: Co-Investigator - Biostatistician

Project period: 06/01/14-05/31/19

Agency: PCORI/NIA

I.D.#: 1U01AG048270-1

Title: Randomized Trial of a Multifactorial Fall Injury Prevention Strategy (STRIDE)

P.I.: Bhasin/Gill/Reuben

Percent Effort: 0.15 FTE

Role on project: Senior Biostatistician

Direct costs per year: $6,781,831

Total costs for project period: $30,000,000

Project period: 05/01/14 – 04/30/19

Agency: VA (HSR&D)

I.D.#:

Title: Women Veteran’s Cohort Study

P.I.: Haskell/Brandt/Mattocks

Percent Effort: 0.15 FTE

Role on project: Senior Biostatistician

Project period: 04/01/2014-03/31/2018

Agency: NIH/NIDA

I.D.# 1K12DA033312-01A1

Title: Yale-Drug Abuse, Addiction, and HIV Research Scholars (Yale-DAHRS)

P.I.: Gail D’Onofrio, MD/Patrick O’Connor, MD

Percent effort: 10% Yr 1; 5% Yr 2; 5% Yr 3; 5% Yr 4; 5% Yr 5

Role on Project: Core Faculty

Direct costs per year: $472,550

Total costs for project period: $2,682,982

Project period: 04/13/13-03/31/18

Agency: NIH/NIDDK

I.D.#: 2P30DK045735-21

Title: Diabetes Research Center

P.I.: Robert Sherwin,MD

Percent Effort: 0.05 FTE

Role on project: Biostatistician

Direct costs per year: $1,178,843

Project period: 03/15/13-01/31/18

Agency: NIH/NHLBI

I.D.#: 1 R18 HL108788-02

Title: Implementation of HIT-Enhanced Tobacco Treatment for Hospitalized Smokers

P.I.: Steven Bernstein, MD

Percent Effort: 0.10 FTE Yr1-4

Role on Project: Co-Investigator - Biostatistician

Direct Costs/year: $477,588

Total costs for project period: $2,410,368

Project period: 08/06/12-07/31/16

Agency: NIH/NCATS

I.D.#: 8 UL1 TR000142-07

Title: Clinical and Translational Science Award

P.I.: Robert Sherwin, MD

Percent Effort: 0.20 FTE

Role on project: Biostatistician

Direct costs per year: $4,640,248

Total costs for project period: $23,201,240

Project period: 07/01/2011-06/30/16

**Pending:**

Agency: PCORI

I.D.#:    SC15-1502-27597

Title: Expanding Methods for Two-Stage Trial Designs Testing Treatment, Self-Selection and Treatment Preference Effects

P.I.: Denise Esserman, PhD

Percent Effort: 0.05 FTE

Role on project: Stakeholder

Direct Costs/year:  $248,935

Total costs for project period: $1,047,740

Project period: 11/1/2015-10/31/2018

Agency: NIH (Sub from Indiana University)

I.D.#:

Title: Geriatric Trial Innovation Center

P.I.: Thomas Gill, MD

Percent Effort: 0.15 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,953,947

Project Period: 6/1/16 – 5/31/23

Agency: NIH/NCI

I.D.#:

Title: Optimizing Tobacco Dependence Treatment in the Emergency Department

P.I.: Steven Bernstein, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,175,840

Project Period: 7/1/16 – 6/30/20

Agency: NIH (Sub from MGH)

I.D.#:

Title: Determining the Mechanism of Ischemic Cerebral Edema on Recovery (DICER study)

P.I.: Kevin Sheth, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $668,965

Project Period: 7/1/16 – 6/30/21

Agency: NIH/NIDDK

I.D.#:

Title: Pathogenesis of youth onset pre diabetes and Type 2 diabetes

P.I.: Sonia Caprio, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,133,527

Project Period: 7/1/16 – 6/30/21

Agency: NIH

I.D.#:

Title: Stress, Sleep, and Arterial Stiffness

P.I.: Matthew Burg, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,060,333

Project Period: 7/1/16 – 6/30/20

Agency: NIH/NIAAA

I.D.#:

Title: A Text Enhanced Brief Intervention to Reduce Adolescent Alcohol and Marijuana Use

P.I.: Federico Vaca, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,488,284

Project Period: 9/1/16 – 8/31/21

Agency: NIH/NIAMS

I.D.#:

Title: The Yale Center for Hyophosphatemic Disorders

P.I.: Thomas Carpenter, MD

Percent Effort: 0.10 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $4,931,485

Project Period: 9/1/16 – 8/31/21

Agency: FIC

I.D.#:

Title: NCD Care: Knowledge, Attitude and Practices of Kenya A&E Departments

P.I.: Christine Ngaruiya, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $250,000

Project Period: 9/1/16 – 8/31/18

Agency: HRSA

I.D.#:

Title: PRIMED: Pediatric Resuscitation Improvement Modules for Community Emergency Departments

P.I.: Marc Auerbach, MD

Percent Effort: 0.01 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $677,329

Project Period: 9/1/16 – 8/31/19

Agency: NIH

I.D.#:

Title: A Stepped Wedge Implementation Study of Shared Decision Making for VBAC with an Interactive Decision Aid

P.I.: Shoten, MD

Percent Effort: 0.10 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $2,814,209

Project Period: 9/1/16 – 8/31/21

Agency: DOD

I.D.#: AR150203

Title:

P.I.: Kevin Pelphrey, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $999,866

Project Period: 9/30/16 – 9/29/20

Agency: AHRQ

I.D.#:

Title: Anesthesia Dosing and Outcomes Among Surgical Patients Age>65

P.I.: Akhtar, MD

Percent Effort: 0.05 FTE

Role on Project: Biostatistician

Direct Costs/Year: $

Total costs for project period: $830,613

Project Period: 10/1/16 – 9/30/19

**Past Grants:**

Agency: NIH/NICHD

I.D.#: 5RO1HD028016-17

Title: Metabolic Markers of Childhood Obesity

P.I.: Sonia Caprio, MD

Percent Effort: 0.02 FTE

Role on project: Biostatistician (09-present)

Project period: 5/16/2015-8/30/2015

Agency: AHRQ

I.D.#: 1R01HS018420-01A1

Title: ED disability diagnostic tool: A HIT feasibility study

P.I.: Lori Post, PhD

Percent Effort: 0.05 FTE Yr1, 0.10 FTE Yr 2-5

Role on Project: Co-Investigator - Biostatistician

Direct Costs per year: $302,114

Total costs for project period: $2,497,434

Project period: 07/01/10-6/30/15

Agency: NIH/NIMH

I.D.#: R01MH081148

Title: Randomized trial of parent training for young children with Autism

P.I.: Lawrence Scahill, ScD

Percent Effort: 0.05 FTE

Role: Co-Investigator Biostatistician (2010-present)

Direct Costs per year: $300,709

Total costs for project period: $2,488,367

Project period: 12/1/09-12/31/15

Agency: NIH/NCI

I.D.#: 5R03CA167765-02

Title: Effect of Exercise on Cortisol Dysregulation in Ovarian Cancer Survivors

P.I.: Brenda Cartmel, PhD

Percent Effort: 0.025 FTE

Role on project: Biostatistician

Direct costs per year: $47,000

Project period: 04/02/2012-03/31/2014

Agency: NIH/NIMH

I.D. #: R01MH083707-02

Title: RUPP Autism Network: Guanfacine for the treatment of hyperactivity in PDD

P.I.: Lawerence Scahill, ScD

Percent Effort: 0.05 FTE

Role: PI of Data Coordinating Center (subcontract)

Direct costs per year: $335,956

Total costs for project period: $2,788,435

Project period: 12/1/09-11/30/14

Agency: NIH/NIAAA

I.D. #: 5R01AA018664-02

Title: Ethanol metabolites for monitoring drinking in clinical trials

P.I.: O’Malley/Jatlow

Percent Effort: 0.025 FTE

Role on Project: Sr. Biostatistician

Direct costs per year: $403,293

Total costs for project period: $2,677,865

Project period: 04/01/10-03/31/13

Agency: NIH/NICHD

I.D. #: 5RO1DK0855577-02

Title: Neural Functioning of Feeding Centers in Obese Youth

P.I.: Sonia Caprio, MD

Percent Effort: 0.05 FTE

Role on project: Biostatistician

Direct costs per year: $315,996

Project period: 5/15/2009-4/20/2014

Agency: NIH/NICHD

I.D #: 5RO1HD028016-17

Title: Metabolic Markers of Childhood Obesity

P.I.: Sonia Caprio, MD

Percent Effort: 0.20 FTE

Role on project: Biostatistician (09-13)

Direct costs per year: $449,246

Project period: 5/15/2009-4/20/2014

Agency: VA (HSR&D)

I.D.#

Title: WomenVeterans Cohort Study (VA IPA)

P.I.: Cynthia Brandt, MD

Percent effort: 15%

Role on project: Co-investigator

Direct costs per year: $52,261

Total costs for project period: $52,261

Project period: 08/01/11-07/30/12

Agency: NIH/NCRR

I.D #: UL1RR024139-01

Title: Clinical and Translational Science Award

P.I.: Robert Sherwin, MD

Percent Effort: 0.30 FTE

Role on project: Biostatistician

Direct costs per year: $2,135,404

Total costs for project period: $23,201,240

Project period: 10/1/06-9/30/11

Agency: NIH/NIAMSD

I.D #: 5R01AR05370-02

Title: Impact of protein on bone mass

P.I.: Karl Insogna, MD

Percent Effort: 0.05 FTE

Role on project: Biostatistician

Direct costs per year: $218,725

Total costs for project period: $1,448,028

Project period: 9/28/06-8/31/10

Agency: NIH/NIDDK

I.D #: P30DK304989-25S1

Title: Silvio O. Conte Digestive Research Core Centers

P.I.: Guadalupe Garcia-Tsao, MD

Percent Effort: 0.25 FTE

Role on project: Biostatistician

Direct costs per year: $214,583

Total costs for project period: $355,135

Project period: 07/22/09-5/31/10

Agency: NIH/NIMH

I.D #: 3R01MH069874-04W1

Title: Behavior Therapy for Adults with Tourette Syndrome

P.I.: Lawrence Scahill, ScD

Percent Effort: 0.20 FTE

Role on project: Biostatistician-Co-Investigator

Direct costs per year: $152,872

Total costs for project period: $506,006

Project period: 7/1/09-5/31/10

Agency: NIH/NHLBI

I.D #: 1-RO1-HL-89340-01

Title: T-wave alternans and emotion in daily life

P.I.: Rachel Lampert, MD

Percent Effort: 0.05 FTE

Role on project: Biostatistician

Direct costs per year: $379,325

Total costs for project period: $2,511,131

Project period: 5/1/08-5/30/13

Agency: NIH/NIDDK

I.D #: 7-RO1-DK-57846-07

Title: Phase II of HOKT3y 1 (ALA-ALA) in Type I Diabetes

P.I.: Kevan Herold, MD

Percent Effort: 0.05 FTE

Role on project: Biostatistician

Project period: 7/1/06-6/30/10

Agency: NIH/NICHD

I.D #: 2 RO1 HD28016-15A1

Title: Metabolic Markers and Predictors of Childhood Obesity

P.I.: Sonia Caprio, MD

Percent Effort: 0.10 FTE

Role on project: Biostatistician-Co-Investigator

Project period: 12/1/08-4/31/10

Agency: NIH/NCRR

I.D #: MO1 RR00125

Title: Yale General Clinical Research Center

P.I.: Robert Alpern, MD

Percent Effort: 1.0 FTE

Role on project: Biostatistician

Direct costs per year: $4,069,498

Total costs for project period: $4,640,248

Project period: 12/01/04-11/30/05

Agency: NIH/NCRR

I.D #: MO1 RR00125

Title: Yale General Clinical Research Center (Adult)

P.I.: David Kessler, MD

Percent Effort: 0.50 FTE

Role on project: Biostatistician

Direct costs per year: $3,550,000

Total costs for project period: $12,143,671

Project period: 12/01/01-11/30/04

Agency: NIH/NCRR

I.D.#: MO1 RR06022

Title: Yale General Clinical Research Center (Children)

P.I.: David Kessler, MD

Percent Effort: 0.50 FTE

Role on project: Biostatistician (02-03)

Direct costs per year: $1,717,316

Total costs for project period: $9,658,756

Project period: 12/1/98-11/30/03

Agency: NIH

I.D.#: AG17163

Title: Exercise and glucose regulation in older women

P.I.: Loretta DiPietro, PhD

Percent Effort: 1.0 FTE

Role: Post-doc (01-02)

Project period: 9/30/99-6/30/04

**Courses and Lectures:**

# Instructor “Biostatistics 540a: Introduction to Clinical Trials” Fall 2014

Yale School of Public Health

Taught the introductory course with over 60 enrolled.

# Instructor “IMP 645: Introduction to Biostatistics in Clinical Research” 2002-present

Yale Graduate School of Arts and Sciences

Currently teaching an intensive 2-week summer graduate school course to

70 faculty members, medical students, and post-doctoral fellows in the basics of

biostatistics. The course is split between lecture and a computer lab designed to

provide a practical introduction to material covered in lecture. Syllabus, course

notes, and assignments are available upon request.

# Lecture:“Sample Size and Power” March 2016

YCCI, Yale School of Medicine:

YCCI Lunch and Learn

# Lecture:“Basics of Study Design” March 2015

YCCI, Yale School of Medicine:

YCCI Lunch and Learn

# Lecture:“Power and Sample Size in Clinical Research” 2004-present

Investigative Medicine Program, Yale School of Medicine:

Seminars in Clinical Investigation

# Lecture:“Basics of Study Design” Feb 2013

Department of Pediatrics, Yale School of Medicine:

Pediatrics Conference

# Lecture:“Statistical Inference” March 2013

Department of Pediatrics, Yale School of Medicine:

Pediatrics Conference

# Lecture:“Results Reporting in Clinicaltrials.gov” May 2012

Investigative Medicine Program, Yale School of Medicine:

# YCCI Scholars Research in Progress

# Lecture:“Developing a Research Question and Testable Hypotheses” Dec 2012

Department of Emergency Medicine, Yale School of Medicine

Junior Faculty Development Seminar

# Seminar: “Combat Exposure and Risk Factors of Cardiovascular Health March 2012 Women Veterans Cohort Study (WVCS)”

YCAS/Yale Program on Aging Biostatistics Seminar

# Seminar:“Inverse Probability Weighting for Missing Data in Clinical Trials” March 2011

YCAS/Yale Program on Aging

Missing Data Working Group

# Lecture:“Issues in Power and Sample Size for Clinical Research” Jan 2012

Department of Emergency Medicine, Yale School of Medicine

Junior Faculty Development Seminar

# Lecture:“Grant Preparation: The Research Methods Section” Feb 2011

Department of Emergency Medicine, Yale School of Medicine

Junior Faculty Development Seminar

# Lecture:“Biostatics at the Yale Center for Clinical Investigation” 2010

Yale Center for Clinical Investigation, Yale School of Medicine:

YCCI Research in Progress Series

# Lecture:“Introduction to Clinical Epidemiology and Biostatistics” 2005, 2007

Department of Internal Medicine, Yale School of Medicine

Section of Digestive Diseases Fellows Seminar

# Lecture Series:“Introduction to Biostatistics” Feb 2007

Department of Diagnostic Radiology, Yale School of Medicine:

Series of 5 lectures to DR Faculty

# Lecture:“Introduction to Biostatistics” Feb 2005

Department of Pediatrics, Yale School of Medicine:

Child Health Research Seminar Series

# GCRC Workshop Instructor:“Identifying Data Management Needs” 2004, 2005

Yale School of Medicine

**Peer-Reviewed Presentations & Symposia Given at Meetings Not Affiliated With Yale:**

**International/National**

2014: Annual Meeting, Society for Academic Emergency Medicine, Dallas, TX, Emergency medicine trials registered in clinicaltrials.gov

2013: Annual Meeting, Society for Academic Emergency Medicine, Chicago, IL, A rapid assessment to predict ED revisits, hospital admissions or death at 30 days following ED discharge in older individuals.

2012: Annual Meeting, Society for Academic Emergency Medicine, Boston, MA, The impact of childhood weight on emergency department visits in a national cohort.

2002: Annual Meeting, American College of Sports Medicine, St. Louis, MO, Physical activity and the risk of diabetes in older people: the Yale Health and Aging Study, 1982-1994.

2001: Annual Meeting, North American Association for the Study of Obesity, Quebec City, Canada, Low fasting insulin levels and increased insulin sensitivity are predictors of accretion of abdominal subcutaneous fat in non-obese offspring of obese parents: a five-year prospective study.

2001: Annual Meeting, American College of Sports Medicine, Baltimore, MD, Physical activity attenuates aging-related weight loss in older people: the Yale Health and Aging Study, 1982-1994.

**Regional**

2014: Annual Meeting, New England Regional SAEM, New Haven, CT, Emergency medicine trials registered in clinicaltrials.gov

2013: Annual Meeting, New England Regional SAEM, Providence, RI, Annual Meeting,

Society for Academic Emergency Medicine, A rapid assessment to predict ED revisits, hospital admissions or death at 30 days following ED discharge in older individuals.

**Journal Service:**

Editor/Associate Editor

Statistical Editor, *Hepatology* 2011-present

Reviewer  
Reviewer for *Academic Emergency Medicine, Journal of Clinical Endocrinology* 2001-present

*and Metabolism, Pediatrics, American Journal of Epidemiology, Journal of Clin*

*Oncology, JAMIA, BMC Cancer, Journal of Physical Activity and Health*

**Professional Service:**

Member, Society for Clinical Trials 2014-present

Member, Data Safety Monitoring Board, TeenConnect Trial 2013-present Yale School of Nursing

Chair, Data Safety Monitoring Board, A Phase I Safety Trial of 2011-present CD4+CD127lo/-CD25+ Polyclonal Treg Adoptive Immunotherapy for the

Treatment of Type 1 Diabetes

Member, Society for Academic Emergency Medicine 2010-present

Member, Society for Epidemiologic Research 2007-present

Member, American Statistical Association 2006-present

Member, Data Safety Monitoring Board, Clevidipine in Cardiac Surgery 2004-2009

The Medicines Company

Member, Data Safety Monitoring Board, Technosphere insulin for the 2004-present

treatment of diabetes, MannKind Pharmaceuticals

Member,Data Safety Monitoring Board, Remote symptom and weight monitoring 2005-2008

in heart failure, Yale School of Medicine

Member, Data Safety Monitoring Board, Autologous CD34+ Cells for the 2005-2008 Treatment of Myocardial Ischemia, Baxter Healthcare Corporation

Member,Data Safety Monitoring Board,Vasoconstrictors as alternative to albumin 2007-2008

after large volume paracentesis in cirrhosis, Yale School of Medicine

Member, Data Safety Monitoring Board, DAIDS HIV Therapeutics 2008-2013

Member, Data Safety Monitoring Board, TeenCope Trial – Internet Coping skills 2008-2013

training for adolescents with diabetes, Yale School of Nursing

Member, Association of GCRC Statisticians 2002-2010

**Yale University Service:**

***Medical School Committees***

2006-present Member, Science and Safety Committee

2004-2010 Member, Pediatric Protocol Review Committee

2010-2013 Member, YCC Protocol Review Committee

**Bibliography:**

My Bibliography <http://www.ncbi.nlm.nih.gov/sites/myncbi/james.dziura.1/bibliography/47436137/public/?sort=date&direction=descending>

**Peer-Reviewed Original Research**

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**In Press/Submission:**

*In press JAACAP:* Scahill, L., Jeon, S., Boorin, S.G., McDougle, C.J., Aman, M.G., **Dziura, J**.,

McCracken, J.T., Caprio, S., Arnold, L.E., Nicol, G., Deng, Y., Challa, S.A., and Vitiello, B. (in

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*In press AJPH:* Incident mental health diagnoses in men and women veterans over 14-years of conflict in Iraq and Afghanistan

*Submitted Translational Medicine: Practice, Policy and Research*: Design and Implementation of Decision Support for Tobacco Dependence Treatment in an Inpatient Electronic Medical Record: A Randomized Trial

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*Submitted Annals of Neurology*: Cavus, Idil; Romanyshyn, Jonathan; Kennard, Jeremy; Farooque, Pue; Williamson, Anne; Eid, Tore; Spencer, Susan; Duckrow, Robert; **Dziura, James**; Spencer, Dennis. Elevated basal glutamate and unchanged glutamine and GABA in refractory epilepsy.

*Submitted Psychosomatic Medicine*: Burg M, Buta E, Bathulapalli H, Goulet J, Skanderson M, **Dziura J**, Brandt C,  Haskell SG.Risk for Incident Hypertension in Veterans of Operations Iraqi Freedom, Enduring Freedom, and New Dawn: Effect of PTSD and PTSD Treatment

*Submitted Epilepsia:* H. Hamid, X. Cong, A. T. Berg, B. G. Vickrey, M. R. Sperling, S. Shinnar, J. T. Langfitt, T. S. Walczak, C. W. Bazil, **J. Dziura**, and O. Devinsky. Presurgical depression and anxiety are not associated with worse epilepsy surgery outcome

*Submitted:* Sukhodolsky DG, Woods DW, Wilhelm S, Piacentini J, Peterson AL, Katsovich L, **Dziura J**, Walkup JT, Scahill L. Moderators and predictors of response to behavior therapy for tics in children and adults with Tourette Disorder and Chronic Tic Disorders.

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*Submitted JCCP:* Lecavalier L, Smith T, Johnson C, Bearss K, Swiezy N, Aman MG, Sukhodolsky DG, Deng Y, **Dziura J**, Scahill L. Moderators of the Efficacy of Parent Training for Disruptive Behaviors in Preschoolers with Autism Spectrum Disorder

*Submitted JAACAP:* Effect of Parent Training on Adaptive Behavior in Children with Autism Spectrum Disorder and Disruptive Behavior: Results of a randomized trial

*In Preparation*: **Dziura J**, Reynolds J, McCarthy M, Johnson B, Omar A, Vaca F, Post LA. Emergency Medicine trials in clinicaltrials.gov.

*In Preparation*: **Dziura J**, Brandt C, Burg M, Haskell S. Incidence of cardiovascular risk factors in women and men Veterans.

*In Preparation*: Varga S, Moadel T, Hile D. A prospective randomized controlled trial comparing simulation, lecture and discussion-based education of sepsis to emergency medicine residents.

*In Preparation*: Safdar B, D’Onofrio GD, **Dziura J**, Russell RR, Johnson C, Sinusas AJ. Ranolazine and microvascular angina by PET in the emergency department (RAMPED) – results from a pilot randomized controlled trial.

*In Preparation:* Bernstein SL, Abujarad F, Grant D, Spielman D, D’Onofrio G, Li F, **Dziura J**. Human health behavior was modeled with a new index derived from network analysis.

*In Preparation:* Edelman EJ, Maisto SA, Hansen NB, Cutter CJ, **Dziura J**, Fiellin LE, O’Connor PG, Bedimo R, Gilbert C, Marconi VC, Rimland D, Rodriguez-Barradas M, Simberkoff M, Justice AC, Bryant KJ, Fiellin DA. The starting treatment for ethanol primary care trials (STEP trials): protocol for three linked multi-site stepped care effectiveness studies for unhealthy alcohol use in HIV-infected patients.

*In Preparation:* Rabinowitz PM, Galusha D, Mosites E, **Dziura J**, Dixon-Ernst C, Cullen MR, Neitzel R. The voluntary use of a daily noise monitoring intervention is associated with decreased hearing loss.

Editorials, Reviews, Chapters, Books

1. L DiPietro, **J Dziura**. Exercise: A prescription to delay the effects of aging. *The Physician and Sportsmedicine*. 2000: 28(10): 77-8.
2. **J Dziura**, L DiPietro. The importance of body weight maintenance in successful aging.  *Chapter* *In* Obesity: Etiology, Assessment, Treatment and Prevention. RE Anderson editor. Human Kinetics Publishers, Champaign, IL, 2003.

**Selected Annotated Bibliography:**

KF Petersen, D Befroy, S Dufour, **J Dziura**, C Ariyan, DL Rothman, L DiPietro, GW Cline, GI Shulman. Mitochondrial dysfunction in the elderly: possible role of insulin resistance. *Science*. 2003: 300(5622): 1140-2.

*Developed research protocol to cross-sectionally compare elderly and young subjects with respect to several metabolic variables. Recruited, enrolled and performed euglycemic-hyperinsulinemic clamp studies. Performed statistical analyses and provided interpretation of study results.*

R Weiss, J Dziura, TS Burgert, WV Tamborlane, SE Taksali, C Yeckel, K Allen, M Lopes, M Savoye, J Morrison, R Sherwin, S Caprio. Impact of severe obesity on the metabolic syndrome in children and adolescents. *NEJM.* 2004: 350(23):2362-74.

*Developed, performed, interpreted and summarized for publication the analytical plan for this secondary analysis of a large cohort of obese youth. Used factor analysis to simplify complex multivariate relations between metabolic and anthropometric variables proposed to be associated with the metabolic syndrome.*

L DiPietro, **J Dziura**, S Blair. Estimated Change in Physical Activity Level (PAL) and Prediction of 5-year Weight Change in Men: The Aerobics Center Longitudinal Study. International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity. 28(12):1541-7, 2004 Dec.

Developed an algorithm to retrospectively determine the PAL (the standard method of expressing total daily energy expenditure in multiples of the resting metabolic rate) in a large longitudinal cohort of middle-age men. Used random coefficient modelling to compare trajectories of weight change as a function of physical activity levels. Prepared statistical and results sections and provided interpretation.

Cartmel B. Dziura **J**. Cullen MR. Vegso S. Omenn GS. Goodman GE. Redlich CA. Changes in cholesterol and triglyceride concentrations in the Vanguard population of the Carotene and Retinol Efficacy Trial (CARET). European Journal of Clinical Nutrition. 59(10):1173-80, 2005 Oct.’

Used random coefficient modeling of unbalanced repeated assessments to compare changes in cholesterol and triglyceride curves for individuals from the Vanguard population of the Carotene and Retinol Efficacy Trial. Prepared statistical and results sections, provided interpretation and responded to reviewers comments.

Petersen KF. Dufour S. Feng J. Befroy D. Dziura **J**. Dalla Man C. Cobelli C. Shulman GI. Increased prevalence of insulin resistance and nonalcoholic fatty liver disease in Asian-Indian men.Proceedings of the National Academy of Sciences of the United States of America. 103(48):18273-7, 2006 Nov 28. PMCID: PMC1693873

*Conducted weighted analysis to determine the distribution and prevalence of insulin resistance and nonalcoholic fatty liver disease. Prepared statistical and results sections and provided interpretation.*

Banaszewska B. Pawelczyk L. Spaczynski RZ.Dziura **J**. Duleba AJ. Effects of simvastatin and oral contraceptive agent on polycystic ovary syndrome: prospective, randomized, crossover trial. Journal of Clinical Endocrinology & Metabolism. 92(2):456-61, 2007 Feb.

Used a mixed model analysis to determine the effects of simvastatin on metabolic parameters associated with PCOS. *Prepared statistical and results sections and provided interpretation.*Paper wins *Society for Reproductive Endocrinology and Infertility Prize.*

Savoye M. Shaw M. **Dziura J**. Tamborlane WV. Rose P. Guandalini C. Goldberg-Gell R. Burgert TS. Cali AM. Weiss R. Caprio S. Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. JAMA. 297(24):2697-704, 2007 Jun 27.

*Designed, performed and analyzed a randomized controlled trial to determine the impact of a weight management program on body composition and metabolic parameters. Used multiple imputation to handle missing data.* *Prepared statistical and results sections and provided interpretation.*

Scahill L, Aman MG, McDougle CJ, Arnold LE, McCracken JT, Handen B, Johnson C, **Dziura J**, Butter E, Sukhodolsky D, Swiezy N, Mulick J, Stigler K, Bearss K, Ritz L, Wagner A, Vitiello B. [Trial Design Challenges When Combining Medication and Parent Training in Children with Pervasive Developmental Disorders.](http://www.ncbi.nlm.nih.gov/pubmed/19096921?ordinalpos=5&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum) *J Autism Dev Disord*. 2008 Dec 19. [Epub ahead of print] PMID: 19096921

*Designed a randomized controlled trial to determine the efficacy of parent training in children with PDD and behavior problems. Prepared statistical and results sections and provided interpretation.*

Aman MG, McDougle CJ, Scahill L, Handen B, Arnold LE, Johnson C, Stigler KA, Bearss K, Butter E, Swiezy NB, Sukhodolsky DD, Ramadan Y, Pozdol SL, Nikolov R, Lecavalier L, Kohn AE, Koenig K, Hollway JA, Korzekwa P, Gavaletz A, Mulick JA, Hall KL, **Dziura J**, et al.; [Medication and Parent Training in Children With Pervasive Developmental Disorders and Serious Behavior Problems: Results From a Randomized Clinical Trial.](http://www.ncbi.nlm.nih.gov/pubmed/19858761) *J Am Acad Child Adolesc* Psychiatry. 2009 Oct 23. PMID: 19858761

*Designed a randomized controlled parallel group trial to determine the impact of parent training to reduce aggressive behavior. Conducted the analysis, provided interpretation and prepared manuscript.*

Piacentini J, Woods DW, Scahill L, Wilhelm S, Peterson AL, Chang S, Ginsburg GS, Deckersbach T, **Dziura J**, Levi-Pearl S, Walkup JT.Behavior Therapy for Children With Tourette Disorder: A Randomized Controlled Trial. JAMA. 2010;303:1929-1937; May 19, 2010.

*Developed a randomized controlled parallel group trial to determine the impact of behavior therapy on tic severity. Conducted the analysis, provided interpretation and prepared manuscript.*