



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 8, 2017

Gary Qualls
K&L Gates, LLP
P.O. Box 14210
Research Triangle Park NC 27709-4210

No Review

Record #: 2377
Facility Name: Rex Hospital d/b/a UNC REX
FID #: 953429
Business Name: Rex Hospital, Inc.
Business #: 1554
Project Description: Performance of structural heart procedures on vascular (non-cardiac) catheterization equipment
County: Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of September 1, 2017 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

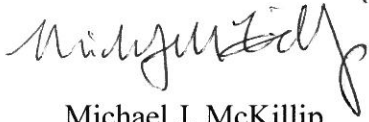
AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



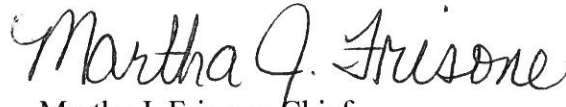
original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Michael J. McKillip
Project Analyst



Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR



September 1, 2017

Gary Qualls
gary.qualls@kigates.com

T +1 919 466 1182
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Via Hand Delivery

Martha Frisone
Chief
Department of Health and Human Services
Division of Health Service Regulation
Health Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: No Review Request for Rex Hospital, Inc. d/b/a UNC REX regarding Structural Heart Procedures

Dear Martha:

We are writing on behalf of our client Rex Hospital, Inc., d/b/a UNC REX (“UNC REX”). UNC REX would like a determination that it can perform Structural Heart Procedures (as defined below) on non-cardiac catheterization (“cath”) equipment as defined in N.C. Gen. Stat. §131E-176(2f). Based on the reasoning articulated below, we request confirmation from the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) that this proposal is not subject to certificate of need review.

The CON statute defines cardiac cath services as follows:

“Cardiac catheterization services” means those procedures, excluding pulmonary angiography procedures, in which a catheter is introduced into a vein or artery and threaded through the circulatory system into the heart specifically to **diagnose** abnormalities in the motion, contraction, and blood flow of the moving heart or to perform surgical therapeutic interventions to restore, repair, or reconstruct the **coronary blood vessels** of the heart.

N.C. Gen. Stat. § 131E-176(2g) (emphasis added).

Together with its cardiologists, UNC REX performs a number of procedures referred to as Structural Heart Procedures. Such procedures are referred to using terminology such as Transcatheter Aortic Valve Replacement (“TAVR”) and other terms. The current CPT codes for these Structural Heart Procedures are as follows:

TAVR Primary Procedures

- 33363 - TAVR Open Axillary Art
- 33362 - TAVR Open Femoral
- 33364 - TAVR Open Iliac Art
- 33361 - TAVR Percutaneous Fem Art
- 33365 - TAVR - Trans-Aortic
- 33366 - TAVR Transapical

TAVR Add Ons

- 33369 - TAVR w/ Central A&V Cannulation
- 33368 - TAVR w/ Open Periph A&V Pump Bypass
- 33367 - TAVR w/ Perc A&V Pumps Bypass

Mitral Clip procedures

- 33418 - Initial Clip
- 33419 - Add'l Clip

Watchman procedures

- 33340 - Percutaneous Transcatheter Closure Left Atrial Appendage

ASD/PFO

- 93580 - Closure ASD/PFO W/ Implant

UNC REX believes that Structural Heart Procedures do not meet the definition of “cardiac catheterization services” under Section 131E-176(2g) of the CON statute because they: (1) are not diagnostic; and (2) do not involve interventions pertaining to the coronary blood vessels of the heart. Rather, physicians who perform these procedures describe Structural Heart Procedures as therapeutic interventions to restore, repair or reconstruct the heart muscle or heart valves, not coronary blood vessels. *See* Affidavits of Dr. James Zidar (Exhibit A) and Dr. Willis M. Wu (Exhibit B).

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September 1, 2017
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UNC REX has historically performed these structural heart procedures on cardiac cath equipment as defined in Section 131E-176(2f). However, UNC REX believes that it is permitted to perform such procedures on non-cardiac cath equipment under the CON Law, because the procedures do not meet the Section 131E-176(2g) definition. Moreover, Structural Heart Procedures are perfectly safe to perform on non-cardiac cath equipment (i.e., equipment often referred to as vascular cath equipment, which is cath equipment, but not cardiac cath equipment as defined in Section 131E-176(2f)).

Based on the foregoing, please confirm that the performance of Structural Heart Procedures on non-cardiac cath equipment is non-reviewable because such activities do not trigger any new institutional health service categories under the CON Law.

If you require additional information, please do not hesitate to contact me at the above number. Thank you in advance for your review of this request.

Sincerely,

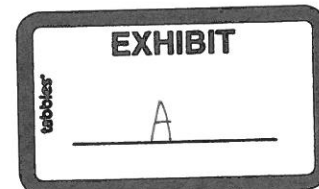
A handwritten signature in blue ink that reads "Gary Qualls". The signature is written in a cursive, flowing style.

Gary Qualls

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Exhibits

- A. Affidavit of Dr. James Zidar
- B. Affidavit of Dr. Willis M. Wu



AFFIDAVIT OF DR. JAMES ZIDAR

1. Dr. James Zidar, being first duly sworn, states as follows:
2. I am over the age of eighteen (18) years and am a resident of Wake County, North Carolina. I do not suffer from any mental disability or infirmity that prevents me from making this Affidavit. This Affidavit is based on my own personal knowledge.
3. I have practiced cardiology for decades and have extensive training and experience in interventional cardiology procedures. My CV is attached to this Affidavit as Exhibit 1.
4. As a cardiologist at UNC REX, I routinely perform a number of procedures referred to as "Structural Heart Procedures." Such procedures are referred to using terminology such as Transcatheter Aortic Valve Replacement ("TAVR") and other terms described below. I have confirmed that the current CPT codes for these Structural Heart Procedures are as follows:

TAVR Primary Procedures

- 33363 - TAVR Open Axillary Art
- 33362 - TAVR Open Femoral
- 33364 - TAVR Open Iliac Art
- 33361 - TAVR Percutaneous Fem Art
- 33365 - TAVR - Trans-Aortic
- 33366 - TAVR Transapical

TAVR Add Ons

- 33369 - TAVR w/ Central A&V Cannulation
- 33368 - TAVR w/ Open Periph A&V Pump Bypass
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Mitral Clip procedures

- 33418 - Initial Clip
- 33419 - Add'l Clip

Watchman procedures

- 33340 - Percutaneous Transcatheter Closure Left Atrial Appendage

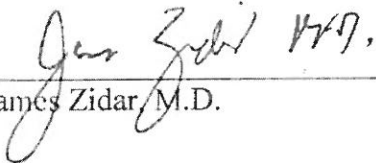
ASD/PFO

- 93580 - Closure ASD/PFO W/ Implant

5. Structural Heart Procedures: (1) are not diagnostic; and (2) do not involve interventions pertaining to the coronary blood vessels of the heart. Rather, Structural Heart Procedures are therapeutic interventions to restore, repair or reconstruct the heart muscle or heart valves, not coronary blood vessels.

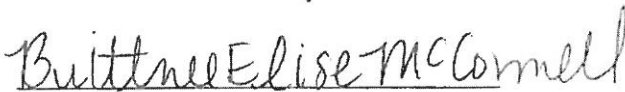
6. At UNC REX, we have historically performed these Structural Heart Procedures on UNC REX medical equipment designated as cardiac cath equipment for certificate of need ("CON") regulatory purposes. However, Structural Heart Procedures are perfectly safe to perform on non-cardiac cath equipment.

Further affiant sayeth not.


James Zidar, M.D.

STATE OF NORTH CAROLINA
COUNTY OF WAKE

Sworn to and subscribed before me this
the 30 day of August, 2017.


Notary Public

My Commission expires:
December 27th, 2021



Exhibit

1. Curriculum Vitae of James Zidar, M.D.

CURRICULUM VITAE

James Patrick Zidar, M.D., F.A.C.C., F.S.C.A.I.
Clinical Professor of Medicine

Birth: Detroit, Michigan

Marital Status: Married, 3 Children

Address: Rex Heart & Vascular Specialists
4414 Lake Boone Trail, Suite 402
Raleigh, North Carolina 27607
Ph. (919) 784-5600
Fax (919) 784-5601

Education: University of Notre Dame, B.S. 1980 Notre Dame, IN
Loyola University Stritch School of Medicine, M.D. 1985
Maywood, Illinois

Training:

Internship / Residency / Chief Resident: Internal Medicine, 1985 – 1989
University of Michigan Medical Center
Ann Arbor, Michigan

Fellowship: Cardiology, 1989 – 1992
Interventional Cardiology, 1992 – 1993
Duke University Medical Center
Durham, North Carolina

Prior Academic Appointments:

Associate, Medicine, Cardiovascular Division, 1992 – 1993
Assistant Professor of Medicine, 1993 – 1998
Associate Professor of Medicine, 1998 – 2002
Associate Professor of Medicine with Tenure, 2002 – 2009

Professor of Medicine with Tenure, 2010
Duke University Medical Center
Durham, North Carolina

Director, Peripheral Vascular Medicine Program
Duke University Medical Center, 1999 – 2004

Director, Cardiovascular Services,
Duke Raleigh Hosp., 2002 – 2010

Medical Director, Duke Cardiology of Raleigh, group practice,
7 person group, 2002 – 2010

Current Appointment:

Clinical Professor of Medicine
University of North Carolina Health Systems, 2010 – present

Corporate Chief, Department of Cardiology,
Rex Healthcare, 2010 – present

President, Rex Heart and Vascular Specialists, 2010 – present

Consultant in Cardiology, Rex Hospital, 2002 – present
Consultant in Cardiology, Duke Raleigh Hospital, 2002 – 2011

Licensure:

Michigan, 1986 – inactive
North Carolina, 1989 – active #38717
Virginia, 2001 – inactive #0101230671

Certification:

National Board of Medical Examiners, 1986
American Board of Internal Medicine, 1989
ABIM, Cardiovascular Disease, 1991, recertified 2001
ABIM, Interventional Cardiology 2003

Honors:

Michigan Competitive Scholar
University of Michigan Regents – Alumni Scholar
Alpha Sigma Nu Jesuit Honor Society
Alpha Omega Alpha Honor Medical Society
Scientific Advisory Board, International Academy of Cardiology
Best Doctors in America, 2003 – present

Professional Societies:

American College of Physicians: Member
American College of Cardiology: Fellow
Society of Coronary Angiography and Intervention: Fellow
Alpha Omega Alpha Honor Medical Society
Andreas Greuntzig Honorary Society: Member

Committees: Duke University Medical Center

Cardiology Fellowship Selection Committee, 1992 – 1997
ODI /PTCA Care Map Committee, 1992 – 1998
Computer Advisory Committee, Department of Medicine
Clinical Practice Group, 1993 – 1999
Duke Clinical Research Institute , Executive Comm, 1995 – 2010
Duke Univ. Cardiology Clinical Site, Exec Comm., 1997 – present
ACC Scientific Program Committee member, 2000 – 2003
ACC Interventional Spotlight Planning Comm. member, 2001 – 2003
ACC Interventional Spotlight Committee, chairman, 2003
ACC I2 Planning Committee, 2005 – 2007
Duke Raleigh Hospital Cardiovascular Service Line, 2002 – 2010
Rex Invasive Cardiology QA committee, 2004 – present

Editorial Boards / Manuscript Review:

J Interventional Cardiology, J Invasive Cardiology, Circulation, JACC, American Journal of Cardiology, American Heart Journal, Catheterization & Cardiac Interventions: 1996 – present

Scientific Advisory Boards:

Abbott Vascular, 2001 – present
Aventis Pharmaceuticals, 1998 – 2004
Cordis Corporation, 1995 – present
Cryovascular Systems, Inc., 2000 – 2004
Eli Lilly, 1997 – 2003
Guidant Corporation, 1996 – 2006
Medtronic Vascular, 2002 – present
Millenium Pharmaceuticals, 2001 – 2005
North Point Domain, 2000 – 2005

Invited Lectures / Grand Rounds:

Duke, U of North Carolina, Carolinas Medical Center, East Carolina University, UNC/Moses Cone Hospitals, UNC/Wake Medical Center, Medical University of South Carolina, Medical College of Virginia, UAB, Emory University, Univ of Mississippi, Baylor University, U of South Florida, U of Michigan, Northwestern University, Loyola University, U of Chicago, U of Pennsylvania, Cornell University, Georgetown, Washington Hospital Center, U of Nebraska, U of Arkansas, Texas Heart Institute, Medical College of Georgia

National / International Course Director / Presenter:

ACC Scientific Sessions: 1993 – present
AHA Scientific Sessions: 1994 – 2005
TCT Annual meeting: 1994 – present
TCT Interventional Board Review presenter: 2000 – 2001
SCAI Annual meeting: 2001 – present
SCAI Carotid Course, presenter, 2006, 2007
ACE Scientific Sessions: 2006, 2007
Duke / Beaumont Beaver Creek meeting: 1996 – present,
co-director, 2004 – present
Scripps Interventional Course, 1995 – 2000, presenter
Duke Vail Interventional mtg, 1995 – 2004, director
Duke Pinehurst Interventional mtg, 1996 – 2005, director
Pebble Beach Interventional mtg, 1995 – 2003, director
SOLACI mtg presenter: 1995 – 1997
ESC mtg presenter: 1996 – 1997
Asia World Congress / Singapore presenter: 1997 – 1998
Interventions 2000 – 2004 – Atlanta, co-director
SIS Annual mtg, presenter 2004 – 2009
Emory Practical Interventional Conf (EPIC): presenter 2002 – 2011
Hot Topics in Cardiology: presenter 2005 – 2009
Cardiovascular Innovations 2010, Bethesda, MD, 2010
CRT mtg, presenter, Washington, DC. 2010 – present
VIVA mtg, Las Vegas, NV, October 2011

Research Experience:

Principle Investigator:

CHOICE: Carotid Stenting For High Surgical-Risk Patients; Evaluating Outcomes Through The CollectIon Of Clinical Evidence, Rex Hospital – Heart & Vascular Research

SAPPHIRE: Stenting and Angioplasty with Protection in Patients at High-Risk for Endarterectomy, Rex Hospital – Heart & Vascular Research

MOMENTUM: A prospective, multi-center, non-randomized, single-arm clinical trial to evaluate the safety and effectiveness of the Absolute Pro® peripheral self-expanding stent system and the Absolute Pro® LL peripheral self-expanding stent system in the treatment of subjects with atherosclerotic *de novo* or restenotic lesions in the native superficial femoral artery and/or native proximal popliteal artery, Rex Hospital – Heart & Vascular Research

CANOPY: Carotid Artery Stenting Outcomes in the Standard Risk Population for Carotid Endarterectomy, Rex Hospital – Heart & Vascular Research

EVOLVE II: A Prospective Multicenter Trial to Assess the Safety and Effectiveness of the Synergy™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Synergy™ Stent System) for the Treatment of Atherosclerotic Lesion(s), Rex Hospital – Heart & Vascular Research

TRANSLATE: Treatment with ADP receptor inhibitors: Longitudinal Assessment of Treatment Patterns and Events after Acute Coronary Sndrome, Rex Hospital – Heart & Vascular Research

IN.PACT: Randomized Trial of IN.PACT (Paclitaxel) Admiral Drug-Eluting Balloon (DEB) vs Standard PTA for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) (“SFA II”), Rex Hospital – Heart & Vascular Research

Sub-Investigator:

ALERTS: Angelmed for Early Recognition and Treatment of STEMI Study, Rex Hospital – Heart & Vascular Research

CLARITY I: Complete Lesion Assessment with fFR and IVUS Technology, Rex Hospital – Heart & Vascular Research

ePAD: A randomized, open-label, parallel-group, multi-center study of adding edoxaban or clopidogrel to aspirin to maintain patency in subjects with peripheral arterial disease following femoropopliteal endovascular intervention-edoxaban in Peripheral Arterial Disease, Rex Hospital – Heart & Vascular Research

CHOCOLATE BAR: The Chocolate Balloon Angioplasty Registry, Rex Hospital – Heart & Vascular Research

CloSys: CloSys™ Closure System US Multi-Center Clinical Investigation, Rex Hospital – Heart & Vascular Research

Cook Tibiopedal: Tibiopedal Access for Crossing of Peripheral Artery Occlusion, Rex Hospital – Heart & Vascular Research

FSS OPEN Trial: Evaluation of Safety and Efficacy of the FlexStent® Femoropopliteal Self-Expanding Stent System, Rex Hospital – Heart & Vascular Research

SuperNOVA: Stenting of the Superficial Femoral and Proximal Popliteal Arteries with the Boston Scientific INNOVA™ Self-Expanding Bare Metal Stent System, Rex Hospital – Heart & Vascular Research

GUIDE SFA Registry: Gaining an Understanding of IVUS Impact on Procedural Time and Decisions in the Superficial Femoral Artery, Rex Hospital- Heart & Vascular Research

Manuscripts:

1. Jackman JD, Zidar JP, Tchong JE, Overman AM, Phillips HP, Stack RS: Outcome After Prolonged Balloon Inflations of >20 Minutes for Initially Unsuccessful Percutaneous Transluminal Coronary Angioplasty. *Am J Cardiol.* 1992; 69:1417.
2. Tenaglia AN, Zidar JP, Jackman JD, Fortin DF, Frid DJ, Krucoff MW, Tchong JE, Phillips HR, Stack RS: Treatment of Long Coronary Artery Lesions with Long Angioplasty Balloon Catheters. *Am J Cardiol.* 1993; 71:1274.
3. Tanguay JF, Zidar JP, Phillips HR, Stack RS: Current Status of Biodegradable Stents. *Cardiology Clinics.* 1994; 12:4:699-713.
4. Armstrong B, Zidar JP, Ohman EM: The Use of Intraaortic Balloon Counterpulsation in Acute Myocardial Infarction and High-Risk Coronary Angioplasty. *J Interven Cardiol.* 1995; 8:2:185-191.
5. Labinaz M, Zidar JP, Stack RS, Phillips HR: Biodegradable Stents: The Future of Interventional Cardiology? *J Interven Cardiol.* 1995; 8:4:1-11.
6. Kruse KR, Tanguay JF, Williams MS, Phillips HR, Stack RS, Zidar JP. Local Drug Delivery: The ACS Locking Stent. *Seminars in Interventional Cardiology.* 1996; 1:1:46-48.
7. Harrison JK, Pulsipher MW, Zidar JP. Management of the Patient with a Coronary Stent. *Emergency Medicine.* 1996; 28:12-32.
8. Zidar JP. Rationale for low-molecular-weight heparin in coronary stenting. *Am Heart J.* 1997; 134:81-S87.
9. Tanguay JF, Crowley JJ, Kruse KR, Armstrong BA, Santos RM, Zidar JP, Virmani R, Phillips HR, Stack RS. Antiplatelet versus warfarin therapy: Platelet, neutrophil, and thrombus deposition for intracoronary stents in a porcine model. *J Interven Cardiol.* 1997; 10:349-356.
10. Hearne SE, Davidson CJ, Zidar JP, Phillips HR, Stack RS, Sketch MH, Jr. Internal mammary artery graft angioplasty: Acute and Long-term Outcome. *Cath Cardiovasc Diag.* 1998; 44:153-156.
11. Zidar, JP. Low-molecular-Weight Heparins in Coronary Stenting: The ENTICES trial. *Am J Cardiol.* 1998; 82 (5B):29-32L.
12. Hearne SE, Amsterdam PB, Baker WA, Sawchak SR, Phillips HR, Sketch MH, Stack RS, Zidar JP. Diagnosing coronary arterial stent thrombosis and arterial closure. *Am J Cardiol.* 1998; 82(5):666-668.
13. Zidar, JP. Low-molecular-weight heparin in coronary stenting. *Can J Cardiol.* 1998; 14:35E-39E.
14. Santos RM, Tanguay JF, Crowley JJ, Kruse KR, Zidar JP, Merhi Y, Garcia-Cantu E, Bonan R, Cote G, Stack RS. Local administration of L-703,801 using a composite polymeric stent reduces platelet deposition in canine coronary arteries. *Am J Cardiol.* 1998; 82(5):673-675.

15. Peterson ED, Cowper PA, DeLong ER, Zidar JP, Stack RS, Mark DB. Acute and Long-term Cost Implications of Coronary Stenting. *J Am Coll Cardiol.* 1999; 33:1610-18.
16. Zidar JP. Glycoprotein IIb/IIIa Receptor Antagonists in Acute Coronary Syndrome. *J Invas Cardiol.* 1999; 11:13A-19A.
17. The ERASER Investigators. Acute platelet inhibition with abciximab does not reduce in-stent restenosis (ERASER Study). *Circulation.* 1999; 100:700-706.
18. Batchelor WB, Zidar, JP. Favorable vascular remodeling from self-expanding stents: Magic or myth? Editorial. *Am Heart J.* 1999; 138:203-205.
19. Kruse KR, Crowley JJ, Tanguay JF, Santos RM, Millare DS, Phillips HR, Zidar JP, Stack RS. Local drug delivery of argatroban from a polymeric-metallic composite stent reduces platelet deposition in a swine coronary model. *Catheterization and Cardiovascular Interventions.* 1999; 46(4): 503-507.
20. Cohen MG, Kong DF, Warner JJ, Wrightman MB, Greenbaum AB, Tchong JE, Peter RH, Sketch MH, Jr, Muhlbaier LM, Zidar JP. Outcomes Following Interventions in Small Coronary Arteries with the Use of Hand-Crimped Palmaz-Schatz Stents. *Am J Cardiol.* 2000; 85:446-450.
21. Cantor WJ, Peterson ED, Popma JJ, Zidar JP, Sketch MH, Jr, Tchong JE, Ohman EM. Provisional Stenting Strategies: Systematic Overview and Implications for Clinical Decision Making. *J Am Coll Cardiol.* 2000; 36:1142-51.
22. Lansky AJ, Roubin GR, O'Shaughnessy CD, Moore PB, Dean LS, Raizner AE, Safian RD, Zidar JP, Kerr JL, Popma JJ, Mehran R, Kuntz RE, Leon MB. Randomized Comparison of GR-II Stent and Palmaz-Schatz Stent for elective treatment of Coronary Stenoses. *Circulation.* 2000; 102:1364-1368.
23. Batchelor WB, Zidar JP. Fragmin and Other Low-Molecular-Weight Heparins in Coronary Intervention. *Current Interven Cardiol Reports.* 2000; 2(1):41-48.
24. Tanguay JF, Cantor WJ, Krucoff MW, Muhlestein B, Barsness GW, Zidar JP, Sketch MH, Jr., Tchong JE, Phillips HR, Stack RS, Kaplan AV, Ohman EM. Local Delivery of Heparin Post-PTCA: A Multicenter, Randomized Pilot Study. *Cathet Cardiovasc Intervent.* 2000; 49:461-467.
25. Fitzgerald PJ, Oshima A, Hayase M, Metz JA, Bailey SR, Baim DS, Cleman MW, Deutsch E, Diver DJ, Leon MB, Moses JW, Oesterle SN, Overlie PA, Pepine CJ, Safian RD, Shani J, Simonton CA, Smalling RW, Teirstein PS, Zidar JP, Yeung AC, Kuntz RE, Yock PG; for the CRUISE investigators. Final Results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) Study. *Circulation.* 2000; 102:523-530.
26. Zidar JP. Prolonged Therapy with Low-Molecular-Weight Heparin after PCI. *J Invas Cardiol.* 2000; 12(4),Suppl C:7C-10C.
27. Kereiakes DJ, Fry E, Matthai W, Niederman A, Barr L, Brodie B, Zidar J, Casale P, Christy G, Moliterno D, Lengerich R, Broderick T, Shimshak T, Cohen M. Combination Enoxaparin and Abciximab Therapy During Percutaneous Coronary Intervention: "NICE Guys Finish First". *J Invas Cardiol.* 2000; 12(Suppl A):1A-5A.

28. Tan HC, Crowley J, Tchong JE, Sng LW, Sketch JH Jr., Phillips HR, Peter RH, Behar VS, Stack RS, Zidar JP. Treatment of Palmaz-Schatz in-stent restenosis: 6-month clinical follow up. *J Interven Cardiol.* 2000; 13:315-322.
29. Zidar JP. Combining Treatment Strategies in the 21st Century: Low-molecular-weight Heparins in Acute Coronary Syndromes. *J Invas Cardiol.* 2000; 12 Suppl B: 16B-21B.
30. de la Serna FA, Tolleson TR, Crowley JJ, Stack RS, Zidar JP. Intraarterial Thrombolysis (Retepase) and ReoPro for Subacute Thrombosis of the Distal Aorta Accomplished by Radial Arterial Access. The radial-kissing-thrombolytic technique. *Cath Cardiovas Interven* 2001;53:264-268.
31. Cantor WJ, Peterson ED, Popma JJ, Zidar JP, Sketch MH Jr, Tchong JE, Ohman EM. Provisional Stenting Strategies: Systematic Overview and Implications for Clinical Decision-Making. *J Am Coll Cardiol* 2000;36:1142-51.
32. Kereiakes DJ, Grines C, Fry E, Esente P, Hoppensteadt D, Midei M, Barr L, Matthai W, Todd M, Broderick T, Rubinstein R, Fareed J, Santoian E, Neiderman A, Brodie B, Zidar J, Cohen M. Enoxaparin and Abciximab Adjunctive Pharmacotherapy During Percutaneous Coronary Intervention. *J Invas Cardiol.* 2001;13:272-278.
33. Cantor WJ, Hellkamp AS, Peterson ED, Zidar JP, Cowper PA, Sketch MH, Tchong JE, Califf RM, Ohman EM. Achieving Optimal Results with Standard Balloon Angioplasty: Can Baseline Angiographic Variables Predict Stent-Like Outcomes? *J Am Coll Cardiol.* 2001;37(7)1883-1890.
34. Batchelor WB, Mahaffey KB, Berger PB, Deutsch E, Meier S, Hasselblad V, Fry ETA, Teirstein PS, Ross AM, Binanay CA, Zidar JP, on behalf of the ATLAST Investigators. A Randomized, Placebo-controlled Trial of Enoxaparin after High-risk Coronary Stenting: The ATLAST Trial. *JACC.* 2001;38(6)1608-1613.
35. Trichon BH, Zidar JP, Bashore TM, Donahue M, Sketch MH Jr. Acute Myocardial Infarction in a Young Female. *J Invasive Cardiol.* 2001 Aug;13(8):597-600.
36. Kandzari, DE, Tchong JE, Zidar JP. Coronary Artery Stents: Evaluating New Designs for Contemporary Percutaneous Intervention. *Cath Cardiovas Interven* 2002; 56: 562-576.
37. Kandzari DE, Zidar JP. Drug-eluting Stents: New Frontiers for Contemporary Percutaneous Intervention. *Harrison's On-line* 2002.
38. Cantor WJ, Miller JM, Hellkamp AS, Kramer JM, Peterson ED, Hasselblad V, Zidar JP, Newby LK, Ohman EM. Role of Target Vessel Size and Body Surface Area on Outcomes after Percutaneous Coronary Interventions in Women. *Am Heart J,* 2002; 144(2): 297-302.
39. Batchelor WB, Tolleson T, Larsen R, Hutchinson J, Mantell RM, Huang Y, Davidian M, Cantor WJ, Sketch MH, Ohman EM, Zidar JP, Gretler D, Dibattiste P, Tchong JE, Califf RM, Harrington RA. Randomized COMparison of PLatelet Inhibition with ABCiximab, TiRofiban, and EPTifibatide During Percutaneous Coronary Intervention in Acute Coronary Syndromes: The COMPARE Trial. Comparison of Measurements of Plate Aggregation with Aggrastat, ReoPro, and Eptifibatide. *Circulation* 2002; 106(12): 1470-6.

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2. **Zidar JP**, Hurwitz JL: Peri-infarct Ventricular Arrhythmias in Patients Treated with Intravenous Thrombolysis, *Circulation* 82 (suppl. IID):A2945, 1990.
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Book Chapters:

1. Muhlestein JB, **Zidar JP**, Jackman JD, Jr.; Vascular Biology of Restenosis: An Overview. Editors: Roubin, Califf, O'Neill, Phillips, and Stack. *INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice*, 1993.
2. **Zidar JP**, Labinaz M, Jackman JD, Stack RS: Bioabsorbable Stents. Editors: Roubin, Califf, O'Neill, Phillips, and Stack. *INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice*, 1993.
3. **Zidar JP**, Phillips HR, Jackman JD, Stack RS: Acute Closure, Dissection, Perforation. Editors: Roubin, Califf, O'Neill, Phillips, and Stack. *INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice*, 1993.
4. Labinaz M, **Zidar JP**, Roubin GS, Stack RS: Choosing Coronary Guidewires and Balloon Catheters. Editors: Roubin, Califf, O'Neill, Phillips, and Stack. *INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice*, 1993.
5. **Zidar JP**, Lincoff AM, Stack RS: Bioabsorbable Stents. Editor: Topol EJ. *Textbook of Interventional Cardiology*, 2nd edition, 1993.
6. Labinaz M, **Zidar JP**, Brott BC, Stack RS: Biodegradable Stents. Editors: Iyer and Roubin. *Coronary Artery Stenting*, 1998.
7. Armstrong BA, **Zidar JP**, Phillips HR, Stack RS: Biodegradable Stents. Editors: Bertrand, Serruys, Sigwart. *The Handbook of Cardiovascular Interventions*, Ch. 59. 1996.

8. Virmani R, Carter AJ, Farb A, Laird JR, **Zidar JP**, Haber RH, Stack RS, Reeves T, Yoklavich M. Experimental observations with stents in canine and porcine coronary models. Editor: Sigwart. Endoluminal Stenting, Ch. 3, 1996
9. Tanguay JF, **Zidar JP**, Phillips HR, Stack RS. Stent Technology Today: The Development, Technology, Choice of Materials, and Engineering Aspects. Coronary Stenting - The First Decade. Editor: Sigwart, 1996.
10. Tanguay JF, Kruse KR, Phillips HR, **Zidar JP**, Stack RS. The Polymer Stent. Editor: Sigwart, Endoluminal Stenting. Ch 30. 1996.
11. Kong D, **Zidar JP**. Dissection, Abrupt Closure, and Perforation. Editors: Roubin, O'Neill, and Stack. INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice, 2nd Edition, 2002.
12. **Zidar JP**, Crowley JJ. The ACS Multi-Link Stent. Editors: Roubin, O'Neill, and Stack. INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice, 2nd Edition, 2002.
13. Muhlestein JB, **Zidar JP**, Blazing MA: Vascular Biology of Restenosis: An Overview. Editors: Roubin, O'Neill, and Stack. INTERVENTIONAL CARDIOVASCULAR MEDICINE: Principles and Practice, 2nd Edition, 2002.
14. **Zidar JP**, Greenbaum AB, Hermiller JB, Goldberg S, Safian R. Coronary Stents. Editors: Freed and Safian. MANUAL OF INTERVENTIONAL CARDIOLOGY, 3rd Edition. 2001.
15. Singh KP, **Zidar JP**. Evolving Approaches to Iliofemoral, Popliteal and Renal Artery Intervention. Science Innovation Synergy 2006 Yearbook. Chapter 7, pg. 83-94., 2006.
16. Zidar FJ, Rao S. **Zidar JP**. Iliac Angioplasty and Stenting. Editors: King, and Yeung. INTERVENTIONAL CARDIOLOGY. Chapter 51, p.551-560., 2007.

AFFIDAVIT OF DR. WILLIS M. WU

1. Dr. Willis Wu, being first duly sworn, states as follows:
2. I am over the age of eighteen (18) years and am a resident of Wake County, North Carolina. I do not suffer from any mental disability or infirmity that prevents me from making this Affidavit. This Affidavit is based on my own personal knowledge.
3. I have practiced cardiology for years and have extensive training and experience in interventional cardiology procedures. My CV is attached to this Affidavit as Exhibit 1.
4. As a cardiologist with special interest in structural heart disease at UNC REX, I routinely perform a number of procedures referred to as "Structural Heart Procedures." Such procedures are referred to using terminology such as Transcatheter Aortic Valve Replacement ("TAVR") and other terms described below. I have confirmed that the current CPT codes for these Structural Heart Procedures are as follows:

TAVR Primary Procedures

- 33363 - TAVR Open Axillary Art
- 33362 - TAVR Open Femoral
- 33364 - TAVR Open Iliac Art
- 33361 - TAVR Percutaneous Fem Art
- 33365 - TAVR - Trans-Aortic
- 33366 - TAVR Transapical

TAVR Add Ons

- 33369 - TAVR w/ Central A&V Cannulation
- 33368 - TAVR w/ Open Periph A&V Pump Bypass
- 33367 - TAVR w/ Perc A&V Pummp Bypass

Mitral Clip procedures

- 33418 - Initial Clip
- 33419 - Add'l Clip

Watchman procedures

- 33340 - Percutaneous Transcatheter Closure Left Atrial Appendage

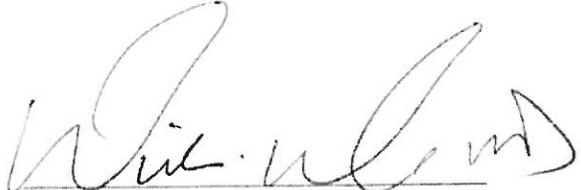
ASD/PFO

- 93580 - Closure ASD/PFO W/ Implant

5. Structural Heart Procedures: (1) are not diagnostic; and (2) do not involve interventions pertaining to the coronary blood vessels of the heart. Rather, Structural Heart Procedures are therapeutic interventions to restore, repair or reconstruct the heart muscle or heart valves, not coronary blood vessels.

6. At UNC REX, we have historically performed these Structural Heart Procedures on UNC REX medical equipment designated as cardiac cath equipment for certificate of need ("CON") regulatory purposes. However, Structural Heart Procedures are perfectly safe to perform on non-cardiac cath equipment.

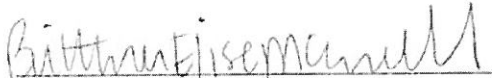
Further affiant sayeth not.



Willis M. Wu, M.D.

STATE OF NORTH CAROLINA
COUNTY OF WAKE

Sworn to and subscribed before me this
the 30th day of August, 2017.



Notary Public

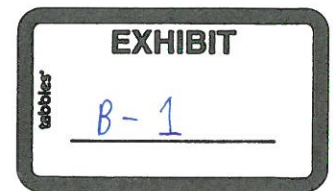


My Commission expires:
December 27, 2021

Exhibit

1. Curriculum Vitae of Ravish Sachar, M.D.

Willis M. Wu, M.D.
3406 Roller Mill Ct.
Raleigh, NC 27607
willis.wu@unchealth.unc.edu



Education and Training:

August 2013 – Present	North Carolina Heart and Vascular , Raleigh, NC Interventional Cardiologist
July 2011 – June 2013	Cleveland Clinic , Cleveland, OH Fellow in Interventional Cardiology
January 2009 – June 2011	Cleveland Clinic , Cleveland, OH Chief Fellow, Department of Cardiovascular Medicine
July 2008 – June 2011	Cleveland Clinic , Cleveland, OH Fellow in Cardiovascular Medicine
July 2007-June 2008	University of North Carolina Hospitals , Chapel Hill, NC Chief Resident in Internal Medicine
June 2004-June 2007	University of North Carolina Hospitals , Chapel Hill, NC Resident in Internal Medicine
August 2000-May 2004	University of Maryland School of Medicine , Baltimore, MD Doctor of Medicine
September 1996-May 2000	Princeton University , Princeton, NJ Bachelor of Arts in History

Awards and Achievements:

2016	Rising Star Award <i>UNC Rex Hospital</i>
2013	Guest Editor of Manual of Cardiovascular Medicine, 4 th edition. Philadelphia, PA: Lippincott 2013. *Winner of British Medical Association Medical Book Awards First Prize in Cardiology 2013
June 2011	Razavi Award for Clinical Excellence <i>Cleveland Clinic</i>
September 2007	Kaiser Permanente Excellence in Teaching Award , UNC School of Medicine Whitehead Medical Society <i>University of North Carolina Hospitals</i>
August 2000-May 2004	Inducted into Benjamin Rush Medical Society , an honor society whose membership is based on character and achievements <i>University of Maryland School of Medicine</i>
September 1996-May 2000	Member of 1998 NCAA Division I National Championship lacrosse team Received three varsity letters in lacrosse <i>Princeton University</i>

Experience:

July 2009-2013 **Clinical Events Adjudicator for PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safely versus Ibuprofen Or Naprosyn)**
Cleveland Clinic

August 2009-June 2011 **Heart and Vascular Institute Documentation and Problem List Committee**
Cleveland Clinic

July 2007-June 2008 **Committee on Pharmacology and Therapeutics**
Committee of Service Chiefs, Department of Medicine
Committee on Commitment to Caring
Pain Review Committee
Clinical Instructor for Introduction to Clinical Medicine
University of North Carolina Hospitals

July 2006-June 2008 **Education Committee, Department of Medicine**
University of North Carolina Hospitals

August 2000-May 2004 **Coordinator of Student Hosting Program for Office of Admissions**
University of Maryland School of Medicine

September 2001-May 2002 **Co-Chairman of Project H.O.P.E., coordinated activities at the American Cancer Society Hope Lodge and Ronald McDonald House**
University of Maryland School of Medicine

Office of Admissions, interviewed applicants for School of Medicine
University of Maryland School of Medicine

May 2001-September 2001 **Co-Chairman of Big Sibling Committee**
University of Maryland School of Medicine

Research Publications:

Wu W, Masri A, Popovic ZB, Smedira NG, Lytle BW, Marwick TH, Griffin BP, Desai MY. "Long-term survival of patients with radiation heart disease undergoing cardiac surgery: a cohort study." *Circulation*. 2013 Apr 9;127(14):1476-84.

Wu W, Lincoff AM. "Pharmacotherapy During Saphenous Vein Graft Intervention." *Intervent Cardiol Clin* 2013: 273-282.

Khurana RK, Wu WM, "The Valsalva Maneuver: A Literature Review and Personal Observations", *Autonomic Review*, 2001, Volume: 5, Pages: 61-70.

Book Chapters:

Wu W, Runge M. "Sudden Cardiac Death in Athletes." In: Runge, Patterson, Stouffer editors. *Netter's Cardiology 2nd Edition*. Philadelphia, PA: Saunders Elsevier 2010.

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Licensure:

Ohio Medical Board 35.098436 Expiration 10/01/2013
North Carolina Medical Board 2007-01060 Expiration 04/12/2017

Certification:

American Board of Internal Medicine

*Internal Medicine 10/2007

*Cardiovascular Medicine 11/2011

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Family:

Married to Christine Wu, M.D. (Pediatrics)

Daughter Evelyn age 7

Son Wesley age 6

Son James age 3

Hobbies:

Spending time with family, exercising, playing golf, traveling