CLINICAL RESEARCH UTILIZING BIO-TECH PHARMACAL PRODUCTS

STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
1. Cholecalciferol Supplementation Alters Calcitriol-Responsive Monocyte Proteins and Decreases Inflammatory Cytokines Bio-Tech D3-50,000 IU **PUBLISHED:** J. Am. Soc. Nephrol., **2010**, 353–361.	The Kidney Institute, University of Kansas Medical Center Jason R. Stubbs – Principal Investigator	Cholecalciferol therapy reduced circulating levels of inflammatory cytokines, including IL-8, IL-6, and TNF. These data suggest that nutritional vitamin D therapy has a biologic effect on circulating monocytes and associated inflammatory markers in patients with end stage renal disease (ESRD).
2. The effect of various vitamin D supplementation regimens in breast cancer patients. Bio-Tech D3-1,000 IU and 50,000 IU **PUBLISHED:** Breast Cancer Research and Treatment, **2011**, 127, 171-7.	University of Rochester Medical Center Peppone L.J., Huston A.J., Reid M.E., Rosier R.N., Zakharia Y., Trump D.L., Mustian K.M., Janelsins M.C., Purnell J.Q., Morrow G.R.	CONCLUSION: Compared to the no supplementation group, weekly high-dose supplementation significantly increased 25(OH)D levels, while daily low-dose supplementation did not significantly increase levels. Vitamin D deficiency and insufficiency were common among women with breast cancer. Clinicians should carefully consider vitamin D supplementation regimens when treating vitamin D deficiency in breast cancer patients.
3. Supplementation for 16 Weeks Improves Flow-Mediated Dilation in Overweight African-American Adults Bio-Tech D3-50,000 IU and 1000 IU **PUBLISHED:** American Journal of Hypertension, **2011**, 24, 557-562.	Georgia Health Sciences University Yanbin Dong, M.D., Ph.D. – Study Director Jennifer Pedersen-White, D.O.	CONCLUSION: Supplementation of 60,000 IU monthly oral vitamin D3 (approx. 2,000 IU/day) for 16 weeks is effective at improving vascular endothelial function in African-American adults.

Updated: October 2012

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
4. Vitamin D3 supplementation improves insulin sensitivity in subjects with impaired fasting glucose Bio-Tech D3-5,000 IU **PUBLISHED:** Translational Research, **2011**, 276-81.	University of Minnesota - Clinical and Translational Science Institute; Minneapolis Medical Research Foundation Cary Mariash, M.D. – Study Director Shaban Nazarian, M.D. – Principal Investigator Sidney Jones, M.D. – Study Chair	CONCLUSION: High-dose vitamin D3 supplementation improves insulin sensitivity in subjects with impaired fasting glucose and suggests that supplementation might provide an inexpensive public health measure in preventing, or at least delaying, the progression from impaired fasting glucose to diabetes.
5. Vitamin D3 Decreases Parathyroid Hormone in HIV-Infected Youth Being Treated With Tenofovir: A Randomized, Placebo-Controlled Trial Bio-Tech D3-50,000 IU **PUBLISHED:** Clin. Infect. Dis., **2012**, 54, 1013-25.	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); National Institute on Drug Abuse (NIDA); National Institute of Mental Health (NIMH); Medical College of Wisconsin Multi-site study Peter L. Havens, M.S., M.D. – Study Chair	CONCLUSION: Randomized, double-blind, placebo controlled trial in HIV-infected youth. High-dose monthly vitamin D supplementation decreased parathyroid levels in those on tenofovir disoproxil fumarate (TDF)-containing antiretroviral therapy (cART) but not in those on regimens not containing TDF. Vitamin D supplementation may offset a potential effect of TDF on regulation of calcium balance and bone metabolism.
6. Increased telomerase activity and vitamin D supplementation in overweight African Americans Bio-Tech D3-50,000 IU and 1000 IU **PUBLISHED:** Intl. Journal of Obesity, **2012**, 36, 805-9.	Georgia Health Sciences University Yanbin Dong, M.D., Ph.D. – Study Director Jennifer Pedersen-White, D.O.	CONCLUSION: Vitamin D supplementation significantly increased PBMC telomerase activity in overweight African Americans. Data suggest that vitamin D may improve telomere maintenance and prevent cell senescence and counteract obesity-induced acceleration of cellular aging.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
7. Efficacy and safety of a short course of very-high-dose cholecalciferol in hemodialysis Bio-Tech D3-50,000 IU **PUBLISHED:** Am. J. Clin. Nutr., **2012**, 522–8.	Emory University Divisions of Nephrology and Cardiology Haimanot Wasse, M.D. – Principal Investigator	Short-term, high-dose oral cholecalciferol treatment of vitamin D deficiency in hemodialysis patients appears to be effective and with no evidence of toxic effects.
8. Serum 25-Hydroxyvitamin D Response to Vitamin D3 Supplementation 50,000 IU Monthly in Youth with HIV-1 Infection Bio-Tech D3-50,000 IU **PUBLISHED:** J. Clin. Endoc.Metab., Ahead of print, August 29, 2012.	Medical College of Wisconsin; University of California at San Francisco; St. Jude Children's Research Hospital; United States Department of Agriculture Human Nutrition Research Center; University of South Florida College of Medicine; University of Alabama at Birmingham Peter L. Havens, M.S., M.D. – Study Chair	Supplementation with vitamin D3 50,000 IU monthly for three doses was safe. Increases in 25(OH)D occurred in treated participants regardless of antiretroviral regimen.
9. The Effect of Vitamin D Supplementation During Caloric Restriction on Intestinal Calcium Absorption ClinicalTrials.gov ID: NCT00472654 Est. Dates: March 2007 – May 2011 Using Bio-Tech D3-2,500 IU	National Institute on Aging (NIA); Rutgers University Sue Shapses, Ph.D., R.D. – Principal Investigator Stephen Schneider, M.D. Robert Brolin, M.D.	Examine how vitamin D supplementation influences intestinal fractional calcium absorption – a measure of the amount of calcium absorbed.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
10. Vitamin D3 supplementation for adults with cystic fibrosis ClinicalTrials.gov ID: NCT00004489 Est. Dates: Oct. 1998 – 2010 Using Bio-Tech D3-5000 IU	Cystic Fibrosis Therapeutics Foundation; University of North Carolina School of Medicine; FDA Office of Orphan Products Development Robert Aris, M.D. – Study Chair	Utility of vitamin D3 supplementation to improve calcium homeostasis, bone metabolism and bone mineral density in adults with cystic fibrosis.
11. A Trial of Vitamin D Therapy in Patients With Heart Failure ClinicalTrials.gov ID: NCT01125436 Est. Dates: July 2008 – May 2012 Using Bio-Tech D3-50,000 IU	University Hospital Case Medical Center Rebecca S. Boxer, M.D. – Principal Investigator	Determine if vitamin D will improve physical performance in older adults with heart failure.
12. Vitamin D3 in Systemic Lupus Erythematosus ClinicalTrials.gov ID: NCT00710021 Est. Dates: Nov. 2008 – March 2010 Using Bio-Tech D3-2000 IU and 4000 IU	National Institute of Allergy and Infectious Diseases (NIAID); Autoimmunity Centers of Excellence; Feinstein Institute for Medical Research; Medical University of South Carolina Multi-site study Cynthia Aranow, M.D. – Study Chair Diane Karmen, M.D. – Study Chair	Explore the impact of vitamin D3 supplementation on IFN-α expression in systemic lupus erythematosus patients with vitamin D deficiency.
13. Analysis of the Response of Subjects with Atopic Dermatitis to Oral Vitamin D3 by Measurement of Antimicrobial Peptide Expression in Skin and Saliva ClincialTrials.gov ID: NCT00789880 Est. Dates: Dec. 2008 – Dec. 2009 Using Bio-Tech D3-4000 IU	National Institute of Allergy and Infectious Diseases (NIAID); Food and Drug Administration (FDA); National Jewish Health; University of California, San Diego; Oregon Health and Science University Richard Gallo, M.D., Ph.D. – Study Chair	Examine whether administration of oral Vitamin D3 will change the antimicrobial peptide expression in the skin or saliva of atopic dermatitis subjects and healthy controls; determine if the lack of expression of antimicrobial peptides in atopic dermatitis subjects could be a component of their susceptibility to eczema vaccinatum.

CLINICAL RESEARCH UTILIZING BIO-TECH PHARMACAL PRODUCTS

STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
14. The Effect of Vitamin D3 on Vascular Function and Cardiovascular Risk Factors ClinicalTrials.gov ID: NCT00948298 Est. Dates: July 2009 – Dec. 2010 Using Bio-Tech D3-50,000 IU	Charles Drew University of Medicine and Science Morehouse School of Medicine David Martins, M.D. Naureen Tareen, M.D.	Assess the role of Vitamin D3 treatment on vascular function in high risk subjects; determine if vitamin D3 treatment improves select mediators of cardiovascular function such as insulin resistance, pro-inflammatory/pro-fibrotic markers and oxidative stress markers; assess the effect of vitamin D supplementation on vascular and adipocyte gene expression profiles.
15. Impact of Vitamin D Supplementation on Host Immunity to Mycobacterium Tuberculosis ClinicalTrials.gov ID: NCT00918086 Est. Dates: July 2009 – July 2012 Using Bio-Tech D3-50,000 IU	Emory Global Health Institute; Republic of Georgia National Tuberculosis Program; National Center of Tuberculosis and Lung Diseases; Rollins School of Public Health Thomas R. Ziegler, M.D. – Principal Investigator	Determine whether correcting low vitamin D levels, in addition to getting standard therapy for tuberculosis, will help the immune system fight off infection more effectively; develop new capacity to carry out long-term translational/clinical research linking nutrition and infectious disease in the former Soviet republic of Georgia.
16. Vitamin D for Chronic Sinusitis ClinicalTrials.gov ID: NCT01007799 Est. Dates: Nov. 2009 – Oct. 2011 Using Bio-Tech D3-1000 IU and 50,000 IU	University of Chicago Jayant M. Pinto, M.D. – Principal Investigator	Determine whether vitamin D affects clinical disease expression in African Americans with chronic rhinosinusitis.
17. Impact of Vitamin D Supplementation on Lactation Associated Bone Loss ClinicalTrials.gov ID: NCT00903344 Est. Dates: Dec. 2009 – June 2012 Using Bio-Tech D3-4000 IU	University of Kansas Medical Center Leigh M. Eck, M.D. – Principal Investigator Candice Rose, M.D. Leland Graves III, M.D. Barbara P. Lukert, M.D.	Measure change in absolute bone mineral density in a population of lactating women supplemented with vitamin D3.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
18. Vitamin D Levels in Stage IV Colorectal Cancer Patients ClinicalTrials.gov ID: NCT01074216 Est. Dates: Feb. 2010 – Feb. 2012 Using Bio-Tech D3-50,000 IU	Memorial Sloan-Kettering Cancer Center Kathleen Wesa, M.D. – Principal Investigator Barrie Cassileth, Ph.D.	Determine if increasing low vitamin D levels will help improve cancer outcomes.
19. Pharmacokinetic Study of Daily Versus Monthly High-Dose Cholecalciferol Supplementation ClinicalTrials.gov ID: NCT01079923 Completed Using Bio-Tech D3-5000 IU and 50,000 IU	Mayo Clinic Bernard R. Lee, Pharm.D. – Principal Investigator Thomas D. Thacher, M.D. – Principal Investigator Michael E. Meekins, Pharm.D. – Study Director	Characterize the differences in pharmacokinetics of oral Vitamin D3 between two dosing regimens within women of child-bearing age by evaluating any changes in the number of days of detectable total serum Vitamin D.
20. The Addition of Vitamin D to Fluticasone Propionate in the Management of Seasonal Allergic Rhinitis ClinicalTrials.gov ID: NCT01103934 Complete Using Bio-Tech D3-4000 IU	The University of Chicago Medical Center Robert Naclerio, M.D. – Principal Investigator	Determine if the addition of vitamin D to fluticasone propionate provides greater symptomatic relief in patients with seasonal allergic rhinitis compared to fluticasone propionate treatment alone.
21. Impact of Vitamin D Repletion in Hemodialysis Patients ClinicalTrials.gov ID: NCT01175798 Est. Dates: August 2010 – August 2013 Using Bio-Tech D3-50,000 IU	Mount Sinai School of Medicine; National Kidney Foundation Peter Heeger, M.D. – Principal Investigator Anita Mehrotra, M.D. – Study Director	Evaluate the effect of Vitamin D supplementation on the immune system of dialysis patients.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
22. Effects of Vitamin D on Lipids ClinicalTrials.gov ID: NCT00723385 Est. Dates: Oct. 2010 – Dec. 2011 Using Bio-Tech D3-1000 IU	Jewish Home, San Francisco; National Institute on Aging (NIA) Janice B. Schwartz, M.D. – Principal Investigator	Examine whether oral vitamin D supplementation will lower LDL-cholesterol and total cholesterol concentrations.
23. Vitamin D Supplementation for Treatment of Heart Failure ClinicalTrials.gov ID: NCT01230307 Est. Dates: Dec. 2010 – Dec. 2012 Using Bio-Tech D3-1000 IU and 50,000 IU	University of Michigan Medical Center Barry E. Bleske, Pharm. D. – Principal Investigator	Establish that vitamin D supplementation in heart failure patients with low vitamin D levels will have improved outcomes compared to placebo. Evaluate the role of genetics in regard to vitamin D and heart failure.
24. Vitamin D add-on therapy enhances corticosteroid responsiveness in asthma (VIDA) ClinicalTrials.gov ID: NCT01248065 Est. Dates: Mar. 2011 – Dec. 2012 Using Bio-Tech D3-50,000 IU and 4000 IU	National Heart, Lung, and Blood Institute (NHLBI) AsthmaNet; Pennsylvania State University College of Medicine David T. Mauger, Ph.D. – Principal Investigator	Determine if the addition of vitamin D is superior to placebo in vitamin D insufficient patients with persistent symptoms on a low dose of inhaled corticosteroid.
25. Vitamin D3 Supplementation and Outcomes in Vitamin D Deficient Obese, African American Adolescents ClinicalTrials.gov ID: NCT01546103 Est. Dates: April 2011 – September 2011 Using Bio-Tech D3-1000 IU and 5000 IU	Children's Hospital of Philadelphia; Division of Endocrinology/Diabetes Sheela N. Magge, M.D. – Principal Investigator	Explore the effect of vitamin D supplementation on serum 25(OH)D in obese, African American adolescents in order to lay the foundation for a larger study aimed at defining optimal vitamin D status and adequate vitamin D intake.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
26. The Effect of a Meal on Vitamin D Absorption ClinicalTrials.gov ID: NCT01268176 Est. Dates: December 2010 – June 2012 Using Bio-Tech D3-50,000 IU	Tufts University; Jean Mayer USDA Human Nutrition Research Center on Aging Bess Dawson-Hughes, M.D. – Principal Investigator	Identify the meal condition (fasting, low-fat, or high-fat meal) under which the 25(OH)D response to supplemental vitamin D3 is greatest and most consistent.
27. Study of Cholecalciferol and Daily Genistein (G-2535) Versus Placebo in Men With Early Stage Prostate Cancer ClinicalTrials.gov ID: NCT01325311 Est. Dates: Nov. 2011 – May 2013 Using Bio-Tech D3-50,000 IU	University of Wisconsin, Madison; University of Alabama at Birmingham; University of Rochester University of Minnesota - Clinical and Translational Science Institute; Lahey Clinic; Urology San Antonio Joel W. Slaton, M.D. – Principal Investigator	Determine if taking Vitamin D and genistein could be used to prevent prostate cancer from developing in men who are at high risk of developing the disease.
28. The Effect of High-Dose Vitamin D and Physical Activity on Bone Health in Breast Cancer Patients Receiving Hormonal Therapy ClinicalTrials.gov ID: NCT01419730 Est. Dates: 2011 Using Bio-Tech D3-50,000 IU	University of Rochester Cancer Center Luke J. Peppone, Ph.D. – Principal Investigator	Determine if a combination of weekly, high-dose vitamin D therapy along with a structured home-based walking and progressive resistance exercise program will be efficacious in preventing bone loss in non-metastatic breast cancer patients who initiated hormonal therapy within the previous six months.
29. Vitamin D Supplementation on Physical and Cognitive Function ClinicalTrials.gov ID: NCT01229878 Est. Dates: July 2011 – June 2013 Using Bio-Tech D3-5000 IU and 50,000 IU	Department of Veterans Affairs , VA Medical Center – Bronx James B. Post, M.D. – Principal Investigator	Double-blind placebo controlled pilot study to determine if vitamin D supplementation in hemodialysis (HD) patients will improve physical function and cognition.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
30. Evaluation of the Effect of 25-OH-Vitamin D3 Therapy on 15-Prostaglandin Dehydrogenase Expression in Primary Tumor and Normal Colorectal Mucosa in Patients with Colorectal Cancer ClinicalTrials.gov ID: NCT01403103 Est. Dates: July 2011 – June 2012 Using Bio-Tech D3- 50,000 IU	University Hospitals Case Medical Center, Cleveland Clinic, Case Comprehensive Cancer Center Smitha Krishnamurthi, M.D. – Principal Investigator	Assess 15-prostaglandin dehydrogenase levels in tumor and normal colorectal mucosa before and after vitamin D supplementation.
31. Vitamin D and Bacterial Vaginosis ClinicalTrials.gov ID: NCT01450462 Est. Dates: August 2011 – Feb. 2013 Using Bio-Tech D3- 50,000 IU	Ohio State University, Division of Infectious Diseases Abigail Norris Turner, Ph.D. – Principal Investigator	Assess the effect of vitamin D supplementation on non-pregnant women with bacterial vaginosis.
32. Supplementation Via Daily or Monthly Regimens and the Effect on Levels of Vitamin D in Human Milk and Infant Serum ClinicalTrials.gov ID: NCT01240265 Est. Dates: Dec. 2010 – August 2011 Using Bio-Tech D3-5000 IU and 50,000 IU	Mayo Clinic Thomas D. Thacher, M.D. – Principal Investigator	Assess the feasibility of providing adequate vitamin D to breastfed infants through maternal vitamin D supplementation. Compare the number of days of detectable milk vitamin D concentrations between two dosing regimens of oral cholecalciferol in lactating mothers. Compare the change in serum 25(OH)D concentrations in infants receiving milk from mothers supplemented with either 5,000 IU daily or 150,000 IU monthly cholecalciferol.
33. Vitamin D Supplementation in Obese African American Adolescent and Adults ClinicalTrials.gov ID: NCT01583621 Est. Dates: Oct. 2011 – Sept. 2012 Using Bio-Tech D3-5000 IU and 50,000 IU	Medical College of Georgia Yanbin Dong, M.D., Ph.D.	Compare the dose-responsive effects of vitamin D on serum 25(OH)D, parathyroid hormone, calcium, and cardiovascular risk factors.

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34. The Effect of Vitamin D Supplementation on Cardiovascular Risk Factors Among Hispanics and African Americans With Type 2 Diabetes Mellitus ClinicalTrials.gov ID: NCT01412710 Est. Dates: July 2011 – October 2012 Using Bio-Tech D3-4000 IU	Florida International University – Human Nutrition Laboratory Fatma E. Huffman, Ph.D. – Principal Investigator	Determine the effect of vitamin D supplementation (4000 IU once daily for 6 months) on reducing heart disease risk and in improving blood glucose control in type 2 Diabetes subjects.
35. Prediabetes, Prehypertension and Vitamin D: A Practice-Based Clinical Intervention Pilot Study ClinicalTrials.gov ID: NCT01425424 Est. Dates: Aug. 2011 – Aug. 2016 Using Bio-Tech D3-1000 IU	Pennington Biomedical Research Center – Baton Rouge, Louisiana Alok K. Gupta, M.D. – Principal Investigator	To reverse modest elevations of fasting blood sugar (prediabetes) and resting blood pressure (prehypertension) by increasing blood levels of vitamin D.
36. Impact of Vitamin D Therapies on Chronic Kidney Disease ClinicalTrials.gov ID: NCT01222234 Est. Dates: 2010 – 2012 Using Bio-Tech D3-50,000 IU	The Kidney Institute, University of Kansas Medical Center Jason R. Stubbs – Principal Investigator	Investigate the effects of cholecalciferol and calcitriol on pathways involved in innate immunity in monocytes of patients with chronic kidney disease.
37. Vitamin D Levels in the Skin of Healthy Subjects After Oral Supplementation ClinicalTrials.gov ID: NCT01447355 Est. Dates: 2012 Using Bio-Tech D3-50,000 IU	University of Arizona Clara Curiel, M.D. – Principal Investigator	Determine if high-dose oral cholecalciferol supplementation increases vitamin D receptor (VDR) expression in keratinocytes from photo-protected areas in healthy subjects with documented insufficient serum levels of 25-hydroxyvitamin D.

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STUDY INFORMATION	INSTITUTIONS AND INVESTIGATORS	STUDY PURPOSE OR CONCLUSION
38. Vitamin D3 Supplementation for Heart Failure Patients ClinicalTrials.gov ID: NCT01636570 Est. Dates: May 2012 – March 2013 Using Bio-Tech D3-5,000 IU	International Heart Institute of Montana Saint Patrick Hospital and Health Sciences Center Bradley Berry, M.D. – Principal Investigator Heidi Moretti, M.S., R.D.	Determine if adjunctive vitamin D3 will be superior to placebo for heart failure patients using validated, objective measures, quality of life, and biomarkers of relevance related to inflammation, hormones, and vitamin D metabolism.
39. Vitamin D for Enhancing the Immune System in Cystic Fibrosis (DISC Study) ClinicalTrials.gov ID: NCT01426256 Est. Dates: October 2011 – April 2014 Using Bio-Tech D3-50,000 IU	Emory University, Cystic Fibrosis Foundation Multi-site study Vin Tangpricha, M.D., Ph.D . – Principal Investigator	Determine if high-dose vitamin D supplementation (bolus dose of 250,000 IU, then maintenance dose of 50,000 IU vitamin D every other week) improves clinical outcomes related to lung function and immunity in patients with cystic fibrosis who are admitted to the hospital with an acute lung infection.
40. Vitamin K to Attenuate Coronary Artery Calcification in Hemodialysis Patients ClinicalTrials.gov ID: NCT01528800 Est. Dates: April 2012 – April 2013 Using Bio-Tech Vitamin K1 (5 mg)	Queens University and Kingston General Hospital Ontario, Canada Rachel Holden, M.D. – Principal Investigator	Determine if vitamin K1 supplementation (10 mg) three times per week reduces the progression of coronary artery calcification over six months in dialysis patients.
41. High Dose Preoperative Cholecalciferol Supplementation and Perioperative Vitamin D Status ClinicalTrials.gov ID: NCT01689779 Est. Dates: Sept. 2012 Using Bio-Tech D3-50,000 IU	Massachusetts General Hospital Sadeq A. Quraishi, M.D. – Principal Investigator	Study the impact of vitamin D status on surgical site infections in patients who will undergo colorectal surgery. Determine whether the administration of a bolus oral dose of cholecalciferol in the preoperative setting alters vitamin D status in the perioperative setting.