PRECISION RESEARCH INSTITUTE

CURRICULUM VITAE

Signature: _____ **Date:** 3/9/16

NAME: **TITLE:**	Cynthia L. Schaeffer, MD Principal Investigator	**DATE UPDATED:**	March 2016

RESEARCH SITE ADDRESS & PHONE:

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EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
National Institute of Health (NIH) Web-based Training	Certificate	2016	Protecting Human Subject Research Participants
Collaborative Institutional Training Initiative (CITI)	Certificate	2014	Good Clinical Practices
Saint Louis University Saint Louis, Missouri		2002-2005	Gastroenterology/ Hepatology Fellowship
Saint Louis University Saint Louis, Missouri		2000-2002	Internal Medicine Residency
Saint Louis University Saint Louis, Missouri		1999-2000	Internal Medicine Internship
Saint Louis University Saint Louis, Missouri	M.D	1999	Medicine
Saint Louis University Saint Louis, Missouri	B. A.	1995	Chemistry

BOARD CERTIFIED:

BOARD CERTIFIED/ELIGIBLE	YEAR(s)	SPECIALTY
Board Certified	2002	Internal Medicine
Board Eligible	2005	Gastroenterology

POSITIONS AND EMPLOYMENT:

2014-Present	Endoscopy Center of Chula Vista, Chula Vista, CA
2011-Present	Investigator-Precision Research Institute, LLC, San Diego, CA
2011-Present	Euclid Endoscopy Center, San Diego, CA
2010-Present	Private Practice-Digestive Disease Associates, San Diego, CA
2009-2011	Investigator- Desta Digestive Disease Medical Center, San Diego, CA
2005-2010	Private Practice-Desta Digestive Disease Medical Center, San Diego, CA
1989-1995	Nurses Aid-for Retired Religious of the Sacred Heart, San CA

RESEARCH EXPERIENCE:

Principal Investigator

Paion: A Phase III Study Evaluating the Efficacy and Safety of XXXX Compared to Placebo and Midazolam in Patients Undergoing Colonoscopy

Synergy: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXXX in Patients with Irritable Bowel Syndrome with Constipation (IBS-C)

Synergy: An Open-Label, Long-Term Safety and Tolerability Study of XXXX in Patients with Irritable Bowel Syndrome with Constipation XXXX

BI: A phase II, multicenter, randomized, double-blind, multiple dose, placebo-controlled, parallel-group study to evaluate the efficacy, pharmacokinetics, and safety of BI 655066, an IL-23 p19 antagonist monoclonal antibody, in patients with moderately to severely active Crohn's disease, who are naïve to, or were previously treated with anti-TNF therapy

gICare: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Proof-Of-Concept Study of XXX-XXXX in the Management of Visceral Pain in Subjects Undergoing Sedation-Free Full Colonoscopy

SK life science: A Double-Blind, Randomized, Placebo-Controlled, 12-Week, Dose-Range-Finding Trial of 5 and 20mg Capsules of XXXXXXXX Administered Once Daily at Doses of 5, 10, or 30mg to Subjects with Chronic Idiopathic Constipation

Astra Zeneca: A Phase 2a to Evaluate the Efficacy and Safety of XXXXXXX in Subjects with Moderate to Severe Crohn's Disease Who Have Failed or Are Intolerant to Anti-Tumor Necrosis Factory-alpha Threapy

Abbvie: A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of XXXXXX® (XXXXXXXXXX) `in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

ONO Pharma: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX-XXXX In Female Subjects with Diarrhea-Predominant Irritable Bowel Syndrome (IBS)

Sub-Investigator

Vertex: A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of 2 Dose Levels of XXXX Administered as Monotherapy and One Dose Level of XXXX Administered in Combination With XXXX for the Treatment of Acute Uncomplicated Seasonal Influenza A in Adult Subjects

Watson: A Randomized, Placebo-Controlled, Parallel Group, Multicenter Study to Evaluate the Efficacy and Safety of XXXX for the Intermittent Treatment of Abnormal Uterine Bleeding Associated with Leiomyomas

Functional Dyspepsia Reduction Evaluation and Safety Trial (FDREST)A randomized, double-blind, placebo-controlled study to assess the safety and efficacy of XXXX, a medical food, in the dietary management of patients with functional dyspepsia

Genentech: A Phase III, Double-Blinded, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of XXXXXXXXXXX During Induction and Maintenance in Patients with Moderate to Severe Active Ulcerative Colitis who Are Refractory to or Intolerant of TNF Inhibitors

Janssen: A Phase 2a Open-label Study to Evaluate Prediction of Response to XXXXXXXXX Using a Transcriptomic Profile in Subjects with Moderately to Severely Active Ulcerative Colitis

Synergy: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXXXXXXXXXX (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation

BMS: A Phase 3 Evaluation of XXXXXXXXXXX Plus XXXXXXXXXX in Treatment-naïve and Treatment experienced Chronic Hepatitis C (Genotype 1, 2, 3, 4, 5, or 6) Subjects Coinfected with Human Immunodeficiency Virus (HIV)

BMS: A Phase 3 Evaluation of XXXXXXXXXXX and XXXXXXXXXX in Treatment Naïve and Treatment Experienced Subjects with Genotype 3 Chronic Hepatitis C Infection

Merck: A Phase II/III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of XX-XXXX and XX-XXXX in Subjects with Chronic Hepatitis C Virus Infection and Chronic Kidney Disease

Ferring: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of XXXXXXXXXX 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period

Ferring: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg

XXXXXXXXXX Daily in the Treatment of Chronic Idiopathic Constipation

BI: Safety, antiviral effect and pharmacokinetics of BI XXXXXX in combination with XXXXXXXX and with or without XXXXXXXXX for 4, 16, 24, 28 or 40 weeks in patients with chronic HCV genotype 1 infection (randomized Phase Ib/II)

BI: A phase III randomised, double-blind and placebo-controlled study of XXXXXXXX in combination with XXXXXXXXXXX and XXXXXXXXX in patients with moderate hepatic impairment (Child-Pugh B) with genotype 1b chronic hepatitis C infection

BI: A phase III randomised, partially double-blind and placebo-controlled study of XXXXXXXXX in combination with XXXXXXXXXXX and XXXXXXXXX for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those ineligible to receive XXXXXXXXXXXX

BMS: A Long-Term Follow-up Study of Subjects Who Participated in a Clinical Trial in Which XXXXXXXXXXX (XXX-XXXXXX) and/or XXXXXXXXXXX (XXX-XXXXXX) Was Administered for the Treatment of Chronic Hepatitis C

Salix: A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Multicenter Study To Assess the Efficacy and Safety of XXXXXXXXX Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects with Early Decompensated Liver Cirrhosis

Sanofi: A randomized, double-blind, placebo-controlled, multicenter study evaluating efficacy and safety of XXXXXXXXX in patients with active moderate to severe Ulcerative Colitis (UC).

Sanofi: A single-arm open label extension study evaluating the long term safety and tolerability of XXXXXXXXX in patients with Ulcerative Colitis (UC)

Cubist: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Safety and Tolerability of XX-XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non Cancer Pain

Cubist: A Randomized, Double-Blind, Placebo controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XX-XXXX for the Treatmetn of Opioid-Induced Constipation in Adults Taking Opioid Theraphy for Chronic Non-Cancer Pain

Novartis: A randomized, multicenter, double-blind, placebo-controlled, parallel-group, 24-week pilot study to assess the efficacy, safety and tolerability of XXXXXX in patients with non-alcoholic fatty liver disease

Astra Zeneca: A Longitudinal Study of Patients with Opioid-Induced Constipation

Salix: A Phase 3, Open Label, Multicenter Study to Assess the Safety and Tolerability of XXXXXX in Subjects with Active Ulcerative Proctitis or Proctosigmoiditis

BMS: A Phase 2 study of XXX-XXXXXX in combination with XXX-XXXXXXXXXX Alfa-2a and XXXXXXXXX in Treatment Naïve Subjects with Chronic Hepatitis C Genotype 1 and 4 Infection

BMS: Open-Label, Multiple-Dose, Dose Escalation Study to Evaluate the Pharmacodynamics, Pharmacokinetics, and Safety of Co administration of XXX-XXXXXX, XXX-XXXXXX, and XXX-XXXXXX when administered for 24 or 12 weeks in Treatment-Naïve Subjects Infected with Hepatitis C Virus Genotype 1

BMS: A Phase 3, Randomized, Double-Blind, Controlled Study Evaluating the Efficacy and Safety of XXXXXXXXXXXXX XXXXXX-XX, with and without XXXXXXXXXXX, Compared to XXXXXXXXXXXXX XXXX-XX, Each in Combination with XXXXXXXXX, in the Treatment of Naïve Genotype 2 and 3 Chronic Hepatitis C Subjects

Salix: A Study to Assess Repeat Treatment Efficacy and Safety of XXXXXXXXXX 550 mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)

Purdue: A Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of XXXXXXXXX/XXXXXXXX Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to XXXXXXXXX Controlled release Tablets in Uncontrolled moderate/ severe Chronic Low back pain

Purdue: A Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of XXXXXXXXX/XXXXXXXX Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to XXXXXXXXX Controlled release Tablets in Controlled moderate/ severe Chronic Low back pain

Millennium: A Phase 3, Open-label Study to Determine the Long-term Safety and Efficacy of XXXXXXXXXXX (XXXXXXX) in Patients with Ulcerative Colitis and Crohn's Disease

Novartis: A Randomized, open-label trial of the safety and efficacy of XXXXXX-XXXXXXXXXXXX in combination with XXXXXXX and XXXXXXXX and XXXXXXXXXX in combination with XXXXXXX/XXX in African-American treatment naïve subjects with Chronic Hepatitis C genotype 1

Pharmasset: XXXXX-XXXX Open-Label, Randomized, Duration finding study to Investigate the Safety, Tolerability, Pharmokinetics and Pharmacodynamics following oral administration of XXX-XXXX in combination with XXXXXXX and XXXXXXXXX in treatment Naïve Patients with Chronic hepatitis C genotype 1,4,5 or 6

Santarus: Randomized, Double-Blind, Placebo controlled study to evaluate the Efficacy and Safety of oral XXXXXXXXXX XXX Extended Release tablets as Add-on therapy in patients with Active, mild-moderate Ulcerative Colitis not adequately controlled on a background Oral 5-ASA Regimen

Prometheus: Research Study to Evaluate XXXXXXXX in Severe IBS-D: Analysis of Current Clinical Practice Environment.

Prometheus: Study to Evaluate The Utilization Of Testing for XXXXXXXXXX And Antibodies to XXXXXXXXXX in Patients Treated with XXXXXXXXXX

Salix: A Randomized, Double Blind, Placebo-Controlled Study of a fixed Dose of Subcutaneous XXXXXXXXXXXXXXXX in Adults With Advanced Illness and Opioid-Induced Constipation: Efficacy, Safety, and Additional Health Outcomes

Salix: Open Label Extension Study to Assess the Safety of a Fixed Dose of Subcutaneous XXXXXXXXXXXXXXXX in Subjects With Advanced Illness and Opioid-Induced Constipation.

BMS XXX: A Phase 2 study of BMS- in combination with Peg-Interferon Alfa-2a and Ribavirin in Treatment Naïve Subjects with Chronic Hepatitis C Genotype 1 and 4 Infection (what BMS are you referring to 014 or 017).

BMS XXX: A Phase 3, Randomized, Double-Blind, Controlled Study Evaluating the Efficacy and Safety of Peginterferon Lambda-1a, with and without Declatasvir, Compared to Peginterferon Alfa-2a, Each in Combination with Ribavirin, in the Treatment of Naïve Genotype 2 and 3 Chronic Hepatitis C Subjects.

BI XXXX.XX: A phase III randomized, partially double-blind and placebo-controlled study of BI 207127 in combination with faldaprevir and ribavirin for chronic genotype 1 hepatatis C infection in an extended population of treatment naïve that includes those ineligibles to receive peginterferon.

Novartis: A Randomized, open-label trial of the safety and efficacy of DEBXXX-Alsiporivir in combination with Peg-Interferon and Ribavirin and boceprevir in combination with Peg-INF/RBV in African-American treatment naïve subjects with Chronic Hepatitis C genotype 1.

Novum: A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multi-Site Study to Evaluate the Clinical Equivalence of Lubiprostone 24mcg Capsules with AMITIZA in the Treatment of Chronic Idiopathic Constipation.

Pharmasset: A Multicenter, Open-Labe;, Randomized, Duration finding study to Investigate the Safety, Tolerability, Pharmokinetics and Pharmacodynamics following oral administration of PSI-XXXX in combination with Peg-Interferon and Ribavirin in treatment Naïve Patients with Chronic hepatitis C genotype 1,4,5 or 6.

Novo Nordisk: A trial comparing cardiovascular safety of XXXXXXX XXXXXXXX versus XXXXXXX XXXXXXXX in subjects with type 2 diabetes at high risk of cardiovascular events

Mitsubishi: A Phase 2, randomized, double-blind, placebo-controlled, fixed-dose, parallel-group, multicenter, efficacy, and safety study of XX-XXXX for treatment of uremic pruritus in subjects with end-stagerenal disease receiving hemodialysis

ManKind: A Phase 3, Multicenter, Open-label, Randomized Clinical Trial to Evaluate the Safety of XXXXXXXXXXXX Insulin Inhalation Powder in Type 1 or Type 2 Diabetic Subjects with Obstructive Pulmonary Disease (Asthma or Chronic Obstructive Pulmonary Disease) Over a12-month Treatment Period with a 2-month Follow-up

BI: A phase III, randomized, double-blind, parallel group study to evaluate the efficacy and safety of XXXXXXXXX 5 mg compared to placebo, administered as oral fixed dose combination with XXXXXXXXXXXXX 10 mg or 25 mg for 24 weeks, in patients with type 2

Intarcia: A Phase 3, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of XXXX XXX to XXXXXXXXXXX as Add-on Therapy to XXXXXXXXX in Patients with Type 2Diabetes

Intarcia: A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with XXXX XXX in Patients Treated with Standard of Care for Type 2 Diabetes

Bayer: A prospective, randomized, open-label, parallel-group, active-controlled, multicenter study exploring the efficacy and safety of once-daily oral XXXXXXXXXXX compared with that of dose-adjusted oral vitamin K antagonists for the prevention of cardiovascular events in subjects with nonvalvular atrial fibrillation scheduled for cardioversion

Amarin: A Multi-Center, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of XXXXXX on Cardiovascular Health and Mortality in Hypertriglyceridemic Patients with Cardiovascular Disease or at High Risk for Cardiovascular Disease: REDUCE-IT (Reduction of Cardiovascular Events with EPA – Intervention Trial)

Takeda: Randomized, Double-Blind, Placebo- and Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XXX-XXX 25 mg and 50 mg Compared to Placebo and XXXXXXXXXXX 100 mg When Used in Combination with XXXXXXXXX in Subjects with Type 2 Diabetes

Takeda: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 24-Week Study to Evaluate the Efficacy and Safety of Daily Oral XXX-XXX 50 mg Compared With Placebo as an Add-On to XXXXXXXXXXX in Subjects With Type 2 Diabetes

Takeda: Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate Cardiovascular Outcomes of XXX-XXX, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events

Astra Zeneca: double-blind, parallel group, multicentre phase IIIb study to compare XXXXXXXXXX with XXXXXXXXXXX treatment on the risk of cardiovascular death, myocardial infarction and ischaemic stroke in patients with established Peripheral Artery Disease (EUCLID – Examining Use of tiCagreLor In paD)

Sanofi: A randomized, double-blinded, placebo-controlled, parallel-group, multicenter study to evaluate cardiovascular outcomes during treatment with XXXXXXXXXXXX in type 2 diabetic patients after an Acute Coronary Syndrome event

GSK-HZCXXX: A Clinical Outcomes Study to compare the effect of XXXXXXXXXXX XXXXXXX/XXXXXXXXXX Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.

Cephalon: A 16-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXXXXXXXX (3.0 mg/kg) Treatment in Patients With Moderate to Severe Asthma

Forest: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of XXXXXXXXX and XXXXXXXX Given as a Fixed-Dose combination in Patients With Stage 1 or 2 Essential Hypertension.

Chiltren: A 12-week Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate XXXXXXXXX XXXXXXXXXX XXXXXXXXXX Dose Response in Adult Subjects with Partly Controlled and Uncontrolled Asthma.

Lilly: A Multinational Observational Study Assessing XXXXXXX use: understanding the challenges associated with progression of therapy - The XXXXXXX Type 2 Diabetes Study.

Novum, Chronic Idiopathic Constipation XXXXXXX001

Astra Zeneca, Opiod Induced Constipation X3820X00004

Astra Zeneca, Opiod Induced Constipation X3820X00007

Eisai, Colonoscopy Sedation, X408

Logical Therapeutics, Osteoarthritis, XX-XX001-003

Sangamo, Diabetic Neuropathy XXXX

TAP Pharmaceutical, GERD X-XXX4-082

Novartis, Hypertension, XXXX100XXX03

Merck, Hypertension/Diabetes Mellitus II, XX0736-007-00

Merck, Weight Loss, 015-XX

Luitpold Pharmaceutical, Iron Deficiency Anemia, 1XXX07017

Merck, Diabetes, XX-0431-024

Pfizer, Diabetes/Asthma, X2171028

Pfizer, Diabetes/COPD, X2171030

Merck, Obesity, XXX-0364

Mylan Bertek Pharmaceutical, Inc, Hypertension, XXX-324

Mylan Bertek Pharmaceutical, Inc, Hypertension, XXX-310

Pfizer, Hypertension, XXXX1001

Takeda, Diabetes, 01-04-XX-XXX-525

Alteon, Hypertension, XX-711

Merck, Diabetic, XX-043

Merck & Co Inc, Weight Loss XXXXX

Endo, LBP EN-3261-001

Tap Pharmaceuticals, Gout X-XX06-153

Pfizer, Tibia Fractured X3241002

Millennium, Crohn's X13007

Millennium, Ulcerative Colitis X13006

Millennium, Rollover X13008

Eisai, Colonoscopy Sedation, X408