



October 8, 2019

Principal Investigator: Rovshan Ismailov, M.D., M.P.H., Ph.D.

Sponsor: CMDAT Research Foundation, Pfizer

Protocol Number: 53704129

Study Title: "Improving awareness and knowledge of shared decision-making and biosimilars among gastroenterology team members in Colorado"

Dear Dr. Ismailov:

The above-referenced study has been determined by Matthew Pfeiffer, Ph.D. to be exempt according to 45 CFR 46.104:

Exempt Category #2

Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

In addition, the informed consent was reviewed and modified as part of the exempt application. Please use the modified IRB version attached.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR:

- (1) Submit for review by IntegReview all modifications to the protocol or consent form(s), when applicable, if planned changes to an exempt study might make that study non-exempt from human subject's research, prior to the implementation of the change;
- (2) Protect the confidentiality of all personally identifiable information collected and train your staff and collaborators on policies and procedures for ensuring confidentiality of this information;

*3815 S. Capital of Texas Hwy, Suite 320, Austin, TX 78704
Tel. 512.326.3001 Local Fax. 512.697.0085 <http://www.integreview.com>*

IRB Registration Numbers: IRB00008463, IRB00003657, IRB00004920, IRB00001035, IRB00006075



If you have any questions please feel free to contact our office at 512-326-3001.

Sincerely,

A handwritten signature in black ink, appearing to read 'Govea', with a stylized flourish at the end.

Victoria Govea, CCRP
Director of Operations

MEMBERSHIP ROSTER
As of September 16, 2019

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB
^M M. Alexander Kenaston	Ph.D., M.S. (Toxicology), R.N., CIP	Scientific	IRB Chairperson (Monday) Toxicology Research Scientist: Specializing in First time in human pharmacology studies Licensed Registered Nurse Prior: Project Manager, CRA and CRC for CRO	Non-affiliated Paid Consultant
^M Jami Brackeen	CST, CCRP	Scientific	IRB Co-chair and Coordinator (Monday) Prior: Quality Control Associate for IRB Regulatory Compliance; Certified Surgical Technologist	Full time Employee
^M Olga Obrda	B.S. (Chemistry)	Scientific	Prior: Project Management and Business Development for CRO	Non-affiliated Paid Consultant
^M Bryson Michael Duhon	Pharm.D., BCPS	Scientific	Clinical Assistant Professor UT College of Pharmacy Adjunct Professor at UT Health Science Center (UTHSCSA) Department of Medicine	Non-affiliated Paid Consultant
^M Ashley Hutson		Non- scientific	Patient advocate for Spinal Cord Injuries Experience volunteering as a research subject in clinical trials	Non-affiliated Paid Consultant
^M Karen Haslund	M.D.	Scientific	Board certified physician, Pediatrics	Non-affiliated Paid Consultant
^T Charles F. Ryan	Ph.D., M.S. (Pharmacology & Toxicology), R.Ph.	Scientific	IRB Chairperson (Tuesday) Specializing in First time in human studies Pharmacology & Toxicology Radiation Safety/Radioisotope, Nutritional/Food supplements and Medical Foods	Non-affiliated Paid Consultant
^T Tonya Reed		Non- scientific	IRB Co-chair and Coordinator (Tuesday) Prior: Project Assistant for CRO	Full time Employee

^M Denotes regular Monday board members ^T Denotes regular Tuesday board members ^W Denotes regular Wednesday board members Th Denotes regular Thursday board members
^F Denotes regular Friday board members Other members are alternates All regular Board members can serve as alternates on other Boards as specified by their positions (e.g. Scientific for Scientific)
Non-scientific members represent the general perspective of study participants

Note: In addition to our regular members, we have access to specialists in therapeutic areas not represented on this roster.

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB
^T Sara Bartos	M.D.	Scientific	Board certified physician, Internal Medicine	Non-affiliated Paid Consultant
^T Marcy Goodfleisch	B.S., M.A. (Liberal Studies); Mediator (Civil & Family Dispute Resolution); Graduate work in Communications and English	Non-scientific	Adjunct University Professor Ethicist Management & Communication Consultant Prior: Clinic Administrator for nationally recognized HIV Clinic and large FQHC community health center.	Non-affiliated Paid Consultant
^T Michael D. Aldridge	Ph.D. (Nursing Education), R.N., CNE	Scientific	Assistant Professor of Nursing Prior: various Nursing roles for pediatric intensive care unit, including Specialty Education Coordinator for pediatric ICU, previous experience as an IRB member for Institutional IRB	Non-affiliated Paid Consultant
^T Christine du Castel	M.D.	Scientific	Medical Advisor; previously licensed to practice General Medicine in France	Non-affiliated Paid Consultant
^W Carolyn Hensler	B.S. (Physical Education)	Scientific	IRB Chairperson (Wednesday) Quality Assurance and Quality Control Administrator for CRO Prior: Clinical Research Monitor and Project Manager for CRO	Non-affiliated Paid Consultant
^W Melanie Castillo		Non-scientific	IRB Co-chair and Coordinator (Wednesday) Prior: Quality Assurance and Clinical Research Coordinator for clinical research site	Full time Employee
^W Raymond Carr	R.Ph.	Scientific	Staff Pharmacist	Non-affiliated Paid Consultant
^W Christopher P. Martin	Pharm.D., M.S., BCPS	Scientific	Clinical Assistant Professor, Division of Pharmacotherapy UT Clinical Pharmacy Coordinator Assistant Professor University of Oklahoma Health Sciences Center, College of Pharmacy	Non-affiliated Paid Consultant
^W Robert A. Blum	Pharm.D.	Scientific	Prior: Principal investigator for Phase I-IV research	Non-affiliated Paid Consultant
^W William K. Rawlinson	M.D., FCCP, FAASM	Scientific	Board certified physician, Pulmonary Disease, Critical Care and Internal Medicine	Non-affiliated Paid Consultant

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Th Frederick Kopec	J.D., B.A. (Philosophy)	Non-scientific	IRB Chairperson (Thursday) Licensed: Practice of Law Ethicist	Non-affiliated Paid Consultant
Th Bridget Briseno		Non-scientific	IRB Co-chair and Coordinator (Thursday) Prior: Project Assistant in Phase I facility	Full time Employee
Th Michael Romain	M.D.	Scientific	Board certified physician, Internal Medicine	Non-affiliated Paid Consultant
Th Mary O'Connell		Scientific	Quality & Regulatory Affairs Manager at CRO Prior: Clinical Research Recruiter, Data Associate, Coordinator and QC Auditor for CRO IRB Administrator Emergency Medical Technician Paramedic	Non-affiliated Paid Consultant
Th Matthew Pfeiffer	Ph.D. (Pharmacology & Toxicology)	Scientific	Project Manager and CRA for CRO Specializing in human studies; Pharmacology, Toxicology, CNS, Infectious disease, Metabolic/Endocrine Disorders, Oncology	Non-affiliated Paid Consultant
Th Susan Parker Ginnings	R.Ph.	Scientific	Prior: Hospital Pharmacy Supervisor	Non-affiliated Paid Consultant
^F Mary Ruwart	Ph.D. (Biophysics); B.S. (Biochemistry)	Scientific	IRB Chairperson (Friday) Research Scientist Specializing in Drug Delivery Systems, Diabetes, GI Diseases, Drug Metabolism	Non-affiliated Paid Consultant
^F Jenna Rozacky	B.S. (Biology), CCRP	Scientific	IRB Co-chair and Coordinator (Friday) Prior: Assistant IRB Coordinator, Research Clinical Coordinator	Full time Employee
^F Laurajo Ryan	Pharm.D., MSc (Clinical Investigations), BCPS, CDE	Scientific	Clinical Associate Professor of Pharmacotherapy UT Austin, Department of Medicine UTHSCSA, Clinical Pharmacist Specialist South Texas Veterans Administration	Non-affiliated Paid Consultant

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^F Dennis Brannon	R.Ph., B.S. (Animal Science)	Scientific	Clinical Research Consultant, Director of Pharmacy; Executive Director Clinical Development Prior: Senior Project Manager and CRA for CRO	Non-affiliated Paid Consultant
^F Bennie C. Lopez	MBA	Non-scientific	Adult and juvenile prisoner population representative Teacher with Austin ISD Alternative Learning Center Prior: Corrections Officer and retired military	Non-affiliated Paid Consultant
^F Patricia M. Houser	M.D.	Scientific	Board certified physician; Family practice	Non-affiliated Paid Consultant
Dawn East	R.N., BSN (Nursing), ONC.	Scientific	Executive management experience in Oncology for 30+ years at multiple CROs and Site networks.	Non-affiliated Paid Consultant
Christina H. Walker	M.D., B.S.	Scientific	Physician: Family Medicine [Sports Medicine]	Non-affiliated Paid Consultant
Yessica Chapa	M.D.	Scientific	Board certified physician; Family practice	Non-affiliated Paid Consultant
Kate D. Jeffers	Pharm.D., MHA, BCOP	Scientific	Board certified Oncology Pharmacist	Non-affiliated Paid Consultant
Victoria Govea	CCRP	Non-scientific	Director of IRB Operations Prior: IRB Coordinator & Co-chair	Full time Employee
Lynn Goldman	B.S. (Nutrition), MSHP (Healthcare Administration), RD, LD, CCRP	Scientific	IRB Operations Manager Prior: IRB Coordinator & Co-chair Research Coordinator, Health Care Administration and Education, Clinical Nutrition, Registered Dietician/Certified Pediatric Nutrition Specialist	Full time Employee
Francine Lopez	B.S. (Human Development & Family Sciences), CCRP	Non-scientific	IRB Operations Supervisor Prior: IRB Co-chair and Coordinator Managed Phase I-IV clinical research site	Full time Employee

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Levi Machado	CCRP	Non-scientific	IRB Training Administrator Prior: IRB Coordinator & Co-chair	Full time Employee
Angelica Martinez	CCRP	Non-scientific	IRB Operations Specialist Prior: IRB Co-chair and Coordinator	Full time Employee

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