



April 2, 2014

Joanne Vega  
Strategic Research Associates, LLC  
25 West Cataldo, Suite D  
Spokane, WA 99201

Re: National Institute on Drug Abuse (NIDA), Protocol Number PEERx, Strategic Research Associates, LLC "Customer Feedback Information for NIDA PEERx Videos"

Dear Ms. Vega:

The above-referenced study has been determined by **M. Alexander Kenaston, Ph.D., M.S., R.N., CIP** to be exempt according to 45 CFR 46.101(b) (1):

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Additionally, the research must meet the following:

- The research is not FDA-regulated
- The research does not involve prisoners as subjects

Although you chose category 2 the reviewer indicated the above category more appropriately meets your project.

#### **RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR:**

- (1) Submit for review by IntegReview all modifications to the protocol or consent form(s), when applicable, 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;
- (3) For funded projects, submit a copy of renewals/continuations and advise whether the study of specimens, records, or human subjects has changed from the original submission; and
- (4) Submit notification if planned changes to an exempt study might make that study non exempt from human subject's research

3001 S. Lamar Blvd., Suite 210, 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,

*Rosa S. Sandoval.*

Rosa S. Sandoval, B.S., CCRP  
Senior IRB Coordinator, Co-chair

**MEMBERSHIP ROSTER**  
**As of April 1, 2014**

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
<sup>M</sup> Susan Parker Ginnings, Chairman <sup>Th</sup> Susan Parker Ginnings	R.Ph.	Scientific	Retired; Hospital Pharmacy Supervisor	Non-affiliated	Scientific members
<sup>M</sup> Levi Machado, Co-chair		Non- Scientific	IRB Coordinator, administrative support for IntegReview	IntegReview Employee	Non-scientific members
<sup>M</sup> Olga Obrda	B.S. (Chemistry)	Scientific	BD Representative; previously employed as Project Management and Business Development for CRO	Non-affiliated	Scientific members
<sup>M</sup> Jennifer Christensen	Pharm. D., BCPS	Scientific	Internal Medicine, Investigational Drugs, Neuropharmacology research scientist	Non-affiliated	Scientific members
<sup>M</sup> Susan Krivacic	B.A. (German), M.P.Aff (Public Affairs)	Scientific	Consultant and patient advocate for oncology trials; previously employed as Senior Executive and Executive Director for CRO	Non-affiliated	Scientific members
<sup>T</sup> Charles F. Ryan, Chairman <sup>W</sup> Charles F. Ryan	Ph.D., M.S. (Pharmacology & Toxicology), R.Ph.	Scientific	Retired; representative for first time in human studies; Pharmacology, Toxicology, Radiation Safety, Radioisotope, Nutritional/Food supplements and Medical Foods	Non-affiliated	Scientific members
<sup>T</sup> Valerie Nelson, Co-chair	B.A. (History and French), M.A. (History), CCRP	Non- scientific	IRB Coordinator, administrative support for IntegReview; previously employed as Lead Project Assistant and a Research Assistant for CRO	IntegReview Employee	Non-scientific members
<sup>T</sup> Sara Bartos	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated	Scientific members
<sup>T</sup> M. Alexander Kenaston	Ph.D., M.S. (Toxicology), R.N., CIP	Scientific	Toxicology Research Scientist, representative for first time in human studies, Pharmacology/ Toxicology, Licensed Registered Nurse; previously employed as Project Manager, CRA and CRC for CRO	Non-affiliated	Scientific members

<sup>M</sup> Denotes regular Monday board members <sup>T</sup> Denotes regular Tuesday board members <sup>W</sup> Denotes regular Wednesday board members <sup>Th</sup> Denotes regular Thursday board members  
<sup>F</sup> 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

NAME	DEGREES/ CERTS.	BOARD POSITION	EXPERIENCE	AFFILIATION WITH IRB	ALTERNATE FOR
<sup>T</sup> Christine du Castel	M.D.	Scientific	Medical Advisor; previously licensed to practice General Medicine in France	Non-affiliated	Scientific members
<sup>T</sup> Marcy Goodfleisch	B.S., M.A. (Liberal Studies)	Non-scientific	Mediator (civil, family & workplace dispute resolution); previously employed as Management & Communication Consultant, Clinic Administrator for nationally recognized HIV Clinic and large FQHC community health center, Ethicist	Non-affiliated	Non-scientific members
<sup>W</sup> Carolyn Hensler, Chairman	B.S. (Physical Education)	Non-scientific	Quality Assurance and Quality Control Administrator for CRO; previously employed as a Clinical Research Monitor; and Project Manager	Non-affiliated	Non-scientific members
<sup>W</sup> Tonya Reed, Co-chair		Non-scientific	IRB Coordinator, administrative support for IntegReview; previously employed as a Project Assistant for CRO	IntegReview Employee	Non-scientific members
<sup>W</sup> Karen Haslund	M.D.	Scientific	Licensed physician, Pediatrics	Non-affiliated	Scientific members
<sup>W</sup> Raymond Carr	R.Ph.	Scientific	Staff Pharmacist	Non-affiliated	Scientific members
<sup>W</sup> Christopher P. Martin	Pharm.D., M.S. (Pharmacy), 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	Scientific members
<sup>Th</sup> Frederick Kopec, Chairman	J.D. , B.A. (Philosophy)	Non-scientific	Licensed, Practice of Law, Ethicist	Non-affiliated	Non-scientific members
<sup>Th</sup> Rosa S. Sandoval, Co-chair	B.S. (Chemistry), CCRP	Scientific	Administrative support for IntegReview; previously employed as Clinical Research Coordinator and Medical Research Assistant for University	IntegReview Employee	Scientific members
<sup>Th</sup> Michael Romain	M.D.	Scientific	Licensed physician, Internal Medicine	Non-affiliated	Scientific members

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<sup>Th</sup> Mary O'Connell		Scientific	Quality & Regulatory Affairs Manager; previously employed as Clinical Research Recruiter, Data Associate, Coordinator and QC Auditor for CRO, IRB Administrator, Emergency Medical Technician Paramedic	Non-affiliated	Scientific members
<sup>Th</sup> Dario Kuzmanovic	B.A., MHSc, CRA	Scientific	Research Ethics Manager; serves as a member on HIV Research Ethics Board, Research Ethics Policy & Advisory Committee, U of T REB Chairs Committee and the Research Ethics & Research Education Committee, Ethicist	Non-affiliated	Scientific members
<sup>F</sup> Mary Ruwart, Chairman	Ph.D. (Biophysics); B.S. (Biochemistry)	Scientific	Research Scientist, Drug Delivery Systems, Diabetes, GI Diseases, Drug Metabolism	Non-affiliated	Scientific members
<sup>F</sup> Jami Brackeen, Co-chair	CST, CCRP	Non-scientific	IRB Coordinator; former Quality Control Associate for IRB Regulatory Compliance department; Certified Surgical Technologist	IntegReview Employee	Non-scientific members
<sup>F</sup> Laurajo Ryan	Pharm.D., MSc, (Clinical Investigations), BCPS, CDE	Scientific	Clinical Assistant Professor of Pharmacy, Division of Pharmacotherapy UT, Department of Medicine UTHSCSA, Clinical Pharmacy Specialist STX VA	Non-affiliated	Scientific members
<sup>F</sup> Dennis Brannon	R.Ph. , B.S. (Animal Science)	Scientific	Clinical Research Consultant, Director of Pharmacy; Executive Director Clinical Development; previously employed as Senior Project Manager and CRA for CRO	Non-affiliated	Scientific members
<sup>F</sup> Ashley Hutson		Non-scientific	Unemployed; previously volunteered as research subject in clinical trials	Non-affiliated	Non-scientific members
<sup>F</sup> Eduardo E. Sandoval	M.D., MBA (Healthcare Administration)	Scientific	Clinical Research Consultant; previously employed as Medical Affairs/Medical Officer, Regional Senior Clinical Research Associate, Quality Assurance Auditor, Clinical Research Manager	Non-affiliated	Scientific members

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Victoria Govea	CCRP	Non-scientific	Management support for IntegReview; former IRB Coordinator, Co-chair for IntegReview	IntegReview Employee	Non-scientific members
Erik Guerra	B.S., CCRP (Biochemistry)	Scientific	Former IRB Coordinator, administrative support for IntegReview; previously employed as Clinical Research Recruiter for CRO, Research Assistant, and Medical Technician for a globally-recognized cancer center	IntegReview Employee	Scientific members
Angelica Martinez		Non-scientific	Former IRB Coordinator, administrative support for IntegReview	IntegReview Employee	Non-scientific members
Lynn Goldman	B.S. (Nutrition), MSHP (Healthcare Administration), RD, LD, CCRP	Scientific	Management support for IntegReview; former IRB Coordinator, administrative support for IntegReview; previously employed as Research Coordinator, Health Care Administration and Education, Clinical Nutrition, Registered Dietician/Certified Pediatric Nutrition Specialist	IntegReview Employee	Scientific members

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