

**WIRB**<sup>®</sup>

**Western Institutional Review Board**<sup>®</sup>

*Certificate  
of  
Approval*

(360) 252-2500  
1-800-562-4789  
Fax (360) 252-2498

3535 SEVENTH AVENUE, SW, OLYMPIA, WA 98502-5010  
P.O. BOX 12029, OLYMPIA, WA 98508-2029

**THE FOLLOWING WERE APPROVED:**

**INVESTIGATOR:** Atilla Brtan M.D.  
Suite 2208  
6560 Fannin Street  
Houston, Texas 77030

**BOARD ACTION DATE:** 9/30/2010  
**PANEL:** 12  
**STUDY APPROVAL EXPIRES:** 10/26/2011  
**STUDY NUM:** 1094447  
**WIRB PRO NUM:** 20070516  
**INVEST NUM:** 65654  
**WO NUM:** 1-632729-1  
**CONTINUING REVIEW:** Annually  
**SITE STATUS REPORTING:** Annually

**SPONSOR:** BARRx Medical, Inc.  
**PROTOCOL NUM:** B-500  
**AMD. PRO. NUM:**  
**TITLE:**  
HALO Patient Registry: Ablation of Barrett's Esophagus

**APPROVAL INCLUDES:**

Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

**WIRB APPROVAL IS GRANTED SUBJECT TO:**

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



Theodore D. Schultz, J.D., Chairman

10/12/2010

(Date)

This document electronically reviewed and approved by Schultz, Ted on 10/12/2010 9:39:47 PM PST

IRB NUMBER: HCG-MR-11-0456

IRB APPROVAL DATE: 10/7/2011



**WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:**

- Atilla Ertan, M.D., P.A., Suite 2208, 6560 Fannin Street, Houston, Texas 77030
- The Methodist Hospital, GI Endoscopy Center, Suite 649, 6550 Fannin Street, Houston, Texas 77030
  - Texas International Endoscopy Center, Suite 1500, 6629 Main Street, Houston, Texas 77030

**If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.**

**ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:**

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.
2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.
3. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate. (Due to the unique circumstances of research conducted at international sites outside the United States and Canada where WIRB approved materials are translated into the local language, the following requirements regarding consent forms bearing the WIRB approval stamp and regarding certification of translations are not applicable.)
  - a. Use only the most current consent form bearing the WIRB "APPROVED" stamp.
  - b. Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by WIRB.
  - c. Obtain pre-approval from WIRB for use of recruitment materials and other materials provided to subjects.
4. Obtain pre-approval from WIRB for changes in research.
5. Obtain pre-approval from WIRB for any planned deviations that could adversely affect the rights, safety or welfare of subjects, or the integrity of the research data and any changes in the research activity. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects. Deviations necessary to eliminate apparent immediate hazards to the human subjects should be reported within 10 days.
6. Promptly report to WIRB all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:
  - a. Unexpected (in terms of nature, severity or frequency);
  - b. Related or possibly related to participation in the research; and
  - c. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

Please go to [www.wirb.com](http://www.wirb.com) for complete definitions and forms for reporting.

7. Provide reports to WIRB concerning the progress of the research, when requested.
8. Ensure that prior to performing study-related duties, each member of the research study team has had training in the protection of human subjects appropriate to the processes required in the approved protocol.

**Federal regulations require that WIRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WIRB. These reports must be returned even though your study may not have started.**

**DISTRIBUTION OF COPIES:****Contact**

Atilla Ertan M.D.  
Fuji  
Shahin R. Hasan  
Miriam Gorena  
Janet (Jan) Miller

**Company Name**

Atilla Ertan, M.D., P.A.  
BARRx Medical, Inc.  
BARRx Medical, Inc.  
BARRx Medical, Inc.  
BARRx Medical, Inc.



WESTERN INSTITUTIONAL REVIEW BOARD®  
3535 SEVENTH AVENUE, SW • OLYMPIA, WA 98502-5010  
P.O. BOX 12029 • OLYMPIA, WA 98508-2029  
(360) 252-2500 • 1-800-562-4789 • FAX (360) 252-2498

Dear Covered Entity,

RE: HIPAA/HITECH Business Associate Agreement

This letter and agreement apply only to organizations that are "Covered Entities," as that term is defined in the Health Insurance Portability and Accountability Act (HIPAA). If your organization is not a Covered Entity, this letter and agreement do not apply and have no legal force or effect. The intent of this agreement is to ensure WIRB and the Covered Entity are in compliance with the Business Associate Agreement requirements of HIPAA/HITECH. If you have a separately negotiated HIPAA/HITECH Business Associate Agreement with WIRB, this agreement does not apply and has no legal force or effect.

The American Recovery and Reinvestment Act (ARRA) was signed into law on February 17, 2009. The ARRA created the Health Information Technology for Economic and Clinical Health Act (HITECH), which establishes new federal privacy and security laws with respect to Protected Health Information and makes changes to existing Health Insurance Portability and Accountability Act (HIPAA) privacy and security regulations. The new requirements under HITECH became effective February 17, 2010. These requirements apply to Covered Entities and Business Associates.

Please find attached a Business Associate Agreement (BAA), which is required under HIPAA/HITECH and incorporates the necessary provisions. Note this BAA does not require a signature from your organization. However, this BAA should be kept in your organization's records.

Please be advised of WIRB's general expectation that any information submitted to WIRB contain only the minimum amount of Protected Health Information necessary to allow WIRB to perform its functions.

We appreciate your understanding and assistance in meeting this regulatory requirement.

Sincerely,

David G. Forster, Chief Compliance Officer

## BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement") is entered into by and between Western Institutional Review Board, Inc. ("WIRB") and covered entity for which WIRB is providing research review services ("Covered Entity"), each a "Party" and collectively, the "Parties." This Agreement is effective upon the later date of February 17, 2010, or the date upon which WIRB first becomes a Business Associate with respect to Covered Entity ("Effective Date"). In consideration of the mutual promises and the exchange of information pursuant to this Agreement, the Parties hereby agree as follows.

### 1. Definitions

1.1 Protected Health Information. Protected Health Information ("PHI") shall have the meaning given to such term under HIPAA, and shall mean individually identifiable health information maintained or transmitted in any form or

medium, including, without limitation, all information (including demographic, medical, and financial information), data, documentation, and materials that relate to (i) the past, present and future physical or mental health or condition of an individual; (ii) the provision of health care to an individual for purposes of both treatment and research; (iii) the past, present, or future payment for the provision of health care to an individual. PHI does not include health information that has been de-identified in accordance with the standards for de-identification provided for in the HIPAA Privacy Rule, 45 CFR §§ 160 and 164.

1.2 Individual. "Individual" has the same meaning as the term "individual" in 45 CFR § 164.501 and includes a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

1.3 Institutional Review Board. Institutional Review Board ("IRB") shall have the same meaning as defined in 21 C.F.R. § 50.3(i).

1.4 Miscellaneous. Terms used, but not otherwise defined, in this Agreement shall have the meaning set forth in HIPAA and the regulations, 45 C.F.R. §§ 160 and 164, as may be amended (the "Privacy and Security Rules"), and the federal Health Information Technology for Economic and Clinical Health Act ("HITECH"), and the regulations promulgated thereunder, as may be amended.

## 2. Background Statements

2.1 Purpose. The purpose of this Agreement is to comply with the requirements of the Privacy and Security Rules and HITECH.

2.2 Relationship. WIRB and Covered Entity have entered into, or are entering into, or may subsequently enter into agreements or other documented arrangements (collectively, the "Business Arrangement") for WIRB's provision of IRB or other research-related services ("Services"). WIRB may receive, use, obtain, access, or create PHI from or on behalf of Covered Entity in the course of such Business Arrangement.

## 3. Permitted Uses and Disclosures

WIRB may use and/or disclose PHI (i) only as permitted or required by this Agreement or the Business Arrangement, (ii) as necessary for its proper management and administration, (iii) to carry out its legal responsibilities, or (iv) as otherwise required by law. WIRB may disclose PHI to, and permit the use of PHI by, its employees, contractors, agents, or other representatives only to the extent related to and necessary for the performance of Services. WIRB will not use or disclose PHI in a manner (i) inconsistent with Covered Entity's obligations under the Privacy and Security Rules or HITECH, or (ii) that would violate the Privacy and Security Rules or HITECH if disclosed or used in such a manner by Covered Entity.

## 4. Security Standards

WIRB will implement and maintain security safeguards to ensure that PHI obtained by or on behalf of Covered Entity is not used or disclosed by WIRB in violation of this Agreement. WIRB will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of the covered entity, in the same manner as it would if WIRB were a Covered Entity. WIRB acknowledges that HITECH requires Business Associates to comply with 45 C.F.R. §§ 164.308, 164.310, 164.312, and 164.316, as if the Business Associate were a Covered Entity.

## 5. Unauthorized Uses and Disclosures; Breaches; Security Incidents

5.1 Reporting and Mitigating the Effect of Unauthorized Uses and Disclosures. If WIRB has knowledge of any use or disclosure of PHI not provided for by this Agreement, WIRB will notify Covered Entity in accordance with Paragraph 10.4. WIRB will establish and implement procedures and other reasonable efforts for mitigating harmful effects arising from improper use and/or disclosure of PHI.

5.2 HIPAA Data Breach Notification and Mitigation. WIRB agrees to implement a reasonable system for the discovery and prompt reporting of any "breach" of "unsecured PHI," as those terms are defined in 45 C.F.R. § 164.402. The Parties acknowledge and agree that 45 C.F.R. § 164.404 *et seq.* govern when a breach shall be treated as discovered, the timeline by which Business Associate must provide notice of a breach, and the information that must be provided in such notice. The parties further acknowledge that WIRB is not acting as the agent of Covered Entity under the Business Arrangement.

5.3 Reporting Security Incidents. WIRB agrees it will promptly report to Covered Entity any "security incident" of which it becomes aware, as this term is defined in the HIPAA Security Rule.

## 6. Use and Disclosure of PHI by Subcontractors, Agents, and Representatives

WIRB will require any subcontractor, agent, or other representative that is authorized to receive, use, or have access to PHI which is obtained or created under the Agreement, to agree, in writing, to (i) adhere to the same restrictions, conditions and requirements regarding the use and/or disclosure of PHI and safeguarding of PHI that apply to WIRB under this Agreement and (ii) implement reasonable and appropriate safeguards to protect PHI.

## 7. Individual Rights.

WIRB will comply with the following Individual rights requirements, as applicable, to PHI used or maintained by WIRB:

7.1 Right of Access. WIRB agrees to provide access to PHI, at the request of Covered Entity, to Covered Entity or, as directed, to an Individual in order to meet the requirements under 45 C.F.R. § 164.524.

7.2 Right of Amendment. WIRB agrees to make amendment(s) to PHI that Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526 at the request of Covered Entity or an Individual.

7.3 Right to Accounting of Disclosures. WIRB agrees to document such disclosures of PHI as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528, as amended by HITECH § 13405(c). WIRB agrees to provide to Covered Entity such information collected in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528, as amended by HITECH § 13405(c).

## 8. Audit, Inspection and Enforcement by Covered Entity

With reasonable notice and during regular business hours, Covered Entity may audit WIRB to monitor compliance with this Agreement. WIRB will correct any violation of this Agreement found by Covered Entity and will certify in writing that the correction has been made. WIRB will make its internal practices, books, records, policies, and procedures relating to the use and disclosure of PHI received from, or created or received by WIRB on behalf of Covered Entity, available to the United States Department of Health and Human Services ("HHS"), or its agents for purposes of monitoring Covered Entity's or WIRB's compliance with the Privacy and Security Rules, and HITECH.

## 9. Term and Termination

9.1 Term. This Agreement will become effective on the Effective Date. This Agreement shall remain in effect for the duration of all Services WIRB provides to Covered Entity, unless terminated pursuant to 9.2, and for so long as WIRB shall remain in possession of any PHI received from, or created or received by WIRB on behalf of Covered Entity.

9.2 Termination. Either Party may provide the other Party with written notice of the existence of a material breach and afford such Party ("Breaching Party") thirty (30) days to cure the material breach. In the event Breaching Party

fails to cure the material breach within such time period, the non-Breaching Party may immediately terminate the Agreement. Either Party may also report the material breach to the Secretary of HHS.

9.3 Effect of Termination. Except as otherwise provided by law governing record-keeping requirements (including but not limited to 21 CFR 56.115(b) and 45 CFR 46.115(b)), upon termination of this Agreement, if feasible, WIRB will return or destroy all PHI received from, or created or received by WIRB on behalf of Covered Entity that WIRB still maintains in any form and will retain no copies of such information. Except as otherwise provided by law, if WIRB believes that it is not feasible to return or destroy the PHI as described above, WIRB shall notify the Covered Entity in writing. The notification shall include: (i) a statement that WIRB has determined that it is infeasible to return or destroy the PHI in its possession, and (ii) the specific reasons for such determination. WIRB will ensure that any and all protections, requirements and restrictions contained in this Agreement will be extended to any PHI retained after the termination of the Agreement, and that any further uses and/or disclosures will be limited to the purposes that make the return or destruction of the PHI infeasible.

## 10. Miscellaneous

10.1 Amendments; Waiver. This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior representations or agreements, whether oral or written, except to the extent Covered Entity has already entered a substantially similar Agreement inclusive of HITECH obligations with WIRB, with respect to such matters. It may not be modified, nor will any provision be waived or amended, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event will not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

10.2 Effective Without Signatures. This Agreement shall not require signatures by the Parties and shall become effective on the Effective Date.

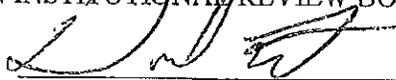
10.3 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors and permitted assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

10.4 Notices. Any notice to be given under this Agreement shall be made, in writing, to the other Party's Privacy Officer, or person delegated the responsibility for HIPAA/HITECH Business Associate Agreements, via U.S. Mail, commercial courier or hand delivery. Any such notice shall be deemed given when so delivered to or received at the above named recipient's address.

10.5 WIRB's Primary Duty. WIRB's primary duty is to research subjects, and nothing in this Agreement will be construed to limit WIRB's independence to take actions necessary to protect the subjects' rights and welfare, or to alter WIRB's primary duty to the subjects under the federal regulations on the protection of human subjects, United States Food and Drug Administration (USFDA) Regulations 21 CFR §§ 50 and 56, and United States Department of Health and Human Services (USDHHS) Regulations 45 CFR § 46.

WESTERN INSTITUTIONAL REVIEW BOARD, INC.

By:



Name:

David G. Forster

Title:

Chief Compliance Officer

WESTERN INSTITUTIONAL REVIEW BOARD® (WIRB®)  
 3535 Seventh Avenue, SW-Olympia, Washington 98502-5010  
 P.O. Box 12029-Olympia, Washington 98508-2029  
 Phone: (800) 562-4789 (360) 252-2500 Fax: (360) 252-2498

PANEL TWELVE  
 [Effective September 20, 2010]

CHAIRMAN  
 Theodore D. Schultz

PANEL CHAIR  
 Kay L. King

MEMBERS						
LAST NAME	FIRST NAME	DEGREES & LICENSES	PRIMARY SPECIALTY OR OCCUPATION	PHYSICIAN SCIENTIST/ OTHER SCIENTIST/ NON-SCIENTIST	GENDER	WIRB AFFILIATED
Cifuentes-Hiss	Yolanda S.	BS	Spanish Instructor	NS	F	None
Ennever	John F.	MD, PhD	Pediatrician	PS	M	WIRB Affiliated
Honeyman-Huff	Carole	BA, HDip.	Photographer (Medical/Forensic/General)	NS	F	None
King	Kay L.	JD	Attorney	NS	F	None
Lane	Jeffrey	JD	Attorney	NS	M	None
O'Connor	Kathleen A.	MD	Preventative Medicine	PS	F	None
Schrager	Laura	BS	Sociologist	OS	F	None
Wells	Christine R.	MD	Neurologist	PS	F	WIRB Affiliated
White	Tery B.	Ph.D.	Science Editor	OS	F	None
ALTERNATE MEMBERS						
Arend	Brenda M.	BA, MA	Speech Language Pathologist	OS	F	None
Armstrong	Joan M.	BS	Retired Clinical Coordinator and Monitor / Volunteer	OS	F	None
Att	Michael	MD, PhD	Anesthesiologist	PS	M	None
Blon	Barbara A.	MA	Psychology - Counselor	NS	F	WIRB Affiliated
Bouillon-Jensen	Cindy	BS, MA	Medical Technology, Medical Ethics	OS	F	None
Broberg	Lucille R.	MD	Pediatrician	PS	F	WIRB Affiliated
Capra	Paul	MDiv, MEd	Business Executive	NS	M	None
Casson	Henry I.	MD	Cardiovascular Anesthesiologist	PS	M	None
Cavazos	Nora M.	MD	Biostatistician	PS	F	None
Coates	Cathy	BA	Medical Assistant/Phlebotomist	OS	F	WIRB Affiliated
Collingwood	Cynthia	PhD	Psychologist	OS	F	None
Cook	Barbara A.	BS	Social Scientist, State Human Rights Commission	NS	F	None
Copple	Dwayne E.	JD	Attorney	NS	M	None
Crabs	Jack M.	MD	Internist	PS	M	None
Cummings	Mariella H.	RN, MS	Nursing Administration	OS	F	None
Dierdorff	John T.	DO	Obstetrics/Gynecology	PS	M	None
Dunkerson	Duane	BA, MA	Freelance Editor	NS	M	None
Dunlop	Cheryl	BSN, MA, MEd	Educator/Writer	OS	F	WIRB Affiliated
Ennever	Fanny K.	Ph.D.	Environmental Scientist	OS	F	WIRB Affiliated
Fitzgerald	Mary	BA	Public Relations and Photography	NS	F	None
Flannery	Ann R.	BA	Insurance Underwriter	NS	F	None
Fornoff	Carolyn	RN	Nursing, Critical Care	OS	F	None
Gadde	Ronald A.	DMin	Minister	NS	M	None
Gallo	Natalie	BHSc	Administrator	OS	F	WIRB Affiliated
Gamache	Maryann	BS	Educator	OS	F	None
Geissler	Francis T.	PhD, MD	Ophthalmologist	PS	M	None
Hanlon	Sharlene	BS	Administrator	NS	F	None
King	Barbara	BSN, RN	Nursing	OS	F	WIRB Affiliated

< May substitute for any Physician Scientist  
 \* Chair Designee  
 ※ Knowledgeable in Complementary or Alternative Healthcare

<< May substitute for any Non-Scientist  
 ✨ Expedited Reviewer  
 © Prisoner Representative  
 ♦ Knowledgeable in Canadian Ethics

<<< May substitute for any Other Scientist  
 □ Executive Policy Committee Member  
 ❖ Canadian Citizen or Permanent Resident



IRB NUMBER: 10C-MS-11-0456  
 IRB APPROVAL DATE: 10/7/2011

WESTERN INSTITUTIONAL REVIEW BOARD® (WIRB®)  
 3535 Seventh Avenue, SW-Olympia, Washington 98502-5010  
 P.O. Box 12029-Olympia, Washington 98508-2029  
 Phone: (800) 562-4789 (360) 252-2500 Fax: (360) 252-2498

ALTERNATE MEMBERS							
Holm	☼◻◻◻◻	Margaret	JD, RN	Attorney, Family Law	OS	F	None
Holman	◻◻	Robert E.	BS, MBA	Chemical Engineer	NS	M	None
Jacob	◻◻	Jean P.	MA	Counselor, Child/Family	NS	F	None
Jacobs	☼◻◻◻	William C.	BA	Consultant, Political Science	NS	M	None
Kaltwasser	◻	Gustavo A.	MD	Infectious Disease	PS	M	None
Kaufman	☼◻	Thomas I.	MD	Emergency Physician	PS	M	WIRB Affiliated
Kirchheim	◻	Dieter	MD	Urologist	PS	M	None
Krug	◻	James A.	MD	OB/GYN	PS	M	WIRB Affiliated
Lakewold	☼◻◻◻	Dorothy S.	BS, MT	Medical Technologist	OS	F	None
Lundborg	◻◻	Rose Ann	MSW	Family Counselor	NS	F	None
McNeill	※◻◻◻◻◻◻◻◻	John H.	MSc, PhD	Pharmaceutical Science	OS	M	None
Moore Lewis	◻◻	Barbara	MPA	Administrator	NS	F	None
Moore	◻◻	Jacqueline P.	BA	Community Volunteer	NS	F	None
Mossman	☼◻◻◻	Shannon	RN	Nursing	OS	F	WIRB Affiliated
Oberg	☼◻*◻◻	James C.	BS, MS, MBA	Administrator	NS	M	None
Ognall	☼◻*◻	Michael J.	MD	Family Physician	PS	M	None
Olson	◻◻◻	Linda J.	MSN, RN	Nursing Administration	OS	F	None
Orive	◻◻◻	Otto	CLS	Medical Technologist	OS	M	WIRB Affiliated
Padget	◻◻◻	Laurie	BA, RN	Nursing	OS	F	None
Perrin	◻	Laurence	MD	OB/GYN	PS	M	None
Powell	☼◻◻◻	Maura	BA	Clinical Research Coordinator	OS	F	WIRB Affiliated
Quan	◻	Arlen	MD	Psychiatrist	PS	M	None
Reese	☼◻*◻◻	Adele B.N.	MD	Psychiatrist, Adult and Child	PS	F	None
Reese	◻	Owen G.	MD	Nephrologist	PS	M	None
R' t	◻	Charles A.	MD	Pathologist	PS	M	None
R -Lee	◻◻◻	Susan	BSN	Nursing	OS	F	None
Roice	◻◻	Wayne	BA	Administrator	NS	M	None
Rumble	◻◻	Jeanine	BA	Program Coordinator	NS	F	None
Schultz	☼◻◻◻	Theodore D.	JD	Attorney	NS	M	None
Siegrist	☼◻◻◻	Gillian A.	BS, MT	Medical Technologist	OS	F	None
Steen	☼◻◻◻	David S.	MTh	Minister	NS	M	None
Swier	☼◻◻◻	Dick W.	BS	Aviation	NS	M	None
Taylor	☼◻	Robert A.	DO, JD	Emergency Physician, Attorney	PS	M	WIRB Affiliated
Tudor	◻◻	Katherine White	JD	Attorney	NS	F	None
Vasek	☼◻	Constance D.	MD	Emergency Physician, Family Practice	PS	F	WIRB Affiliated
Vasishth	◻◻◻	Veena	BS, MT	Medical Technologist	OS	F	None
Vazeux	☼◻	Rosemay	MD	Hematologist	PS	F	WIRB Affiliated
Vleck	☼◻	Jan P.	MD	Family Practice	PS	M	WIRB Affiliated
Waite	☼◻	Bradley E.	DO	Emergency Physician	PS	M	WIRB Affiliated
West	◻◻	Susan	BA	Educator	NS	F	WIRB Affiliated
Weyrauch	☼◻	Karl F.	MD, MPH	Family Physician	PS	M	None
Williams	☼◻◻◻	Susan	RN, MHA	Health Administration	OS	F	None

- ◻ May substitute for any Physician Scientist
- \* Chair Designee
- ※ Knowledgeable in Complementary or Alternative Healthcare
- ◻◻ May substitute for any Non-Scientist
- ☼ Expedited Reviewer
- ◻ Prisoner Representative
- ◻ Knowledgeable in Canadian Ethics
- ◻◻◻ May substitute for any Other Scientist
- ◻ Executive Policy Committee Member
- ◻ Canadian Citizen or Permanent Resident

WESTERN INSTITUTIONAL REVIEW BOARD® (WIRB®)  
 3535 Seventh Avenue, SW-Olympia, Washington 98502-5010  
 P.O. Box 12029-Olympia, Washington 98508-2029  
 Phone: (800) 562-4789 (360) 252-2500 Fax: (360) 252-2498

International Board Members  
 Alternates to all Panels except  
 Panels 10, 14, and 35  
 [Effective September 20, 2010]

ALTERNATE MEMBERS (International Fellows)

LAST NAME	FIRST NAME	DEGREES & LICENSES	PRIMARY SPECIALTY OR OCCUPATION	PHYSICIAN SCIENTIST/ OTHER SCIENTIST/ NON-SCIENTIST	GENDER	WIRB AFFILIATED
Abreha	<<< Yemane Teklai	PhD	Physiologist	OS	M	None
Alemu	< Shitaye	MD	Internal Medicine	PS	F	None
Anannamcharoen	< Sahaphol	MD	Surgeon	PS	M	None
Awah	<<< Paschal	PhD	Medical Anthropology	OS	M	None
Banchonhattakit	< Pannee	DPH	Public Health	PS	F	None
Cabrera	< Rene	MD	Internist	PS	M	None
Caceres	<<< Sonia	MA	Psychologist	OS	F	None
Chamnanvanakij	< Sangkae	MD	Pediatrician	PS	F	None
Chang	< Fung-Wei	MD	Administrator/ OB/GYN	PS	M	None
Chen	<<< Shu-Yu	MS, BS	Oncology Nurse	OS	F	None
Choi	< Hyun Il	MD	OB/GYN	PS	M	None
Djokam Tamo	< Rosine	PhD	Lecturer/Researcher	OS	F	None
Guan	<<< Xin	MA, Acupuncture	Masters in Traditional Chinese Medicine; Acupuncture Doctor Degree	OS	M	None
Han	< Aini	MD	Surgery	PS	F	None
Hu	<<< Teh-Min	PhD, MS, BS	Pharmacologist	OS	M	None
Jr	<<< Ihn Sook	RN, MPH, PhD	Nursing, Public Health, Epidemiologist	OS	F	None
Jr	<<< Nuljaree P.	PharmD, Ph.D	Pharmaceutical Sciences Professor	OS	F	None
Jotwani	<<< Geeta	PhD	Genomics, Molecular Medicine, Stem Cell Research	OS	F	None
Kim	< Bong-Seog	MD, PhD	Administrator/Internist	PS	M	None
Kim	< Jang Han	MD	Forensic Medicine	PS	M	None
Kim	< Ock-Joo	MD, PhD	Medical Historian	PS	F	None
Komwilaisak	< Ratana	MD	Associate Professor/Maternal-Fetal Medicine	PS	F	None
Koo	<< Young-Mo	PhD	Philosophy	NS	M	None
Kumar	<<< Rachakulla Hari	MBBS, DPH	Communicable Diseases, Nutrition	PS	M	None
Kumar	<<< Vijay	PhD	Physiologist	OS	M	None
Kumaran	< Paul	MBBS, MPH, BA	Public Health, Psychology	PS	M	None
Laosee	<<< Orapin	MPH, MS, BS	Public Health, Nursing	OS	F	None
Lee	<<< Hwei-Ling	PhD	Biostatistician	OS	F	None
Lee	<< Kwai-Fong (Dois)	MA	Administrator	NS	F	None
Lertsithichai	< Panuwat	MD	Surgeon	PS	M	None
Liu	< Hai Tao (Heidi)	MD	General Practitioner	PS	F	None
Lu	<<< Qi	BA	Public Health	OS	M	None
Luk	< Hsiang-Ning	MD	Anesthesiologist	PS	M	None
Magalhaes	<<< Pollyana A.	RN	Nursing	OS	F	None
Mahaisavariya	< Punkae	MD	Dermatologist/Pathologist	PS	F	None
Manaloto	<< Renato	LLB, MA, BA	Attorney, Bioethicist	NS	M	None
Manochopinig	< Sriwinon	PhD	Communications Disorders/Physical Therapy	OS	F	None
Mathur	<<< Roli	PhD	Genetics	OS	F	None
Mulate	< Yintubezinash	MD, PhD	Microbiologist	PS	F	None
Munoz	< Agueda	MD	Family Practice	PS	F	None
Nimnuan	< Chaichana	MD, PhD	Psychiatrist	PS	M	None
Oh	< Myungho	MD, PhD	Neonatologist	PS	M	None
P. o Garrido	< Heman	MD	OB/GYN	PS	M	None
P. kul	< Suthee	MD	OB/GYN	PS	M	None

< May substitute for any Physician Scientist

\* Chair Designee

※ Knowledgeable in Complementary or Alternative Healthcare

<< May substitute for any Non-Scientist

✪ Expedited Reviewer

⊗ Prisoner Representative

⊕ Knowledgeable in Canadian Ethics

<<< May substitute for any Other Scientist

□ Executive Policy Committee Member

⊕ Canadian Citizen or Permanent Resident

⊕ Knowledgeable in Canadian Ethics

**WESTERN INSTITUTIONAL REVIEW BOARD® (WIRB®)**  
 3535 Seventh Avenue, SW-Olympia, Washington 98502-5010  
 P.O. Box 12029-Olympia, Washington 98508-2029  
 Phone: (800) 562-4789 (360) 252-2500 Fax: (360) 252-2498

ALTERNATE MEMBERS (International Fellows)						
Pogonea	<	Ina	MD	Rheumatologist, Pharmacologist	PS	F None
Rogov	<	Eugene	MD, PhD, JD	General Practitioner	PS	M None
Sayinsakova	<	Bakhyt	MD, PhD, DSc	Immunology, Infectious Diseases	PS	F None
Savardekar	<	Lalita	MBBS	General Practitioner	PS	F None
Sharma	<<<	Meenakshi	PhD	Cardiovascular Disease	OS	F None
Shin	<	Hee-Young	MD, PhD	Preventative Medicine	PS	M None
Sirichotiyakul	<	Supatra	MD	OB/GYN	PS	F None
Son	<<	Ge-Yong	JD	Attorney	NS	M None
Songpatanasilp	<	Thavee	MD, MSc	Orthopedist	PS	M None
Su	<<<	Ya-Hui	BSN, MSN	Oncology Nurse	OS	F None
Tanudsintum	<	Surasek	MD	Anesthesiologist	PS	M None
Torres	<<<	Cristina	PhD	Professor	OS	F None
Wang	<<<	Bailu	BS, MS	Quality Assurance Manager	OS	F None
Wongwai	<	Phanthipha	MD	Ophthalmology	PS	F None
Wu	<<<	Rong	MMSc	Hospital Management	OS	F None
Xue	<	Di	MD, MPH, PhD	Public Health	PS	F None
Yimtae	<	Kwanchanok	MD	Otolaryngologist	PS	F None
Yu	<	Zhi Qing	MD	Pediatric Cardiologist	PS	M None

SIGNATURE AUTHORITY			
Chairman	Theodore D. Schultz, JD	Panel Chair	David S. Steen, MTh
Panel Chair	Brenda M. Arend, BA, MA	Panel Chair	Dick W. Swier, BS
Panel Chair	Barbara Cook, BS	Panel Member	Lucille Broberg, MD
Panel Chair	Mariella Cummings, RN, MS	Panel Member	Jan Vleck, MD
Panel Chair	Jack M. Crabs, MD	Panel Member	Bradley Waite, DO
Panel Chair	Ronald A. Gadde, D.Min	Panel Member	Robert A. Taylor, DO, JD
Panel Chair	Margaret Holm, JD, RN	Vice President, Medical Affairs	John F. Ennever, PhD, MD
Panel Chair	William C. Jacobs, BA	Regulatory Analyst	James R. Baldwin, PhD
Panel Chair	Kay King, JD	Subject Complaint Representative	Barbara Benson, MA
Panel Chair	*John H. McNeill, MSc, PhD		

\* Documents Specific to Panel 10

**Summary of Changes:**

- Pannee Banchonhattakit, DPH WIRB International Fellows Program, has been added as an alternate of Panels One, Two, Three, Four, Five, Six, Seven, Eight, Eleven, Twelve, and Thirteen.
- Jang Han Kim, MD WIRB International Fellows Program has been added as an alternate of Panels One, Two, Three, Four, Five, Six, Seven, Eight, Eleven, Twelve, and Thirteen.
- Laura Schrager, BS has been added as a member of Panel Twelve and an alternate of Panels One, Two, Three, Four, Five, Six, Seven, Eight, Eleven, and Thirteen.
- Bailu Wang, BS, MS WIRB International Fellows Program, has been added as an alternate of Panels One, Two, Three, Four, Five, Six, Seven, Eight, Eleven, Twelve, and Thirteen.

< May substitute for any Physician Scientist  
 \* Chair Designee  
 ※ Knowledgeable in Complementary or Alternative Healthcare

<< May substitute for any Non-Scientist  
 ✱ Expedited Reviewer  
 Ⓢ Prisoner Representative  
 Ⓢ Knowledgeable in Canadian Ethics

<<< May substitute for any Other Scientist  
 □ Executive Policy Committee Member  
 ✪ Canadian Citizen or Permanent Resident