Western Institutional Review Board, Regional Location with Global Reach
AAHRPP Accredited 2003

- First independent to be accredited
- Re-accredited in 2006 and 2009, granted 5 year extension
- Regularly audited by FDA, sponsors and CROs
Historic Milestones

- 1968: founded as the first independent IRB in the US
  - Established before the Belmont Report of 1979
- 1996: serves as the first independent IRB to provide remedial services to institutions
- 2000: first international clients in Latin America
- 2001: established Canadian review panel
- 2002: partnered with WHO to create Fellows Training program, 100th graduate in 2011
- 2003: first independent IRB to receive AAHRPP accreditation
- 2003: launched customized IT system
- 2007: launched authenticated web-portal
WIRB is...

- the first independent IRB allowed by OPRR (OHRP) to participate on an institution’s MPA
- A “Rescue Board” of record
- deeply experienced at reviewing federally-funded, unfunded and industry-sponsored research at large and small institutions
- knowledgeable in the review of NIH funded research (30% of new protocols)
First Institutional Relationships

- University of Rochester
- University of Colorado at Denver
- Johns Hopkins University
- Columbia University
- University of Miami
- Rush Presbyterian – St. Luke’s Medical Center
- Virginia Commonwealth University
- Ochsner Clinic Foundation
WIRB by the Numbers

- WIRB is twice the size and conducts twice as many reviews as the next largest independent IRB
  - 6,000 open protocols
  - 9000 investigators
  - 20,000 active studies
  - 2500 new protocols per year
  - 300+ employees
  - 100+ Board members and alternates
  - 200+ universities and institutions
  - 40 consultants, 10 staff physicians
  - 11 regulatory analysts
WIRB Corporate Structure
Executive Policy Committee

WIRB Business
- Regulatory
- Medical Affairs
- Operations
- IT
- Institutions
- Finance
- QA / QC
- Corporate Counsel

WIRB Board
- Senior Chair
- Board Chairs
  - Panels 1 – 14
- Physicians
- Expedited Reviewers
- Community members
- Support Staff
Expert Reviews
Our 14 individual panels and more than 100 experienced Board members have more combined expertise than any other organization of its kind.

Learn more about our IRB Services.

To Protect the Rights & Welfare of the Human Research Subject...
Board Structure

Board Chairman

Panel Chairs
- Consulting Physicians
- Local Advisors

Quality Assurance and Training
- Regional Reps
- Board Committees
The Board – 14 Review Panels

- Each Panel has nine standing members, plus alternates
  - 3 physician scientists, 3 other scientists and 3 non-scientists
- Some members change based upon availability & special review needs
- WIRB Staff Physicians
- Regulatory Counsel/Analyst
- Administrative staff support
- Executive policy committee (EPC) provides consistency through policy
Board Autonomy

Staff can

- remind of past approvals e.g. language
- request reconsiderations
- encourage consistency

Staff cannot

- override the Board’s decision
- unduly influence the Board’s authority
WIRB Panel Schedule

- All protocols assigned to an individual panel

Monday: Panels 1, 7 & 14
Tuesday: Panels 2 & 5
Wednesday: Panels 3, 11 & 14
Thursday: Panels 4, 12, & 13
Friday: Panels 6, 8, & 14

Bi-Weekly: Panel 10 (Canada)
“Central” IRB vs. “Local” IRB

- WIRB acts as a “local” IRB when reviewing for institutions

- Different processing is often required for institutional investigators to meet contractual obligations.
  - Consent form language is modified as needed.
  - Institutional review and approval occurs prior to submission to WIRB for review.
WIRB – as a “Local” IRB

- WIRB defers to more conservative institutional standards as desired e.g. conflict of interest
- Local community attitudes are carefully assessed through personal visits that highlight the setting, the institution and the local IRB process.
- Consent form templates are negotiated to include required language and approved by WIRB Executive Policy Committee (EPC).
- Institution is copied on all correspondence regarding Board actions.
WIRB and Financial COI

- An independent IRB helps the institution manage implicit institutional COI

- WIRB manages apparent and declared financial COI
  - Over 80% of Board members are volunteers, receive a per-meeting honorarium
  - No equity interest is held by Board or staff
  - Business interests are kept separate from the Board
Institutional Control

- Does the Institution retain ability to suspend or terminate a study?
  - Institution cannot approve any research study that has been disapproved by WIRB. 21 CFR 56.112
  - Institution can disapprove any study approved by WIRB
  - Institution can suspend/terminate a study – must inform WIRB

- How can we coordinate other local committee reviews e.g. radiation safety, biosafety, COI?
  - Institution and WIRB develop submission plan
  - Majority of academic institutions require prior documentation of review before submitting to WIRB
WIRB’s “IRIS”

- 21 CFR Part 11 & FDA compliant
- Integrated decision support
- Enhanced quality & customer focus
- Automated, paperless processing
- Business to business interface with external clinical trials management systems through a custom developed web service
Turnaround Time

- New Protocol without PI: 11 – 13 days
- New Protocol with PI: 12 – 14 days
- New PI to approved protocol: 6 – 7 days
- Changes in research
  - Expedited review: 6 – 7 days
  - Full Board: 12 – 13 days
WIRB Services

- IRB Review Services
- International Review Services
- IBC Services
- Data & Safety Monitoring
- CPU/Phase 1 Review
- Education & Consulting
- Regulatory Support
- International Fellows Program
Questions?
Thank You

Sherry Felchlin, sfelchlin@wirb.com