Allegheny Health Network

David S. Parda, M.D., FACP
System Chair, Cancer Institute and Radiation Oncology
System Chair, Institutional Review Board
Associate Director, Medical Affairs, NSABP
Professor, Temple University School of Medicine
Allegheny General Hospital
Allegheny Health Network

The AHN integrated care delivery portfolio

Hospitals & Key Statistics

- 7 Hospitals in Western PA with 2,000+ Beds
- Urban, Academic & Community Focus
- Establishing Delivery Models in 4 Regions with 200 locations
- 2,100 employed /aligned physicians; 500 residents & fellows
- 17,000 employees

Allegheny General Hospital

Forbes Hospital

Allegheny Valley Hospital

Jefferson Hospital

Canonsburg Hospital

Saint Vincent Hospital

West Penn Hospital

Allegheny Clinic

- Employed Physicians
- Managed Services Organization
- Clinical Service Lines
- Leadership in Each Hospital

Affiliated Physicians

- Regional PCPs
- Independent Specialists

Clinical Affiliations

Ambulatory Centers

Health & Wellness Pavilions

AHN Diversified Services

- Group Purchasing Organization
- Properties
- Partnerships & Joint Ventures

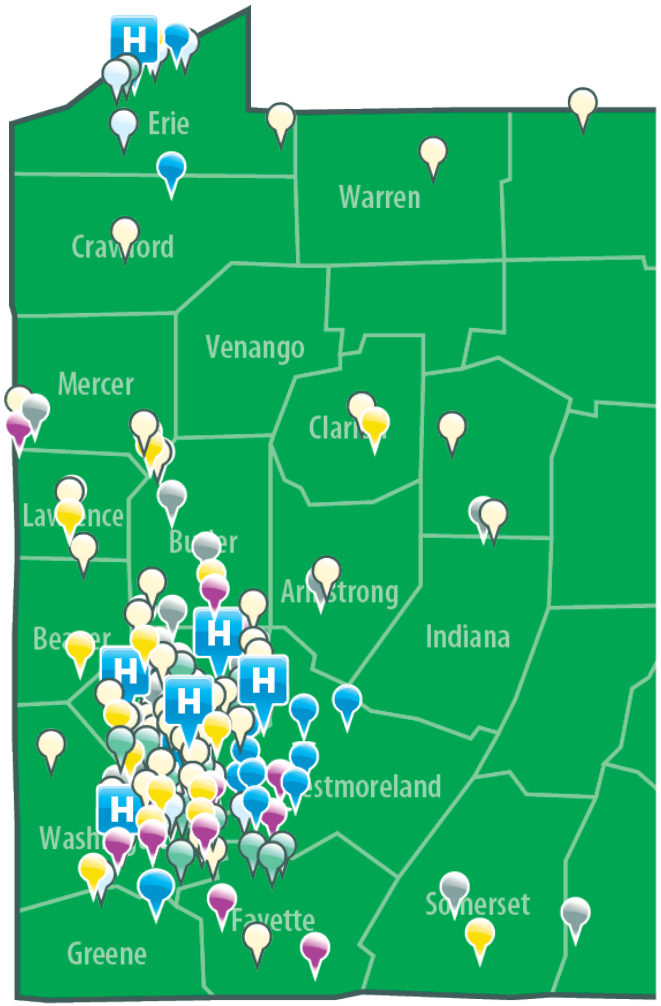
Research & Innovation

Allegheny Singer Research Institute

Carnegie Mellon University

Allegheny Health Network

Allegheny
Health Network



Hundreds of Health Care Facilities for Our Members

- Allegheny Health Network Hospitals
- Outpatient Centers
- Additional Outpatient Testing Centers
- Orthopaedic & Rehabilitation Centers
- Cancer Care Centers
- Women's Health Centers
- Neuroscience Centers
- Cardiovascular Centers

Cancer Institute Locations – 22 Sites*
(43 Med Onc, Rad Onc, Surg Onc Clinics)

*Includes all distinct chemotherapy or radiation treatment locations; does not include some locations for surgical only clinics.

Total # Medical Oncologists:	46
Total # Radiation Oncologists:	14
Total # Surgical Oncologists:	90
	150

More than 10,000 cancer patients and 125,000 cancer treatments delivered.

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Allegheny General Hospital	WPAHS Surg Onc (Surgical Oncology) WPAHS RON (Radiation Oncology) WPAON (Medical Oncology) AGH Medical Oncology
Allegheny Valley Hospital	WPAON, WPAHS RON, WPAHS Surg Onc
Bellevue	WPAON
Butler Regional Cancer Center	WPAON
Butler – Hansen Office, Lyndora	WPAON
Canonsburg General Hospital	WPAHS RON, WPAHS Surg Onc
Forbes Intercommunity Cancer Center	WPAHS RON
Forbes, Monroeville	WPAON, WPAHS Surg Onc
Grove City	WPAHS RON, WPAHS Surg Onc
Jefferson Hills – Jefferson Regional Medical Ctr	WPAON
Kittanning, Richard G. Laube Cancer Center (Armstrong)	WPAON, WPAHS RON, WPAHS Surg Onc (pending)
New Castle	WPAON
New Kensington	WPAON
Mellon Pavilion (WPH)	WPAON, WPAHS Surg Onc
Peters Ambulatory Care Center	WPAON, WPAHS RON, WPAHS Surg Onc
Punxsutawney	WPAON
Robinson Township	WPAON, WPAHS Surg Onc
Sharon Regional Cancer Center	WPAHS RON, WPAHS Surg Onc
Somerset Oncology Center	WPAHS RON, AGH Medical Oncology
Tony Teramana Cancer Center, Steubenville OH	WPAHS RON, WPAHS Surg Onc (pending)
West Mifflin Century III	WPAON
West Penn Hospital	BMT Hematology/Oncology Associates, WPAHS Surg Onc WPAHS RON

Integration is the Key to Success in Healthcare Difficult to Achieve

Integrate Patient Care/Education/R&D
Integrate Quaternary/Tertiary/Community Care
Integrate Clinical/Operational/Financial/IT Functions
Integrate Competencies/Values

The Institute of Medicine states: ***"Academic health centers will need to recognize the interdependent and complementary nature of their traditionally independent (education, research and patient care) roles within an overall context that encompasses a commitment to improving the health of patients and populations."***

- ***Institute of Medicine of the National Academies.*** **"Academic Health Centers:**
- **Leading Change in the 21st Century". Washington DC:**
- **The National Academies Press, 2004.**

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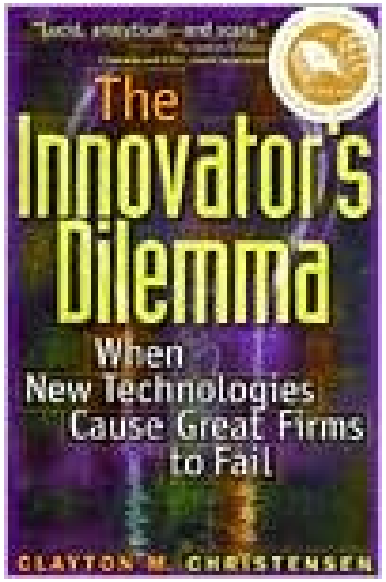
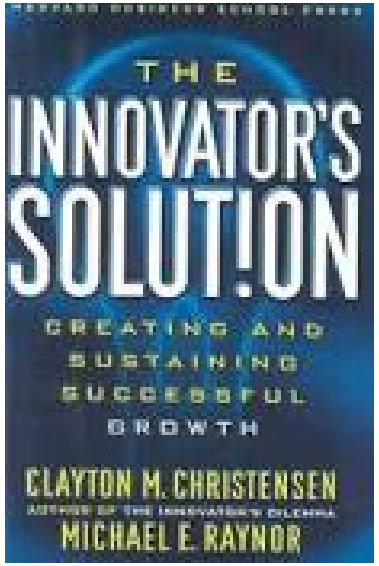
Clayton M. Christensen, Ph.D., MBA, DBA
Professor

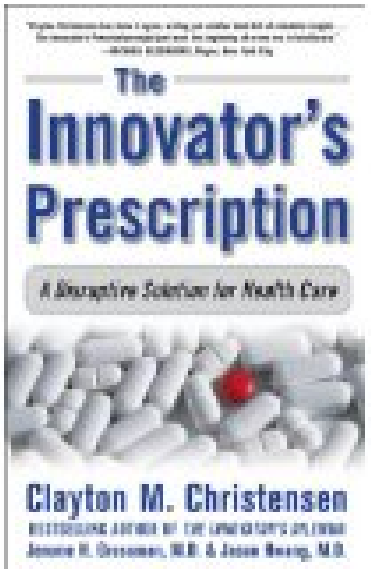
Clayton M. Christensen is the Kim B. Clark Professor of Business Administration at the Harvard Business School, with a joint appointment in the Technology & Operations Management and General Management faculty groups



1997



2003



2009

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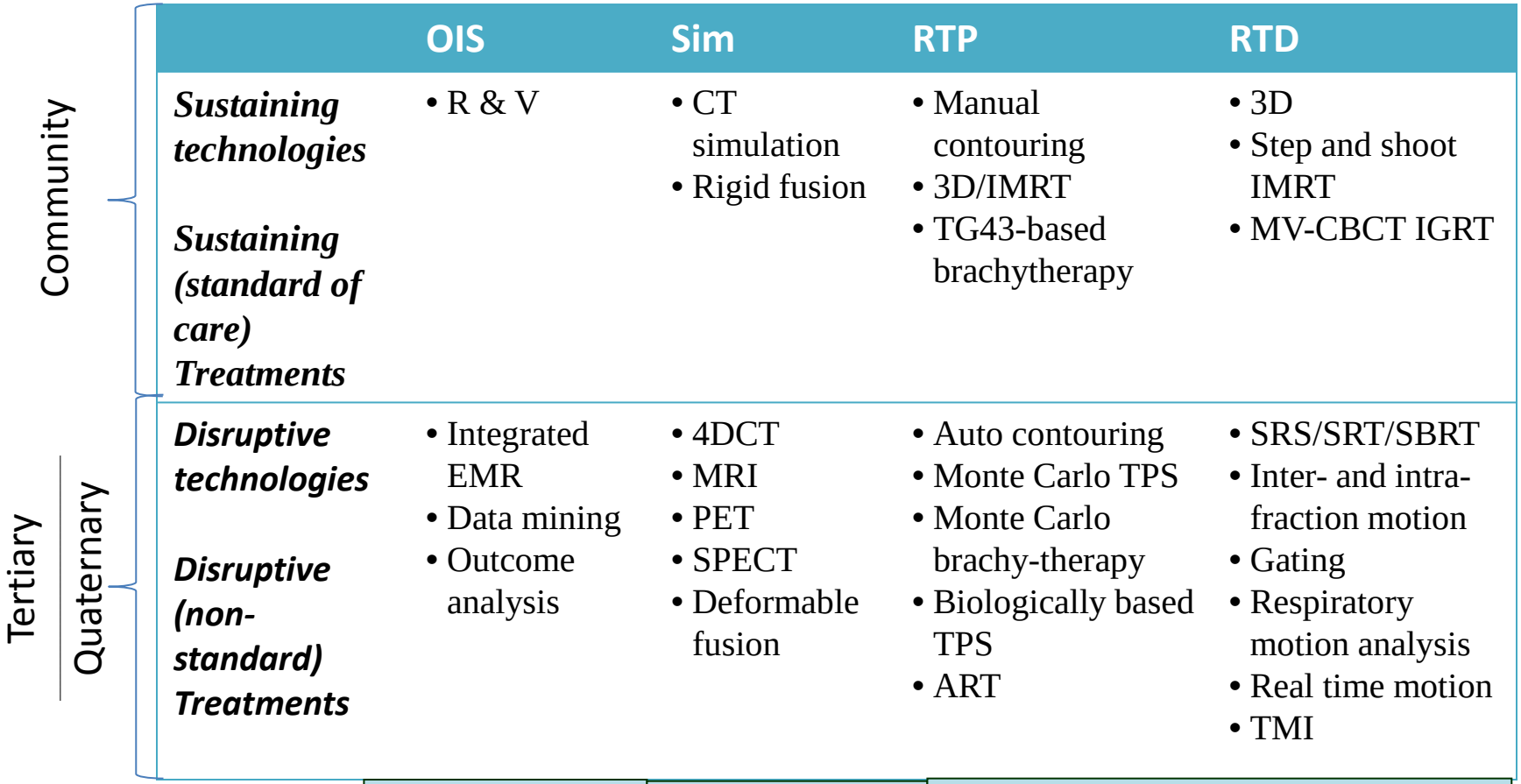
Innovation
Comprehensive and Expert Configurations



	OIS	Sim	RTP	RTD
Sustaining technologies ***Sustaining (standard of care) Treatments***	• R & V	• CT simulation • Rigid fusion	• Manual contouring • 3D/IMRT • TG43-based brachytherapy	• 3D • Step and shoot IMRT • MV-CBCT IGRT
Disruptive technologies ***Disruptive (non-standard) Treatments***	• Integrated EMR • Data mining • Outcome analysis	• 4DCT • MRI • PET • SPECT • Deformable fusion	• Auto contouring • Monte Carlo TPS • Monte Carlo brachy-therapy • Biologically based TPS • ART	• SRS/SRT/SBRT • Inter- and intra-fraction motion • Gating • Respiratory motion analysis • Real time motion • TMI

Optimize

Evidence-based multidisciplinary individualized patient care

Anatomic, functional and 4-D imaging data – Biological conformality

Physical conformality – covers 1/3 of needed solutions.

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We can drive Integration and Innovation by focusing all of our work on these 3 outcomes in these 2 primary areas of Healthcare Management

	Quality	Experience	Cost
Finance			
Delivery			

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In Cancer

Assess Quality, Experience, and Cost by patient and cancer type for all aspects of finance and delivery.

	Quality	Experience	Cost/Revenue
Finance	Incentives promote right care, right place, right time	• Simple • Understandable • Packaged for patient, family, healthcare professionals, payers.	Per member
Delivery	Individual and collective patient outcomes (disease control, toxicity, QOL)	• Patient • Family • Healthcare Professionals caring directly for patient • Other healthcare professionals in clinical, operational, and financial roles • Payers (government, commercial, businesses, patients/families) • Vendors	• Per patient • Per doctor • Per department/service line • Per hospital

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Affiliation

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Cancer Institute

JOHNS HOPKINS MEDICINE

The Sidney Kimmel Comprehensive Cancer Center

Partnering with Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Allows for:

1. **Clinical collaborations**
   - Disease-specific clinical program development
   - Physician-to-physician consultation for rare cancer cases and novel therapies.
   - Quality and safety projects
   - Big data analytics
2. **Medical education**
   - Training of health professionals (physicians, medical students, nurses, etc.) within both systems, larger available CME portfolio, and telecommunication education opportunities.

Partnering with Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Allows for:

3. **Broad range of cancer research initiatives**
   - **Brings together leadership in early phase clinical trials with our strong phase 3 clinical trials program**
4. **Similar Values**
   - **Share knowledge and expertise**
   - **Improve the quality and safety of cancer care in the community**
   - **Facilitate Patient-centric cancer care**
   - **Promote a collaborative and collegial culture**

Partnering with Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

- **Accelerate knowledge transfer and treatment advances for cancer patients to the community**

- **"…Allegheny Health Network will be better able to meet the current and growing healthcare care needs of the communities we serve today as well as play a critical role in helping establish new standards of cancer care innovation and quality for the future," says David Parda, M.D., Chair of the Allegheny Health Network Cancer Institute.**

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Partnering with Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

"This collaboration would provide us with new opportunities for cancer research within a broad-based Western Pennsylvania health system that already has strength in a wide range of cancer treatments and research programs," says William Nelson, M.D., Ph.D., director of the Johns Hopkins Kimmel Cancer Center. "In the changing landscape of healthcare services, innovative initiatives like this will keep us at the forefront of discovery and patient-centered care."

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Research Studies

Institute	Number of Studies
Cancer	205
Cardiovascular	159
Interdisciplinary	148
Neuroscience	78
Orthopedics	53
Autoimmunity Institute	43
Pathology	38
Pharmacy	35
Obstetrics	34
Nursing	14
Other	9
TOTAL	816

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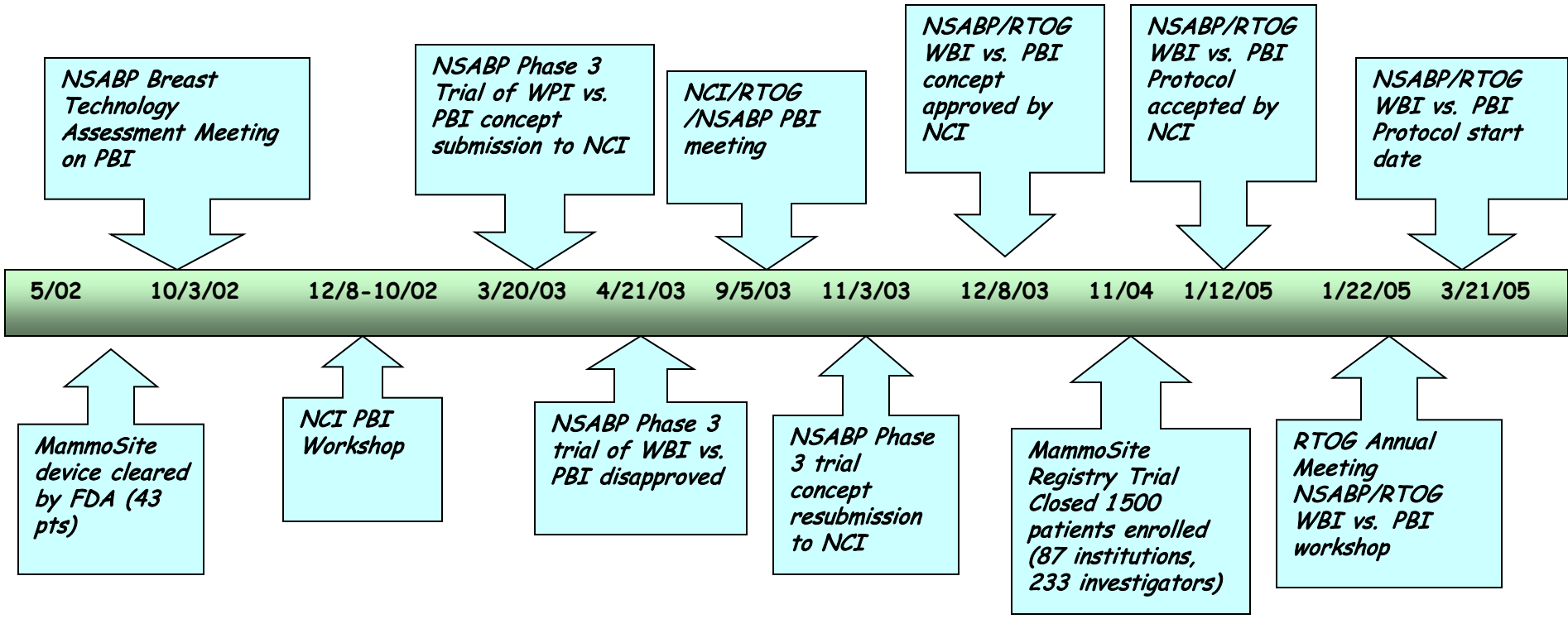
WBI vs. PBI Timeline



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WPAHS IRB

Average # of Days to Approve an NCI Sponsored Phase 3 Cancer Cooperative Group Clinical Trial

Year	Days
2006	116
2010	16

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Equipoise Lost

"Regulatory Fundamentalists" follow the exact letter of the regulations, and defend themselves by claiming to be faultless because they fully complied with and enforced all regulations.

"Regulatory Rationalists" exercise judgment in aiming to fulfill the intent of the regulations while attempting to facilitate progress, and are much less able to defend themselves.

Stewart DJ, Whitney SN, Kurzrock R: Equipoise Lost: Ethics, Costs and the Regulation of Cancer Clinical Research. JCO 28:17;2925-2935

Equipoise Lost: Risk of Cancer >>> Risk of Research

- Time from drug discovery to marketing increased from 8 years in 1960 to 12-15 years currently.
- Toxic death rates on Phase I trials have decreased from 0.8% in 1979 to 0.5% in 2002.
- Regulatory delays in development of effective therapies result in tens to hundreds of thousands of life-years lost (stringent regulations save extremely few).
- Regulatory burden is a major disincentive to patient and clinician participation in clinical research (<5% of adult cancer patients participate in clinical trials, the most important tool to advance clinical cancer care).
- Marked imbalance between potential life-years lost versus saved renders the regulatory burden potentially unethical.

Equipoise Lost: Ethics, Costs, and the Regulation of Cancer Clinical Research. JCO 28:17;2925. June 10, 2010

Costs per Year of Life Gained by Selected Interventions

Procedure	*Cost/Life-Year Saved**
Clinical trials regulations	$2,700,000
Hemodialysis	$43,000 - $104,000
Statins for heart disease (moderate- to high-risk patients)	$19,000 - $25,000
Colorectal cancer screening by colonoscopy	$14,000
Adjuvant trastuzumab breast cancer	$20,000
Bevacizumab advanced non-small-cell lung cancer	$380,000
Paclitaxel/cisplatin for advanced ovarian cancer	$26,000

***Converted to 2009 US dollars using an online inflation calculator.**

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Equipoise Lost: Ethics, Costs, and the Regulation of Cancer Clinical Research. JCO 28:17;2927. June 10, 2010

National Cancer Institute
Central Institutional Review Board

- The Central IRB (CIRB) Initiative is designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants.

- CIRB enables an investigator to enroll patients into adult and pediatric NCI-sponsored clinical trials significantly faster than when employing traditional method of IRB review.

- The CIRB Initiative is sponsored by NCI in consultation with the Department of Health and Human Services Office for Human Research Protections (OHRP).

IRB EXPERTISE

David S. Parda, M.D., FACP

NCI CIRB*:
Member: May, 2006 – Present
Vice Chair: March, 2009 – December, 2010
Chair: January, 2011 – June 30, 2013

***CIRB Initiative instituted January, 2001**

AGH/ASRI/WPAHS IRB
Chair: March, 2008 - present

Dawnmarie DeFazio, CHRC, CIP, CIM

CMU Research Compliance Administration (IRB, IACUC, IBC, RCR, & COI):1998– 2008
UPMC IRB Member: 2005 – 2009
Volunteer Editor, Scientific Journals International: 2007 – present
Founding Board Member IACUC Administrator Association: March 2010 – present
Treasurer, Northeast Section, Society of Research Administrators International: April 2010 – present
Director Research Regulatory Affairs: June 2008 – Present

Athanasios Colonias, M.D.

System Director, Thoracic and Clinical Trials Programs, Allegheny Health Network Radiation Oncology
Vice Chair, AGH/ASRI/WPAHS IRB
2011 - Present

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ALLEGHENY HEALTH NETWORK
INSTITUTIONAL REVIEW BOARD (IRB)

Mission Statement of the IRB

"Have expert understanding regarding the importance of protection of human subjects' rights, welfare and safety with a balanced interpretation of research rules and regulations that will assist with the facilitation and delivery of clinical research between investigators and patients."

Criteria for IRB approval of research (45 CFR §46.111)

- Is the risk to subjects minimized?
- Will the study yield results?
- Is the consent form clear and easy to understand?
- Is privacy/confidentiality and data management appropriate?
- Is the subject selection appropriate?

Strategy

Develop expert knowledge, people and processes to optimize and balance:

1. Patient safety
2. Investigator support
3. Institutional compliance (interpretation of Code of Federal Regulations, maintenance of FWA, minimization of institutional risk)

Vision

"Allegheny Health Network IRB will reduce process complexity and cost of research oversight with expert, efficient and integrated operation throughout hospital and practice sites."

David S. Parda, M.D., FACP, System Chair
Institutional Review Board

Dawn DeFazio, CIP-CIM, System Director
Research Regulatory Affairs, Allegheny Health Network

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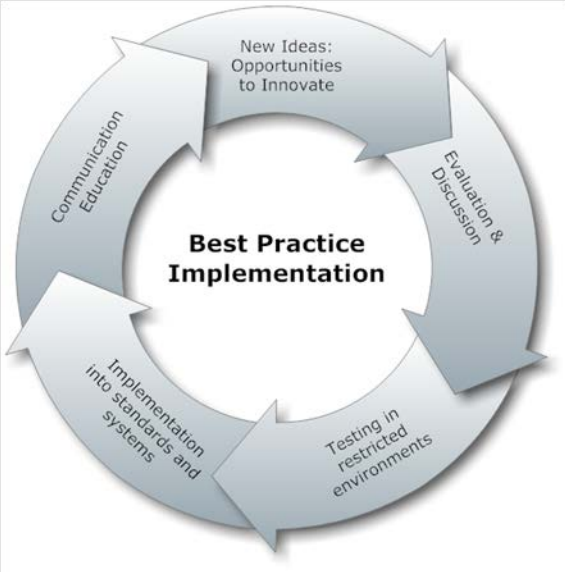
IRB Review Models

- Local IRB review - single site study
  - Local IRB reviews research at its own site
- Local IRB review - multi-site study
  - Each local IRB participating in a multi-site study does its own review
- Institution relies on another institution's IRB review – single site study
  - For a given study, one institution turns to the IRB of another (e.g., the latter has more appropriate expertise)
- Independent IRB review – single or multi-site studies (Central IRB)
  - A single independent (central/commercial) IRB conducts review on behalf of one or more sites - all sites accept the independent review - no local review (e.g., NCI CIRB, Western, Chesapeake, Quorum)

Human Research Protection Program (HRPP)

Develop Linkages to Other HRPP Components

- Pre-review by Ancillary Committees
  - P&T
  - COI
  - IBC
  - Department/cancer center
- Subject Injury Language
- HIPAA
- Completed Contract Negotiations
- Post-Approval Monitoring Program



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Local IRB Review

Advantages

- **Knowledge of investigators**
- **Responsiveness to subjects and investigators**
- **Knowledge of local culture and values**
- **Clear authority and accountability**
- **Increase of community awareness**
- **Address state and local laws**
- **Ensure that research subjects has access to accurate information on enrollment/costs**
- **Ensures equitable recruitment and safety of subjects**
- **Ensures reputation, public relations and compliance**
- **COI review process**
- **Coordination of other committee reviews, i.e., IBC**
- **Coordination of other contract commitments**
- **Integrated compliance programs**
- **Service-oriented procedures and staff**
- **Reviews IRB and grant applications for congruency**

Disadvantages

- **Limited reviewer expertise**
- **Inefficient process**
- **Lower quality and variability of reviews**
- **Challenge to identify members**
- **Time consuming to analyze adverse events from multi-site trials**
- **Overwhelmed with volume**
- **Limited funding**
- **Inadequate and extended review**
- **Duplication**
  - Duplicate reviews are not required
  - Duplicate reviews are expensive, wasteful
  - Duplicate review outcomes are variable
  - Duplicate processes are inefficient and duplication of effort/time/resources

Reasons to "*Outsource*" IRB Review

- Primarily multi-center clinical trials
- Sponsor pressure
- Unable to significantly increase number of clinical trials
- Perception of quick approvals
- Central IRB perceived as more efficient and customer friendly

Central IRB Review

Advantages

- Local issues do not require geographic proximity
- Disease specific expertise
- Promote efficiency by reducing time delays and duplicative review (enhance speed while retaining quality of oversight)
- Reduce variation on consent forms
- Increased safety for full study – DSMBs/AEs
- Maximize process and administrative efficiency with use
- Objective, non-biased reviews
- Eliminates duplication of effort
- Cost effective – potential to reduce costs (stretches IRB resources)
- Allows local IRB to focus resources on monitoring onsite trials
- Standardize submission forms, protocol changes and consent forms for enhanced efficiency

Disadvantages

- Inherently conflicted (highest priority? – speed, efficiency, profit or protection of human subjects)
- Need to address questions of authority, accountability and liability
- Perception that human subjects are not protected as fully as with local IRB
- Loss of revenue for each review
- Quality of review for local content, laws and compliance
- Disconnect the PI from the human subject protection process via IRB service
- Communication lapse could result in problems such as a delay in responding to an adverse event
- Possible diminished disclosure and ability to manage conflicts of interest
- Possible decreased quality of review
- Increased potential for liability through loss of control of managing the IRB review
- Consider who will review IRB and grant applications for congruency

Central IRB review of multisite studies (single IRB of record)

Concerns:

- Many institutions will not rely on “outside” review, whether for lack of familiarity, liability concerns or preference for control
- Some institutions will not review on behalf of another, citing responsibilities and work load

Result:

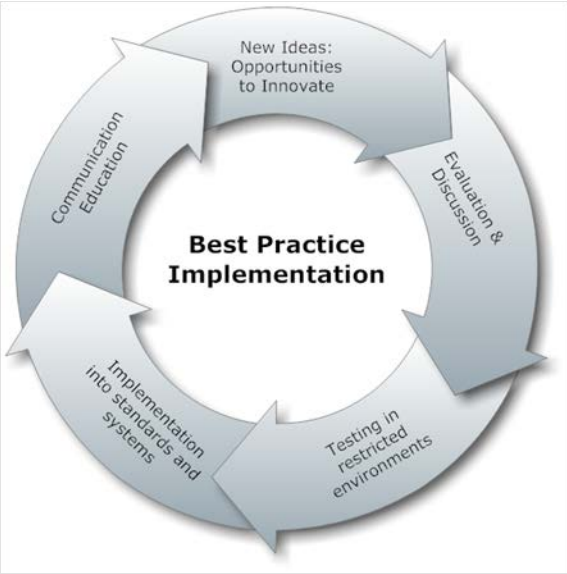
- Significant increase in workload and resource commitment without clear benefit
- Delays in approval and initiation of clinical trial, since all sites must use same protocol

Ethical concerns with multi-institutional studies:

- Scientific integrity requires same protocol used at each institution (bias and risk introduced if protocols differ significantly and results are aggregated)
- Central IRBs less likely to introduce changes, and no one local IRB has authority over others
- If significant concern is raised by local IRB, often only option is NOT to participate rather than addressing concern to all IRBs for study
- IRBs do not communicate among each other
- Informed consent document can change: boilerplate (insignificant), trivial (wasteful), significant (potentially bias introduced)

Potential Advantages

- Streamline process
- Better control over compliance
- Administrative efficiencies
- Sharing of resources and responsibility
- Competitive advantages
- Improved Review Process
- Investigator satisfaction
- Resource Efficiencies
  - Overall costs
  - Speed for local start-up
- Opportunities for Quality Improvement from Redundant Reviews



Central IRB Review - Agreements

Negotiate an agreement with a central IRB to review research under your FWA; designate the IRB under your assurance; the institution holding the FWA retains the ultimate responsibility for the protection of human subjects.

Shared responsibilities

- Central IRB
  - Separation between business and IRB functions
- Agreements
  - Should be in writing
  - Address all the issues that are related to regulatory requirements

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Central IRB Service Agreement or MOU

- Division of responsibility: Who is responsible for what aspect of the review, and in what order are reviews conducted?
- Who is the final authority? The local institution must retain the authority to say “no” to a study approved by a central IRB.
- Understanding of local context: How will critical information be shared or learned?
- Institutional knowledge of investigator histories: How will information on past difficulties be relayed?
- Effective communications with the investigators: How will information be exchanged in a timely way?

Central IRB Service Agreement or MOU

- Effective communications with internal research support: How are new or changed requirements communicated?
- Training: Who is responsible for designing and delivering training, as well as any refresher courses?
- Faculty openness: Will the faculty be as open with a third party as they are with colleagues?
- Logistics and coordination: How are other committee approvals coordinated?
- Routine post-approval monitoring: Who is responsible and how does reporting occur?
- Incident investigations and reporting: What control does the institution have over this process?

Central IRB Service Agreement or MOU

- **IRB responsibility – central IRB may require institutes to assure:**
  - Verification of qualifications of research and adequacy of site
  - Researcher(s) not restricted or disqualified per database
  - Researcher(s) credentialed in department
  - Institute/University has adequate staff, equipment or specialized care required for study.
  - Verify local consent form requirements

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Overview of the CIRB

- Goal
  - *Reduce the significant local administrative burdens of multi-site trials while maintaining a high level of human subjects protection*
- Three CIRBs
  - *Adult CIRB – Late Phase Emphasis*
    - Began reviews of Cooperative Group Phase 3 treatment trials in 2001
  - *Adult CIRB – Early Phase Emphasis*
    - Began reviews of phase 0, 1, 2 trials late 2013
  - *Pediatric CIRB*
    - Began reviews of COG phase 2, 3 and pilot trials in 2004

CIRB Profile

Total Number of Institutions Enrolled	295
Number of Institutions using Adult CIRB only	165
Number of Institutions using Pediatric CIRB only	44
Number of Institutions using both Adult and Pediatric CIRB	86
Total Number of Institutions Enrolled including other institutions relying on their IRB	880
Total Number of NCI Designated Cancer Centers enrolled out of 59 eligible (36 have conducted at least one FR; 5 apparently using CIRB documents)	41

Current as of 08/31/2010

CIRB Profile

- Number of Facilitated Reviews Conducted 11,376
  - Adult 6,725
  - Pediatric 4,651

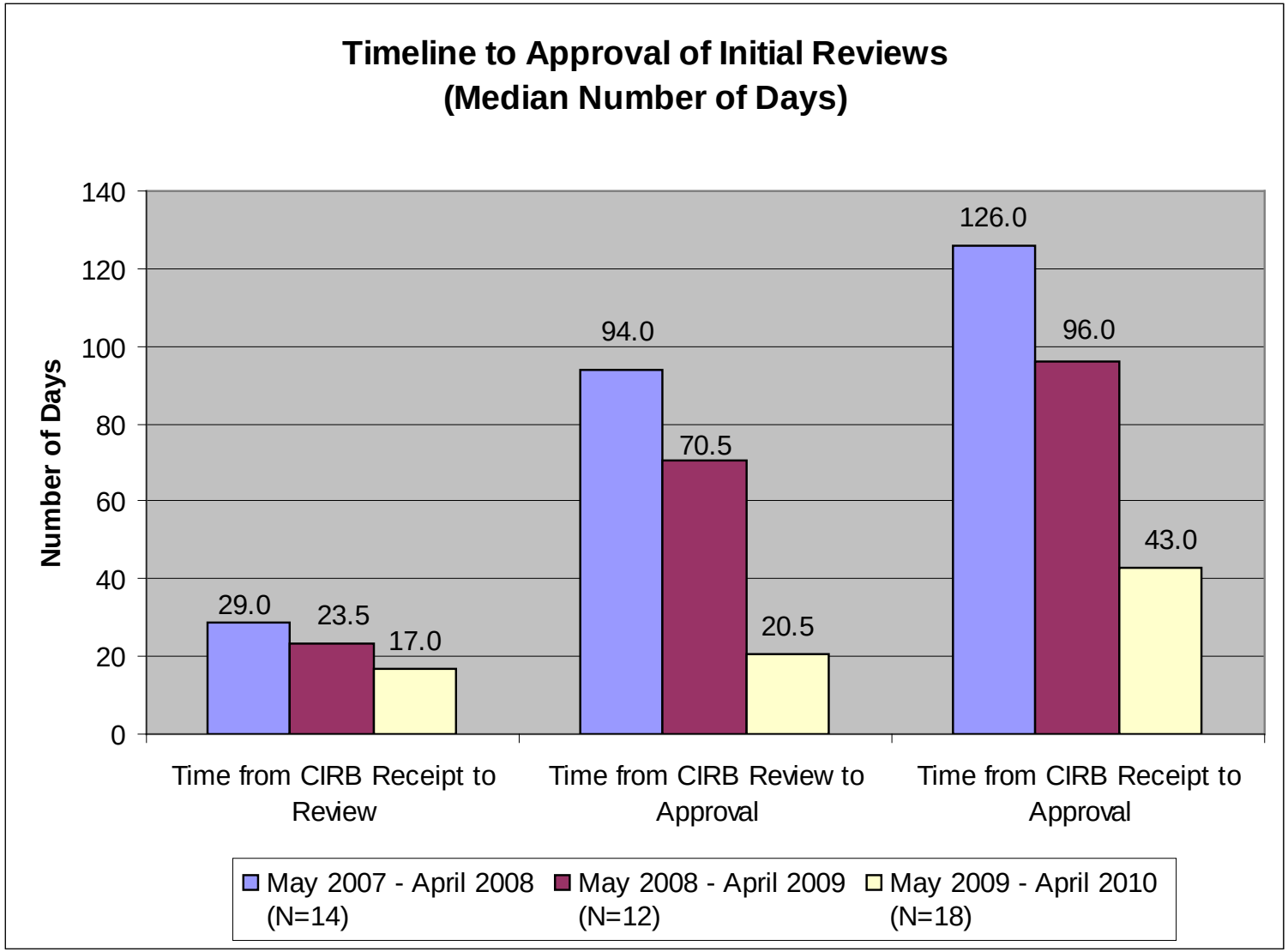
- Number of Total Studies Available for Facilitated Review 248
  - Adult 159
  - Pediatric 89

Current as of 08/31/2010

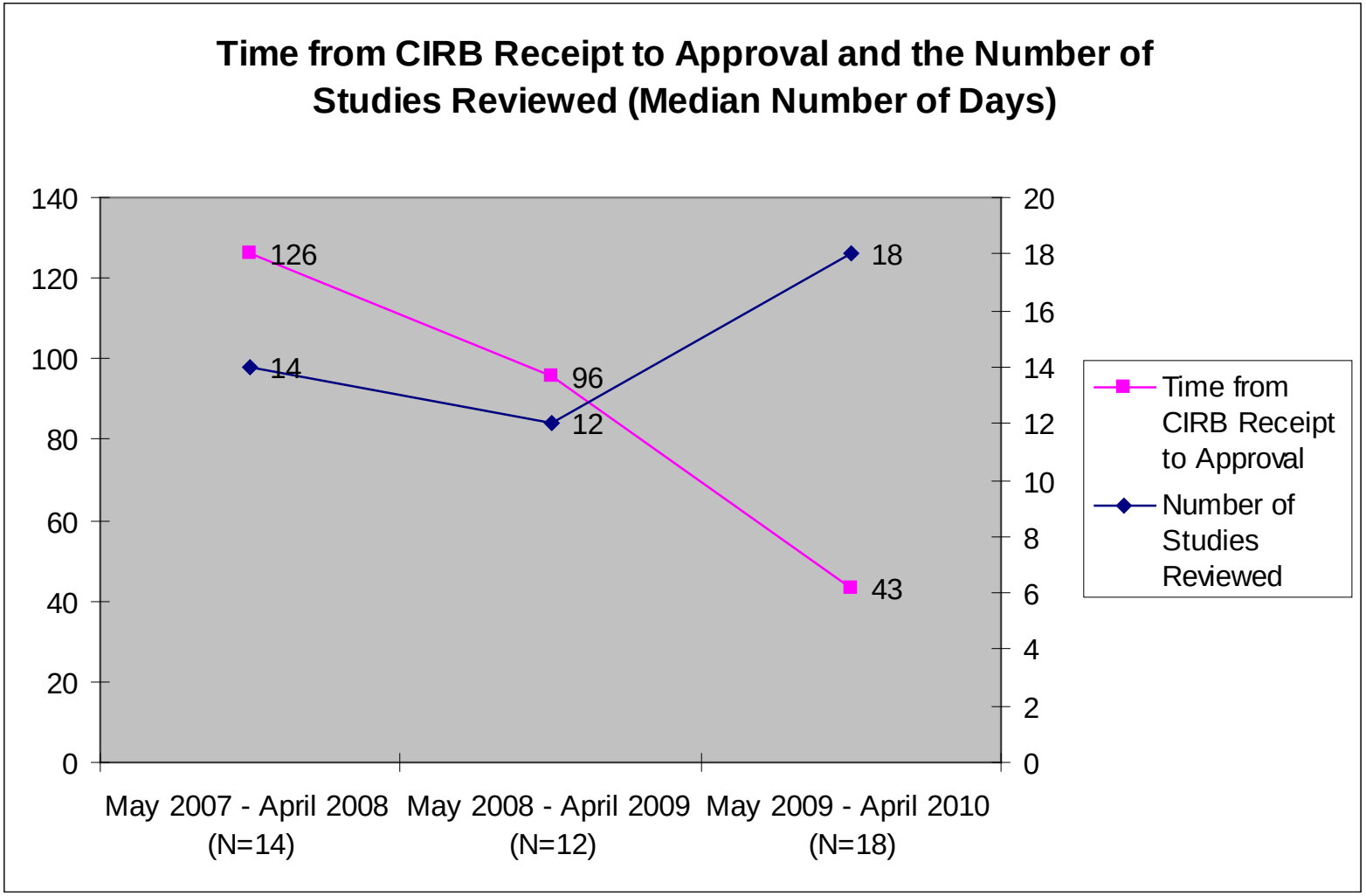
Metrics: CIRB Stipulations Requiring Group Response

Year	Number of Protocol Stipulations (Median)	Number of ICD Changes (Median)	Number of Group Resubmissions (Median)
May 2007 – April 2008	7	9	2
May 2008 – April 2009	4	14	1
May 2009 – April 2010	0	6	1

Metrics: Initial Review Timeline Comparison



Metrics: Comparison of Time to Approval and Number of Studies Reviewed



Accreditation

- **Pursuing accreditation**
  - **Association for the Accreditation of Human Research Protection Programs (AAHRPP) accredits IRBs**
  - **Accreditation is perceived as significant marker of quality in IRB community**
  - **Accreditation would enhance recruitment efforts**
- **AAHRPP suggested redesign to "independent" model**
  - **CIRB would be the IRB of record; no need to partner with local IRB**
  - **Facilitated review would be eliminated**
  - **Encouraged us to make change because**
    - **CTEP comprehensive human subject's protection program allows the CIRB to serve as an "independent" IRB**

Overview of the CIRB Model

- As of January 1, 2013 the CIRB operates under an independent model for review of NCI-sponsored research
- What is the "independent model"?
  - *CIRB continues to review studies as before*
  - *CIRB becomes IRB of Record for investigators*
    - Local IRB has no review responsibilities
  - *CIRB reviews institution's local context considerations before approving new study at institution*
  - *CIRB reviews locally-developed recruitment/educational materials; locally-occurring unanticipated problems or serious or continuing non-compliance; responds to investigator/institution questions*
  - *Institution is responsible for monitoring conduct of research*
    - Includes reporting concerns to CIRB

Division of Responsibilities under CIRB Model

CIRB

- *Initial Review*
- *Continuing Review*
- *Amendment Review*
- *Conducts reviews for institutional local context considerations*
- *Reviews/determines Unanticipated Problems both locally-occurring and trial-wide impact*

Signatory Institution

- *Ensures safe and appropriate conduct of research at the institution*
- *Maintains records for CIRB-approved studies per network/program guidelines*

Benefits of Using the CIRB

- Benefits patients and research participants
  - *Oncology-specific, multidisciplinary Boards*
  - *Dedicated review for study participant protections*
  - *Opens trials faster, supports completing trials faster*
  - *Easier to open trials for rare diseases*
- Benefits for investigators and research staff
  - *Eliminates back-and-forth with IRB to gain study approval*
  - *Eliminates frequent submissions to IRB for amendments, continuing reviews, adverse events, etc.*
  - *Eliminates completing IRB application and duplicating IRB submission packets*
- Benefits for IRB members
  - *Saves IRB members' time and effort by eliminating full board review of network/program trials*

Contacting the CIRB

Helpdesk Email: ncicirbcontact@emmes.com

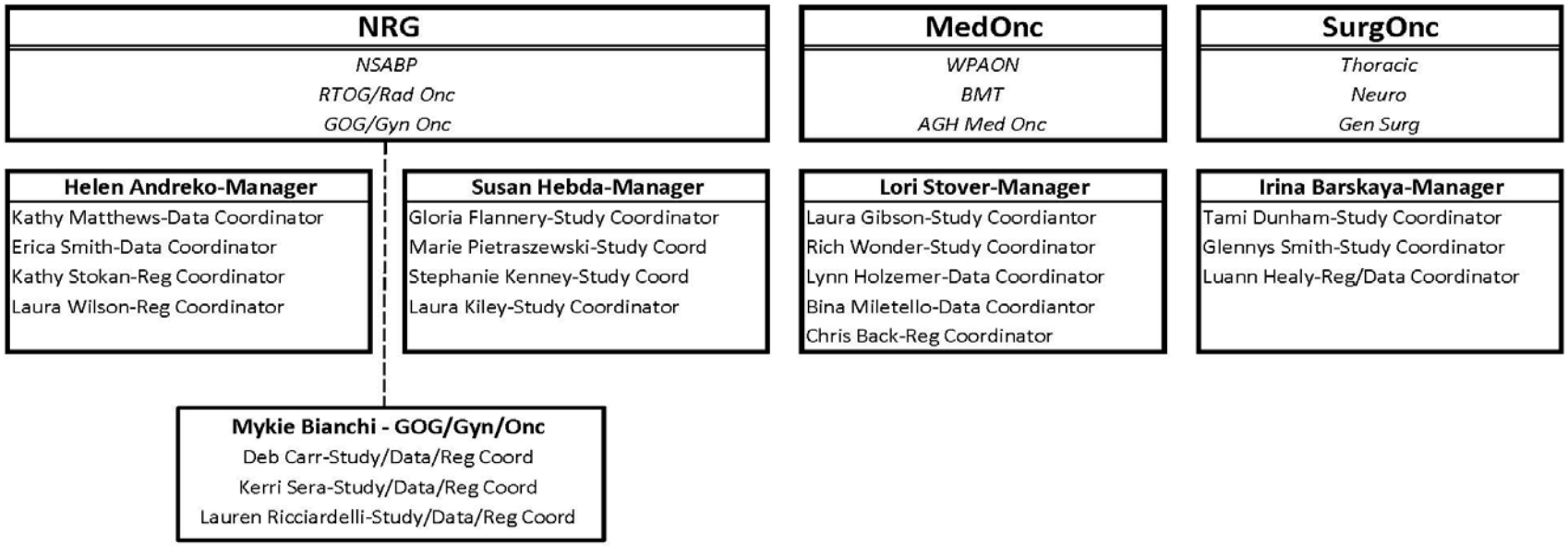
Helpdesk Toll-free Number: 1-888-657-3711

(May request a specific staff member when calling)

Fax Number: 1-301-560-6538

CIRB Website: http://www.ncicirb.org

Cancer Institute Research Administration (CIRA)



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Patient Management

Navigator Groups

- ***Team 1*** **Breast/Gyn**
- ***Team 2*** **Brain/Base of Skull/Spine/ Endocrine/Sarcoma/Melanoma/Skin (basal and squamous)/Bone**
- ***Team 3*** **Digestive/Respiratory/Head & Neck/Oral/Eye and Orbit**
- ***Team 4*** **Prostate/GU**
- ***Team 5*** **Blood/Lymph**

Cancer Management

Disease Site Programs

1. Breast
2. Prostate/GU
3. Lung/Bronchus/Esophagus
4. Colorectal
5. Liver
6. GI/Pancreatic/Biliary/Endocrine
7. Brain/Base of Skull/Spine/Endocrine/Ear
8. Head and Neck
9. Eye and Orbit
10. Sarcoma/Melanoma/Skin (basal and squamous)/Bone
11. Gyn-Oncology
12. Leukemia/Lymphoma/Myeloma/Cell Transplant

Red = System-Wide Integration Leaders
Green = Local Integration Leaders

Breast Leaders

Disease Site	PCP	Surgery	Medical Oncology	Radiation Oncology	Pathology	Imaging	IT	Research	Navigation	Personalized Care	Other Key Depts/ Services
System	**G Rossman** **J Riley**	N Wolmark T Julian D Keenan	J Raymond H Analo A Christou	M Trombetta D Parda P Guerrieri	U Krishnamurti J Silverman	W Poller B Klepchick N. Dash	D Chuirazzi T Bezek	A Colonias D DeFazio	J Phillips C Ross	R Hebert J. Engleka S Frank	Plastic Surgery F Heckler M White
Jefferson	**N Furlong** **M McGonigal**	**M. Gannon** C Cline B Fingeret	A Jalil **M Castaner** D. Buckbarker	**J Betler**	M Moustofi	N Eshbaugh G DiMarino	J Witenske	Glennys Smith	B. Cline	U. Kahn	R Raszewski
St. Vincent/Erie		D Haupt D Duchini S Bedwell G Prylinski	J Li C Marsh	D Figura Stachalek Fisher	M Fowler	D Oppenheim	P Jones M Moskalczyk	M Haynes (TRCC)	L Brennan	TRCC	
WPH		K Erb D Keenan	H Analo A Barsouk M Islam S Petursson C Srodes H Younes C Moffa	P Guerrieri	U. Krishnamurti	Kiproff		L. Stover	B Sobolweski	R. Hebert J. Engleka	
Forbes		D Keenan A Tandin P Naman	H Analo C Evans D Mayernik S Petersson J Thomas	S Anolik K Kotinsley	R Surampudi	M Bidula	S Lewis	S. Kenney	K Schwaderer	R. Hebert J. Engleka	
Peters/CGH		C Slomski	A Sanjeevi S Petursson	D. Makishi		Kiproff		D. DeFazio	TBD	TBD	
AVH		Dr. Hower general surgeon	G Finley A Barsouk S Miller	Y Arshoun	J. Oehrle	M. Colella	L. Fergus	D. DeFazio	L. Schaeffer	R. Hebert J. Engleka	
Clarion											
Wexford Pavilion		TBD by Dr. Julian	C Srodes C Moffa	R Fuhrer A Colonias S Karlovits Secondary Coverage: A Kirichenko M Trombetta D Parda	U Krishnamurti J Silverman	W. Poller	T. Bezek	TBD	TBD	R. Hebert J. Engleka S. Frank	
Weirton/ Robinson		C Slomski	S L Jasthy								
Bethel Park		TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD
Armstrong											

Ver. 1/30/14

Challenges In Using Central IRBs

Balancing local-central leadership and cultures (all politics are local)

Information transfer: need web-based electronic solution

Need full-time operational and regulatory experts and support

Allegheny Health Network

Successes In Using Central IRBs

Facilitates more clinical trial participation in community where expertise, time, and money to run IRB and clinical research enterprise is limited.

Improves quality, experience, and cost for patients and healthcare professionals

Promotes participant culture rather than spectator culture and improves professionalism/scholarly approach to medical practice that most physicians will embrace (helps overcome finance-based silos of care and valuation that degenerate medical profession to counting widgets)

Helps integrate programs—can only integrate through inclusive service-oriented approach with both patients and healthcare professionals. Central mandates do not work.