



Johns Hopkins Clinical Research Network (JHCRN)

A Collaborative Approach to Clinical Research

Charles M. Balch, MD
ICTR Deputy Director and JHCRN Director
Professor of Surgery, Oncology, and Dermatology
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What is JHCRN?

- An organization that conduct collaborative clinical research with investigators practicing at medical facilities within JHM, and at AAMC, and GBMC to serve patients of Maryland and the region.
- It is intended to be complementary to or an extension of clinical research activities conducted at Johns Hopkins or other Network sites .
- Johns Hopkins Clinical Research Network (JHCRN) functions within the Johns Hopkins Institute for Clinical and Translational Research (ICTR).

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Goals of JHCRN:

- Increase the number and types of protocols and the capacity to conduct collaborative clinical research
- Expand collaborations across a range of conditions and diseases
- Provide dedicated research personnel, including a network coordinator for each community-based site, to coordinate JHCRN protocols.

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Unique JHCRN Characteristics

- The Network access to a large and diverse pool of patients.
- Johns Hopkins functions as the prime contractor for third- party contracts.
- Johns Hopkins acts as the primary IRB of record.
- eIRB and CRMS provides a shared, web-based informatics system.



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Advantages of JHCRN

1. Ability to increase the breadth and scale of clinical research and outcomes-based research
2. Increased access to innovative drugs, diagnostics, and devices
3. Increased revenue from grants and contracts for clinical research infrastructure
4. Education and training of physicians and staff on clinical trials and outcomes research

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Advantages, cont.



5. Broader access to clinical research personnel across the network (Network Coordinators, Research Training Educator)
6. Broader access to Hopkins and ICTR core research services
7. Enhanced environment for research collaborations

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PROGRESS TO DATE:

- Wrote initial strategy in ICTR grant (2006) and created initial leadership with Dr Balch (as Director) and Suzanne Nelson (as Administrative Coordinator)
- Completed Network contracts between JHU and Anne Arundel Research Institute (2009) and GBMC (2010)
- Hired Network Coordinators
- Initiated Protocols (6 at present) largely around Medical Oncology studies
- Created Governance, Structure, and SOPs

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PROGRESS TO DATE:

- Started Educational workshops (with Dr Charmaine Cummings) with web-based access to video recordings
- Begun to expand the Network (reviewing 3 major medical centers)
- Developed Corporate Relations with Abbott, Genentech, Lilly, Amgen, and Diagnostics Photonics

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JHCRN Staff

- **Director:** Charles M. Balch, M.D.
- **Associate Program Directors (JH):**
 - Julie Brahmer, M.D. (Oncology)
 - Lisa Jacobs, M.D. (Surgery)
 - Fred Brancati, M.D. (Internal Medicine)
- **Network Coordinators:**
 - Sandra Schaefer, BSN, RN, OCN (AAMC)
 - Cynthia MacInnis, BS, CCRP (GBMC)
- **Administrative Coordinator:** Suzanne Nelson, MA
- **Educational Consultant:** Charmaine Cummings, RN, PhD

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JHCRN Educational Workshops

[http://webcast.jhu.edu/mediasite/Catalog/pages/catalog.aspx?
catalogId=cd1551eb-b3df-4854-a9a9-83d9e7ec6d14](http://webcast.jhu.edu/mediasite/Catalog/pages/catalog.aspx?catalogId=cd1551eb-b3df-4854-a9a9-83d9e7ec6d14)

- **Tips for Incorporating Clinical Trials into a Busy Practice**
- **Clinical Trials in Community Practice: Funding, Resources and Budget**
- **Discussing Clinical Trials with Patients in the Office: Common Pitfalls and Best Practices**
- **Recruitment and Retention of Patients**
- **Monitoring and Reporting of Adverse Events**
- **Maintaining Quality Data Collection**

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II. The Anne Arundel Perspective

Leadership:



- Dr. Joseph Moser, Senior VP Medical Affairs
- Dr. Stanley Watkins, AAHSRI Medical Director
- Margaret Matula, BSN, RN, MGA, AAHSRI Director
- Dr. Barry R. Meisenberg, Director, DeCaesaris Cancer Institute
- Catherine Brady-Copertino, RN, MS, OCN, Executive Director, DeCaesaris Cancer Institute
- Sandra Schaefer, BSN, RN, OCN, JHCRN Coordinator

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Anne Arundel Overview



- 300 inpatient beds
- 24,500+ annual admissions
- 20,500+ annual surgical cases
- 2800 employees, with 845 medical staff
- AAHS Research Institute
 - 97 active protocols
 - 15 research nurses and staff
- DeCaesaris Cancer Center
 - 1650+ new cancer patients
 - 18 cancer protocols

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JHCRN Trials at AAHSRI

- 1) MSLT-II: Phase III Multicenter Randomized Trial of SL and CLND vs. SL Alone in Cutaneous Melanoma Patients with Molecular or Histopathologic Evidence of Metastases in the Sentinel Node.
- 2) Phase I/II Partial Breast Irradiation with Various Concurrent Chemotherapy Regimens (PBIC).
- 3) Phase I/2 Study of Afilbercept Administered in Combination with Pemetrexed and Cisplatin in Patients with Advanced Carcinoma.
- 4) Early Detection and Predicting Recurrence in NSCL.
- 5) A Multi-Institutional Double-Blind Phase II Study Evaluating Response and Surrogate Biomarkers to Carboplatin and nab-Paclitaxel (CP) with or without Vorinostat as Preoperative Chemotherapy in HER2-negative Primary Operable Breast Cancer.

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III. The GBMC Perspective



Leadership:

- Dr. Gary Cohen, Medical Director, Berman Cancer Institute
- Dr. Paul Celano, Chief Medical Oncologist, Berman Cancer Institute
- Dr. James Mersey, Director, Geckle Diabetes and Nutrition Center
- Dr. John R. Saunders, Director, Milton J. Dance Jr. Head & Neck Center
- Dr. Ronald Tutrone, Chief of Urology
- Cynthia MacInnis, BS, CCRP, JHCRN Coordinator

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Overview of GBMC



- 310 inpatient beds
- 26,700 annual admissions
- 38,000 annual surgical cases
- 3500 employees, with 1250 medical staff
- Berman Cancer Institute
 - 2200+ new cancer patients
 - 55+ number of cancer protocols

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GBMC BERMAN CANCER CENTER

- 2250 analytical cancer cases (2007); breast 550, lung 177, colorectal 184, prostate 231, lymphoma 88
- 5 hospital based med oncs: 1,800 new consults/yr
- 26 med onc in-patient beds; ADC ~ 15
- Hospital infusion center: 55 – 60 treatments/day
- Radiation Oncology: 3 Linear Acc, IMRT, stereotactic radiosurgery, ~ 80 patients/day
- 50 - 60 active clinical trials; 150 accruals/year
- Hospice program, 400 pts daily census, 24 bed facility



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FUTURE STRATEGIES

- Fully integrate clinical research collaborative capacity across the geographically separate institutions that comprise Johns Hopkins Medicine
- Add up to five affiliated sites that fulfill the following goals:
 - Increase capacity of JH investigators to conduct research studies that could not be done as well ---or as fast— at a single institution study
 - Increase capacity to conduct studies in patient populations that do not ordinarily come to JH Hospitals
 - Increase opportunities to collaborate with qualified clinical investigators who practice in an affiliated center

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FUTURE STRATEGIES (Cont.)

- Add up to five affiliated sites that fulfill the following goals
 - Are located geographically in sites that do not compete with JH Medicine and the present affiliated institutions
 - Are located geographically in locations not more than 2 hours drive so MDs and staff can participate in face-to-face meetings
 - Have an institutional financial commitment to recruit and support physician investigators, including research staff
- Develop robust training and certification programs for MDs and staff
 - Workshops and tutorials
 - Electronic and print reference material

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FUTURE STRATEGIES (Cont.)

- Develop a robust corporate relations program to facilitate commercial collaborations with Network Investigators for scientifically interesting and significant research studies and that enhance the revenue to support the clinical research infrastructure and enterprise
 - Have a portfolio that comprises a diverse mix of drug, device, and diagnostic studies
 - Have a portfolio that comprises a spectrum of disease focus and specialty focus

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FUTURE STRATEGIES (Cont.)

- Develop capacity to conduct Comparative Effectiveness, Clinical Outcomes and Health Economics Research
— Increase collaborations and involvement with faculty in JHSPH
- Develop capacity to conduct Nursing research collaborative studies
- Enhance the web-based capacity to conduct clinical research (CRMS, CaTissue etc)
- Develop a stable cadre of research navigators who facilitate the start-up of high-quality and fully-funded clinical trials

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LOGISTICAL PRIORITIES

- Complete logistical, staffing and legal arrangements to incorporate investigators and research staff throughout Johns Hopkins Medicine
- Assess candidate institutions for new membership ,and incorporate into JHCRN as appropriate
- Expand disease/specialty programs beyond Oncology
 - Diabetes
 - Surgery
 - Intensive Care/Critical Care
 - Neurosciences
 - Cardiothoracic and Vascular
 - Pediatrics

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SUMMARY

- JHCRN is a new core function of the Institute for Clinical and Translational Research
- Plan to have up to 5 affiliate members of the JHCRN
- Intended to be address clinical research issues across major diseases (with oncology as a template)
- Should increase the types of trials conducted through collaborations, the rate of patient accrual, and funding levels
- Still in the formative stages of providing infrastructure and learning how to collaborate together!

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QUESTIONS?

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