

Research Institute Progress Update

CPMR Meeting

April 08, 2019

Amit Acharya, BDS, MS, PhD
Executive Director, MCRI



MISSION:

WE ENRICH LIVES

...through discovery, translation and application of scientific knowledge that improves health and well being.

VISION:

WE WILL INNOVATE AND DEFINE THE FUTURE OF HEALTH CARE FOR GENERATIONS

...Our research will be the source of innovation for the future of disease and injury prevention and integrated health care locally and globally.

VALUES:

Discovery – will be the foundation of the overall activities of the research group.

Translation – A major effort will be made to apply our discoveries in the health care setting.

Dissemination – Results of work done will be distributed broadly on a timely basis.

Teamwork – Will be a hallmark of the research group.

Excellence – Will be the standard for all research and program activities.

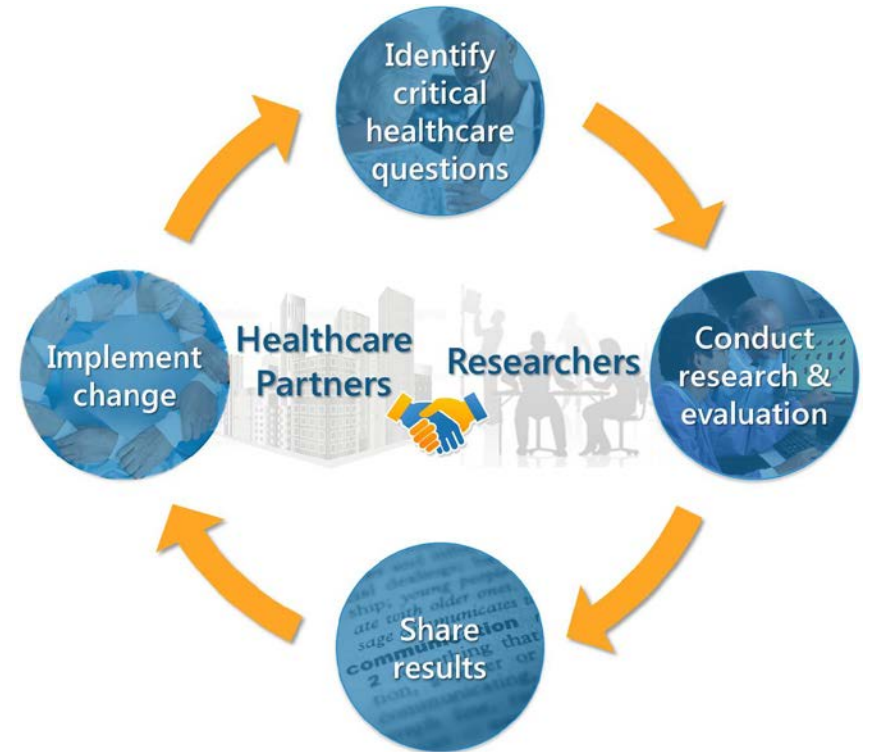
Collaboration – Partnerships both internal and external will be sought and encouraged.



Learning Health Systems

- The impact of translational research on health improvements hinges on research infrastructure integrated into the health system

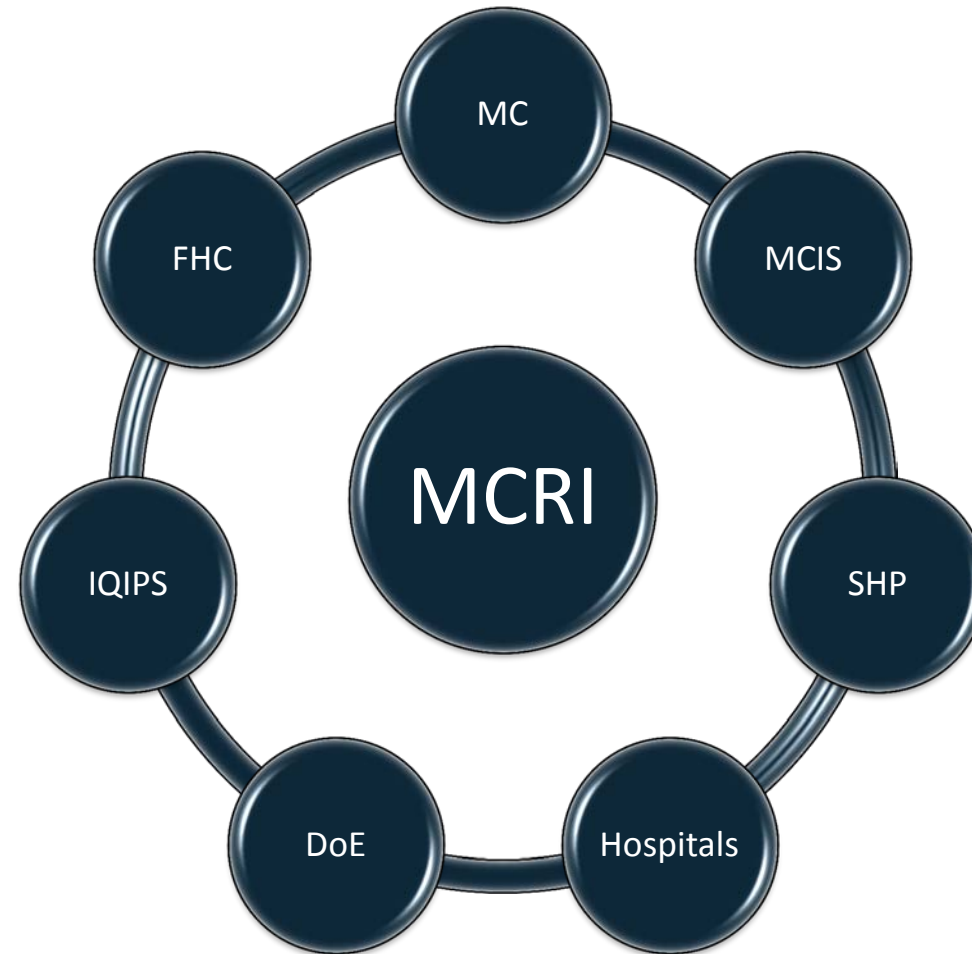
A LHS is a system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience (IOM, 2015)



HIP model recognized by the **AAMC** with the **2014 Learning Health Systems Research Champion Award**



Engaging MCHS Stakeholders and Creating Value Research-As-A-Service



Re-engaging and Supporting Clinician Researchers



Medical Professionals

Our more than 80 specialties and sub-specialties are available to help your patient.

Clinician Dedicated Research Time (CDRT)

Subject Matter Expert Research Time (SMERT)

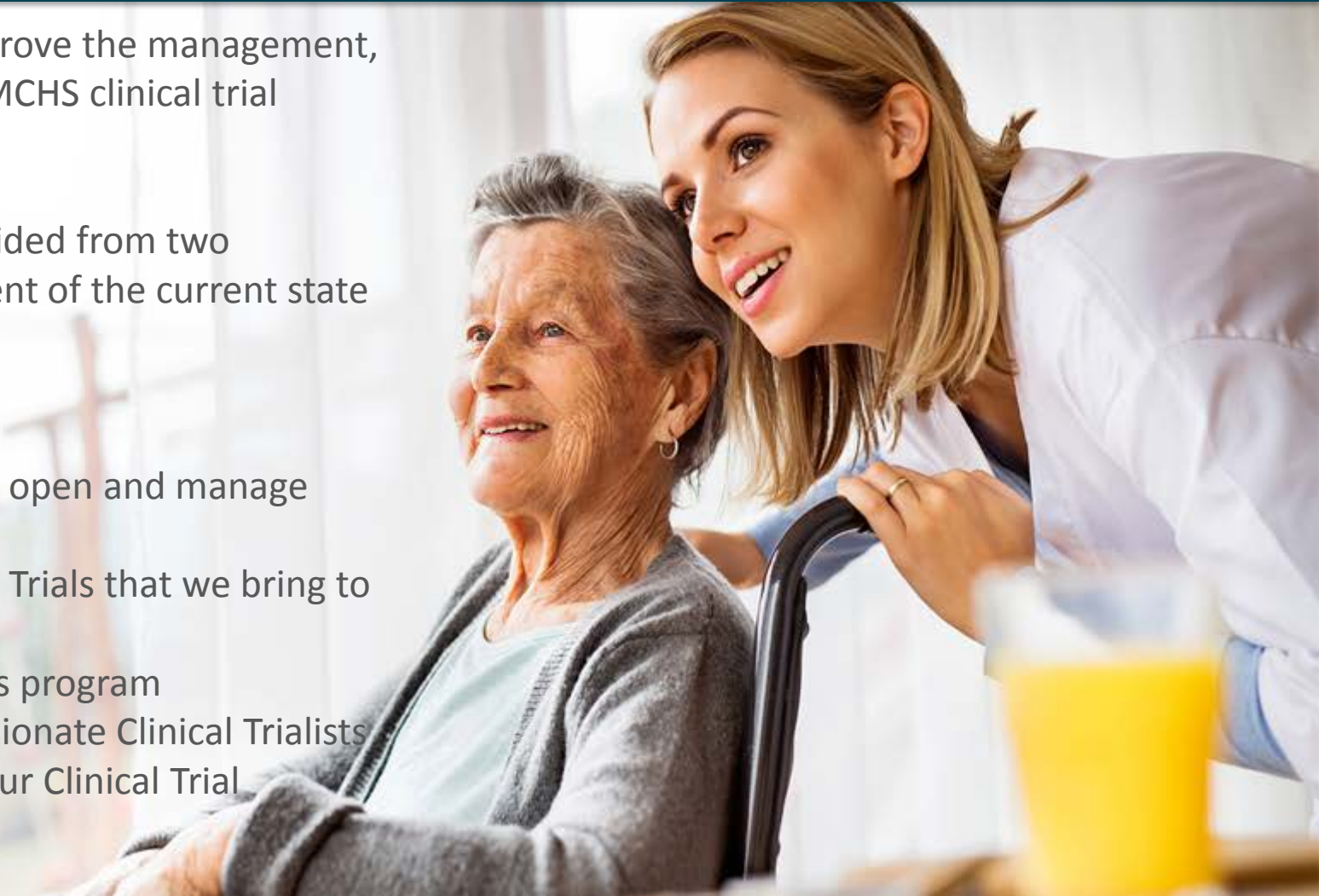


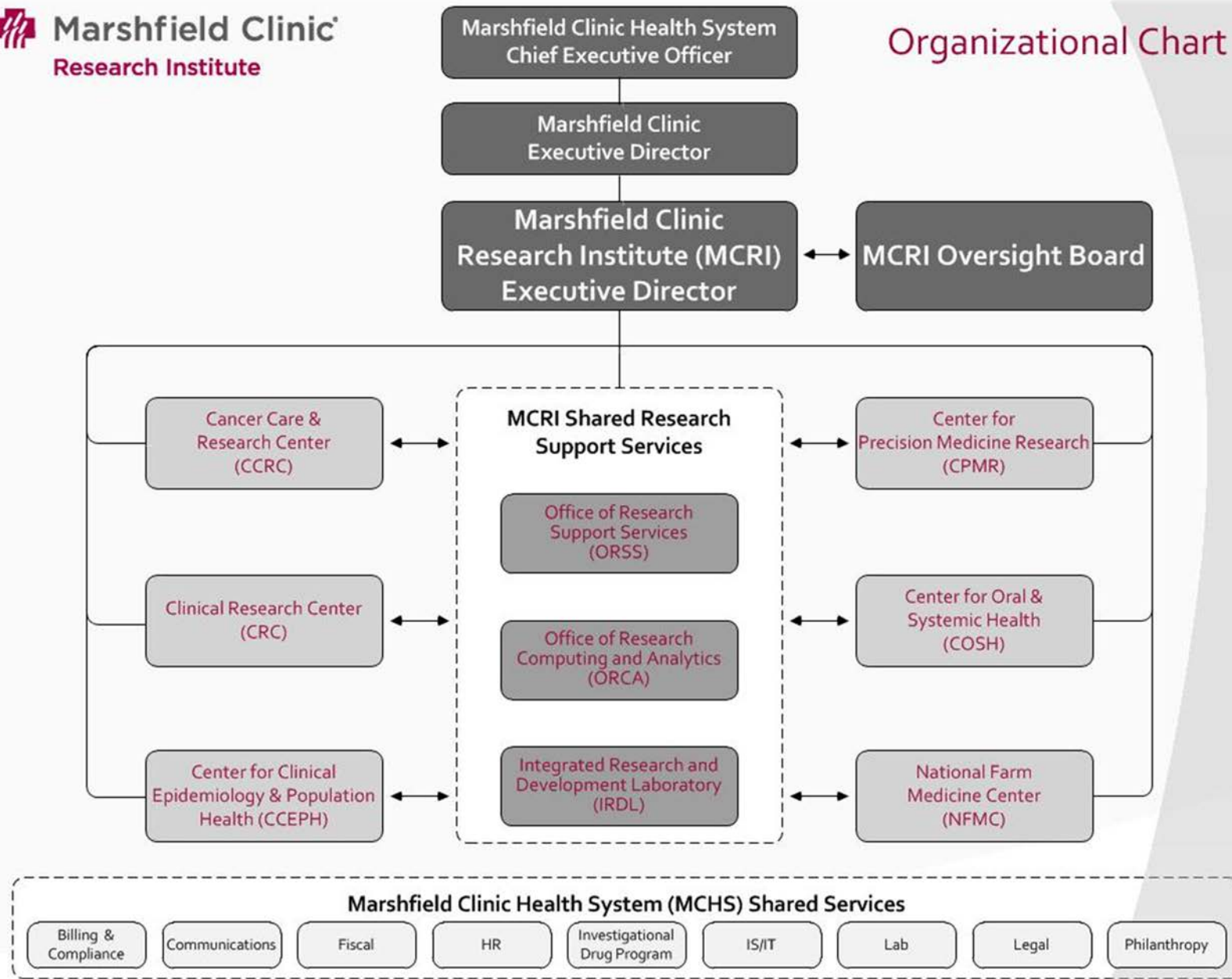
Clinical Trial Workflow Redesign Team



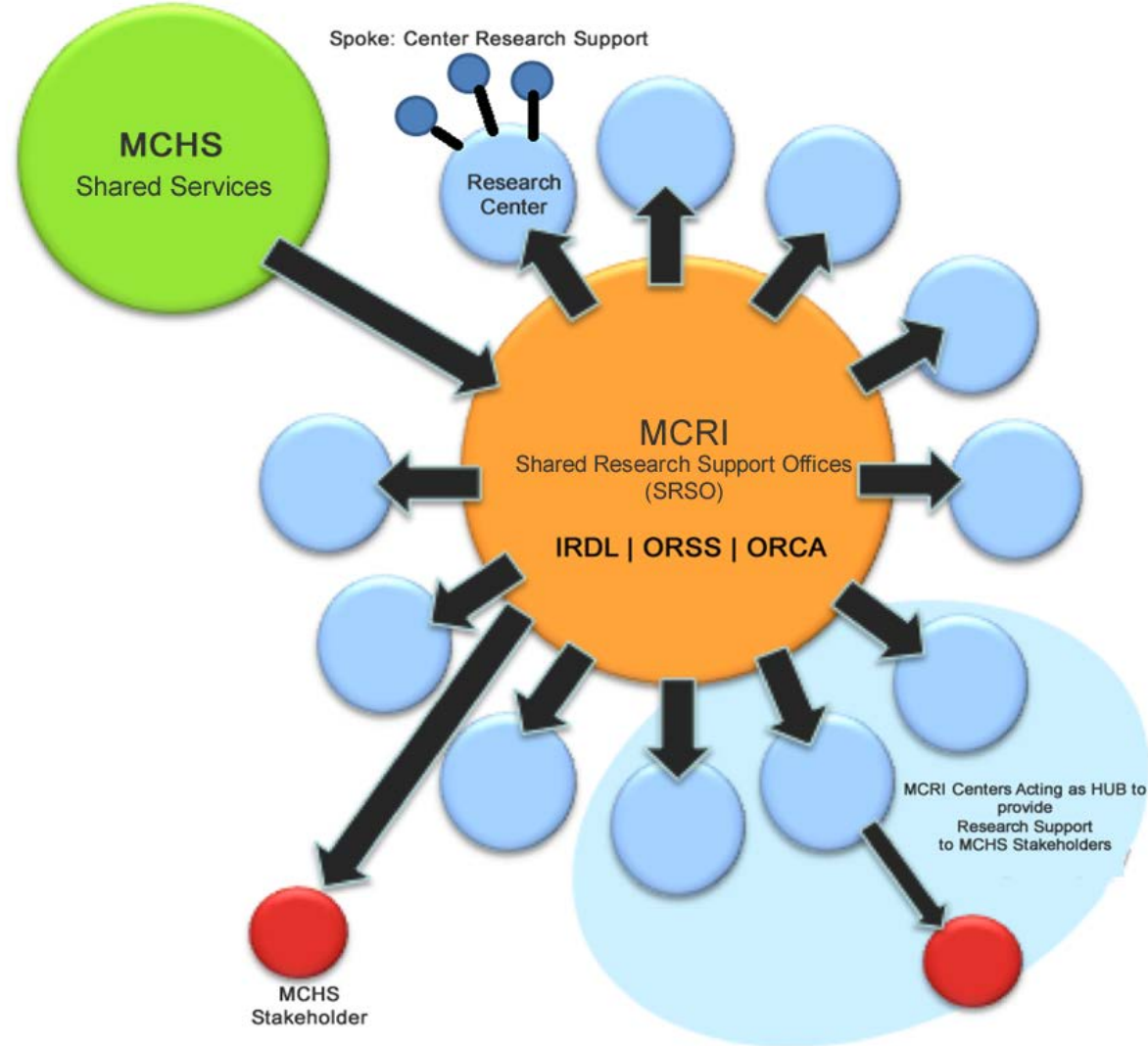
Marshfield Clinic Health System

- **Goal:** Develop strategic initiatives that can improve the management, effectiveness, and financial administration of MCHS clinical trial program.
- **Action Plan:** Developed based on reports provided from two consulting groups who conducted an assessment of the current state and workflow for Clinical Trials.
- **Expected Outcome:**
 - ✓ Establish an efficient and clean process to open and manage clinical trials at MCHS
 - ✓ Identify and prioritize the areas of Clinical Trials that we bring to MCHS
 - ✓ Elevate the reputation of our Clinical Trials program
 - ✓ Identify a group of well qualified and passionate Clinical Trialists
 - ✓ Achieve a positive financial portfolio for our Clinical Trial program





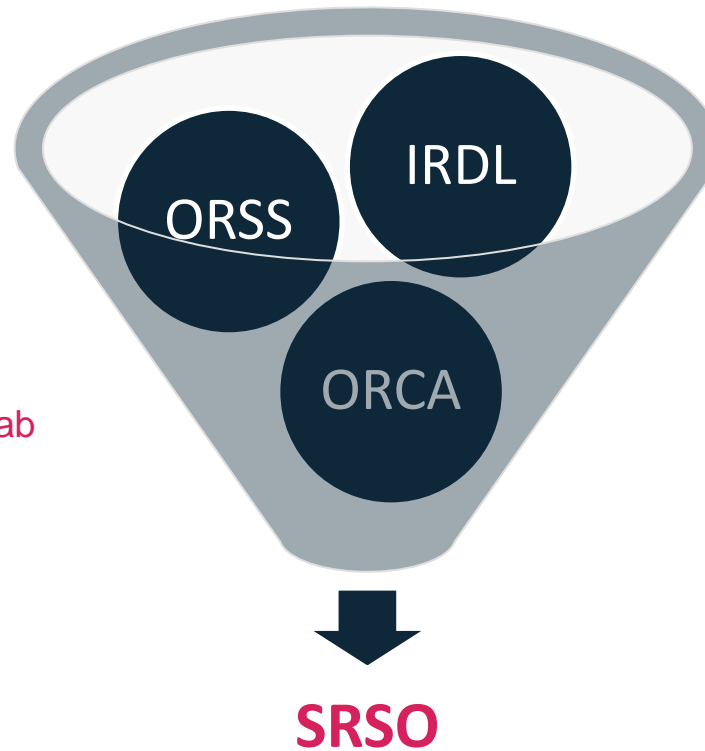
Center of Excellence Model (Hub and Spoke)



MCRI Shared Research Service Offices (SRSO)



Dr. Jen Meece
Integrated Research & Development Lab



Ms. Jordon Ott
Office of Research Support Services



Mr. Joe Ellefson
Office of Research Computing & Analytics





- ✓ Research Navigation
- ✓ Sponsored Programs – External Funding
- ✓ Human Subjects Protection/Institutional Review Board
- ✓ Data Use/Material Transfer Agreements
- ✓ MCRI Collaborative Networks (ICTR/WiNR)
- ✓ Scientific Writing and Publications
- ✓ Research Committee/Internal Project Funding
- ✓ Research Intern and Education Programs

CM&R Highlights



- CM&R articles were read via PDF download 38,789 times with an additional 69,759 read via full-text HTML view
- Published articles were cited 1601 times (per Google Scholar)
- CM&R received submissions from 14 countries
- Utilized expert peer reviewers from 30 countries
- CM&R has been published within MCRI for 16 yrs



Human Subjects Protection

2018 IRB	AAHRP National Median	MCRI 2018
New & continuing reviews	295	357
Days in time submission to approval:		
Convened IRB	38 days	22 days
Expedited Review IRB	16 days	4 days
Days in time Exempt determination	10 days	2 days
Random internal audits completed	50	82

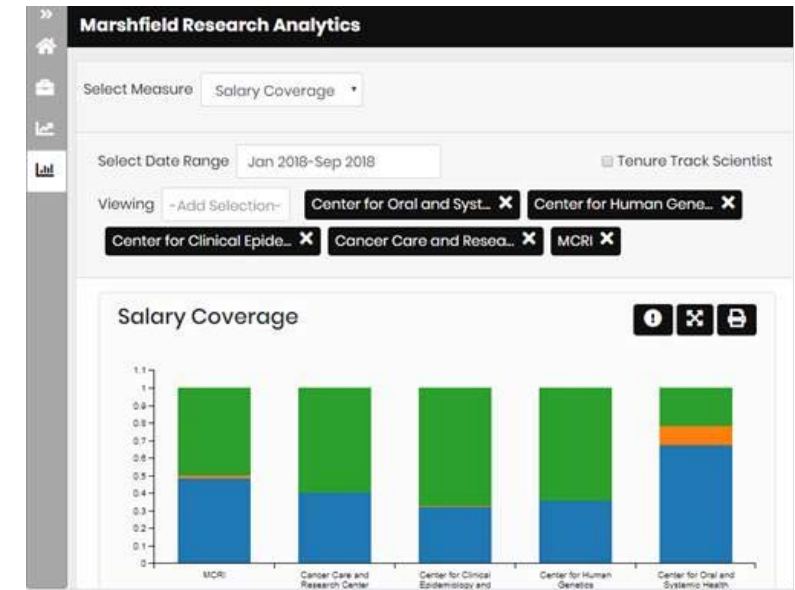


- Maintained, updated and further secured a state of the art systems in support of Research
- Developed a fully functional REDCap infrastructure to support Administrative, Internal and Externally funded projects
- Chart of Accounts Conversion in MCRI and MCHS
- Introduced a centralized KPI Dashboard
- Introduced Notifications and major enhancements to our MCRI Administrative HUB Modules
- MCRI Recruit Tracker Application for supporting the All of Us Research Grant and all future recruitment efforts in MCRI
- CRIBBS Registry Enhancements
- Built and proven the efficiencies of using ETLs, APIs between the RDW, REDCap and our Research Applications

MCRI Metrics/Key Performance Indicators

Complete:

- MCRI Research Analytics Dashboard infrastructure development
- Salary Coverage Metric. Quickly assess coverage of salary expense into three categories:
 1. Activities funded by Marshfield Clinic
 2. Activities funded by Marshfield Clinic Health System, e.g. FHC, SHP, etc.
 3. Activities funded by external entities, including donated funding



In Production:

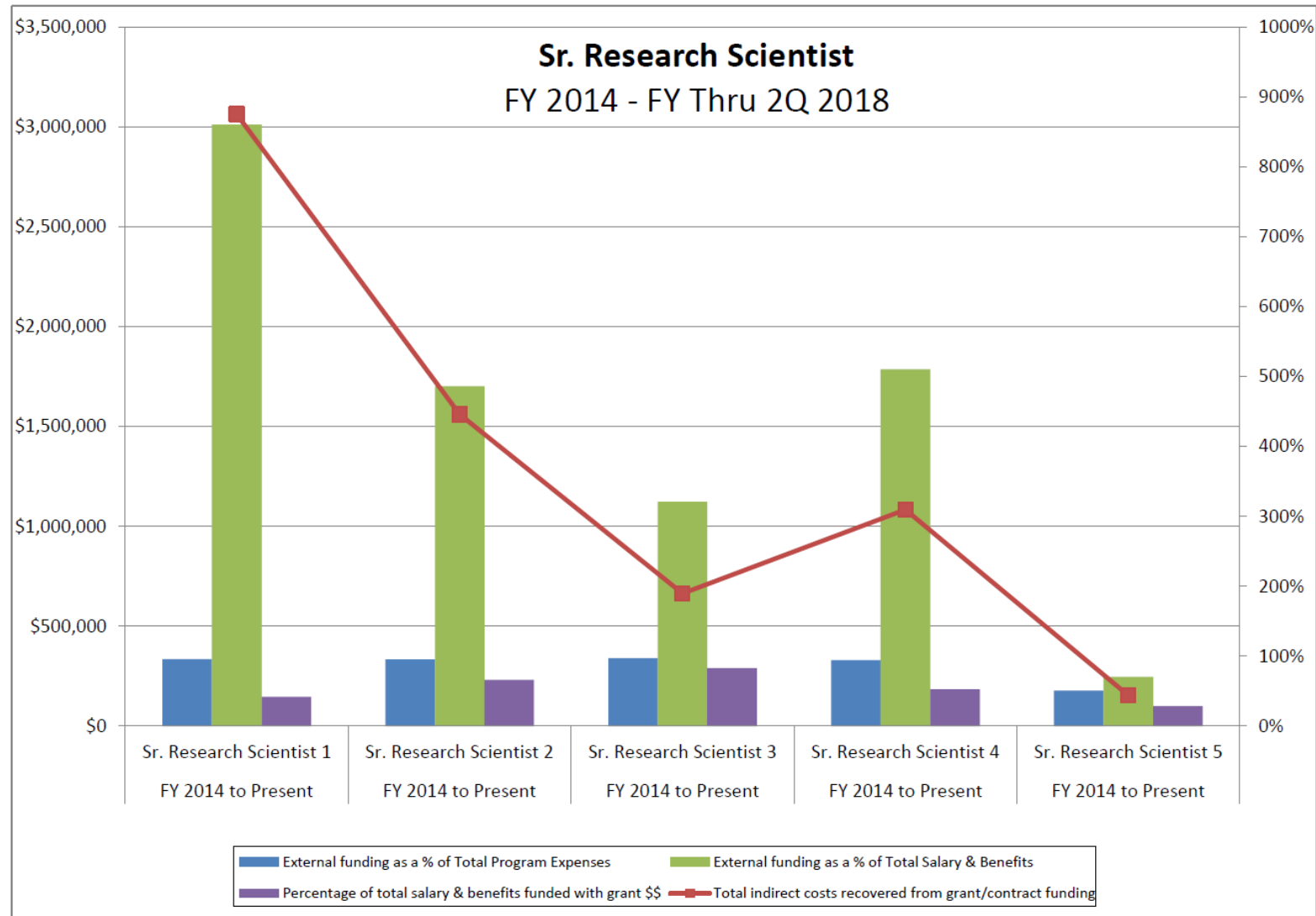
- Facilities & Administration (F&A) Recovery Metric. Allows MCRI to assess its indirect recovery against its eligible recovery. Metric required transition to new chart of accounts and will be launched in February.
- Publication Metric. Requires enhancements to the publication database. Once publication database is updated, metric will be completed and released to production.

Future Development:

- Metrics development in 2019 includes grant & contract performance indicators, scientific presentations, clinical trial metrics, study participant recruitment measures, etc.



Key Performance Metrics and Indicators



- To provide laboratory services from pre-award through manuscript preparation to clinician, scientists and external customers/collaborators
- Oversee facilities and equipment for Marshfield Clinic Research Institute
- Serve as an incubator Laboratory for Infectious Disease Research
 - ✓ Blastomycosis research
 - ✓ Tick-borne Infectious Diseases
 - ✓ Microbiome research

IRDL - Key Internal Collaborations



Marshfield Clinic Research Institute

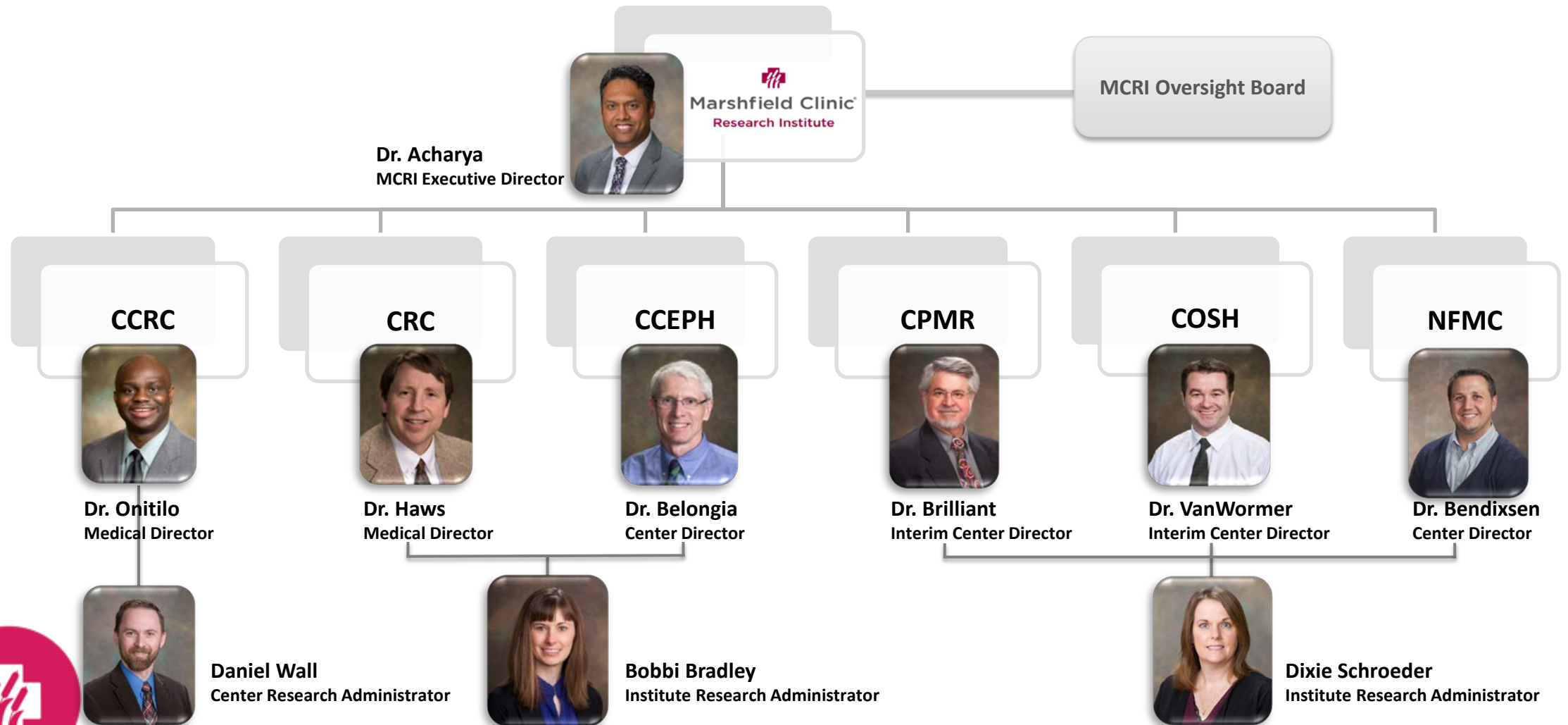
- WISC/CREW studies
 - ✓ Biospecimen management, isolation of PMBC and CBMCs for infant cohort study
- Influenza Vaccine Effectiveness, FLUTES and RIVER studies
 - ✓ Provide laboratory testing for influenza A and B (estimate 5,000+ tests) and subtypes/lineages (estimate 2,000 tests)
- Precision Medicine Initiative
 - ✓ DNA extractions, bio-banking (DNA and plasma) and sample management
- All of Us
 - ✓ Central processing and sample management
- Marshfield Labs Clinical Studies
 - ✓ Device and chemistry evaluation for microbiology and molecular pathology focused on new infectious disease laboratory tests



Provides valuable research space:

- The Clinical Research Unit provides a convenient location for patients to participate in research studies and clinical trials.
- Located within Marshfield Medical Center in Marshfield, the Clinical Research Unit provides a clinical setting for:
 - ✓ participants to consent for studies
 - ✓ have samples collected
 - ✓ undergo physical examinations that are required of study participants
- This resource is invaluable to our ability to compete for grants and contracts and greatly improves our patient experience.

MCRI Research Centers and Leadership Team



MCRI Administrative Leadership Team



Dr. Jen Meece
Director, IRDL



Mr. Joe Ellefson
Director, ORCA



Ms. Jordon Ott
Director, ORSS



Ms. Bobbi Bradley
Institute Research Administrator



Ms. Michelle Wellsandt
Executive Secretary



Dr. Acharya
Executive Director, MCRI



Ms. Dixie Schroeder
Institute Research Administrator



MCRI Oversight Board Membership Representation

Marshfield Clinic Physician
Leaders
(4 Members)

Community Leaders
(5 Members)

MCHS Leaders
(4 Members)

Ex-Officio Member
MCRI ED

Total 13 Voting Members;

Officer Positions

- Chairman
- Vice Chairman
- Secretary

MCRI

SHP

Hospital

DoE



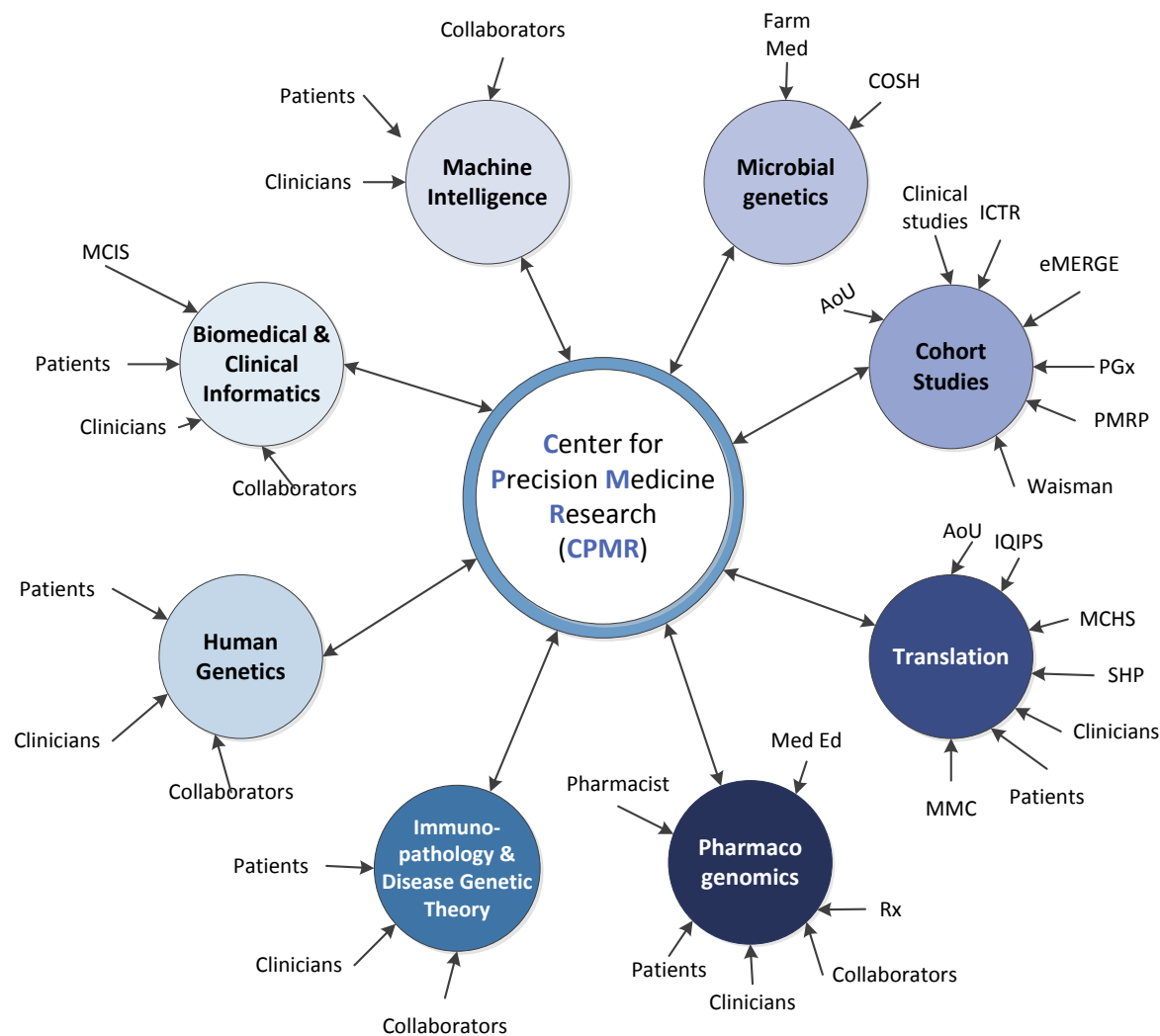
November 1, 2018: Establishment of Center for Precision Medicine Research



Dr. Murray Brilliant
Interim Center Director, CPMR



Ms. Dixie Schroeder
Research Administrator



Center for Precision Medicine Research

All of Us
Wisconsin



Murray Brilliant, PhD
Interim Director CPMR
Lead Principle Investigator

- 1 of 10 Healthcare Provider Organizations for national All of Us Research Program
- Recruit 100,000 Wisconsinites reflecting diversity of rural and urban population of State
- Resource for future precision medicine research consisting of DNA samples, electronic health record-linked data, online surveys and data from mobile health technologies



Genomic Medicine in Clinical Care

- Scott Hebbring, PhD Research Scientist
- Pilot study of 2,000 Marshfield Clinic patients
- Goal of implementing genetic testing as part of clinical care
- Utilizes eMERGE model including genetic testing at Baylor College
- 3% of individuals have “clinically actionable” variant → increased risk for cancer, cardiovascular and metabolic diseases
- Also incorporates pharmacogenetic testing; variants influence drug response in 95% of individuals



Precision Medicine Initiative



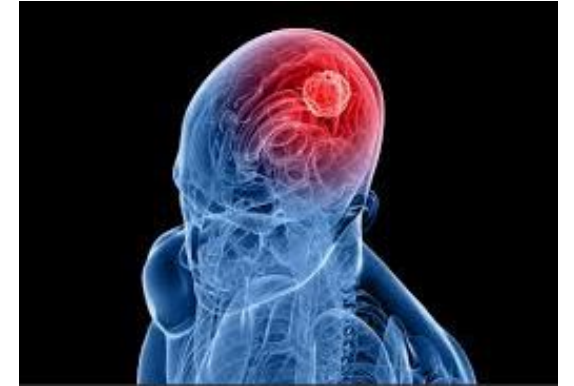
Credit: Shutterstock



Precision Medicine in Cancer



- Rafael Medina-Flores, MD Pathologist and Tonia Carter, PhD Assoc. Research Scientist
- Study looking at genetic diversity and biological pathways of glioblastoma tumors and patient response to temozolomide chemotherapy



Credit: Shutterstock



Role of gut microbiome in multiple sclerosis

- Paula Aston, MD Neurologist and Sanjay K Shukla, PhD Sr. Research Scientist
- Investigates changes in type or numbers of gut bacteria and its link to MS, a chronic inflammatory diseases



Credit: Darryl Leja, National Human Genome Research Institute, National Institutes of Health
<https://www.flickr.com/photos/genomego/v/28442056996>



Cancer Research

"Many of us know someone who has been diagnosed with cancer or even had cancer ourselves. We will continue conducting groundbreaking research and practicing the best medicine we can. As long as we draw breath ourselves, we will do our best to improve the health of the communities we live in."

- Dr. Adedayo Onitilo, Director of Oncology/Hematology and Radiation Oncology



- Dr. Onitilo was recognized by the National Cancer Institute as the Top Enrolling Physician for Treatment Clinical Trials across all of the NCORP Sites in the nation
- WiNCORP was recognized as a Platinum NCORP earning greater than 115 Accruals



"I was blessed to have stem cell replacement through research at Marshfield Clinic. What advancements we have made. The type of cancer I have, ten years ago I probably wouldn't be here. But because of research I'm able to be here for my kids."

- Len Luedtke, Jr., grateful patient



Development of a fully integrated Cancer Care and Research Center

On March 1, 2018 the Oncology Research Program was removed from the Clinical Research Center and integrated into the Clinical Service Line

Goals:

1. To change the culture of Oncology Research
2. To improve patient access to cutting edge clinical research trials.
3. To ensure continued success for Marshfield's National Cancer Institute NCORP Program
4. Improve staff retention and job satisfaction



Cancer Epidemiology Research

- MCRI, HealthPartners (Minneapolis) and Henry Ford Health System (Detroit), have been funded by the NCI to plan a large national cohort study of cancer occurrence and outcomes in adults.
- Participants will be followed over a decade or more to provide new information on cancer causes, and strategies to improve survival and quality of life. The Research Institute team will develop and test study recruitment and follow up procedures during the planning phase.
- Bob Greenlee, Ph.D., Principal Investigator



Marshfield Clinic Research Institute



A New Prospective U.S. Cohort set within the Health Care system Institutions to Study Cancer

Total Award for MCRI: **\$7,898,853**

Center for Research to Optimize Precision Lung Cancer Screening in Diverse Populations

Total Award for MCRI: **\$1,660,183**

Current Federally Funded Research

Influenza vaccine effectiveness (CDC)

Cancer incidence and outcomes (NIH)

Vaccine Safety Datalink (CDC)

Medical product safety (FDA)

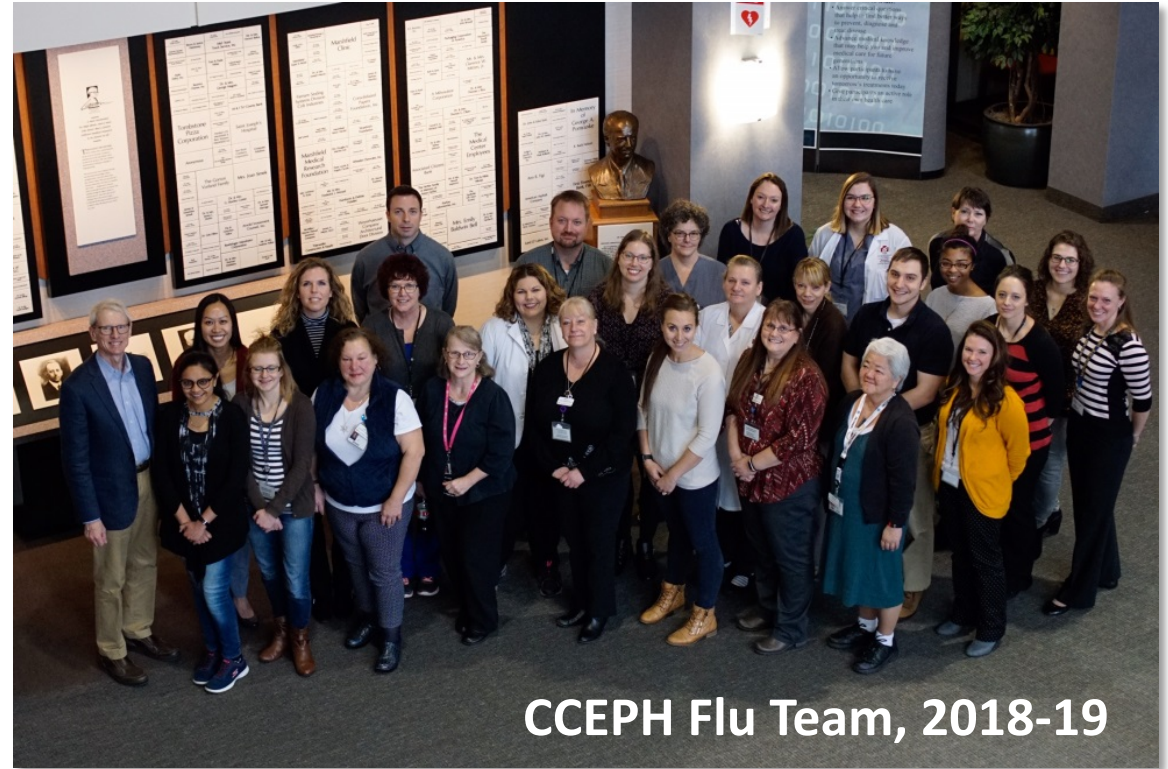
Increasing adolescent vaccination (CDC)

Lung cancer screening (NIH)

Obesity management in primary care (PCORI)



Marshfield Clinic Research Institute



CCEPH Flu Team, 2018-19

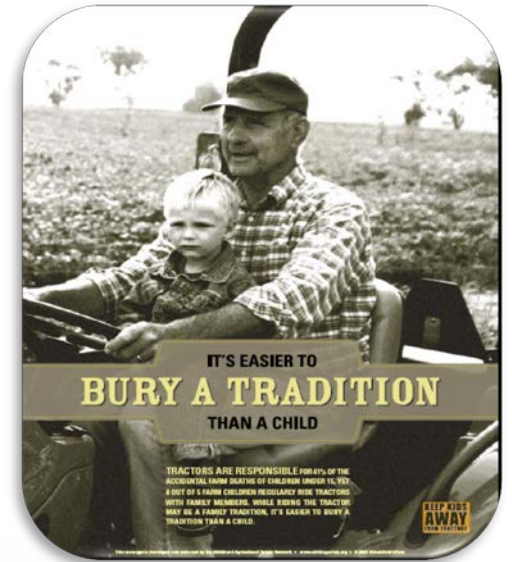
Cultivating Collaboration

- The National Farm Medicine Center, and its CDC/NIOSH-funded National Children's Center for Rural and Agricultural Health and Safety, work in partnership with many individuals and organizations to improve the health and safety of adults and children living, working and visiting agricultural settings across the country.



Childhood Agricultural Injury Prevention

- NIOSH-funded center since 1997, grant renewed 2014
- Studying youth tractor operation, hearing conservation, etc.
- Leads national consensus development initiatives
- Developed guidelines for:
 - Children at Work
 - Children at Play
 - Children and Agritourism



National Children's Center
for Rural and Agricultural Health and Safety



Oral-Systemic Connection

Research is Catching Up
with Clinical Practice, page 1

Perio Reports Vol. 24 No. 1
Oral-Systemic Connection, page 5

hygienetown

January 2012

with Perio Reports by Trisha E. Stroh, DMD, MS

It is All Related

"Oral-Systemic Periodontal Therapy" – A Case Study
page 11

Surrounded by the Top Minds in Medicine
Discussing Oral-Systemic Health page 13

A Publication of Hygienetown, LLC



Without good periodontal health, there can not be good general health.
Periodontal disease commonly known as gum disease can affect the state of your whole body. Over the past few years, studies have shown a definitive link between your oral health and your general health.

Mouthing OFF

Here are a few of the many health problems that can be aggravated by poor oral hygiene:

- STROKE**
 - Those with adult periodontitis may have increased risk of stroke.
- RESPIRATORY INFECTIONS**
 - Inhaling bacteria from the mouth and throat can lead to pneumonia.
 - Oral chronic buildup creates a dangerous source of bacteria that can be inhaled into the lungs.
- HEART DISEASE**
 - Those with adult periodontitis may have increased risk of heart heart attack.
 - And, are more likely to be diagnosed with cardiovascular disease.
 - Bacteria from the mouth may cause narrowing problems in the cardiovascular system.
- SEVERE OSTEOPOROSIS**
 - Periodontitis is more than 100% associated in association with peak disease and related bone loss.
 - Periodontitis has been connected to tooth loss in postmenopausal women.
- UNCONTROLLED DIABETES**
 - Chronic periodontal disease can trigger diabetes control.
 - Chronic periodontitis increases the risk of tooth loss by twenty times.
 - People with type 2 diabetes are three times more likely to develop periodontitis than non-diabetics.
- PRETERM OR LOW BIRTHWEIGHT BABIES**
 - Women with advanced gum disease are more likely to give birth to an underweight or premature baby.
 - Chronic inflammation in the periodontal tissue may increase the potential for preterm, low birth weight babies.

Remember: There are a number of additional oral care benefits available to women with advanced periodontitis, including: improved overall health, better pregnancy, and enhanced confidence. And, remember all you needed was a toothbrush.

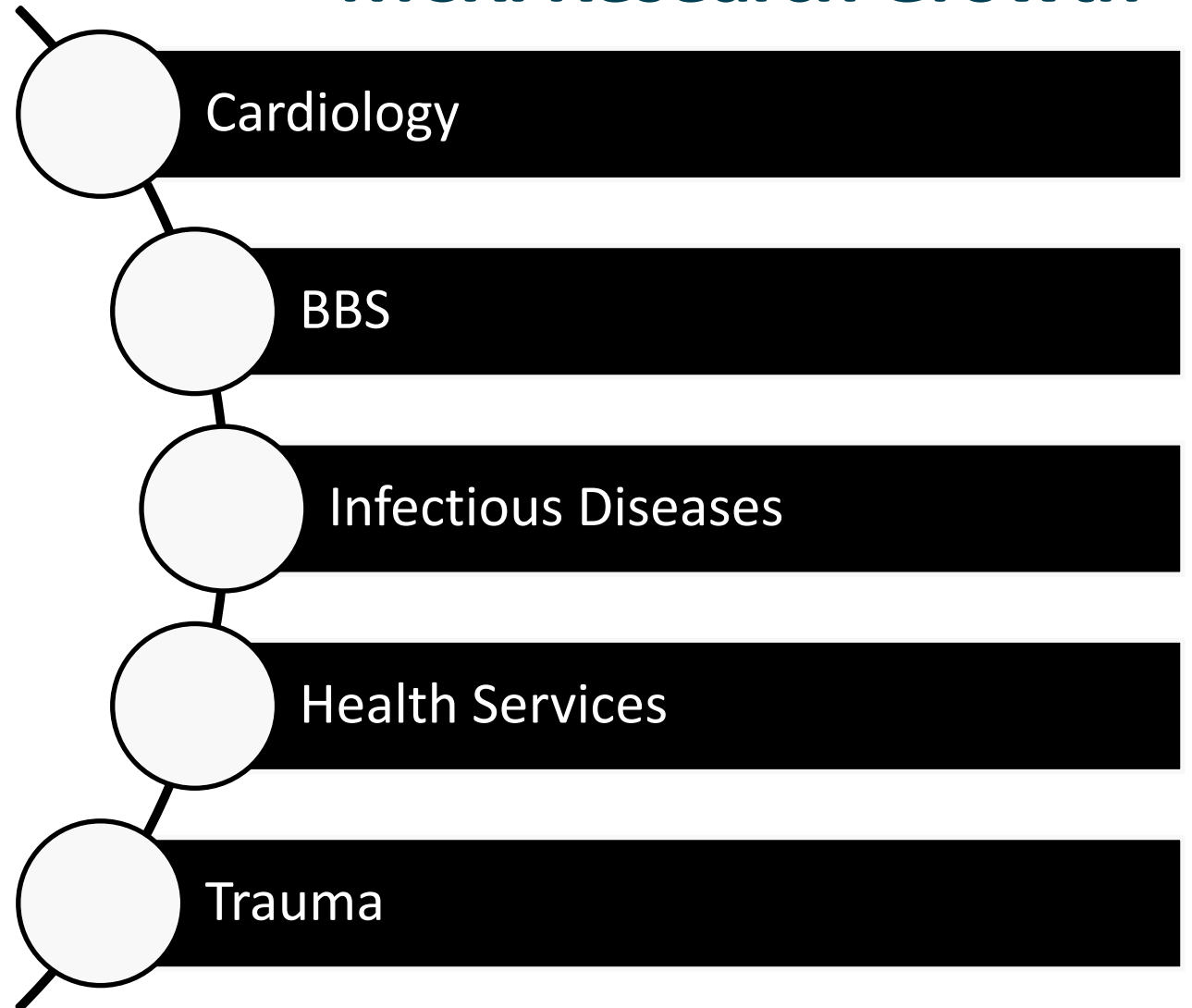
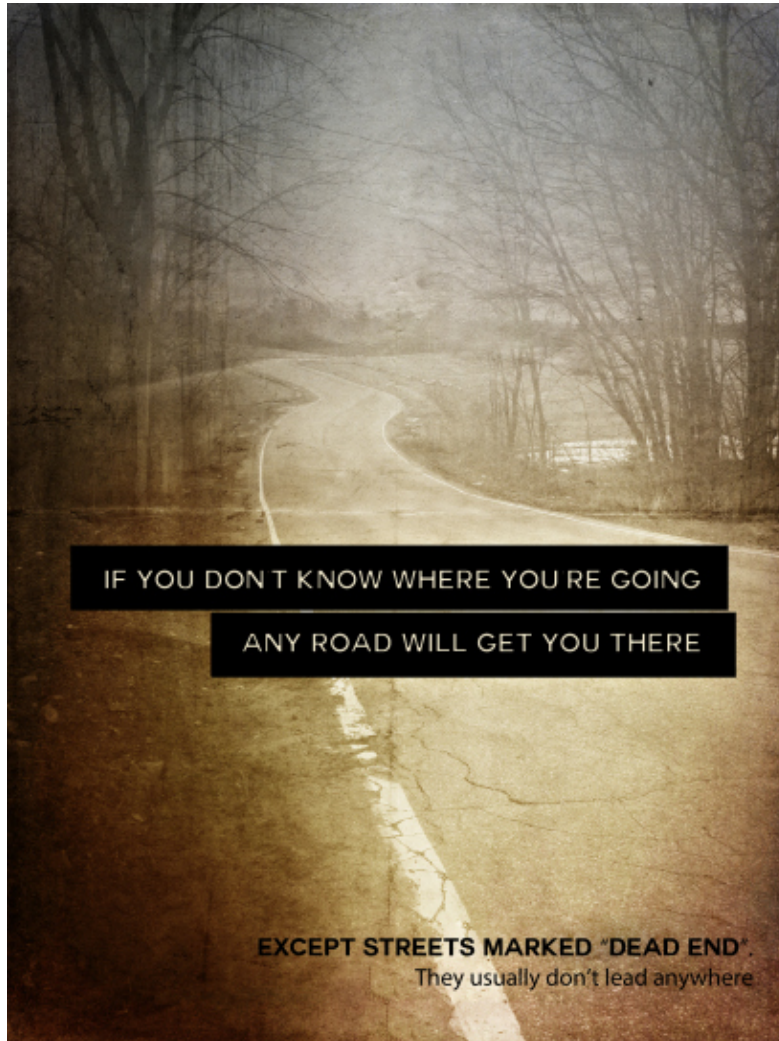
Do You Have Adult Periodontitis? What Are You Doing About It?
Ask your dentist for a full periodontal examination as well as information about the latest developments in periodontal treatment.
For more information, visit www.perio.org/healthyteeth.org/periodontitis

News Based on Science
For a greater awareness of periodontal disease and other diseases mentioned in this article, check out these helpful associations:

- American Academy of Periodontology**
www.aap.org For news, journals, and publications.
- American Academy of Periodontology**
News, journals, and publications.
- American Heart Association**
www.heart.org For news, journals, and publications.
- National Osteoporosis Foundation**
www.nof.org For news, journals, and publications.
- The National Women's Health Resource Center**
www.healthyparent.org For news, journals, and publications.

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MCRI Research Growth





The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

SEPTEMBER 20, 2018

VOL. 379 NO. 12



PI's: Dr. Shereif Rezkalla and Dr. Mateen Abidi

Cardiovascular Safety of Lorcaserin in Overweight

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The NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE

Low-Dose Methotrexate for the Prevention of Atherosclerotic Events

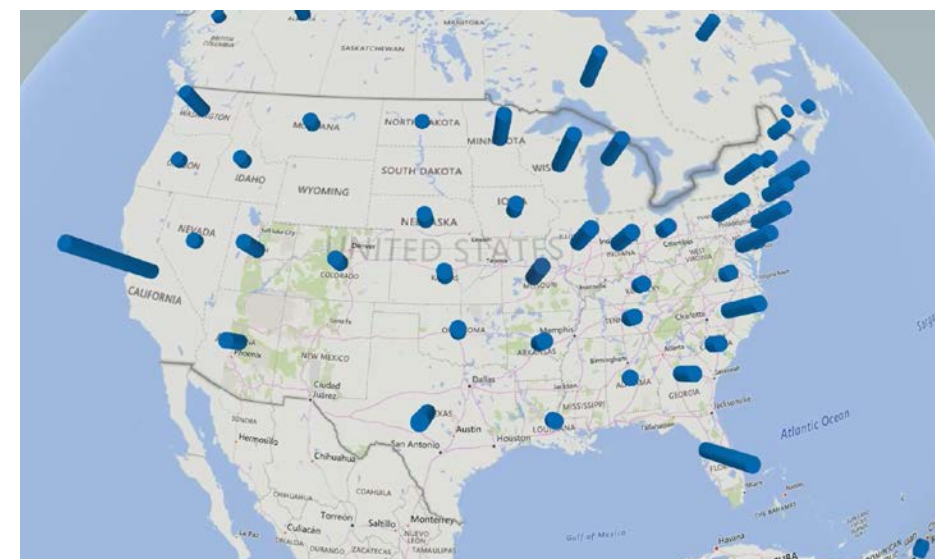
November 10, 2018

Bardet-Biedl Syndrome Research



Marshfield Clinic Research Institute

- Making a difference in rare diseases
- Center of Excellence for BBS
- Clinical Registry Investigating BBS – CRIBBS
- The largest worldwide registry for BBS
- MCRI leads pharmacologic research in syndromic obesity
- Collaboration with other MCRI centers, MC providers and public and private partners



Infectious Disease



Marshfield Clinic Research Institute



- Dr. Matt Hall
- Dr. Keith Pulvermacher
- Dr. Ray Haselby
 - ✓ Each is a leader in 2018 as they champion numerous vaccine studies helping to protect all of our patients from life-threatening diseases



Trauma Research Group



- **Background:**

- ✓ Pilot project was initiated in early 2018 to establish MCHS trauma research program with joint contributions from clinicians and MCRI investigators. Objectives included new research studies, greater utilization of trauma registry, and publication of original research.

- **FY19 Projects:**

- ✓ **Medically attended snowmobile injuries treated at MCHS from 2008-2018 by MESA vs non-MESA residents** – Dr. Dan Cullinane
- ✓ **Incidence and prevalence of rural orthopedic trauma** – Dr. Tyler Dahl
- ✓ **Surgical outcomes of hip fracture treatment** – Dr. Dave Polga
- ✓ **Study of rural trauma mortality** – Dr. David McClure
- ✓ **Transform MCHS trauma registry data into a research database accessible to scientist and clinician researchers** – ORCA, CCEPH, Trauma/Marshfield Medical Center

- **Infrastructure Team:**

- | | |
|---|-------------------------------------|
| ✓ Administrator – Bobbi Bradley, MPH | ✓ Epidemiologist – Jenny King, MPH |
| ✓ Project Scientist – Tosin Olaiya, MBChB | ✓ Project Manager – Judith Hase, BS |



MCRI Postdoctoral Fellowship Program



Scott Hebbring, PhD
Program Lead Scientist



Patti Baer
Program Administrator

- Anticipate first Fellow to begin in Summer 2019
- Two-year fixed appointments
- Dr. Scott Hebbring is serving as Post-Doc program scientific lead
- MCRI Postdoctoral Fellowship Selection/Advisory Committee to award MCRI-sponsored Post-Doc opportunities to proposing MCRI mentor scientists
- Salary plus individually assigned funds for professional development (e.g., for conference travel, membership dues, educational materials, etc.)
- Opportunity to channel ICTR-trained Post-Docs from Marshfield to Madison for further career development



MCRI		2018 Period 12 YTD Actuals	2017 Period 12 YTD Actuals	YTD Variance
REVENUE	Grant & Contract			
	Direct Cost	15,893,038	12,282,867	3,610,171
	Indirect Recovery Cost	5,054,231	3,582,957	1,471,274
	Other - Revenue	4,506,826	2,173,542	2,333,284
	Donated/Endow \$\$	3,014,880	3,171,411	(156,531)
REVENUE Total		28,468,975	21,210,777	7,258,198
EXPENSE	Salaries & Benefits	(22,223,546)	(20,365,547)	(1,857,999)
	Other Expense	(13,871,441)	(10,264,305)	(3,607,136)
EXPENSE Total		(36,094,987)	(30,629,852)	(5,465,135)

External Revenue:
\$7,258,198 (34%)

Expenses:
\$4,707,246 (14%)

Internal Dependency:
\$2,550,952 (22.6%)

Research Net Revenue / (Expense)	(7,626,012)	(9,419,075)	1,793,063
Service / Resource Included in Center			
Service Revenue / (Expense)	(1,120,657)	(1,878,546)	757,889
Total Net Revenue / (Expense)	(8,746,669)	(11,297,621)	2,550,952

Notes:

FY 2018 YTD Donated/Endow \$\$ Break Out
Endowment Dollars- \$ 1,748,547
Non Endowment Dollars- \$ 1,266,333



Financial Summary 5 Months Ending in February

MCRI		2019	2018	2017
REVENUE	Grant & Contract			
	Direct Cost	7,597,179	5,606,792	4,172,615
	Indirect Recovery Cost	2,233,113	1,770,558	1,415,846
	Other - Revenue	172,154	293,616	445,598
	Donated/Endow \$\$	1,716,642	1,111,761	1,115,342
REVENUE Total		11,719,088	8,782,727	7,149,401
EXPENSE	Salaries & Benefits	(8,419,153)	(7,357,211)	(7,230,644)
	Other Expense	(6,102,017)	(4,317,845)	(3,627,622)
EXPENSE Total		(14,521,170)	(11,675,056)	(10,858,266)
Research Net Revenue / (Expense)		(2,802,082)	(2,892,329)	(3,708,865)

MCHS Shared Services

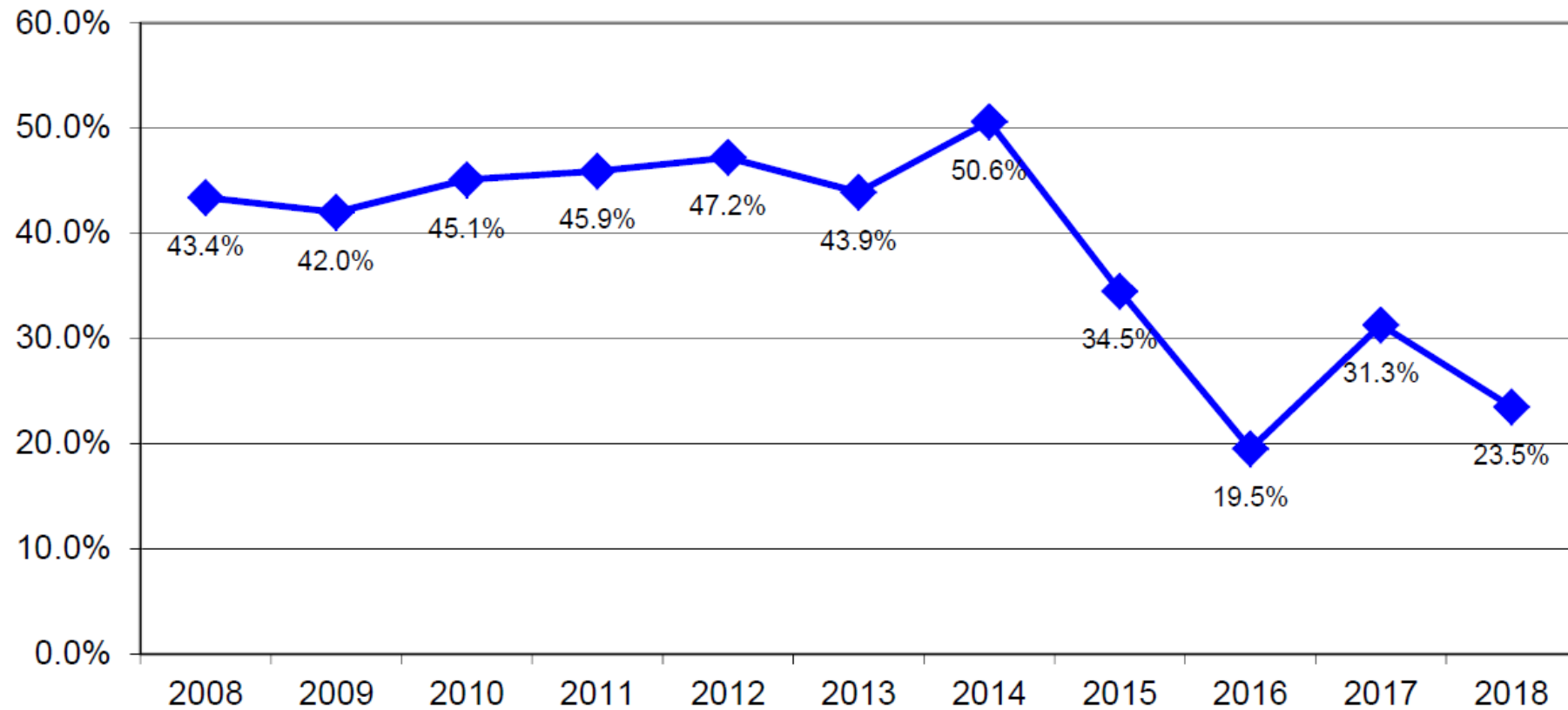
(1,925,759)

(1,292,986)

(816,996)



Marshfield Clinic UR Support for its Research Program as % of Total Research Expenses



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
UR Support *	9,537	10,154	12,103	13,129	13,923	12,779	15,168	10,370	6,508	11,297	8,747
Total Research Program Expenses	21,966	24,187	26,853	28,576	29,502	29,111	29,995	30,075	33,390	36,141	37,216
* excludes investment income (rounded to nearest 1,000)											



MCHS Investments in Precision Medicine

- **Research Fellowship in Precision Medicine**

Philanthropic Support Ebenreiter Family → FY 18 - \$300,000

- **Precision Medicine Initiative at Marshfield Clinic Health System**

Philanthropic Support from MCRI Donor \$ → FY 17 - \$920,000

Dr. John Melski Informatics Endowment Funds → FY 18 - \$ 16,000

MCRI Unrestricted \$ Support → FY 18 - \$711,000

Security Health Plan Support → FY 19 - \$331,000

Philanthropic Support from Strum Family → FY 19 - \$100,000

- **Total MCHS Investment**

→ **\$2,378,000**



MCRI Financial Stewardship Plan

Percentage savings calculated based on the following information:

1. Scope: Unrestricted Dollars (MCHS Support) Utilized vs External Funding;
2. Fact: FY18 MCHS Support of MCRI was \$8.75 Million;
3. Forecasting: FY19 MCHS Support Projected at \$9.5 Million;
4. Defined Denominator: We are assuming a \$10 Million MCHS Support to calculate the savings;
5. Target Saving: We are targeting a 5% saving that equates to \$500,000;





Frank and Betty Koller along with Mel Laird

\$4 Million raised by MCHS Foundation in FY 2018 to support research;



Sebold Award Recipient

Danielle and Dewey Sebold along with Dr. Donahue



Tom and Sally Ebenreiter



Richard D. Kohl



Marshfield Clinic Research Institute

2018 Year in Review



Marshfield Clinic Research Institute

MCRI Annual Report



Marshfield Clinic Research Institute



Thank You!

