

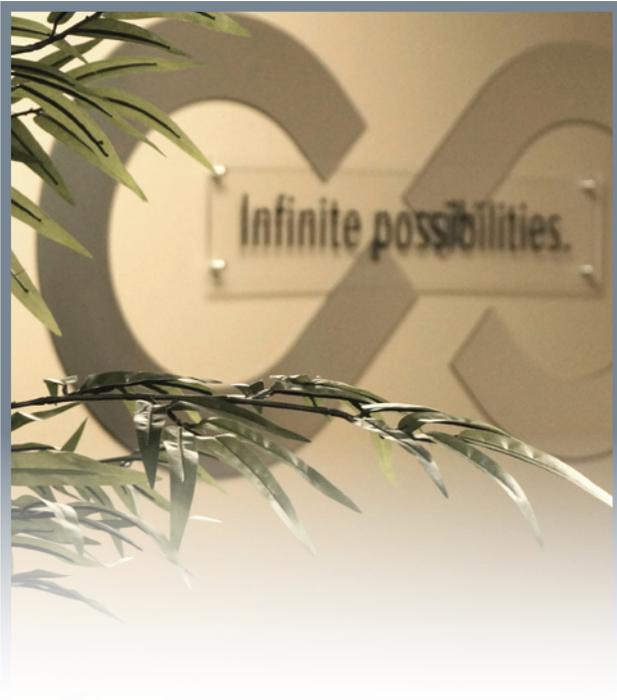
Annual Report

2015



hoosierSM
CANCER RESEARCH NETWORK

Board of Directors



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Statistician

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Hoosier Cancer Research Network's vision and mission is to form **unparalleled** relationships between academic, community, pharmaceutical, and biotech partners with the goal of **advancing** cancer research, education, and patient advocacy.

Our **highly qualified** team provides **comprehensive** study management and support, from conception and study design through project completion and publication.

A message from our Chairman of the Board

Over the past year, Hoosier Cancer Research Network has continued to increase its standing as a nonprofit contract research organization. HCRN formed new partnerships and strengthened existing relationships; we expanded our capacity to support the demands of genomically driven research; and we completed the monumental task of moving to a new EDC system and training our member sites.

In September 2015, HCRN announced a partnership with the Bladder Cancer Advocacy Network (BCAN) and Paradigm to launch a genomically driven bladder cancer study. This prospective study is the first project of the Bladder Cancer Genomics Consortium (BCGC), a collaboration of BCAN and major medical centers across the United States. HCRN will serve as the coordinating center of the study, which is expected to open in early 2016.

HCRN's relationship with the Big Ten Cancer Research Consortium remains strong. The consortium's first study opened in March 2015. Accrual is ahead of schedule, and the trial is expected to complete enrollment this year. Seven additional BTCRC studies are projected to open in 2016.

HCRN doubled its biospecimen storage capacity. We anticipate additional biorepository enhancements in 2016, further expanding the correlative services we provide to our research partners.

I would like to congratulate HCRN's data team for completing a successful transition to the OnCore EDC system. It is no small task to move a mountain of data — all the more challenging when you are still supporting the day to day demands of clinical research. The team accomplished this work with excellence, giving attention to the needs of our member sites at every step of the process.

As always, we are deeply grateful to those who support the mission of HCRN through generous donations. These gifts support unfunded or under-funded components of HCRN studies, particularly correlative laboratory work. These studies lay the groundwork for deciphering new information that leads researchers to design more precisely targeted clinical trials, yielding better treatment options for our patients.



**Christopher A. Fausel,
PharmD, MHA, BCOP**

Clinical Manager, Oncology Pharmacy
Indiana University School of Medicine

A message from our Chief Scientific Officer



Bert H. O'Neil, MD

Cusick Professor of Oncology
Director, Phase I & GI Oncology
Indiana University School of Medicine

Hoosier Cancer Research Network's momentum increased strongly over the past year. I am pleased that investigators from many institutions have brought their ideas forward through our Clinical Trial Working Groups. These groups form the backbone of HCRN's research development pipeline; they are the means by which good ideas are honed into exceptional clinical trials that translate to real benefit to our patients.

We hear from many investigators that HCRN is a refreshing alternative to the cooperative groups — an alternative that quickly moves research ideas to fruition while fostering collaboration and mentorship between today's leading experts and those who will lead a new generation of investigators.

It is my pleasure to serve as HCRN's Chief Scientific Officer at a time of tremendous growth for the organization. A few highlights from 2015 include:

- More than 150 investigators from 42 institutions represented in HCRN Clinical Trial Working Groups.
- 7 clinical trial agreements executed.
- 4 abstracts accepted to ASCO 2015.

The HCRN research development pipeline is stronger than ever. At the end of 2015, more than 25 concepts were in development, spanning a variety of cancer types and therapeutic modalities.

In 2016 and beyond, we will continue to develop novel clinical trials that reflect the best of academic and community collaboration — a partnership model that HCRN pioneered more than 30 years ago. Today, we are proud to continue leading the advance as we take on some of the most difficult challenges in cancer research.

A handwritten signature in black ink, appearing to read "Bert H. O'Neil". The signature is fluid and cursive, written on a white background.

Honoring Excellence

Sandra Turner Excellence in Clinical Research Award

“ I was influenced by the fact that my wife is a breast cancer survivor. Going to the infusion room and talking to the other cancer patients that were there and seeing the real-life struggles families go through with cancer treatments, it’s not hard for me to keep in mind that even though my work isn’t directly noticed by or it doesn’t directly impact the patient, it’s a way to make a behind-the-scenes contribution. There are patients out there that are going through real-life struggles while I’m doing my paperwork. ”

2015 Recipient Stephen Glick

Regulatory Affairs Specialist,
IU Health Goshen Center for Cancer Care

A continuing education

Stephen Glick plans to use the \$3,000 award to attend educational conferences offered by the Society of Clinical Research Associates (SOCRA). “This award will allow me to move forward with these opportunities,” he says. “I look forward to furthering my education!”



About the Award

The Sandra Turner Excellence in Clinical Research Award was established in 2002 by William B. Fisher, MD, through the George and Sarah Jane Fisher Fund to honor the memory of Sandra Turner, the first executive director of Hoosier Cancer Research Network. Recipients exemplify qualities which Sandra Turner possessed, such as sustained professional commitment, contribution to the progress of oncology care, and unflinching compassion.

Honoring Excellence



Sandra Turner Excellence in Clinical Research Award

“ I don't think anyone wakes up and says 'I want to be a regulatory person.' I think it's one of those things people discover and then say, 'this is interesting.' . . . At the end of the day, our job is to protect the physicians so they can continue to offer cutting-edge treatment to future patients. The reward is knowing I am giving back. It may not be in a way that is completely apparent, but I am facilitating research that is going to change someone's life in the future. ”

2015 Recipient

William Ian Towler, MS, CCRP

Regulatory Manager, Indiana University Melvin and Bren Simon Cancer Center



From Basic Science to Regulatory Affairs

Ian Towler earned an undergraduate degree in zoology and a master's in biology. He spent the better part of a decade doing basic bench science, but ultimately joined a startup company. "Our first big client asked all kinds of questions about rules and regulations and how we were meeting those, and none of us had answers," he recalls. "So I decided I needed to figure that out. I went back to school and got a degree in regulatory affairs. I ended up in an HIV clinical trial group, and from there moved into cancer."

By the Numbers

The regulatory team at the IU Simon Cancer Center is responsible for all IRB submissions, FDA IND submissions, and ClinicalTrials.gov submissions. "Last year we opened 118 trials. This year we are on pace to hit 120-125," he says. "We had over 2,800 submissions last year. Divided among 6 people, it is a huge volume of work. On top of that we currently manage about 38 INDs."

Honoring Excellence

George and Sarah Jane Fisher Young Investigator Award

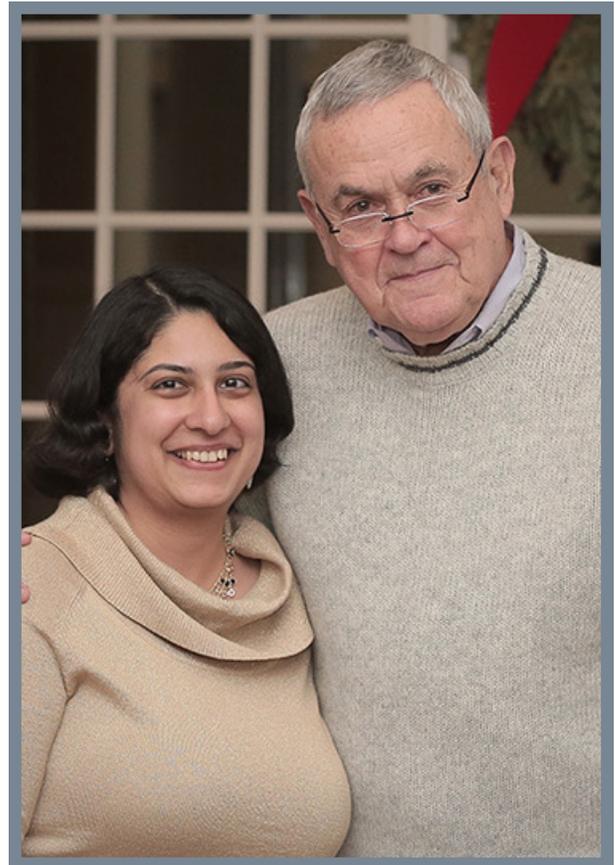
“I grew up in a family of physicians, so I always saw my dad and siblings working very hard, taking care of patients, and making them feel better. As you can imagine, I was little, so it kind of started out as a curiosity: How can they know so much about the human body, and how can they cure them of their illnesses? I was asking questions of my dad: ‘Dad, you’re a doctor. Can’t you treat cancer?’ That curiosity turned into an ambition to go into the field of medicine.”

2015 Recipient Hirva Mamdani, MD

Hematology/Oncology Fellow,
Indiana University School of Medicine

About the Research

Dr. Mamdani plans to use the \$15,000 award to advance her research in platinum-resistant small-cell lung cancer. “We want to see if DNA repair pathways are overactive in resistant small-cell lung cancer,” she says. “This project will include getting tissue biopsy from patients when they are initially diagnosed and then another tissue sample when the disease has progressed so we can compare the expression of DNA repair proteins in the same patient rather than different groups of patients.”



About the Award

In 2011, William B. Fisher, MD (pictured with Dr. Mamdani) and others generously endowed a new award through the George and Sarah Jane Fisher Fund to challenge the next generation of cancer researchers. The George and Sarah Jane Fisher Young Investigator Award honors Indiana University oncology fellows and faculty members who have made significant contributions to clinical or basic science research in collaboration with Hoosier Cancer Research Network.

Honoring Excellence



Danny Danielson Translational Innovation Award

“**W**hen I was an undergraduate, we had just finished sequencing the human genome. It took years to sequence the first time, and now we’re doing things like sequencing entire tumor genomes from a cell block. We now have drugs that might be able to put that information to good use, and I think that’s the stage we’re entering now in oncology. We are beginning to gather this information in a useable manner, and it’s going to be more and more precise in the coming years.”

2015 Recipient John Paul Flores, MD

Hematology/Oncology Fellow,
Tufts Medical Center



About the Research

Dr. Flores will use the \$10,000 award to conduct additional correlative testing for the HCRN GU14-202 clinical trial based on new data that came out toward the end of the trial design. Flores is co-investigator of the study, which is testing the safety and toxicity of the investigational drug niraparib in combination with enzalutamide. Learn more about the GU14-202 study at www.hoosiercancer.org/clinical-trials/gu14-202.

About the Award

The late Donald C. “Danny” Danielson established the Danny Danielson Translational Innovation Award in 2013, granted by the Walther Cancer Foundation. The award is given to investigators working in partnership with Hoosier Cancer Research Network to support the correlative components of clinical trial protocols when financial support is not otherwise available.

Honoring Excellence

Terry Hoepner Patient Advocacy Award

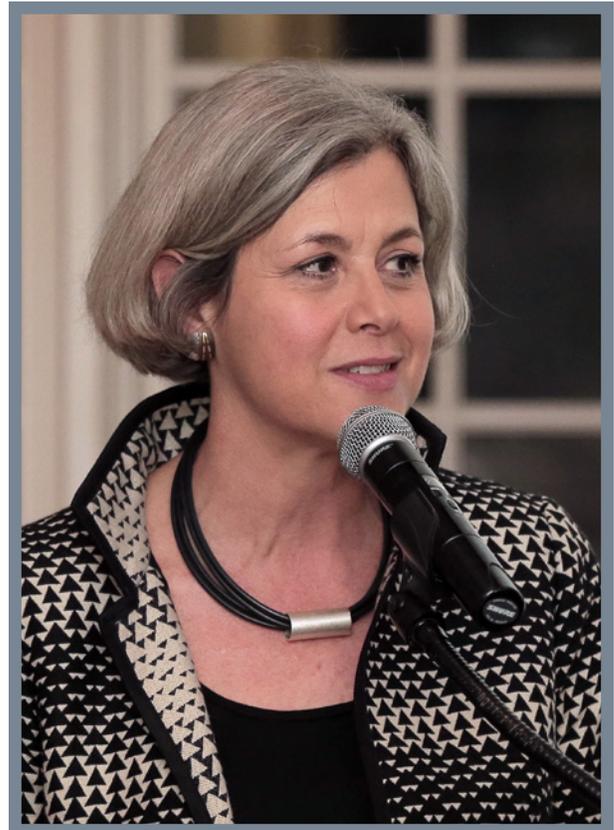
“It is never about one person. It is really about a community, and that is what we have done for bladder cancer — we’ve created this wonderful community that has a voice. Advancing research and finding a cure is key, but equally important is giving so that no one ever feels they are alone, and that people have the support they need to go through this experience with cancer. I am incredibly proud of BCAN; it has been a community effort these past 10 years.”

2014 Recipient Diane Zipursky Quale

President and Co-Founder,
Bladder Cancer Advocacy Network (BCAN)

A “Never Quit” Champion

HCRN honored Diane Zipursky Quale with the Terry Hoepner Patient Advocacy Award in recognition of her long-standing support for cancer research and patient advocacy. Quale has been a champion of the bladder cancer community for more than 10 years. Her story of uncommon determination reflects the characteristic spirit of her late husband, attorney John Quale, and of Coach Hep, two men who “never quit.” BCAN recently celebrated its 10th anniversary.



About the Award

Terry Hoepner, beloved Indiana University football coach, lost his battle with brain cancer in 2007. Coach Hep was known for his “never quit” attitude and determination to face challenges head-on. To honor his memory, his wife, Jane Hoepner, created the Terry Hoepner Patient Advocacy Award. The award honors individuals who embody Coach Hep’s spirit and determination to champion their cause.

Publications & Abstracts



Kathy Miller, MD

Indiana University
School of Medicine

BRE09-146

ASCO 2015 Poster Session

Authors: Miller K, Tong Y, Jones DR, Walsh T, Danso MA, Ma CX, Silverman P, King MC, Badve SS, Perkins SM.

Cisplatin with or without rucaparib after preoperative chemotherapy in patients with triple negative breast cancer: Final efficacy results of Hoosier Cancer Research Network BRE09-146. Accepted as Poster Presentation at General Poster Session at the ASCO Annual Meeting, May 29-June 2, 2015, Chicago IL. J Clin Oncol 33:5s, 2015 (suppl; abstr 1082).



Gabriela Chiorean, MD

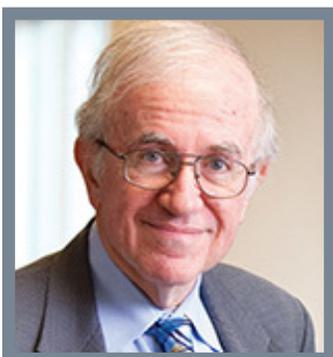
University of Washington
School of Medicine

GI05-102

ASCO 2015 Poster Session

Authors: Chiorean EG, Picus J, Breen T, Ansari RH, Harb WA, Burns M, Spittler AJ, Loehrer PJ.

Phase I/II study of everolimus (E) with irinotecan (Iri) and cetuximab (C) in 2nd line metastatic colorectal cancer (mCRC): Hoosier Cancer Research Network GI05-102. Accepted as Poster Presentation at General Poster Session at the ASCO Annual Meeting, May 29-June 2, 2015, Chicago IL. J Clin Oncol 33:5s, 2015 (suppl; abstr 3618).



Lawrence Einhorn, MD

Indiana University
School of Medicine

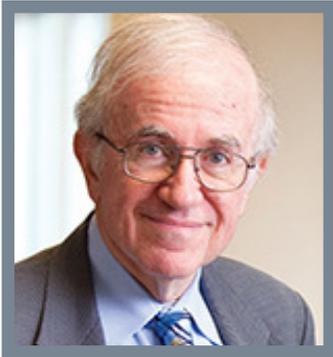
QL12-153

MASCC/ISOO Annual Meeting 2015 Poster Session

Authors: Brames M, Case-Eads S, Hanna N, Fausel C, Breen T, Einhorn LH.

Phase II study of fosaprepitant plus 5HT3 receptor antagonists plus dexamethasone in patients with germ cell tumors undergoing 5-day cisplatin-based chemotherapy: Hoosier Cancer Research Network QL12-153. Accepted for poster presentation at the MASCC/ISOO Annual Meeting on Supportive Care in Cancer, June 25-27, 2015, Copenhagen, Denmark.

Publications & Abstracts



Lawrence Einhorn, MD

Indiana University
School of Medicine

QL12-153

ASCO 2015 Publication-Only Abstract

Authors: Brames MJ, Case-Eads S, Hanna NH, Fausel CA, Breen T, Einhorn LH.

Phase II study of fosaprepitant +5HT3 receptor antagonist + dexamethasone in patients with germ cell tumors undergoing 5-day cisplatin-based chemotherapy: Hoosier Cancer Research Network QL12-153. Accepted as an electronic publication at the ASCO Annual Meeting, May 29-June 2, 2015, Chicago IL. J Clin Oncol 33:5s, 2015 (suppl; abstr e20737).



Noah Hahn, MD

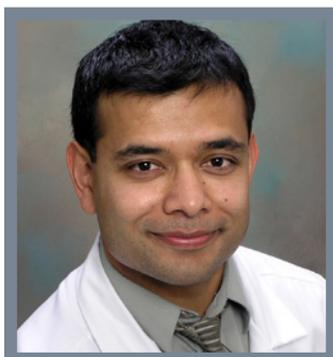
Johns Hopkins University
School of Medicine

GU12-160

ASCO 2015 Trial in Progress Poster

Authors: Choueiri TK, Hahn NM, Alva AS, Lauer RC, Dreicer R, Picus J, Pili R, Balar AV, Sonpavde G, Hoffman-Censits JH, Guancial EA, Alter R, Regan MM, Jacobs C, Stewart PS, Pal SK, Rosenberg JE.

The Borealis-2 clinical trial: A randomized phase 2 study of OGX-427 (Apatorsen) plus docetaxel versus docetaxel alone in relapsed/refractory metastatic urothelial cancer: Hoosier Cancer Research Network GU12-160. Accepted as a TiP poster at the genitourinary (non-prostate) cancer general poster session at the ASCO Annual Meeting, May 29 – June 2, 2015, Chicago IL. J Clin Oncol 33:5s, 2015 (suppl; abstr TPS4577).



Sumanta Pal, MD

City of Hope

GU09-145

Journal Article

Authors: Pal SK, Azad AA, Bhatia S, Drabkin HA, Costello B, Sarantopoulos J, Kanesvaran R, Lauer R, Starodub AN, Hauke RJ, Sweeney CJ, Hahn NM, Sonpavde G, Richey S, Breen T, Kremmidiotis G, Leske AF, Doolin E, Bibby DC, Simpson J, Iglesias J, Hutson TE.

A phase I/II trial of BNC105P with everolimus in metastatic renal cell carcinoma (mRCC): Hoosier Cancer Research Network GU09-145. Clin Cancer Res. 2015 Mar 18. pii: clincanres.3370.2014. [Epub ahead of print] PMID: 25788492.

Our Member Network

Academic Sites

ALABAMA

University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham

ARIZONA

Mayo Clinic Cancer Center, Phoenix

CALIFORNIA

City of Hope, Duarte
University of California Los Angeles (TRIO), Pasadena
USC Norris Comprehensive Cancer Center, Los Angeles

COLORADO

University of Colorado Cancer Center, Aurora

FLORIDA

University of Florida Health Cancer Center, Gainesville
University of Miami, Miami

GEORGIA

Winship Cancer Institute of Emory University, Atlanta

ILLINOIS

Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago
University of Chicago Medical Center, Chicago

INDIANA

Indiana University Melvin and Bren Simon Cancer Center, Indianapolis

KENTUCKY

University of Louisville, Louisville

LOUISIANA

LSU Health Care Center, Houma

MARYLAND

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore
University of Maryland Greenebaum Cancer Center, Baltimore

MASSACHUSETTS

Dana-Farber Cancer Institute, Boston
Tufts Medical Center, Boston

MICHIGAN

University of Michigan Comprehensive Cancer Center, Ann Arbor

MISSOURI

Washington University School of Medicine / Siteman Cancer Center, St. Louis

NEW HAMPSHIRE

Dartmouth-Hitchcock Norris Cotton Cancer Center, Lebanon

NEW JERSEY

John Theurer Cancer Center at Hackensack University Medical Center, Hackensack
Rutgers Cancer Institute of New Jersey, New Brunswick

NEW MEXICO

University of New Mexico Cancer Center (NMCCA), Albuquerque

NEW YORK

Tisch Cancer Institute at Mount Sinai, New York
Memorial Sloan Kettering Cancer Center, New York
New York University Cancer Institute, New York
Roswell Park Cancer Institute, Buffalo
University of Rochester Medical Center, Rochester

NORTH CAROLINA

Comprehensive Cancer Center of Wake Forest University, Winston-Salem
University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill

OHIO

Cleveland Clinic Taussig Cancer Institute, Cleveland
The Ohio State University, Columbus
University of Cincinnati Cancer Institute, Cincinnati
University Hospitals Seidman Cancer Center, Cleveland

OREGON

Oregon Health & Sciences University, Portland

PENNSYLVANIA

Fox Chase Cancer Center, Philadelphia
Thomas Jefferson University / Sidney Kimmel Cancer Center, Philadelphia
University of Pennsylvania, Philadelphia

SOUTH CAROLINA

Medical University of South Carolina / Hollings Cancer Center, Charleston

TENNESSEE

Erlanger Health System, Chattanooga

TEXAS

Baylor College of Medicine - Methodist Breast Center, Houston
Cancer Therapy & Research Center at UT Health Science Center, San Antonio
MD Anderson Cancer Center, Houston
UT Medical Branch at Galveston, Galveston

UTAH

Huntsman Cancer Institute at the University of Utah, Salt Lake City

VIRGINIA

University of Virginia Cancer Center, Charlottesville

WASHINGTON

University of Washington, Seattle

WASHINGTON, D.C.

Georgetown University Medical Center

WISCONSIN

Froedtert & the Medical College of Wisconsin, Milwaukee
University of Wisconsin Carbone Cancer Center, Madison

CANADA

Cancer Care Manitoba, Winnipeg
Centre Hospitalier de l'Université de Montréal, Montréal

Our Member Network

Community Sites

ARIZONA

Yuma Regional Cancer Center, LLC, Yuma

ARKANSAS

Genesis Cancer Center, Hot Springs

CALIFORNIA

Marin Specialty Care, Greenbrae
Prostate Oncology Specialists, Inc., Marina Del Rey

FLORIDA

Memorial Breast Cancer Center at Memorial Regional Hospital,
Hollywood
UF Health Cancer Center at Orlando Health, Orlando

ILLINOIS

Illinois Cancer Care, PC, Galesburg
Oncology Specialists, S.C., Niles

INDIANA

Community Healthcare - Primary Care Oncology, Munster
Community Regional Cancer Centers, Indianapolis
Floyd Memorial Cancer Center of Indiana, New Albany
Fort Wayne Medical Oncology & Hematology, Fort Wayne
Good Samaritan Hospital, Vincennes
Hope Center, Terre Haute
Horizon Oncology Research, Inc., Lafayette
IU Health Arnett Cancer Centers, Lafayette
IU Health Ball Memorial Hospital Cancer Center, Muncie
IU Health Cancer Centers Bloomington, Bloomington
IU Health Central Indiana Cancer Centers, Indianapolis
IU Health Goshen Center for Cancer Care, Goshen
Jasper Memorial Hospital, Jasper
Kosciusko Community Hospital Cancer Care Center, Warsaw
Northern Indiana Cancer Research Consortium, Inc., South Bend
Oncology Hematology Associates of Southwest Indiana, Newburgh
Radiation Oncology Associates, Fort Wayne
St.Vincent Health, Indianapolis
Union Hospital, Inc., Terre Haute

KANSAS

Cancer Center of Kansas, Wichita

MARYLAND

Meritus Center for Clinical Research / John R. Marsh Cancer Center,
Hagerstown

MICHIGAN

The Cancer Center at Metro Health Village, Wyoming

NEBRASKA

GU Research Network, LLC, Omaha
Nebraska Methodist Hospital, Omaha

NEW JERSEY

Regional Cancer Care Associates, LLC, Cherry Hill
Virtua Fox Chase Cancer Program, Mt. Holly

OKLAHOMA

Mercy Clinic Oncology and Hematology - McAuley, Oklahoma City

OREGON

Providence Cancer Center, Portland

PENNSYLVANIA

Allegheny General Hospital, Pittsburgh
Gettysburg Cancer Center, Gettysburg
PinnacleHealth Cancer Care, Harrisburg

TENNESSEE

The Jones Clinic PC, Germantown
The West Clinic, Memphis

TEXAS

Joe Arrington Cancer Research and Treatment Center, Lubbock
Medicus Alliance Clinical Research, Houston
Texas Oncology PA, Dallas

VIRGINIA

Virginia Oncology Associates, Norfolk

CANADA

Cross Cancer Institute, Edmonton
Juravinski Cancer Centre at Hamilton Health Sciences, Hamilton
Tom Baker Cancer Centre, Calgary
Vancouver Centre - BC Cancer Agency, Vancouver



Learn more about our network
and membership advantages at:
hoosiercancer.org/our-network/

Partners in Research

Courage to Climb

Columbus North High School
Columbus, Indiana

When Columbus North High School choir director Janie Gordon was diagnosed with breast cancer in 2009, her students wanted to do something to encourage her. They secretly planned a benefit concert in her honor, naming it Courage to Climb, and the concert became an annual event. Since 2011, Columbus North High School students have organized this inspiring annual event, with donations to HCRN exceeding \$20,000.



Indiana Department of the VFW Auxiliary

For more than 100 years, the Veterans of Foreign Wars (VFW) Auxiliary has served American veterans and active duty service members through a variety of programs, including Cancer Aid and Research. Each year, state departments receive back a portion of their contribution to the Cancer Aid and Research program, and donate the funds to a research facility. Under the leadership of 2014-2015 president Karen Muston (pictured with HCRN chairman Chris Fausel), the Indiana Department of the VFW Auxiliary raised \$97,000 toward the national Cancer Aid and Research program — the fourth largest amount among all state departments — and received back nearly \$14,500, which the organization donated to HCRN.

Reps for Research

HCRN Chairman Chris Fausel has once again raised the bar in the fight against cancer. This spring, he reissued his unique challenge to friends and supporters of HCRN: the Reps for Research challenge. Combining his interest in strength training and his passion for investigator-initiated research, Fausel invited pledges for every bench-press “rep” he could complete at the Arnold Sports Festival’s 5K Pump and Run event in Columbus, Ohio. In the two years since it began, Reps for Research has raised nearly \$5,000 in donations to HCRN.



Our Contributors

Thank you to all who have contributed to Hoosier Cancer Research Network. We are grateful for your commitment of time and resources to help us fulfill our mission. Your generous support strengthens our ability to fund investigator-initiated research. Learn how YOU can contribute to cancer research at www.hoosiercancer.org/make-a-difference/.

Contributions Received in 2015

John Baute — *in memory of William and Marie Wood*
Cynthia Burkhardt — *in memory of John Waffle*
Columbus North High School — *in honor of Janie Gordon*
Randy Dillinger — *in memory of Gerald Dillinger*
Christopher Fausel — *in memory of Gerald Fausel*
Nasser Hanna
HCRN Staff — *in memory of Joseph Breen*
LeaEtta Hyer
Indiana Department of the Veterans of Foreign Wars Auxiliary
Patrick Kiel
Patricia Kneebone
Christopher LeMasters — *in memory of Mildred Dobson*
Edward Margolis
Rakesh Mehta
Dianna Miller — *in memory of June Brune*
Lida Mina
John Nell
Bert O'Neil
James Paris
Kevin and Nancy Petraits — *in memory of Joseph Breen*
Maria Piddoubny — *in honor of Elia*
Megan Reimann
Jessica Roy
Daniel Rushing
Hamid Sayar
Deb and Jim Scahill — *in memory of Greg Newland*
Debbie Stockwell
Lisa Wood — *in memory of William Wood*

Support Hoosier Cancer Research Network through Amazon Smile

Did you know you can support HCRN through purchases made through Amazon Smile? When you shop, Amazon will donate a portion of your purchase cost to HCRN. Scan the code to the right or visit <https://smile.amazon.com/ch/26-0303542> to get started!





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