ICARE Initiative

Cristi Radford, MS, CGC ICARE Outreach Coordinator



Agenda

- Overview of ICARE
 - History
 - Mission
 - Benefits
- Patient enrollment
- Website contents
- Questions

What is ICARE?

- Research initiative representing a clinical-researchcommunity partnership between medical practitioners, researchers, and individuals facing inherited cancer risk
- Mission Statement: To end the cycle of inherited cancer through research, education, and outreach



ICARE Grant - 2010

Funding: Florida Biomedical (IBG09-34198)

Grant Objectives:

1. Increase enrollment of BRCA mutation carriers to ICARE by 20% yearly.

Target: 1000 BRCA carriers by year 5

↑access to the clinical cancer genetics expertise ↑ # of BRCA mutation carriers in research registry ↑ Capacity to perform translational studies among those with inherited cancer

Number of ICARE Participants
2220

Number of BRCA Carriers Enrolled

1054

Explore ICARE

What is Hereditary Cancer?

Why Participate in ICARE?

Other Research Opportunities

Contact ICARE

Participant Contact Form

Provider Contact Form

www.inheritedcancer.net

ICARE Grant - 2010

Funding: Florida Biomedical (IBG09-34198)

Grant Objectives:

2. Assess adherence to cancer risk management strategies for *BRCA* carriers at the provider and patient level

2016

→ Meet the Study Team

Participants

Providers

∨ Gene Specific Efforts

Newsletters

Our Research

Contact Us

ICARE Research

Please view the publications, abstracts, and presentations made possible by the Inherited Cancer Registry (ICARE) Initiative, its recruiting providers, and, of course, its participants. Only through these research efforts, will we be able to learn more about inherited cancer susceptibility genes, and determine how to better manage at risk family members and those with inherited cancer.

www.inheritedcancer.net



Abstracts & Presentations

Publications

- Cragun et al., Healthcare: Hereditary Cancer: Example of a Public Health Approach to Ensure Population Health Benefits of Genetic Medicine
- Gronwald et al., Fertility and Sterility: Treatment of infertility does not increase the risk of ovarian cancer among women with a BRCA1 or BRCA2 mutation
- Kotsopoulos et al., Journal of the National Cancer Institute: Bilateral Oophorectomy and Breast Cancer Risk in BRCA1 and BRCA2 Mutation Carriers
- Cragun et al., Genetic Testing and Molecular Biomarkers: Evolution of Hereditary Breast Cancer Genetic Services: Are Changes Reflected in the Knowledge and Clinical Practices of Florida Providers?
- Iqbal et al., British Journal of Cancer: The incidence of leukaemia in women with BRCA1 and BRCA2 mutations: an International Prospective Cohort Study

Patient Participation: Eligibility

Who is eligible?

- Men and Women age 18 and older
- Anyone with an inherited cancer syndrome
- Anyone who appears high risk (hereditary) with a negative or VUS test result
- Current targeted initiatives: PALB2 and PMS2

Gene Specific Efforts:

- PALB2
 - Aim to determine the best treatment for women with a PALB2 mutation and breast cancer
 - Part of "ICARE umbrella"
 - Commercial lab collaborations
- PMS2
 - Phenotype??



Patient Participation: Expectations

- Patient enrollment/participation facilitated remotely
- Informed consent form
- Questionnaire(s)
 - Initial
 - Follow-up to gather updates
- Copy of genetic test results / pedigree
- Sometimes saliva sample



Provider Expectations

- Inform participant of ICARE initiative
- Obtain permission for ICARE team to contact patient
- By becoming a recruitment site, you would be offering the following to your patients:
 - The opportunity to contribute to research for the future benefit of their families and others
 - Access to new research opportunities as they become available, such as new screening tools or medications for chemoprevention
- Select a recruitment method(s) that works best for your workflow
- Brochures are available



Recruitment Options:

- Online participant contact form
- E-mail patient's information to the study team: icare@inheritedcancer.net
- Provide patient with an online enrollment card directing them to ICARE website where they can enroll directly
- Complete a prepaid provider postcard and drop it in the mail or fax a copy to the study team's secure fax line (813-449-8403)

PARTNERSHIP

Provider Benefits:

ICARE Newsletter

 Electronic and hard copy version

ICARE Referral Number Letters

- Count towards
 CoC/NAPBC requirements
- Newsletter hard copy to accompany letter

Monthly Case Conference

 Outside cases are encouraged



ICARE NEWSLETTER



What's Inside?

Welcome Message
ICARE Recruitment and
Participation Update

Clinical and Research Updates. 2-3
Ask the Expert. 3
Community Spotlight. 4

ICARE Recruitment and Participation Update

Participation in the ICARE initiative minus to expend through referrals, events, and active outweet efforts. As of January 2017, there are 2193 participants, including 1049 multiations, earolled in the registry—Participants in CARE represent 46 U.S. states, the District of Columbia, Deserto Rico, and 13 countries

We appreciate the time our participants have that on complete their minal and follow-up their minal and follow-up and their minal and follow-up their minal their

Please visit our newest webpage (inheritedcancer.net/icare-research) dedicated to the research made possible by ICARE efforts!

Welcome Message

We have some vary exciting news to there with you! In the New Year, ICARE will begin a tensition to our new house at the Vandarduli-legarm Cancer, an No.7-beiginated Comprehensive Cancer Caster that is part of Vandarduli University Medical Center in Nutrituile, Feamessee, A few ICARE and meaning and if will be moving in March to join successed clinical cancer guesticist, Dr. Georgia Wasser, and has team. We do not satisfayes any long mendicular communications with our participants and healthcare partners as we selected our effects. Our samel Medical Software with the software of the control of the software of the s

Since initiating the ICARE effort in 2010, our registry has exponentially grown making it possible to contribute to both motion and miturational efforts, while developing cogning partnerships with healthcare providers. In an attempt to keep you informed of our architrist, we have compiled a comprehensively as the possible of the presentations and publications, unde possible strough ICARE efforts, now included in these publications is a recent article which continue the effect of copheractory or subtunity bare statement with most profile of the providers of the

Sincerel

Jugo Palus

Tuya Pal, MD, FACMG on behalf of the ICARE Team

NCCN Guidelines Version 1.2017: Genetic/Familial High-Risk Assessment: Breast and Ovarian

Breast and Overian

Additional guidance pertaining to cancer risk management was provided in
the most recent various of the NCCN Guidalines for inherited breast and ovarian
cancer. These guidalines now include an expended table outlining cancer risks
and management for each gues, taking into account the age at initiation of such
its management modality as well as footnows to highlight some of the manages
concurring particular mantions in specific guess. For example, among ATM and
OHEKZ craites, recommanded age at instantion of high risk breast recensing with
treast AMT is 40 years. Furthermore, the higher breast cancer risks associated
the state of the concernation of the control of the

August 31, 2016

Name Institution Address

Dear XXX,

On behalf of the Inherited Cancer Registry (ICARE) team, we would like to thank you for your continued support. In addition to the many benefits for your patients, referring individuals to ICARE counts towards the research requirement for maintaining Commission of Cancer (GoC) accreditation. As you know, CoC requires programs refer a certain amount of patients into research studies. If this is a requirement for your CoC accreditation, referring patients to ICARE can help your program meet this standard. In order to accurately capture your ICARE referral numbers, we send amust updates about the number of individuals you have referred to our research registry. Please contact was directly if you would like more detailed information.

Number of patients referred to ICARE through June, 28th 2016: 15 Number of patients enrolled into ICARE through June, 28th 2016: 10

We have also enclosed some additional information we hope you find beneficial 1. Recent ICARE Newsletter Edition

- Recent ICARE Newsletter Edition
 ICARE Recruitment Post Cards
- ICARE Recruitment Post Cards
 ICARE Recruiting Tips for Providers
- ICARE Genetics Case Conference Flyer

Please contact us if you would like more of any of the above materials.

If you have any questions, please do not hesitate to contact the ICARE study team directly at (813) 745-6446 (or toll free at 1-800-456-3434 extension 6446) or email us at ICARE@InheritedCancer.net; We also encourage you to browse our website, InheritedCancer.net, to learn more about the registry.

Sincerely.

Courtney Lewis, 1

Courtney Lewis, MS, CGC Genetic Counselor ICARE Outreach Coordinator TugoPalus

CANCER REGISTRY

Tuya Pal, MD, FACMG Clinical Geneticist Principal Investigator, ICARE

Instituion Acronum - EXT-XXX

2017 ICARE Case Conference Schedule

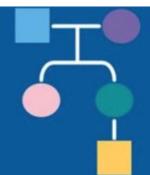
Date	Time (EST)	Focus
Thursday, January 19th	9:30am – 10:30am	Complex Case
Monday, February 20th	1:30pm – 2:30pm	Complex Cases (continued)
Thursday, March 9th	9:30am – 10:30am	Colorectal Cancer
Monday, April 17 th	1:30pm – 2:30pm	Possible Topics include: • PALB2 • Exome • ATM
Thursday, May 18th	9:30am – 10:30am	
Monday, June 19 th	1:30pm – 2:30pm	

... July topics and dates to be announced!



www.inheritedcancer.net

ICARE Inherited Cancer Registry



→ Meet the Study Team

→ Participants

Providers

∨ Gene Specific Efforts

Newsletters

∨ Our Research

∨ Contact Us

Español (Spanish)











Explore ICARE

What is Hereditary Cancer?

Why Participate in ICARE?

Enroll in ICARE Now!

ICARE@inheritedcancer.net

Welcome to the Inherited Cancer Registry!

"To end the cycle of inherited cancer through research, education, and outreach"

ICARE is a questionnaire-based research study established in June 2010, representing a clinical-research-community partnership among medical practitioners, researchers, and members of the general population. The goal of our research efforts is to maintain a registry of individuals interested in participating in inherited cancer research studies. Through this registry we hope to improve access to cancer genetics expertise for patients and healthcare providers. There is no cost to participate in ICARE and communications can be conducted via phone, email, or mail.



Contact ICARE

→ Meet the Study Team

∨ Participants

Providers → Gene Specific Efforts **Newsletters**

Vour Research

Contact Us

What is Hereditary Cancer?

CARE Now!

English

Why Participate in ICARE?

Participant Resources

Community Spotlight

Enroll in ICARE Now!

Other Research

cycle of inherited cancer through research, education, and outreach"

istry, please complete one of the below online Informed Consent Forms. Once the Informed Consent Form, you will be automatically directed to the online nnaire. You may choose to complete the questionnaire immediately or save and er time. If you have any questions regarding participation, or wish to complete Consent Form or Initial Questionnaire on paper, please fill out a participant

contact form and a member of the study team will be in contact with you shortly.

Community Spotlight



Click here to read inspiring stories from our ICARE participantel

Enroll Now (English)

To download a copy of the English Informed Consent Form for your personal records, click here.

Enroll Now (Spanish)

To download a copy of the Spanish Informed Consent Form for your personal records, click here.



Español (Spanish)

How to Recruit to ICARE?

Provider Resources registry
nealthcare providers information and guid

ICARE
INHERITED
CANCER REGISTRY
REGISTRO DE CÁNCER
HEREDITARIO

To end the cycle of inherited cancer through research, education and outreach

Poner fin al ciclo del cáncer hereditario mediante investigación, educación y extensión a la comunidad



Email/Correo electrónico: ICARE@inheritedcancer.net

Phone/Teléfono: (813) 745-6446

Toll-free/Linea gratuita: 1-800-456-3434 x6446

Website/Sitio web: inheritedcancer.net

ICARE
Inherited
Cancer Registry
Registro de cáncer
hereditario

"Our mission is to end the cycle of
inherited cancer through research,
education and outreach."

"Nuestra misión es acabar con el ciclo del cáncer
hereditario mediante la investigación,
educación y la divulgación."

Unique acronym on the postcards

CANCER REGISTRY The Inherited Cancer Registry (ICARE) Initiative represents a clinicalresearch-community partnership. The common goal of our efforts is to improve the lives of patients and families at risk for inherited cancer. This involves performing research in all aspects of familial cancer spanning from prevention and detection to treatment. Our participants have helped us take an important step towards achieving this goal. If you are interested in learning more about this initiative, please complete and return this card. State: Zip: Phone: () -Email: Date of Birth: / / Preferred Contact Method (please check one): _Phone -> Please circle: Morning or Afternoon or Evening Email Who referred you to ICARE?__ If you have any questions, please do not hesitate to contact the ICARE study team directly by: Phone: (813) 745-6446 Toll free: 1-800-456-3434 ext. 6446 Fax: (813) 449-8403 Email: ICARE@moffitt.org

We invite you to visit our Website (www.Moffitt.org/ICARE) and Facebook page (www.facebook.com/ICAREatMoffitt) to learn more about us. ✓ Meet the Study Team
 ✓ Participants
 ✓ Providers
 ✓ Gene Specific Efforts
 ✓ Poviders
 ✓ Poviders<

WHO ARE WE?

- We are a group of scientists who study hereditary breast cancer
- Our research focuses on the prevention and treatment of breast cancer in women with a genetic mutation
- We have studied the treatment of breast cancer in women with a BRCA1or BRCA2 mutation and how treatment can be personalized for these women
- We now want to understand if we should also personalize treatment for women with a PALB2 mutation who develop breast cancer
- This study is a collaboration between Women's College Hospital in Toronto (Drs. Kelly Metcalfe and Steven Narod) and Moffitt Cancer Center in Tampa, Florida (Dr. Tuya Pal)

"I had negative BRCA testing several years ago, but my strong family history of breast cancer led my breast surgeon to offer me additional genetic testing for several other inherited breast cancer genes (called multi-gene panel testing) once it became available. Through this testing, I was found to carry a PALB2 gene mutation. I have



a PALE2 gene initiation. There since enrolled in the Inherited Cancer Registry, as I am interested in participating in research in any way that I can to learn more about inherited cancers in people with a PALB2 mutation."

Mari-Lynn Slayton, two-time breast cancer survivor and carrier of a PALB2 mutation

FOR MORE INFORMATION ABOUT THIS RESEARCH STUDY, PLEASE CONTACT OUR STUDY TEAM:

United States: (813) 745-6446 Toll Free: 1(800) 456-3434 x6446 Canada: (416) 351-3800 x2761

Email: ICARE@InheritedCancer.net

Website:

http://inheritedcancer.net/palb2-study/

RESOURCES



Inherited Cancer Registry (ICARE)

ICARE's mission is to end the cycle of inherited cancer through research, education and outreach. Through ICARE, we partner with healthcare providers and patients facing inherited cancer risk to meet this goal. To learn more, visit inheritedcancer.net or contact the study team:

Email: ICARE@inheritedcancer.net Phone: (813) 745-6446 Toll-free: 1(800) 456-3434 x6446



National Society of Genetic Counselors (NSGC)

To locate a genetic counselor near you, please visit: http://www.nsgc.org

PALB2

∨ Contact Us

A STUDY TO BETTER UNDERSTAND BREAST CANCER TREATMENT AMONG WOMEN WITH A PALB2 GENE MUTATION







→ Participants

Providers

∨ Gene Specific Efforts

Newsletters

∨ Our Researc

∨ Contact Us

Participant Contact Form

Provider Contact Form

Materials Request Form

English

Español (Spanish)













Contact Us

OUR MISSION IS TO END THE CYCLE OF INHERITED CANCER THROUGH RESEARCH, EDUCATION, AND OUTREACH

Explore ICARE

What is Hereditary Cancer?

Why Participate in ICARE?

Enroll in ICARE Now!

Contact ICARE

Participant Contact Form

Provider Contact Form

FOR INFORMATION ABOUT ICARE PLEASE CONTACT OUR STUDY TEAM:

Phone: 813-745-6446

Toll free: 1-800-456-3434 x6446

Email: ICARE@inheritedcancer.net

Fax: 813-449-8403

Mail: 12902 Magnolia Drive MRC-CANCONT-PAL Tampa, FL 33612

TO MAKE AN APPOINTMENT FOR GENETIC COUNSELING, PLEASE CALL:

Phone: 813-745-6769

Toll free: 1-800-456-3434 x6769

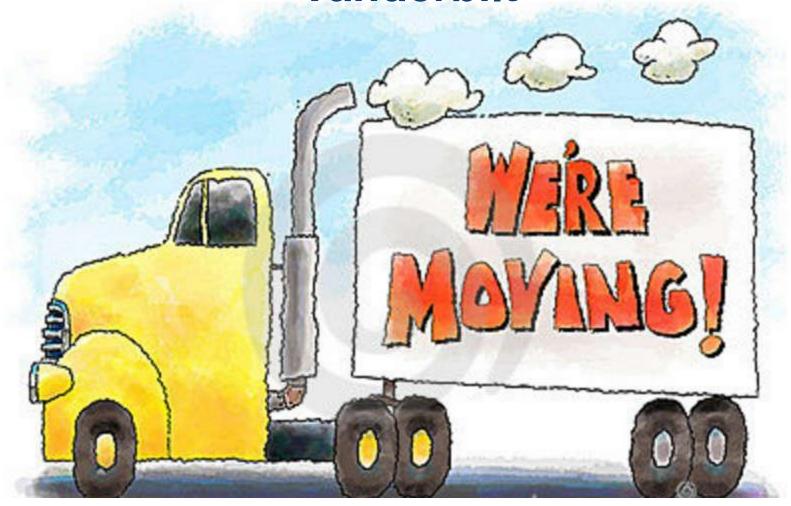


An NCI Designated Comprehensive Cancer Center

If you are interested in participating in ICARE, please fill out a participant contact form.

If you are a provider interested in recruiting for ICARE, please fill out a provider contact form.

ICARE Case Conference will be moving to Vanderbilt



Please direct all e-mails to ICARE@inheritedcancer.net during the transition period

ICARE Benefits

 Generates information to guide the identification and management of individuals at-risk for developing inherited cancers

Provider

- Regular updates through newsletters
- Education/Outre ach, including monthly virtual case conferences

Patient

- Ongoing contact about other research opportunities
- Receive up-todate info through periodic newsletters

Center

 Referring patients counts towards COC goals

CLINICAL

PARTNERSHIP

To request a starter kit:

Email: ICARE@inheritedcancer.net

Phone: (813) 745-6446

Website: www.inheritedcancer.net

Questions?