



BRINGING THE  
**FUTURE**  
INTO  
**FOCUS**



FOCUSED  
ULTRASOUND  
FOUNDATION

**ANNUAL REPORT 2014**



# WE SEE A FUTURE WHERE...

brain tumors are treated without cutting into the skull

cancer is destroyed without harmful radiation

depression, untreatable by medication, is relieved with a simple procedure

## A NEW SOLUTION

Focused ultrasound is a breakthrough non-invasive treatment. Much like a magnifying glass focusing multiple beams of light on a single point, focused ultrasound concentrates intersecting beams of ultrasound energy deep in the body, with extreme precision, on a target as small as a grain of rice. As individual beams pass through healthy tissue, there is no effect. But at the focal point, the ultrasound energy results in biological effects that create the possibility to treat a variety of medical disorders.

Focused ultrasound procedures are performed in conjunction with real-time imaging to precisely target and track the treatment. Treatments usually take place in an outpatient setting without general anesthesia or incisions, resulting in minimal pain and discomfort and a more rapid recovery.

## THE FOUNDATION SETS ITS SIGHTS ON MAKING A DIFFERENCE

The Focused Ultrasound Foundation was created to improve the lives of millions of people worldwide by accelerating the development and adoption of focused ultrasound therapies. As a unique, philanthropic organization, the Foundation works to clear the path to ensure that focused ultrasound finds its place as a mainstream therapy for a range of serious medical conditions within years, rather than decades. Since its establishment in 2006, the Foundation has become the largest non-governmental source of funding for focused ultrasound research.

We're working to bring this vision of the future into focus in the fastest time possible.

## WILL YOU JOIN US?



## 2014 PROGRESS BY THE NUMBERS

1st malignant brain tumors treated

14 research projects funded

More than 400 attendees from 24 countries at the 2014 Symposium

23 ARTICLES PUBLISHED in the *Journal of Therapeutic Ultrasound*

76 PATIENTS enrolled in essential tremor pivotal trial

1st pediatric treatment in North America

55 conditions being researched

## MESSAGE FROM THE CHAIRMAN

Dear Friends,

In 2014, the field's momentum was tangible. Research breakthroughs allowed us to visualize focused ultrasound improving countless lives of patients with life-threatening or disabling conditions. Strides were made in tackling challenging neurological conditions like brain tumors and Parkinson's disease, creating the possibility for a new non-invasive treatment alternative. Promising results for obsessive-compulsive disorder have fostered hope for many psychiatric indications. The technology earned a place in the pediatric arena, treating a teenager's painful bone tumor, enabling him to enjoy sports and activities again.

While research is opening up new possibilities, focused ultrasound is far from being a standard of care. More research must be done, more resources must be applied, and more barriers must be overcome.

The Foundation's efforts toward the cause have made real progress, and it is due to our generous donors who have helped us advance this innovative technology. With your help, we are able to keep our eye trained on the target – a future where focused ultrasound is available to help your friends, your family, and yourself.

Be well,

  
Neal F. Kassell, MD



## SETTING OUR SIGHTS ON SUCCESS

The Foundation has focused its resources and efforts on select strategic initiatives designed to maximize our impact and energize innovation around this revolutionary technology.



## FIVE STRATEGIC INITIATIVES

**CREATE KNOWLEDGE**  
Accelerating research, setting priorities, and influencing the field

**OVERCOME BARRIERS**  
Closing the gap to patient use

**CONVENE THE COMMUNITY**  
Catalyzing the field through collaboration

**CULTIVATE THE NEXT GENERATION**  
Fostering promising researchers and students

**INCREASE AWARENESS**  
Spreading knowledge within the community and around the world

STATE OF THE FIELD

# GLOBAL RESEARCH

## Tackling gateway diseases

Focused ultrasound is an early-stage technology, with groundwork being laid across the field by dedicated researchers at more than 160 centers around the world, progressing from technical research to clinical trials on the path toward widespread access. In 2014, global research made strides, helping to establish focused ultrasound’s potential to treat many more diseases, including cancers and psychiatric disorders.

### BREAST TUMORS

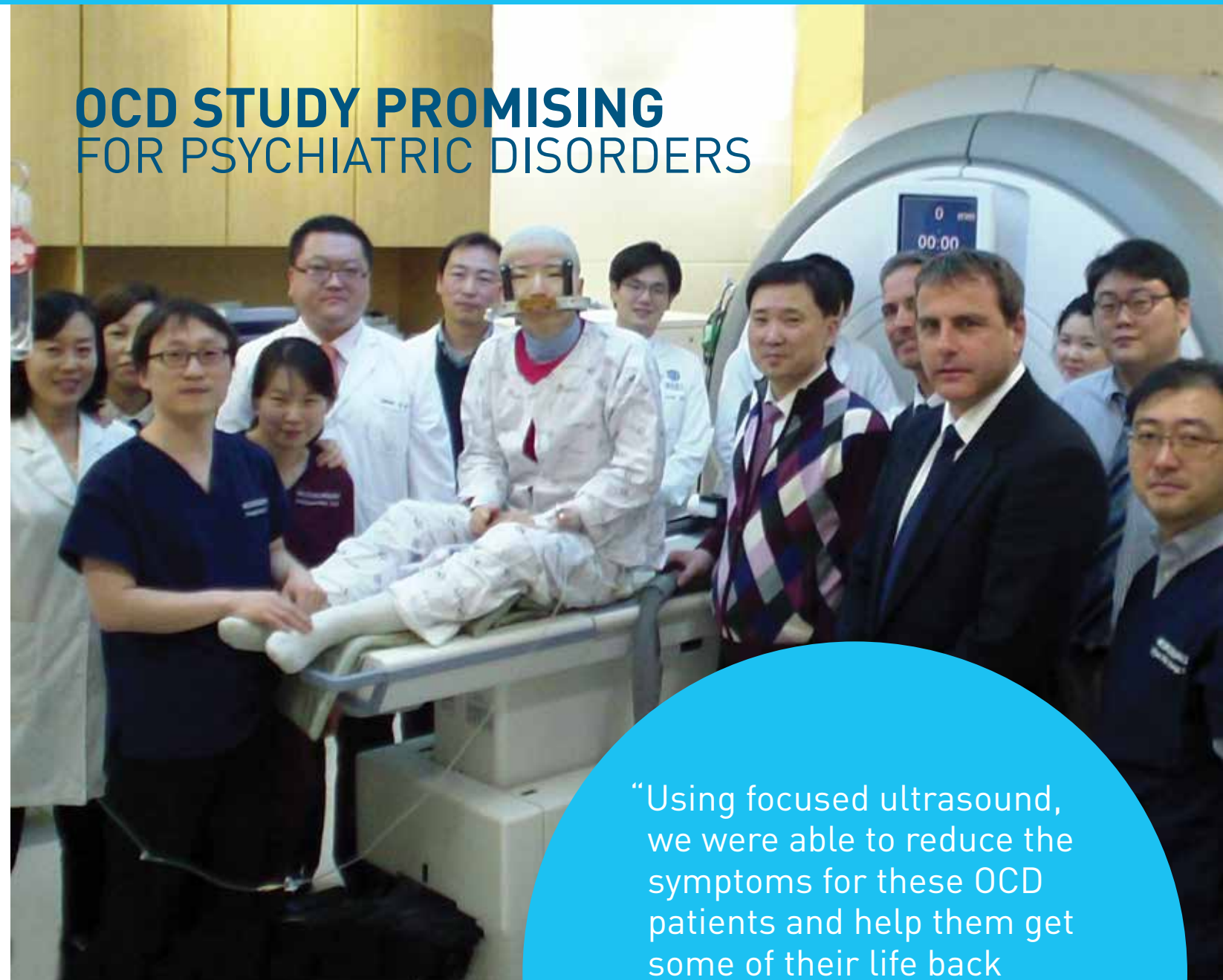
A study at the University of Virginia is paving the way for non-invasive breast treatment. In an early-stage trial, researchers are assessing focused ultrasound to destroy common benign breast lumps. If it is successful, then a larger multicenter trial will be conducted. This research is an important stepping stone to the ultimate goal of treating breast cancer tumors.

### SOFT TISSUE TUMORS

Researchers at Stanford are reporting promising initial results in a study with five patients exploring the use of focused ultrasound to destroy soft tissue tumors in the extremities. In April, they reported that focused ultrasound resulted in an average of 63% of the patients’ tumors eliminated after one or two treatments. This research is leading to plans for a larger study and may open the door to treating other types of tumors.

### PSYCHIATRIC DISORDERS

Early results in a 12-patient Korean study support the potential of focused ultrasound to treat disabling obsessive-compulsive disorder (OCD). The first four patients had the targeted areas of the brain treated without complications or side effects. The procedure resulted in gradual improvement in their OCD, depression, and anxiety. Researchers are planning a depression trial in the coming year, suggesting a potential non-invasive option for treating various psychiatric disorders.



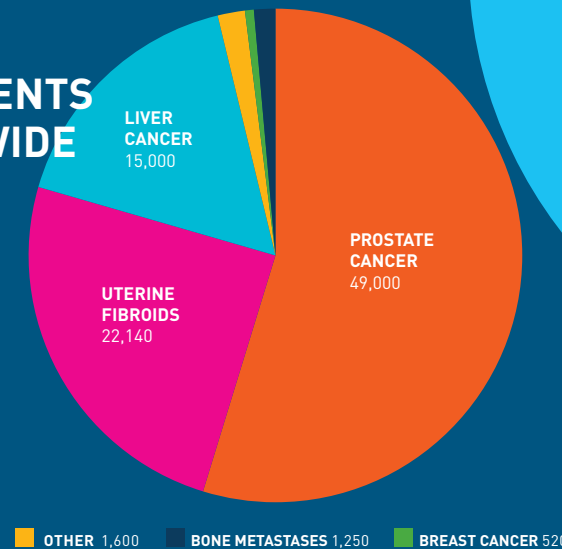
## OCD STUDY PROMISING FOR PSYCHIATRIC DISORDERS

“Using focused ultrasound, we were able to reduce the symptoms for these OCD patients and help them get some of their life back without the risks or complications of the more invasive surgical approaches that are currently available.”  
 –Dr. Jin Woo Chang

**MORE THAN 50 MEDICAL CONDITIONS ARE IN VARIOUS STAGES OF R&D AND COMMERCIALIZATION AROUND THE WORLD.**



### TREATMENTS WORLDWIDE TO DATE





# CREATE KNOWLEDGE

Accelerating research, setting priorities, and influencing the field

The Foundation’s research program enjoyed a year of firsts in 2014. From neurological advances to cancers and pediatrics, our research funds helped fuel significant progress.

## PARKINSON’S DISEASE

The year began with a major milestone: the first treatment in a study assessing focused ultrasound for dyskinesia in Parkinson’s disease. The treatment was performed in Korea as part of a 20-patient pilot study funded by the Foundation and the Michael J. Fox Foundation. This study builds on experience gained during Foundation-funded pilot trials for essential tremor and Parkinsonian tremor.

## ESSENTIAL TREMOR

Following years of research supported by the Foundation, enrollment is now complete in the international pivotal trial treating 76 patients with essential tremor. Patients will be followed for a year to assess the ability of focused ultrasound to reduce debilitating tremor. This study is the last step in generating data to support approval by the FDA.

## BRAIN TUMORS

In March, focused ultrasound was used for the first time through the intact skull to destroy a portion of a recurrent brain cancer. The treatment was performed as part of an ongoing study in Switzerland.

Building on this momentum, focused ultrasound was first used on a metastatic brain tumor in October. In a pilot study, neurosurgeons at Swedish Neurological Institute in Seattle destroyed a portion of a tumor deep within the patient’s brain without complications. This study, supported by the Foundation’s Keller Memorial Fund, is a small but essential step towards non-invasive treatments for a variety of brain tumors.



# FIRST PEDIATRIC PATIENT TREATED IN NORTH AMERICA

“I can do more things now that I couldn’t do before without getting a jolt of pain.”  
–Jack

“For us, it was an overnight success.”  
–Robin, Jack’s mom

## MULTIPLYING IMPACT

In its nine years, the Foundation has invested \$8.9 million in research, including \$2.7 million to fund investigator-initiated research projects through a peer-reviewed process. Of the \$4.7 million granted to 47 projects completed to date, 10 of these have received follow-on funding totaling \$22.5 million, more than four times the return on our donors’ investment.

In 2014, the Foundation granted 12 awards totaling \$1.3 million for research on conditions including pediatric bone disorders, lower back pain, thyroid cancer, osteoarthritis, and multiple sclerosis.



Doctors at The Hospital for Sick Children in Toronto used focused ultrasound to eliminate a teenager’s disabling pain from an osteoid osteoma, a rare and at times debilitating benign bone tumor that occurs most commonly in males ages 10 to 35.

This was the first treatment in a multi-center Foundation-supported study to assess focused ultrasound’s ability to provide suffering children and adolescents with a scalpel-free alternative.

Before treatment, Jack required heavy doses of pain medications and wasn’t able to sleep through the night, much less lead the life of an active teenager. After focused ultrasound, Jack felt relief the same day.



# CONVENE THE COMMUNITY

Catalyzing the field through collaboration

The Foundation brings together leaders in the field by organizing meetings and symposia to report on research, share ideas and forge new partnerships.

## WORKSHOP EXPLORES MODIFYING NEURAL ACTIVITY

A group of 24 researchers from academia, industry, government, and the Foundation spent two days in March discussing focused ultrasound's use in neuromodulation. By stimulating or suppressing brain activity, focused ultrasound could enable a range of therapeutic benefits, including targeting regions of the brain for procedures, suppressing epileptic seizures or psychiatric symptoms, producing reversible nerve blocks to treat pain, and brain mapping.

The workshop proved vital in furthering progress by charting a course toward the first clinical use of FUS-induced neuromodulation.

## CANCER CENTER OF EXCELLENCE OPENS IN LONDON

In September, the Foundation, the Institute of Cancer Research, the Royal Marsden, and Philips Healthcare celebrated the Center's grand opening and the start of a clinical trial for bone metastases. This public/private collaboration is a model for translating the science of focused ultrasound into cancer clinical practice.



ICR The Institute of Cancer Research  
The ROYAL MARSDEN  
NHS Foundation Trust

## YOUNG INVESTIGATORS PRESENT AT SYMPOSIUM

The Foundation awarded 15 young clinicians and scientists the opportunity to present their research and network with leaders in the field at the 2014 symposium. In its third year, the Young Investigator Award Program has become a competitive arena for those beginning their career in focused ultrasound.



# SYMPOSIUM DRAWS RECORD CROWD



“This symposium offers a chance to see how focused ultrasound is being used in other fields of medicine and gives a broad view to the researcher and clinician. This is essential to pushing acceptance of therapeutic ultrasound as an emerging technology.”

-Attendee

The Foundation's 4th International Symposium on Focused Ultrasound, held in October 2014, served as an important forum for sharing data, fostering collaboration, and incubating new ideas among more than 400 clinicians, scientists, industry leaders, and government representatives from around the world. An unprecedented 200+ presentations were given on the utilization of focused ultrasound for brain disorders, cancer, pain management, and other emerging applications. The Symposium is held biennially, and the next one is slated for August 2016.



# INCREASE AWARENESS

Spreading knowledge within the community

As the world's leading source of focused ultrasound information, the Foundation works tirelessly to glean and disseminate news of the field around the world. This year, we debuted a new website and newsletter, while bolstering social media efforts.

## JOURNAL OF THERAPEUTIC ULTRASOUND

In its second year, the Journal of Therapeutic Ultrasound has already been established as a reliable and relevant source of research findings in the field. This open-access, peer-reviewed, online journal was created through a partnership with the Foundation and the International Society of Therapeutic Ultrasound to enable investigators to rapidly publish and disseminate important research. To date, the journal has published 35 translational and clinical research articles.



## FOCUSED ULTRASOUND AND THE FUTURE OF HEALTHCARE

The Foundation serves as a thought leader by publishing bylined articles in agenda-setting media. We illuminate how new technologies like focused ultrasound can provide the superior outcomes, improved population health, and cost savings demanded by today's healthcare systems.



## TONY AND JONNA MENDEZ SPEAK OUT

At the Foundation's 2014 symposium, former CIA spymaster and *ARGO* mastermind Tony Mendez spoke publicly for the first time about his battle with Parkinson's disease. Tony and his wife Jonna addressed his diagnosis and their hope that focused ultrasound might soon be a non-invasive treatment option for others. The discussion was reported by *The Washington Post* and media around the globe. Tony and Jonna joined the Foundation's Council in 2013.



# REACHING THE COMMUNITY BUILDING ENGAGEMENT

**87,050**  
website visits

**15,640**  
YouTube views

**7,890**  
newsletter subscribers

**28%**  
INCREASE  
in Twitter followers



## IN THE NEWS

"From brain to prostate, focused waves of sound can reach places a scalpel can't, putting us on the brink of a surgical shake-up."



"[Focused Ultrasound] redefines the very meaning of surgery."



"FUS is a perfect example of how innovation can disrupt entire industries (for the better) and how data is helping make it happen."



U.S. Chamber of Commerce

"The benefits of focused ultrasound might extend well beyond restoring mobility and delivering drugs."





# OVERCOME BARRIERS

Closing the gap to patient use

In addition to advancing science, it is also important to break down barriers and ensure that focused ultrasound is available to as many patients as possible. The Foundation educates and advocates for patients and engages with regulators about the technology.

## ALIGNING STAKEHOLDERS FOR REIMBURSEMENT

The Foundation hosted a productive summit in May as part of a multi-year initiative to achieve U.S. insurance coverage of focused ultrasound treatment for uterine fibroids and palliation of painful bone metastases. The more than 20 industry attendees and consultants reviewed treatment and reimbursement landscapes and explored evidence gaps to create a detailed action plan. The Foundation is optimistic that these efforts will pave the path for coverage within the next few years.

## ADVOCATING FOR PROSTATE CANCER PATIENTS

Chief Scientific Officer Jessica Foley, PhD, represented the Foundation at two FDA advisory committee meetings to review focused ultrasound devices for treating prostate cancer. Foley stressed the value of patient choice and non-invasive treatment alternatives at panel sessions for EDAP and SonaCare. Both companies have devices approved outside of the U.S. to treat prostate cancer and are awaiting an FDA decision on approving their systems to treat U.S. patients.

## SUPPORTING FIBROID PATIENTS

Fibroid Relief – the Foundation’s program for women with uterine fibroids – continues to serve as a popular resource for women seeking information about fibroids, including treatment options such as focused ultrasound. The organization helps women every day to find answers about treatments and seek support from others via Facebook and the website, which had a record 85,000 visits in 2014.



“Choosing Focused Ultrasound was one of the best decisions I have ever made! I returned to my normal activities as soon as I arrived home. My energy levels have raised, and my anemia is gone. It gave me my life back.”  
–Marie, Fibroid patient



# CULTIVATE THE NEXT GENERATION

Fostering promising researchers and students

The Foundation is dedicated to inspiring and supporting the focused ultrasound pioneers of the future. We have several programs to provide promising researchers with opportunities to collaborate with established experts and help accelerate progress.

## NEW MERKIN FELLOW

Dong-guk Paeng, PhD, from Jeju National University in Korea will work with the Foundation’s technical brain program in 2015 to help lead efforts to develop safe and effective ways to expand the regions of the brain that can be accessed and treated with the technology.

The fellowship, a gift from Dr. Richard Merkin, is designed to stimulate innovation by embedding a scientist into the Foundation’s team. A renowned physician, entrepreneur, and philanthropist, Merkin is the CEO of Heritage Provider Network and co-founder of FasterCures.



## GLOBAL INTERNSHIP PROGRAM DEBUTS

The Foundation launched a program for 12 interns to work with leading researchers at focused ultrasound laboratories around the globe. Jemma Brown, intern at the Institute of Cancer Research in London, was awarded travel support to the Foundation’s symposium to share her work on imaging bone and soft tissue.



## RECORD FOR SUMMER INTERNS

Twelve students collaborated with Foundation staff on technical, clinical, and business projects as part of the Foundation’s Summer Internship Program. We appreciate the Claude Moore Charitable Foundation funding a portion of the 2014 program.





# MOBILIZING RESOURCES

To maximize progress

The Foundation is supported through a balance of visionary individuals and public and private organizations that recognize the importance of our work. These funds have been strategically leveraged to conduct research at institutions around the world and enable the Foundation to advance the field by fostering collaboration, overcoming barriers, and cultivating the next generation.

TOTAL FUNDS RAISED SINCE 2006

**\$58.6**  
MILLION

NEW COMMITMENTS IN 2014

**\$4**  
MILLION

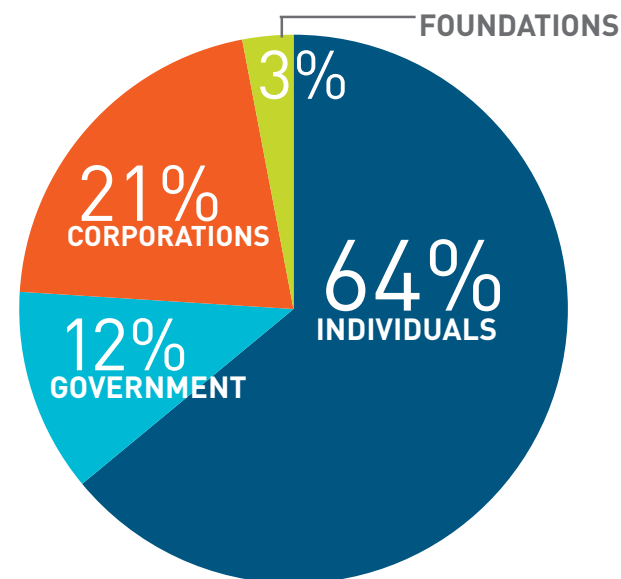
INCREMENTAL FUNDING NEEDS FOR 2015-2017

**\$20**  
MILLION

All of these figures include monies the Foundation has helped secure that go directly to research institutions to advance the field.

## 2006-2014 FUNDING SOURCES

Individuals	\$ 37,659,000
Corporations	\$ 12,409,000
Government	\$ 7,019,000
Foundations	\$ 1,569,000
<b>TOTAL</b>	<b>\$ 58,656,000</b>

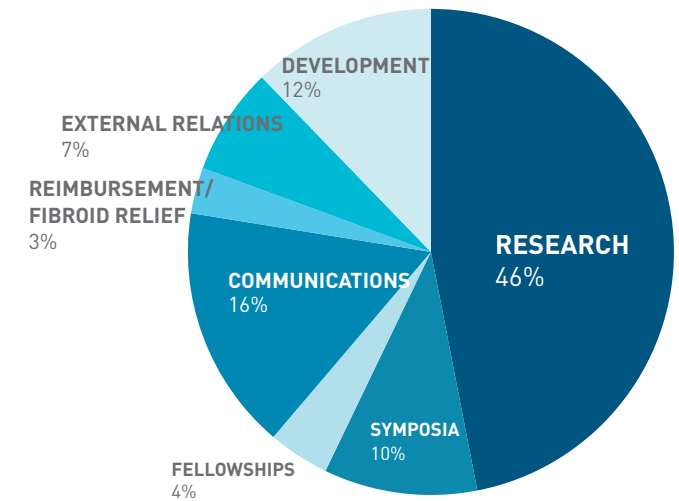


## 2014 USE OF FUNDS\*

Research	\$2,310,000
Communications	\$ 796,000
Development	\$ 622,000
Symposia	\$ 520,000
External Relations	\$ 374,000
Fellowships	\$ 220,000
Reimbursement/Fibroid Relief	\$ 163,000

**TOTAL \$ 5,006,000**

Numbers include fully allocated administrative expenses. Figures are unaudited.

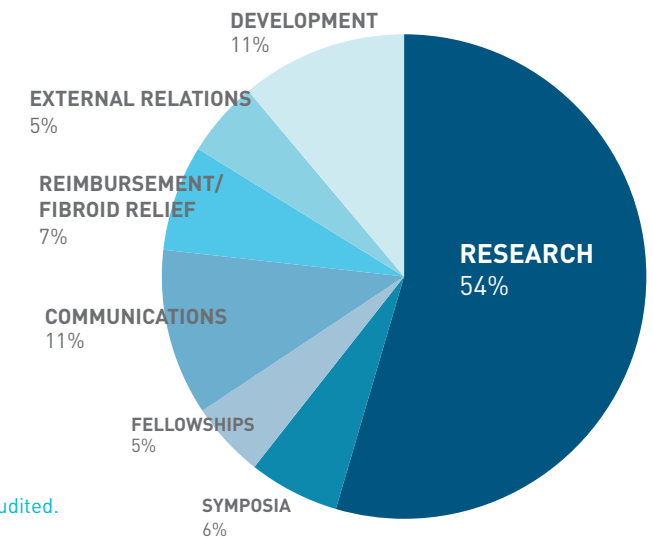


## 2006-2014 USE OF FUNDS\*

Research	\$17,537,000
Communications	\$ 3,601,000
Development	\$ 3,547,000
Reimbursement/Fibroid Relief	\$ 2,291,000
Symposia	\$ 2,071,000
External Relations	\$ 1,762,000
Fellowships	\$ 1,709,000

**TOTAL \$ 32,518,000**

Numbers include fully allocated administrative expenses. Figures for 2014 are unaudited.

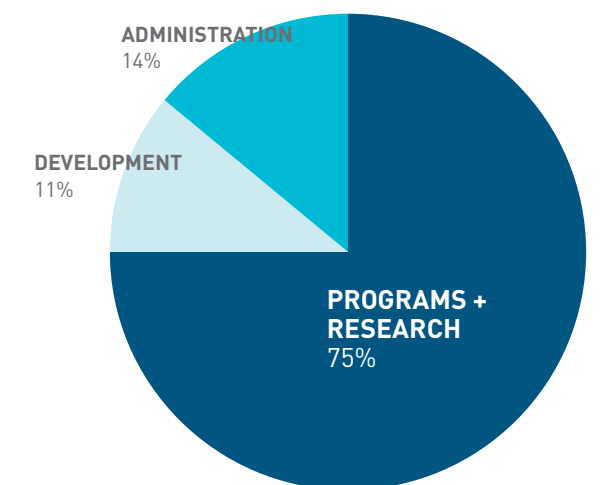


## 2006-2014 SUMMARY OF EXPENSES\*

Programs + Research	\$ 24,547,000
Administration	\$ 4,424,000
Development	\$ 3,547,000

\*All figures are reported on a cash basis.

Audited financials and IRS Form 990 are available upon request.



# TURNING VISION

## Into reality

We appreciate the generosity of our donors, who have committed more than \$58 million since the Foundation was established. Thank you for the tremendous breakthroughs you have helped to make possible. Your continued support plays an outsized role in spurring innovation and building upon this progress. Below is a list of those donors who contributed funds in 2014.

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In Memory of Caroline Murphy Keller Winter:  
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John and Betsy Lane

“The promise of focused ultrasound is immense, but so are the challenges in realizing it. The Foundation has enjoyed remarkable success in bringing together donors, scientists, and clinicians, in both academia and industry, in a collaborative effort to meet those challenges.”

–Carita and Ned Kelly



### In Honor of

Mr. and Mrs. Norman R. Frisbie:  
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Diane Heller:  
Mr. and Mrs. Donald Mazzoni  
Dr. Daniel P. Jordan:  
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Our Council members act as goodwill ambassadors, connecting us to the greater community, increasing awareness and assisting in development.

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“The Foundation’s creative use of ultrasound technology in managing Parkinson’s initially attracted us; the potential for future advancements will continue to command our attention and interest. We are proud to be associated with such an effort.”

–Tony Mendez, Council Member



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“My beloved husband was diagnosed with recurrent glioblastoma in early 2014 and ultimately became the first person in the world to undergo FUS treatment of a brain tumor through the intact skull. He attributed the months that he survived after the recurrence to the treatment. We are pleased to carry on his wish to continue progress and give hope by supporting the Foundation and its very important work.”

–Cheryl, wife of clinical trial participant

If you would like additional information or want to discuss how you can support our mission, please contact:

Mike Cashman, [mcashman@fusfoundation.org](mailto:mcashman@fusfoundation.org)  
Nora Seilheimer, [nseilheimer@fusfoundation.org](mailto:nseilheimer@fusfoundation.org)  
434.220-4993

[www.fusfoundation.org](http://www.fusfoundation.org)



“The work the Foundation is doing will dramatically alter the future of medicine as we know it. Having already lost loved ones to cancer and other diseases, I am passionate and hopeful about what the future holds due to the efforts of the Foundation.”

–Tom Johnson, Foundation supporter



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