# **Retina InSight**



#### Volume 1 Issue 1

## Welcome to our GHRRF Newsletter!

We are passionate about fighting blindness through cutting edge research. The purpose of this newsletter is to share information about our exciting work with you. The Greater Houston Retina Research Foundation (GHRRF), in collaboration with Retina Consultants of Houston (RCH), is one of the top research sites in the world committed to studying vitreoretinal disorders. We have led highly successful clinical research for the past two decades through Investigator Sponsored Trials, National Institute of Health (NIH) trials, & investigational pharmaceutical trials.

Our research focuses on blinding diseases including agerelated macular degeneration (AMD), retinal vein occlusions, diabetic retinopathy, uveitis, vitreomacular adhesions, macular holes, ocular tumors, radiation retinopathy and retinal detachments.

This first edition of *Retina InSight* will introduce our physicians, and update you on the groundbreaking scientific papers, presentations, and grants that RCH physicians are centrally involved with. Future editions will cover our ongoing cutting edge work in preventing blindness and death from diseases affecting the retina. Please visit our website at www.houstonretina.com for more details and daily updates. We hope to inspire you to join us in the fight against blindness.



Retina Consultants of Houston's newest office near Pasadena on Space Center Boulevard is now open!

#### Fall 2014



Mrs. Ray was in a 3-year clinical trial for Diabetic Macular Edema (DME) that helped improve her vision.

"The research program is amazing! It changed my whole outlook on life. I did not think I would ever be able to see clearly again. I'm so grateful to the study and for the results. Thank you so much." –Kimberly Ray June 13, 2014

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#### New RCH Office Opens in Southeast Houston

Retina Consultants of Houston opened a new office between Clear Lake and Pasadena in June 2014, providing southeast Houston convenient access to the latest technology, advanced treatments and cutting edge research for all retina diseases. Our state-of-the-art medical space features 10 diagnostic and treatment rooms, a spacious reception area, and free parking.

Call 713-524-3434 or visit us online to make an appointment. This clinic is located at 11460 Space Center Boulevard, Suite #200; Houston, Texas 77059.

#### RCH & GHRRF Doctors: All Fellowship-Trained at Leading US Centers and Board Certified by the American Board of Ophthalmology



Dr. Amy Schefler is an ocular oncologist for pediatric and adult intraocular tumors



Left to right: Dr. Charles Wykoff and Dr. David Brown are Co-Directors of GHRRF; Dr. Tien Wong is a specialist in complex retinal surgical procedures; Dr. Richard Fish is a leading Houston retina specialist and the senior-most member of RCH since 1992; and Dr. James Major Jr. trained at the #1 ranked eye Hospital, Bascom Palmer Eye Institute



Dr. Ronan O'Malley is a leading pediatric retina surgeon and retinopathy of prematurity specialist



Dr. Matthew Benz is a lead investigator for ongoing studies of ocriplasmin (Jetrea) for retinal diseases



Dr. Eric Chen completed his retina fellowship at the world-renowned Wills Eye Institute; Dr. Rosa Kim is a uveitis specialist for ocular inflammatory diseases

## **Diabetic Retinopathy: RCH is Advancing the Fight Against Blindness**

Diabetes is the leading cause of blindness in working age Americans by damaging small blood vessels in the body. The main cause of vision loss from diabetes is diabetic macular edema (DME), or swelling of the retina. Since the 1970's, laser therapy has been known to reduce the chance of vision loss from DME, but rarely improves vision.

In 2008, clinical trials using injections of Lucentis, a medication that blocks vascular endothelial growth factor (VEGF) which causes DME, began at the Retina Consultants of Houston (RCH). RCH was the leading site worldwide in the phase III trials that lead to FDA approval of Lucentis for DME in 2012. The approval of Lucentis represented the first advancement in DME treatment



Dr. Brown presents at the American Diabetes Association's 74th Scientific Sessions, June 2014.

leading to significant visual gains since the 1970's. Dr. David Brown was on the steering committee directing these trials and was the lead author of the primary manuscripts. In 2009, Dr. Brown helped design a DME clinical trial program in the U.S. and internationally for Eylea (a medication that also blocks VEGF). RCH was the leading site for the phase II & III DME Eylea trials and Dr. Brown was the lead US author of the publications reporting successful visual results with this medication. Based on these studies, Eylea was FDA approved for the treatment of DME in July, 2014. The publications related to these clinical trials are listed on page 6.

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#### How to Get Involved as a Patient in Clinical Research at RCH

The GHRRF is proud to be one of the world's leading sites for the design, initiation, and enrollment of new clinical trials for retinal diseases, giving our patients exceptional access to cutting edge investigational clinical treatments that are not otherwise available to the general public.

For a patient, the advantages of participating in a clinic trial include access to investigational treatments, close routine monitoring by RCH physicians, direct access to study coordinators who guide patients step-by-step through the entire study, and the opportunity to help advance science. Many of our clinical trials last as long as three years. All of the medical care provided through our clinical trials occurs at the same RCH locations as our routine care with the same high-quality staff, cutting edge investigational technology, and attention to detail that is the hallmark of our practice.

Participation in clinical trials is entirely voluntary and patients are free to withdraw at any time. Upon completion of a study or withdrawal, patients always continue to receive our exceptional standard of clinical care.

Visit us online at www.houstonretina.com to learn more about our clinical trials program

## **RCH Team Takes a Step with Community Towards Fighting Blindness**

Foundation Fighting Blindness (FFB), a nonprofit organization dedicated to raising awareness and supporting research for blinding eye diseases has raised over \$550 million since 1971. FFB's primary fundraising events are 5K VisionWalks held annually in over 60 cities across North America. In 2013 RCH doctors, staff, family and friends rallied and formed the Retina Rangers. Our own Dr. Wykoff delivered the race-opening speech stressing the importance of sight-saving research and expressed his appreciation to participants and donors. Retina Rangers team leader, Chris Hunkler, was proud to accept the Top Rookie Fundraising Team Award after raising over \$7,700.

This year, please consider supporting the Retina Ranger team at VisionWalk 2014! Whether you would like to donate, participate in the 5K or both; we would love YOU to be a part of our team!



**Retina Rangers Team 2013** 

Mark your calendars! Houston VisionWalk 2014 When: Saturday, October 4th Where: Discovery Green, Houston To donate towards this year's VisionWalk visit our website and link to our team page **www.houstonretina.com** 



Dr. Richard Fish on the drums at Hard Rock Cafe in Atlanta, GA

#### **Drumming to Raise Awareness & Funds for a Good Cause**

In 2003, Dr. Richard Fish co-founded the rock & roll band "Double Vision," with 7 members including 3 ophthalmologists. Over the last decade, Double Vision has raised over \$50,000 for Benevolent Missions International (BMI), a Houston-based charity providing medical and surgical eye care to developing countries. Double Vision has played at fantastic venues including the Ellington Field Air Force Base, the Atlanta Hard Rock Cafe and Pat O'Brien's in New Orleans. Their repertoire includes jazz, country, disco, and popular music from the 60's through today. Keep an ear out for them or seek them out for your next event!

# **Enrolling Clinical Trials**

The GHRRF is constantly designing and enrolling new clinical trials for patients affected by blinding retinal diseases. Patients are thus able to have access to cutting-edge investigational treatments that are not otherwise available to the general public. Here is a partial list of our currently enrolling clinical trials along with their identifying clinicaltrials.gov number:

### Wet Age-Related Macular Degeneration Trials

- NCT01908816 Trial of novel medication in addition to ranibizumab
- NCT01674569 Trial of medication blocking PDGF in addition to VEGF blockade

## Dry Age-Related Macular Degeneration Trials

• NCT01342926 - Trial of novel intravitreal pharmaceutical to slow progression of geographic atrophy

#### **Diabetic Macular Edema Trials**

- NCT02050828 Subcutaneous medication alone or in combination with ranibizumab
- NCT01552408 Widefield angiography guided targeted-retinal photocoagulation combined with ranibizumab
- NCT01934556 Treat & extend management using ranibizumab with and without focal laser
- NCT01994291 Oral pill medication compared to intravitreal injections of ranibizumab
- NCT01909791 Treatment of eyes with very good visual acuity
- NCT01945866 Combination corticosteroid & ranibizumab for persistent DME in pseudophakic eyes
- NCT02186119 Comparison of a novel intravitreal anti-VEGF agent to ranibizumab

#### **Retinal Vein Occlusion Trial**

NCT01710839 - Widefield angiography guided targeted-retinal photocoagulation combined with ranibizumab

#### Vitreomacular Traction Trials

• NCT02079883 - Safety analysis of Jetrea (ocriplasmin) for symptomatic vitreomacular traction

#### Non-infectious Posterior/Intermediate/Pan-Uveitis Trials

- NCT01684345- Subcutaneous injections of a new monoclonal antibody for active uveitis
- NCT01747538- Subcutaneous injections of a new monoclonal antibody for controlled uveitis
- NCT01358266- Intravitreal injections of an immunosuppressive for active non-infectious uveitis
- NCT01694186- Corticosteroid eluding device for chronic uveitis affecting posterior segment

#### Eye Tumor Trials

- NCT01925599 Identification of germline BAP1 mutation in young patients with nevi
- NCT02222610 Trial of ranibizumab for the treatment of radiation retinopathy
- NCT01579760 Trial of aflibercept for the treatment of radiation retinopathy

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#### www.houstonretina.com

## **Grants Awarded To RCH Physicians for Research**

GHRRF leads the fight against blindness by designing and performing innovative clinical trials aimed at improving treatments for retinal diseases. These trials give our patients access to cuttingedge treatments not otherwise available to patients. Each of these grants written by RCH physicians was awarded competitive funding to support all associated patient care.

#### Grants Awarded to Charles C. Wykoff MD PhD of RCH and the GHRRF

- **TREX AMD Trial:** Treat and Extend Treatment with Ranibizumab vs Monthly Ranibizumab in Neovascular AMD. *Grant to fund management of 60 patients*
- WAVE Trial: Widefield Angiography Guided Targeted-Retinal Photocoagulation Combined with Ranibizumab for Ischemic RVO. *Grant to fund management of 30 patients*

#### Grants Awarded to David M. Brown MD of RCH and the GHRRF

- **TURF Trial:** Aflibercept for Neovascular AMD Patients Incompletely Responsive to Multiple Intravitreal Injections of Ranibizumab. *Grant to fund management of 60 patients*
- DAVE Trial: Widefield Angiography Guided Targeted-Retinal Photocoagulation Combined with Ranibizumab for DME. Grant to fund management of 40 patients

#### Grant Awarded to Amy C. Schefler MD of RCH and the GHRRF

• **RRR Trial:** Ranibizumab for Radiation Retinopathy. *Grant to fund management of 40 patients* 

## Awards and Recognition for RCH Physicians

James C. Major Jr. MD PhD	Elected into Retina Society 2014 Course Co-Director, Third Coast Retina
Charles C. Wykoff MD PhD	Elected into Macula Society 2014 Academic Program Chair, Vit-Buckle Soc.
Amy C. Schefler MD	Elected into Macula Society 2014 Director of Retina Section, UT National Board Review Course
David M. Brown MD	Elected into Retina Society 2006 Elected into Macula Society 2008 ASRS Board Practice Management Chair, Nominated 2014 Senior Achievement Award, AAO 2014
Eric Chen MD	Elected into Retina Society 2012
Richard H. Fish MD	American Society of Retina Specialists
Matthew S. Benz MD	Elected into Retina Society 2010
Rosa Y. Kim MD	Elected into Retina Society 2005



Dr. Amy Schefler and Dr. Charles Wykoff elected into Macula Society, 2014

G	reater Houston Retina Research Foundation				
Recent Publications by RCH Physicians					
RETINA	Brown DM, Wykoff CC, Wong TP, Mariani AF, Croft DE, Schuetzle K; RAVE Study Group. Ranibizumab in pre- proliferative (ischemic) CRVO: The RAVE trial (Rubeosis Anti-VEgF). 2014.				
	Major JC, Wykoff CC, Mariani AF, Chen E, Croft DE, & Brown DM. Comparison of spectral-domain and time- domain OCT in the detection of neovascular AMD activity. 2014.				
	Brown DM, Tuomi L, Shapiro H; For The Pier Study Group. Anatomical measures as predictors of visual outcomes in ranibizumab-treated eyes with neovascular AMD. 2013				
Ophthalmology	Wykoff CC, Brown DM, Croft DE, Wong TP. Two year SAVE (Super-dose anti-VEGF) outcomes: 2.0 mg ranibizumab for recalcitrant neovascular AMD. 2013.				
	Brown DM, Chen E, Mariani AF, Major JC; SAVE Study Group. The SAVE trial (Super-dose anti-VEGF): 2.0 mg ranibizumab for recalcitrant neovascular AMD: 3-month results. 2013.				
	Brown DM, et.al. Long-term Outcomes of Ranibizumab for DME: 36-month results from the phase III RISE & RIDE trials. 2013.				
	Brown DM, Nguyen QD, Ehrlich JS; RISE and RIDE Research Group. Ranibizumab for DME. 2013.				
New England Journal of Medicine	Stalmans P, Benz MS, et.al.; MIVI-TRUST Study Group. Enzymatic vitreolysis with ocriplasmin for VMT and macular holes. 2012.				
Journal of the American Medical Association	Wykoff CC, et al. What is the optimal timing for rhegmatogenous retinal detachment repair? 2013.				
Ophthalmology	Schefler AC, et al. Extraocular extension of uveal melanoma after fine needle aspiration, vitrectomy, & open biopsy. 2013.				
	Schefler AC, Wong TP, Bretana ME, Chevez-Barrios P. Histopathologic analysis of new technique for fine needle aspiration biopsy sites in uveal melanoma. 2014.				
British Journal of Ophthalmology	Wykoff CC, Brown DM, Maldonado ME, Croft DE. Aflibercept treatment for patients with exudative AMD who were incomplete responders to multiple ranibizumab injections (TURF trial). 2014.				
Ophthalmic Surgeries Lasers & Imaging	Wykoff CC, Brown DM, Chen E, Major JC, Croft DE, Mariani A, Wong TP. The SAVE trial (Super-dose anti-VEGF): 2.0mg ranibizumab for recalcitrant neovascular AMD:1-year results. 2013.				
	Major JC. Current concepts in managing wet AMD suboptimally responsive to anti-VEGF therapy. 2013				
American Journal of Ophthalmology	Brown DM, et al. Aflibercept for CRVO: 1-year results from the phase 3 COPERNICUS trial. 2013.				

## **RCH Preceptorship Program for Medical Students**

The Retina Consultants of Houston's **Pre-medical Clinical Preceptorship** is targeted for motivated individuals who want to expand their involvement with clinical research. This is a 1 or 2 year position that we fill from a highly-competitive application pool. In 2014 we had two outstanding graduates who finished our program and are entering medical school. Here is what they had to say about their experience at RCH:

"I thoroughly enjoyed my time in RCH's clinical research preceptorship where I had the privilege of working beside Dr. Brown and Dr. Wykoff. Interacting directly with patients and learning directly from some of the most passionate and experienced doctors in their field has taught me more than I imagined. I am most grateful for the time these doctors invested in preparing me as a young medical professional. I am better prepared for medical school at The University of Texas Medical Branch at Galveston because of this opportunity."



-Andrew Z. Coskey (started at UTMB in June 2014)



"After graduation from Rice, I joined the RCH team to gain clinical and research experience before medical school. I began my time at RCH in clinic learning about retinal anatomy, pathology, and treatments. I worked-up patients, scribed for the MDs, imaged the retina with several platforms, interpreted the images, and observed in surgery. I then transitioned my time towards RCH's investigator initiated clinical trials. In research, I collected and analyzed data, wrote protocols, manuscripts and case reports, and traveled to conferences to present our results. I loved feeling and being treated like a professional at RCH - I was no longer viewed as "an undergraduate volunteer". Instead, I was seen as bringing an important skill-set to the table and played a pivotal role in many of the ongoing studies. As a result of my efforts, I have coauthored several papers in leading journals, with more in progress. It has

studies. As a result of my efforts, I have coauthored several papers in leading journals, with more in progress. It has been a truly transformative experience working with the doctors at RCH, preparing me for the future challenges of medical school at Baylor College of Medicine."

- Daniel E. Croft (started at BCM in July 2014)

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## Selected National & International Presentations Delivered by RCH Physicians

- Benz MS. Rationale for the Management of Diabetic Macular Edema and New Therapeutic Options. 32nd Congress of the Mexican Society of Ophthalmology. Cancun, Mexico. June 2014.
- Benz MS. The Role of Ocriplasmin in the Management of Vitreomacular Adhesion Syndrome. 32nd Congress of the Mexican Society of Ophthalmology. Cancun, Mexico. 2014.
- Brown DM. Vision and Diabetic Retinopathy Severity Score Following Intravitreal Aflibercept Injection in DME Patients with Hemoglobin A1c Levels ≤ 8% and >8% at Baseline. ADA 74th Scientific Sessions. San Francisco, CA. 2014.
- Brown DM. The HOME Study: Lesion Characteristics of Early CNV. The Macula Society. Key Largo, FL. 2014
- Brown DM. Oral Anti-VEGF Therapy for Wet AMD. Angiogenesis, Exudation, & Degeneration Meeting. Miami, FL. 2014
- Brown DM. Intravitreal Aflibercept Injection for DME: Primary and Additional Endpoint Results from the 12-Month Phase 3 VISTA-DME and VIVID-DME Studies. ARVO. Orlando, FL. 2014.
- Fish RH. The Eye, Ocular Diseases in Performing and Visual Artists. The Samuel G. Dunn Lectureship in the Medical Humanities. Galveston, TX. 2014
- Fish RH. The Eye, Ocular Diseases and Visual Artists. Inaugural Lecture in Houston Arts & Medicine Lecture Series; 4th Annual Delta Gamma Foundation, Richard D. Shirk Family Lectureship in Healthcare Values & Ethics. Houston, TX. 2013.
- Major Jr. JC. Persistent Pigment Epithelial Detachment Improvement in Treatment Non-naïve Neovascular AMD Patients after Intravitreal Aflibercept. AAO Annual Meeting. New Orleans, LA. 2013.
- Major Jr. JC. Systematic Review of Safety Across the Phase 2 and 3 Clinical Trials of Intravitreal Aflibercept Injection. American Society of Retina Specialists Annual Meeting. San Diego, CA. 2014.
- Schefler AC. Prospective Histopathologic Analysis of Fine Needle Aspiration Biopsy Sites. Macula Society. Key Largo, FL. 2014.
- Schefler AC. Prospective Histopathologic Analysis of Fine Needle Aspiration Biopsy Sites. International Society of Ocular Oncology. Cleveland, OH. 2013.
- Schefler AC. Extraocular Extension of Uveal Melanoma After Fine Needle Aspiration, Vitrectomy, or Open Biopsy. Association for Research in Vision and Ophthalmology. Seattle, WA. 2013.
- Wong TP. Jetrea Injection vs. Vitrectomy. Atlantic Coast Retina Club Meeting. Philadelphia, PA. 2014.
- Wong TP. Management of Complex Retinal Detachments. Vit-Buckle Society Annual Meeting. Miami, FL. 2013.
- Wong TP. Peeling of the ILM and ERM during Vitreo-Retinal Surgery. Vit-Buckle Society Annual Meeting. Las Vegas, NV. 2014.
- Wykoff CC, Aspirin, AREDS & AMD. 3<sup>rd</sup> Geriatric Ophthalmology. Houston, TX. 2014.
- Wykoff CC, Shapiro H, Tuomi L. Early vs Delayed 20/40 Visual Acuity Achievers with Ranibizumab Treatment in the 24 Month HARBOR Study. The Macula Society. Key Largo, FL. 2014.
- Wykoff CC, Yau L, Sternberg G. Efficacy and Safety of Alternate Ranibizumab Dosing in Retinal Vein Occlusion The SHORE Study. AAO. New Orleans, LA. 2013.



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# Greater Houston Retina Research Foundation

RCH Clinical Care Centers Across Greater Houston					
Texas Medical Center 6560 Fannin, Suite 750 Houston, TX 77030 (713) 524-3434	<b>Memorial</b> 902 Frostwood, Suite 280 Houston, TX 77024 (832) 358-9306	Livingston 400 Bypass Ln., Suite 105 Livingston, TX 77351 (936) 327-8733	Brenham 2620 Hwy 36 South Brenham, TX 77833 (979) 836-2187		
<b>Bellaire</b> 6750 W Loop S, Suite 1060 Bellaire, TX 77401 (713) 521-0555	<b>1960 Area</b> 17030 Nanes Dr., Suite 214 Houston, TX 77090 (281) 587-1987	Northwest/Cypress 21216 NW Fwy, Suite 630 Cypress, TX 77429 (281) 970-9660	<b>Sugar Land</b> 16605 SW Fwy, Suite 305 Sugar Land, TX 77479 (281) 494-5995		
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