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Attachments: Final OHTS Progress Report 01-24-11.docx; Final Invention Statement Michnowicz sign.pdf

Grant Number: 5 U10 EY009341-16
PI Name: GORDON, MAE O
Project Title: Ocular Hypertension Treatment Study: Coordinating Center
Institution: WASHINGTON UNIVERSITY
Appl ID: 7350145

The link to upload close-out documents through eCommons is not available in Dr. Gordon's account. So, please find attached the final Progress Report as well as the Final Invention Statement for the OHTS project. The FSR will arrive under a separate cover.

Thank you.

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Department of Health and Human Services
Final Invention Statement and Certification
(For Grant or Award)

DHHS Grant or Award No.
5 U10 EY9341-16

A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

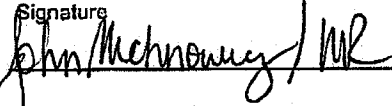
09/30/1992 through 11/30/2010
original effective date *date of termination*

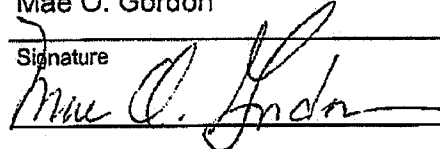
B. Inventions (Note: If no inventions have been made under the grant or award, insert the word "NONE" under Title below.)

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS
	None	

(Use continuation sheet if necessary)

C. Signature — This block *must* be signed by an official authorized to sign on behalf of the institution.

Title Director, Office of Sponsored Research Services		Name and Mailing Address of Institution Washington University 660 South Euclid Avenue Campus Box 8018 St. Louis, MO 63110
Typed Name John Michnowicz		
Signature 	Date 02/04/2011	

Title Professor and Director of the Coordinating Center of the Ocular Hypertension Treatment Study (OHTS)		Name and Mailing Address of Institution Washington University 660 South Euclid Avenue Campus Box 8018 St. Louis, MO 63110
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OHTS Changed Our Understanding of Ocular Hypertension and Primary Open Angle Glaucoma (POAG)

Grant fund #5 U10 EY09341-16 started 9/30/92 and ended 11/30/10

Specific Aim 1: To determine whether medical reduction of IOP prevents or delays the onset of glaucomatous visual field loss and/or optic nerve damage in ocular hypertensive individuals judged to be at moderate risk of developing open-angle glaucoma.

OHTS is the 1st study to definitively demonstrate the safety and efficacy of ocular hypotensive medication in preventing open angle glaucoma (Kass, et. al., 2002).

OHTS is the 1st study to demonstrate safety and efficacy of ocular hypotensive medication in African Americans (Higginbotham, et. al., 2004).

Specific Aim 2: To identify risk factors that predict which ocular hypertensive individuals are most likely to develop glaucomatous visual field loss and/or optic nerve damage.

OHTS is the 1st prospective cohort study to show that central corneal thickness is a risk factor for the development of glaucoma in ocular hypertensive individuals (Gordon, et. al., 2002). The prediction model uses baseline age, IOP, cup-to-disc ratio, central corneal thickness and pattern standard deviation to predict the 5 year risk of developing POAG in an individual with ocular hypertension. OHTS is the 1st study to validate the predictive model in a large (n=1,077 participants) independent sample from the European Glaucoma Prevention Study (Gordon, et. al., 2007).

OHTS is the 1st study to provide a clinical explanation for the higher incidence and prevalence of POAG in individuals of African origin (Gordon, et. al., 2002).

The OHTS prediction model is being utilized world-wide (pg. 2, "OHTS Impact on Clinical Practice")

Specific Aim 3: To determine if there is a long-term penalty or disadvantage for delaying treatment in ocular hypertensive individuals.

OHTS is the 1st study to show that deferred treatment results in a higher proportion of ocular hypertensive individuals developing open-angle glaucoma; however, deferred treatment is immediately effective in lowering the risk of POAG (Kass, et. al., 2010). The incremental risk for delaying treatment is high among individuals at high risk of developing POAG and low in low risk individuals.

Advancing Careers of Early Stage Investigators

Data from OHTS has enabled 6 early stage investigators to be awarded a total of 8 NIH grants. Three grants were R0-1's (Herman D R01 EY02037; Fingert J R01 EY018825-01A1; Zangwill L R01 EY019117) and five were R-21's or R-03's (Budenz D R21 EY019954-02; Gao F R21 EY091369; Kymes

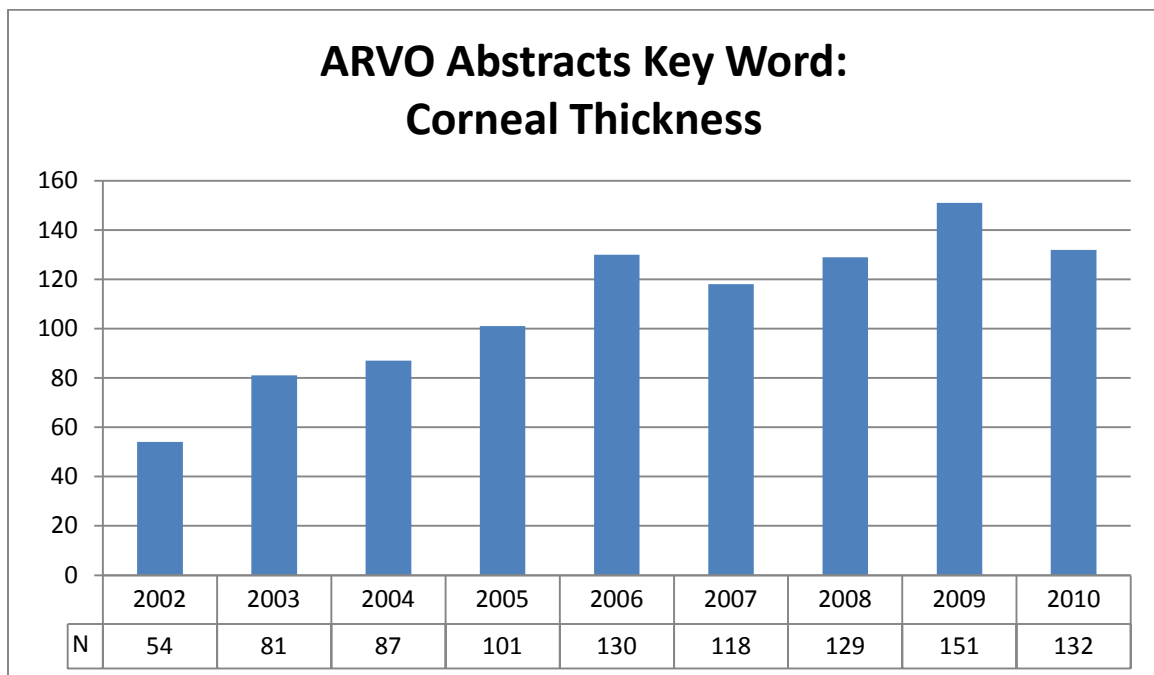
S R03 EY017862-01; Kymes S R21 EY019521-01; Zangwill L 5R21EY019117-02). An R0-1 application from Dr. Todd Scheetz is currently under review.

Intellectual Impact of OHTS

According to **Essential Science Indicators Citations**, 2 OHTS articles published in 2002 (Kass, et. al., 2002 and Gordon, et. al., 2002) rank in the top 10% of all papers published in clinical medicine, not just ophthalmology, as of 2007.

Of the 18 **Most Highly Cited** papers identified for “Glaucoma” for the decade 1997-2007, the two articles above were ranked #2 and #3.

ARVO abstracts with the key word “corneal thickness” more than doubled from 54 in 2002 to more than 100 following the OHTS 2002 publications. The increase is temporal and may or may not be causally related to the OHTS publications.



OHTS' Impact on Policy

The justification of CPT1 Code status for ultrasound pachymetry specifically cites Gordon et. al., 2002 publication, “Procedure’s clinical efficacy is proven and documented,” Medicare assigned a regular CPT category 1 code: 76514 for ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral effective Jan. 1, 2004.

AMA CPT Assistant Coding publication states, “..pachymetry is ...essential tool for glaucoma diagnosis and management ...improves the diagnosis, screening and management of patients with glaucoma and OHT.”

US Preventive Services Task Force Evidence Synthesis #34, 2005 and preferred practice guidelines of the American Academy of Ophthalmology, American Optometric Association, International Council on Ophthalmology, Singapore Ministry of Health, Royal College of Ophthalmologists among many others have now incorporated CCT measurement in the screening of patients with ocular hypertension and glaucoma.

Private insurance coverage of pachymetry: Cigna Health Care, Aetna Clinical Policy Bulletin, among others now cover the cost of pachymetry.

Documentation of T3 Translation: OHTS' Impact on Clinical Practice

Utilization of pachymetry: A 5% random sample of the Medicare database 2003-2006 showed that pachymetry utilization among POAG suspects increased from 11.1% to 24.5%, 22.1% and 16.4% respectively following publication of the OHTS 2002 prediction article. Odds ratios comparing pachymetry utilization to "other glaucoma" were 2.3, 2.8, 3.0 and 4.2, respectively provide evidence that pachymetry was being used diagnostically appropriately (Lin S, Pekmezci M, Kymes S, Stwalley D, Huang J, Kass M, Gordon M, AAO2009, Utilization of the Pachymetry CPT Code with ICD-9 Codes for Open-Angle Glaucoma and Suspect).

Utilization of OHTS Web Site to Calculate Risk for Developing POAG: From 2006 to date, there have been 88,044 page loads world-wide according to STATCOUNTER. In 2010, there were 23,220 page loads - 2,837 were returning visitors. Eight percent of the visitors spent 5-20 minutes on the site, 3% spent 20 minutes to an hour and 18% spent more than an hour per visit. The web site attracted visitors world-wide - 359 visitors from Spain, 215 from India, 160 from Thailand and 125 from the Russian federation. Pfizer Pharmaceuticals distributed hand held risk calculators with the OHTS Prediction Model to ophthalmologists and optometrists world-wide.

Boland et. al. (J Glaucoma. 2008 Dec;17(8):631-8) in a survey of 58 glaucoma specialists, concluded that the "Inclusion of the calculator changed recommendations, increasing the measure of confidence and decreasing the measure of inconsistency."

Mansberger and Cioffi (J Glaucoma. 2006 Oct;15(5):426-31) in a study of 51 ophthalmologists, concluded that the prediction model would help enable clinicians to make evidence-based treatment decisions and reduce variability in patient management. They presented 4 standardized patient scenarios and found that clinicians differed greatly in their estimate of an ocular hypertensive patient's risk of developing POAG and that the clinician's estimate of risk differed from those calculated by the OHTS risk calculator by 13.7% to 53.8%.

**Inclusion of Gender and Minority Randomized Participants in OHTS
(n=1,636)**

	Randomization assignment		All N
	Medication N	Observation N	
Gender			
Male	359	346	705
Female	458	473	931
All	817	819	1636
Race			
AmerInd/Alaskan	1	3	4
Asian/Pacific	4	10	14
Black, Non-Hisp	203	204	407
Hispanic	24	35	59
White, Non-Hisp	577	561	1138
Other	8	6	14
All	817	819	1636

Children were not enrolled because POAG is an eye condition affecting older adults.

OHTS Data Shared in New Research Studies

Available on a public website <http://ohts.wustl.edu/> are the following:

- OHTS Manual of Procedures
- annotated case report forms
- publications in PDF with links for Pub Med
- power point slides to accompany published papers
- interactive web calculator for the risk of developing POAG

Data Set(s) provided under the OHTS data sharing agreement is limited and excludes personal identifiers as required by the HIPAA Privacy Regulations. GWAS analysis of bloods from 1,057 of 1065 samples from OHTS participants are banked at CIDER. Phenotypic data are available from DBGaP effective 2011.

Years	Grant	PI** **Early stage investigator	Institution
1994	R01 EY02037 Endothelial Cell Density Effect of Topical Ocular Hypotensive Agents on the Corneal Endothelium in Eyes with Ocular Hypertension	Bourne, W **Herman, D	Mayo Clinic
06/01/04 05/31/06	R03 EY015498-02 EGPS/OHTS Collaborative Analysis	Gordon, MO	Washington University School of Medicine
08/31/09	R01 EY017299 Computer Analysis of Optic Disc Images in Glaucoma	Stone, R	University of Pennsylvania
07/01/05 06/30/10	U10 EY11158 Quantitative analysis of the optic disc/ocular hypertension	Weinreb, R	UC-San Diego
04/01/07 03/31/10	R03 EY017862-01 Development of a Vision Specific Utilities Elicitation Method	**Kymes, S	Washington University School of Medicine
09/30/08 08/31/11	5R21EY019117-02 OHTS and EGPS: Glaucoma Detection using Confocal Scanning Laser Ophthalmoscopy	Zangwill, L et. al.	UC-San Diego
04/01/09 03/31/10	R01 EY018825-01A1 Genetic Study of the OHTS Cohort to Identify Glaucoma Genes GWAS analysis of bloods from 1,057 of 1065 samples from OHTS participants are banked at CIDER. Phenotypic data are available from DBGaP.	**Fingert, J et. al.	University of Iowa

04/01/09 03/31/11	R21 EY019521-01 Evaluation of the Frequency of Visual Field Testing in Ocular Hypertensives	**Kymes, S	Washington University School of Medicine
07/01/09 06/30/11	R21 EY091369 Follow-up Intraocular Pressure and the Risk of Developing Primary Open-Angle Glaucoma	**Gao, F	Washington University School of Medicine
12/01/09 11/30/11	R21 Supplemental Grant for the Optic Disc Reading Center for the Ocular Hypertension Treatment Study (OHTS)	**Budenz, D	University of Miami
04/01/10 03/31/12	R21 EY019954-02 Peripapillary Atrophy Progression During the Ocular Hypertension Treatment Study	**Budenz, D	University of Miami
01/01/08 open	COA Change in Mean Deviation Project: Value of IOP Model Pfizer	**Kymes, S	Washington University School of Medicine
09/30/09 09/29/11	3 U10 EY009341-16S1 Administrative Supplement: Ocular Hypertension Treatment Study (OHTS): Coordinating Center	Gordon, MO	Washington University School of Medicine
09/13/10 Submitted	R0-1 Genetics of Optic Disc Morphology	**Scheetz, T Fingert, J Abramoff, M	Carver College of Medicine, University of Iowa
OHTS Non-funded Ancillary Studies			
11/98	Central Corneal Thickness Measurement	**Brandt, JD	UC-Davis
3/03	LOCS III Lens Opacification Grading	Chylack Jr, LT	Harvard
06/17/05	Visual Field Analysis March 2006 De-identified VF dataset, endpoint forms through 6/1/02 from the 09/11/03 snapshot	**Artes/Chauhan	Dalhousie University
09/15/09	Visual field database and endpoint database	Cioffi, G Demirel, S Liebmann, J **De Moraes, G	Devers Eye Institute NY Eye and Ear Infirmary

Publications from Ocular Hypertension Treatment Study (OHTS)

Current to 01/07/2011

1. Gordon, MO, Kass MA and the Ocular Hypertension Treatment Study (OHTS) Group: [The Ocular Hypertension Treatment Study: Design and Baseline Description of the Participants](#). Arch Ophthalmol 1999; 117:573-583. [PMID:10326953](#).
2. Keltner JL, Johnson CA, Quigg JM, Cello KE, Kass MA, Gordon MA for the Ocular Hypertension Study Group. [Confirmation of Visual Field Abnormalities in the Ocular Hypertension Treatment Study \(OHTS\)](#). Arch Ophthalmol 2000; 118:1187-1194. [PMID:10980763](#). [View PowerPoint Presentation](#).
3. Piltz J, Gross R, Shin DH, Beiser JA, Dorr DA, Kass MA, Gordon MO and the OHTS Study Group. [Contralateral Effect of Topical \$\beta\$ -Adrenergic Antagonists in Initial One-eyed Trials in the Ocular Hypertension Treatment Study](#). Am J Ophthalmol 2000; 130:441-453. [PMID:11024416](#).
4. Brandt JD, Beiser JA, Gordon MO, Kass MA and the OHTS Group. [Central Corneal Thickness in the Ocular Hypertension Treatment Study \(OHTS\)](#). Ophthalmology 2001; 108:1779-1788. [PMID:11581049](#). [View PowerPoint Presentation](#).
5. Feuer WJ, Parrish RK, II, Schiffman JC, Anderson DR, Budenz DL, Wells MC, Hess DJ, Kass MA, Gordon MO, and the OHTS Group. [The Ocular Hypertension Treatment Study: Reproducibility of Cup/Disk Ratio Measurements Over Time at an Optic Disc Reading Center](#). Am J Ophthalmol 2002; 133:19-28. [PMID:11755836](#).
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7. Kass MA, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JK, Miller JP, Parrish, RK, Wilson MR, Gordon MO for the Ocular Hypertension Treatment Study Group. [The Ocular Hypertension Treatment Study: A Randomized Trial Determines That Topical Ocular Hypotensive Medication Delays or Prevents the Onset of Primary Open-Angle Glaucoma](#). Arch Ophthalmol 2002; 120:701-713. [PMID:12049574](#). [View PowerPoint Presentation](#).
8. Gordon MO, Beiser JA, Brandt JD, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JK, Miller JP, Parrish RK, Wilson MR, Kass MA for the Ocular Hypertension Treatment Study Group. [The Ocular Hypertension Treatment Study: Baseline Factors That Predict The Onset of Primary Open-Angle Glaucoma](#). Arch Ophthalmol 2002; 120:714-720. [PMID:12049575](#).
9. Keltner JL, Johnson CA, Cello KE, Edwards MA, Bandermann SE, Kass MA, Gordon MO for the Ocular Hypertension Study Group. [Classification of Visual Field Abnormalities in the Ocular Hypertension Treatment Study](#). Arch Ophthalmol 2003;121:643-650. [PMID:12742841](#).
10. Zangwill LM, Weinreb RN, Berry CC, Smith AR, Dirkes KA, Coleman AL, Piltz-Seymour JR, Liebmann JM, Cioffi GA, Trick G, Brandt JD, Gordon MO, Kass MA for the Confocal Scanning Laser Ophthalmoscopy Ancillary Study to the Ocular Hypertension Treatment Study. [Racial Differences in Optic Disc Topography: Baseline Results From the Confocal Scanning Laser Ophthalmoscopy Ancillary Study to the Ocular Hypertension Treatment Study](#). Arch Ophthalmol 2004; 122:22-28. [PMID:14718290](#).

11. Zangwill LM, Weinreb RN, Berry CC, Smith AR, Dirkes KA, Liebmann JM, Brandt JD, Trick G, Cioffi GA, Coleman AL, Piltz-Seymour JR, Gordon MO, Kass MA for the Confocal Scanning Laser Ophthalmoscopy Ancillary Study to the Ocular Hypertension Treatment Study. [The Confocal Scanning Laser Ophthalmoscopy Ancillary Study to the Ocular Hypertension Treatment Study: Study Design and Baseline Factors](#). Am J Ophthalmol 2004; 137:219-227. [PMID:14962409](#). [View PowerPoint Presentation](#).
12. Higginbotham EJ, Gordon MO, Beiser JA, Drake MV, Bennett GR, Wilson MR, Kass MA for the Ocular Hypertension Treatment Study Group. [The Ocular Hypertension Treatment Study: Topical Medication Delays or Prevents Primary Open-Angle Glaucoma in African American Individuals](#). Arch Ophthalmol 2004; 122:813-820. [PMID:15197055](#). [View PowerPoint Presentation](#).
13. Coleman AL, Gordon MO, Beiser JA, Kass MA for the Ocular Hypertension Treatment Study (OHTS) Group. [Baseline Risk Factors for the Development of POAG in the Ocular Hypertension Treatment Study](#). Am J Ophthalmol 2004; 138(4):684-5. [PMID:15488816](#).
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18. Parrish RK, Schiffman JC, Feuer WJ, Anderson DR, Budenz DL, Wells-Albornoz M-C, Vandenbroucke R, Kass MA, Gordon MO, the Ocular Hypertension Treatment Group: [Test-retest Reproducibility of Optic Disk Deterioration Detected From Stereophotographs by Masked Graders](#). Am J Ophthalmol 2005; 140:762-764. [PMID:16226544](#). [View PowerPoint Presentation](#)
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20. Levine RA, Demirel S, Fan J, Keltner JL, Johnson CA, Kass MA and the Ocular Hypertension Treatment Study (OHTS) Group. [Asymmetries and Visual Field Summaries as Predictors of Glaucoma in the Ocular Hypertension Treatment Study \(OHTS\)](#). Ophthalmol Vis Sci 2006; 47:3896-3903. [PMCID:1995656](#).
21. Keltner JL, Johnson CA, Anderson DR, Levine RA, Fan JJ, Cello KE, Quigley HA, Budenz DL, Parrish II RK, Kass MA, Gordon MO, and the Ocular Hypertension Treatment Study

- Group. [The Association Between Glaucomatous Visual Fields and Optic Nerve Head Features in the OHTS](#). Ophthalmology 2006; 113(9):1603-12. [PMID:16949445](#).
22. Herman DC, Gordon MO, Beiser JA, Chylack Jr. LT, Lamping KA, Schein OD, Soltau JB, Kass MA. [Topical Ocular Hypotensive Medication and Lens Opacification: Evidence From the Ocular Hypertension Treatment Study \(OHTS\)](#). Am J Ophthalmol 2006; 142:800-12. [PMCID:1976472](#). [View PowerPoint Presentation](#).
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 25. Mansberger SL, Hughes BA, Gordon MO, Spaner SD, Beiser JA, Cioffi GA, Kass MA and the Ocular Hypertension Treatment Study (OHTS) Group. [Comparison of Initial Intraocular Pressure Response to Topical Beta-Adrenergic Antagonists and Prostaglandin Analogues in African Americans and Whites in the Ocular Hypertension Treatment Study \(OHTS\)](#). Archives of Ophthalmology 2007; 125(4):454-9. [PMID:17420364](#).
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 32. Kass MA, Gordon MO, Gao F, Heuer DK, Higginbotham EJ, Johnson CA, Keltner JK, Miller JP, Parrish RK, Wilson MR, and the Ocular Hypertension Treatment Study (OHTS) Group. [Delaying Treatment of Ocular Hypertension](#). Arch Ophthalmol 2010; 128(3):276-287. [PMID:20212196](#). [View PowerPoint Presentation](#).

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37. Gao F, Miller JP, Xiong C, Beiser JA, Gordon MO. [A joint-Modeling Approach to Assess the Impact of Biomarker Variability on the Risk of Developing Clinical Outcome](#). Statistical Methods & Applications. 2010:1-18.
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