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Award Number: W81XWH-11-2-0198

TITLE: Advanced Pediatric Brain Imaging Research and Training Program

PRINCIPAL INVESTIGATOR: Catherine Limperopoulos, PhD

CONTRACTING ORGANIZATION: Children's National Medical Center
Washington, DC 20010

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Brain injury is a leading cause of death and disability in children. Recent advances in pediatric magnetic resonance imaging (MRI) techniques are revolutionizing our understanding of brain injury, its potential for recovery, and demonstrating enormous potential for advancing the field of neuroprotection. We have created a highly structured, collaborative, and multidisciplinary training program in BRAIN (Brain Research Advanced Imaging with NMR) to advance research skills of investigators from all branches of the US military focusing on pediatric brain injury. Our goal is to train, with the highest rigor, military trainees in conducting clinical research using advanced brain imaging technologies to study the causes and consequences of pediatric brain injury. Training in this new field of advanced pediatric MRI technologies will open critical windows of therapeutic opportunity and facilitate the formulation of effective anticipatory and neuroprotective strategies. Over the past year, we successfully recruited two high-caliber military trainees who began their training in BRAIN July 2012. In parallel with our recruitment efforts, we have finalized the BRAIN teaching curriculum and our Neurocognitive and MRI training cores are now firmly in place. The mentoring teams for each trainee have been established and our trainees have successfully completed all requirements for the first phase of their training. They are now entering the next phase of their training which will involve hands-on computational training in advanced MRI techniques that will be tailored to their specific research proposals.					
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Table of Contents

	Page
Introduction.....	1
Body.....	2
Key Research Accomplishments.....	6
Reportable Outcomes.....	7
Conclusion.....	7
References.....	8
Appendices.....	9

INTRODUCTION

Recent advances in our understanding of brain injury and its translation into neurocritical care have been remarkable. A major impetus for this progress can be ascribed to more sophisticated magnetic resonance imaging (MRI) techniques that are revolutionizing our understanding of brain injury, its recovery after injury, and demonstrating enormous potential for advancing the field of neuroprotection¹⁻⁶. Training in this new and rapidly developing field of advanced pediatric brain imaging technologies is critically important in paving the way for a new generation of military clinician-scientists to provide truly informed brain-oriented care. We have created a highly structured, collaborative, and multidisciplinary training program in **BRAIN (Brain Research Advanced Imaging with NMR)** to advance research skills of investigators from all branches of the US military focusing on pediatric brain injury. Central to the pediatric training program in BRAIN is the application of state-of-the-art neuroimaging technologies to study brain injury and plasticity using a highly integrated and quantitative approach. The program encompasses (i) didactic training on how to perform high-quality research, (ii) hands-on computational training in advanced MRI techniques, and (iii) the development of a research project under the supervision of a senior researcher team. The overarching *objective* of BRAIN is to train, with the highest rigor, military trainees in conducting clinical research using advanced brain imaging technologies to study the causes and consequences of pediatric brain injury; and translating discoveries, with the goal to assess, treat, and protect the injured brain.

BODY

Over the past year, we embarked on an intensive recruitment effort and successfully recruited two high-caliber military trainees who began their training in BRAIN July 2012. Our first research scholar, Dr. Gerald E. York is a neuroradiologist from Brooke Army Medical Center in Houston, Texas. Our second scholar, Dr. Nicole Dobson is a neonatologist at Walter Reed Army Medical Center from Uniformed Services University in Bethesda, Maryland. In parallel with our recruitment efforts, the PI together with the scholarly oversight committee finalized the BRAIN teaching curriculum including the selection of coursework and seminars in clinical research methodology, our seminar series on the fundamental principles and application of advanced MRI techniques, as well as our clinical teaching on the mechanisms and consequences of pediatric brain injury. Finally, our advanced MRI training cores are now firmly in place.

Statement of work – progress to date:

Specific Aim 1: To advance the understanding of the fundamental principles and clinical application of sophisticated MRI techniques that is revolutionizing clinical research into the causes, consequences and care of pediatric brain injury.

Training in the fundamental principles and clinical application of advanced MRI technologies is currently firmly in place, in the form of seminars (Appendix 1) and hands-on training in MR imaging acquisitions and advanced MRI post-processing, supervised by Dr. Limperopoulos (Program PI) and Dr. Sze (co-investigator, and Associate Program Director). MRI methods are being taught for interrogating features of acute brain injury using conventional and advanced MRI techniques including susceptibility-weighted MRI, role of contrast, diffusion-weighted techniques, and MR spectroscopy (single voxel, multivoxel, PEPSI). Mechanisms of recovery include application of the above techniques but also measures of normal and abnormal connectivity (diffusion tensor imaging), and brain morphometry including tissue segmentation and parcellation, voxel-based morphometry, deformation based morphometry, tensor based morphometry, and cortical surface development. Moreover, resting state functional MRI techniques are also being taught to assess brain connectivity. Available to each trainee are five imaging training cores including MR spectroscopy, Diffusion MRI, Perfusion MRI, Morphometric MRI and Functional MRI training cores with designated lead mentors for each core by our CNMC-NIH team of investigators. The 5 MRI cores offer personalized training for i) protocol pulse sequence development and MRI data analysis, ii) review of data quality by the trainees

and strategies for improvement, and iii) training in the use of MRI post-processing pipelines. Our military trainees are also enrolled in an intensive 3-day class at the NIH (November, 2012) that will introduce them to functional MRI data analysis and visualization with the AFNI software package. The class will be conducted in a computer lab, and will contain a great deal of hands-on practice with the software.

In order for our trainees to gain an in depth understanding of the impact for brain injury on child function, we have also incorporated a Neurocognitive training core. Our Neurocognitive core is providing teaching on developmental, cognitive, and behavioral outcomes for children who have suffered brain injury. The neurocognitive training core (led by Dr. Gioia, co-investigator on the training grant) is exposing trainees to a range of neuropsychological and neurobehavioral functions including general intellectual functioning, attention, learning and memory, language, executive functioning, motor skills, adaptive behavior, and social-emotional functioning. Using the expertise of the faculty, the selection of appropriate test batteries is being taught to assess important structural (MRI) -functional (child) relationships. To date, the DoD trainees have completed the Pediatric Neuropsychology Training Day (Appendix 2) which covered a number of topics includes neurodevelopmental principles and functional neuroanatomy, neurocognitive testing: general guidelines and helpful hints, and breakout sessions for testing and autism/pediatric concussion, case conceptualization, and behavior observation.

Our trainee's have been actively developing their clinical research projects that will incorporate advanced MRI techniques to study the causes, consequences, and care of pediatric brain injury. These projects are summarized below:

Dr. York has a long standing interest in studying the impact of traumatic brain injury (TBI) on brain plasticity following injury. His project will focus on the application of serial and quantitative MRI techniques to examine the structural, functional, and metabolic consequences following mild TBI in children. Neurocognitive outcomes will be correlated with the proposed quantitative MRI measurements. This project will happen under the supervision of Dr. Gerry Gioia (co-investigator, and Neuropsychology training core lead), Dr. Chris Vaughan (neuropsychologist at Children's National with expertise in TBI), Dr. Carlo Pierpaoli (co-investigator, and Diffusion MRI training core lead), Dr. Stanley Fricke (co-investigator, and MR Spectroscopy training core lead), and Dr. William Gaillard (co-investigator, and Functional MRI training core lead). Dr. York is beginning to apply advanced MRI techniques to analyze the diffusion tensor imaging data,

resting state functional MRI data, and proton magnetic resonance spectroscopy data for his study and plans to correlate these quantitative brain measures to neurocognitive outcomes. Once this is completed, he will analyze the data, prepare his manuscripts for submission and begin to transfer the skills he has acquired in BRAIN to the development of ongoing research projects in TBI, and a research imaging core at Brook Army Medical Center.

Dr. Dobson's research will investigate mechanisms of injury to the developing brain and potential neuroprotective strategies in premature infants. Specifically, her research project will examine the potential neuroprotective effects of caffeine on the immature preterm brain using advanced brain imaging techniques. Dr. Dobson's training will focus on acquiring skills in 3-D volumetric MRI and diffusion tensor imaging to measure the impact of caffeine exposure on subsequent cerebral and cerebellar growth, and microstructural organization in preterm infants. This work will be conducted under the mentorship of Dr. Catherine Limperopoulos (PI; MRI morphometry training core lead), Dr. Adre du Plessis (co-investigator and Associate Director of BRAIN), and Dr. Carlo Pierpaoli (co-investigator and diffusion MR training core lead). Dr. Dobson's training will include hands-on application of advanced MRI techniques to analyze diffusion tensor imaging and three-dimensional volumetric MRI data and to relate measures of global and regional brain growth and microarchitectural organization to caffeine therapy (therapy initiation, dose, length of treatment, etc). Once she has completed these measurements, Dr. Dobson will analyze her data and prepare her manuscripts. Dr. Dobson's long-term goal is to apply the advanced pediatric brain imaging techniques she will acquire during her training in BRAIN to embark on a randomized clinical trial to delineate the neuroprotective effects of caffeine in preterm infants who are treated with caffeine versus placebo on the developing brain.

Specific Aim 2: To enhance through didactic and clinical teaching the basic science and clinical understanding of the causes, mechanisms, and consequences of pediatric brain injury.

Work in this area has progressed very well over the last year under the auspices of Dr. du Plessis (co-investigator and Associate Program Director). Teaching seminars on the Principles of Pediatric Brain Injury led by Dr. Adre du Plessis and well underway and are covering a range of topics including current understanding of underlying mechanisms of brain injury across a broad spectrum of etiologies, including hypoxia-ischemia/reperfusion, hemorrhage, trauma, metabolic, and others (Appendix 3). In these lectures a direct link is made between ongoing discoveries in basic experimental neuroscience and specific features of the 'toolbox' of

established and emerging quantitative MRI techniques (described in Aim 1). The military trainees are also attending Children's National Neuroscience seminar series and participate in brown-bag lunch journal clubs.

Specific Aim 3: To provide training in clinical research methodology through courses and seminars in biostatistics and research design, and responsible conduct of clinical investigation.

Significant progress has been made with the work proposed in this aim. Our trainees successfully completed an intensive two-week course on Introduction to Clinical Research at Johns Hopkins University School of Medicine (July 9-July 20). This curriculum included 37 hours of direct teaching focused on epidemiologic, biostatistical and other issues related to the conduct of clinical research, 20 hours of associated course laboratory time, and extensive readings (Appendix 4a and Appendix 4b). To reinforce and compliment this intensive two-week course, which took place at the very beginning of their training, each trainee is also participating in the **Children's Research Education And Career Training (CREAT)** Program at Children's National Medical Center (Appendix 5). Both trainees have successfully completed the on-line Collaborative Institutional Training Initiative (CITI) course on responsible conduct of research within the first three months of training (Appendix 6) and have been actively developing their research projects following completion of their two-week course work on Introduction to Clinical Research and CITI training under the supervision of their mentoring team (described in aim 1). Specifically, Dr. York's research project which will take place within the context of an existing IRB protocol at Children's National entitled, Non-Invasive Neuro-imaging Techniques for Identifying Neurometabolic and Hydrodynamic Changes following Mild TBI in the Developing Child (Pro#00000361, Chris Vaughan, PI), in which Dr. York has been added as a co-Investigator since completing his CITI course (Appendix 7). Similarly, upon completion of her coursework and CITI certification, Dr. Dobson was added as a co-Investigator on a currently active IRB research protocol entitled, Cerebellar Development in the Preterm Infant (Pro#00002391; Catherine Limperopoulos, PI) (Appendix 7).

KEY RESEARCH ACCOMPLISHMENTS

- Seminar series and advanced MRI and neurocognitive training cores are firmly in place.
- Successful recruitment of two military trainees in year 1 of the training program (Dr. Dobson and Dr. York). Start date: July 1, 2012.
- Successful completion of a two-week intensive course on Introduction to Clinical Research Course Johns Hopkins University (Dr. Dobson and Dr. York).
- Successful completion of the on-line Collaborative Institutional Training Initiative (CITI) course on responsible conduct of research (Dr. Dobson and Dr. York).
- Successful completion of the Pediatric Neuropsychology Training Day (Dr. Dobson and Dr. York).
- Mentoring teams for Drs. York and Dobson are established.
- Research projects have been developed by Dr. York and Dobson, and Institutional Review Board approvals are in place.

REPORTABLE OUTCOMES

There are no reportable outcomes with regard to abstracts/manuscripts to date as our first year trainees (Drs. Dobson and York) officially started in the program three months ago (July 2012).

CONCLUSION

In summary, we have successfully recruited two high-caliber military trainees that begin their BRAIN training in July 2012. Over the past three months, Drs. Dobson and York have completed the necessary initial requirements to enable them to embark on their MRI core training activities including completing the course entitled, Introduction to Clinical Research and the Collaborative Institutional Training Initiative. The trainees applied the knowledge and skills they acquired during the earlier phase of their training and developed their research questions and protocols under the supervision of their mentors. Active IRB protocols have been amended to support their research projects, and Drs. York and Dobson have been added as co-investigators on these studies at Children's National to allow them to successfully undertake the next phase of their training. The trainees are now entering the second phase of their training and will continue to be closely supervised by their principal mentors, and will have access to the expertise of preceptors at CNMC in the three pillars of the program, i.e., clinical research design and implementation, the underlying pathophysiology of brain injury and recovery following injury, and the application of quantitative MRI techniques to address their research question. This will allow them to successfully complete their training in advanced MRI techniques specific to their research projects, to analyze and interpret the results, and prepare their manuscripts over the next year.

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6. Gaillard WD, Berl MM. Functional magnetic resonance imaging: functional mapping. *Handb Clin Neurol.* 2012;107:387-98.

APPENDICES

Appendix 1 Seminars in Advanced Pediatric MRI Techniques

Appendix 2 Pediatric Neuropsychology Training Day

Appendix 3 Principles of Pediatric Brain Injury Seminars

Appendix 4a Introduction to Clinical Research: A Two-Week Intensive Course

Appendix 4b John Hopkins Letters of completion for Dr. Dobson and Dr. York

Appendix 5 Children's Research Education and Career Training (CREAT) Seminars

Appendix 6 Online collaborative Institutional Training Initiative (CITI) completion certificates for Drs. Dobson and York

Appendix 7 Institutional Review Board Amendment Approvals for Drs. Dobson and York

Appendix 1 Seminars in Advanced Pediatric MRI Techniques

Title	Presenter	Completed (C) Not Completed (NC)
Basic MRI		
Hazards and Safety of MRI	Dr. Stanley Fricke	C
Introduction to MRI: Basic Principles and Methodologies	Dr. Stanley Fricke	C
Spectroscopy	Dr. Stanley Fricke	C
Metabolic mapping of the pediatric brain	Dr. Stanley Fricke	C
Pulse Sequences and Quality Control	Dr. Stanley Fricke	C
Pulse Sequences and Coil Selection: Physics for Physicians	Dr. Iordanis Evangelou	C
Conventional MRI: Strengths and limitations for detecting brain injury		NC
More MRI Techniques		
Microstructural assessment of the injured brain: Diffusion weighted and tensor imaging		NC
Strengths and limitations of diffusion MRI for investigating the brain in health and disease	Dr. Carlo Pierpaoli	NC
Novel susceptibility weighted imaging techniques and their emerging role in pediatric brain injury	Dr. Iordanis Evangelou	NC
Pediatric high resolution morphometric brain techniques	Dr. Cedric Clouchoux	NC
Functional MRI and MRI Hardware Components	Dr. William Gaillard	NC
fMRI Principles and Applications	Dr. William Gaillard	NC
Resting functional connectivity: What is the physiologic basis and clinical application?	Dr. Nadja Kadom	NC
A new era of fast and furious MRI	Dr. Stanley Fricke	NC
Introduction to AFNI data analysis for fMRI		NC
Basic Principles of fMRI, paradigm design, and image analysis	Dr. William Gaillard	NC
Comparison of TORTOISE versus DTI studio for diffusion imaging analysis		NC
So many DTI data, so many software packages, so little time. A survival guide to DTI data processing	Dr. Carlo Pierpaoli	NC
SPM versus FSL in fMRI: Advantages and disadvantages	Dr. Madison Berl	NC

LC model and quantification of metabolic disturbances following brain injury	Dr. Stanley Fricke	NC
3D Modeling of the Brain	Dr. Cedric Clouchoux	NC
Quantification of cerebral perfusion: Where are we at?	Dr. Zarir Khademian	NC
Motion correction and high resolution reconstruction	Dr. Cedric Clouchoux	NC



Division of Pediatric Neuropsychology
 15245 Shady Grove Rd., Suite 350
 Rockville, MD 20850
 (301) 765-5430 (phone), (301) 765-5497 (fax)

**CNMC Division of Pediatric Neuropsychology Training Day
 September 5, 2012**

Morning meetings take place in the basement level Conference Room in our Shady Grove office building.

Schedule:

8:15	Breakfast Welcome, Introductions	Laura Kenealy, PhD
8:30-8:45	Intro to the Division of Pediatric Neuropsych	Laura Kenealy, PhD
8:45-9:30	Neurodevelopmental Principles & Functional Neuroanatomy	Gerard Gioia, PhD
9:30-10:00	Testing: General Guidelines and Helpful Hints	Julie Newman, PhD
10:00-10:15	Break	
10:15-11:45	Process Approach in Action: Behavioral Observations	Lauren Kenworthy, PhD
11:45-11:55	When to Call a Supervisor	Chris Vaughan, PsyD
11:55-12:15	TOUR	Amy Youmatz, MS Justine Schellhammer, MS
12:15-12:20	Externs Only: Intro to Externship Coordinators	Chris Vaughan, PsyD Karin Walsh, PsyD
12:15-1:00	Lunch (In Suite 350)	

Afternoon break-out sessions: See table on reverse for your specific assignments

1:00-2:00	Session 1
2:00-2:15	BREAK
2:15-3:15	Session 2
3:15	Extern Meeting – Basement Conference Room New Postdoc Meeting – Laura Kenealy’s Office End of Training Day

Participant	Session		
	Session 1 1:00-2:00	Break 2:00-2:15	Session 2 2:15-3:15
Alana O'Malley	BObs		Aut
Alexandra Coietta	Conc		Conc
Alison Ratto	Case		Aut
Ana Popovska	Conc		Conc
Anna Crisologo	BObs		Aut
Bailey Andrews	BObs		Aut
Billy Holcombe	BObs		Case
Blake Zakarin	BObs		Case
Camille Wilson	Case		Aut
Caroline Luong-Tran	No assignment		Aut
Cat McGill	Conc		Conc
Cate Kraper	Case		Aut
Chelsea Sharber	No assignment		Aut
Chmelka Mills	BObs		Case
Christina Waksmunski	Case		Aut
Claire Semerjian	BObs		Case
Cody Pratson	Conc		Conc
Danielle Ransom	Conc		Aut
Desiree Blindus	BObs		Case
DeVoshia Mason	Conc		Conc
Eileen Twohy	BObs		Case
Elgiz Bal	No assignment		Aut
Erica Etter	BObs		Case
Fern Race	Case		Aut
Gabriel Somarriba	Case		Aut
Gerry York	Conc		Conc
Greg Wochos	Conc		Conc
Jane Meyerson	BObs		Case
Jessica Winkles	BObs		Case
Joe Mollo	Case		Aut
Katie Nirschl	BObs		Aut
Laura Gray	Conc		Case
Lauren Barrett	BObs		Aut
Meredith Amaya-Hodges	Conc		Aut
Nicole Dobson	Conc		Conc
Sonya Bruton	Conc		Conc
Srishti Seth	BObs		Case
Teneish Amon	BObs		Case
Valerie Needham	Conc		Conc
Yael Granader	Case		Aut

KEY

- AUT: Autism Team (Lauren Kenworthy and CASD faculty) – Basement Conference Room
- CASE: Case Conceptualization Workshop (Kristi Hardy, Karin Walsh) – Waiting Room, Suite 350
- CONC: Concussion Clinic Team (Gerry Gioia, Chris Vaughan, Julie Newman, Macgan Sady) – Upstairs Conference Room (Suite 350)
- BOBS: Behavior Observation Workshop (Angie Bollich, Amy Youmatz) – Basement Conference Room

Appendix 3 Seminars in Advanced Pediatric MRI Techniques

Title	Presenter	Completed (C) Not Completed (NC)
Basic MRI		
Hazards and Safety of MRI	Dr. Stanley Fricke	C
Introduction to MRI: Basic Principles and Methodologies	Dr. Stanley Fricke	C
Spectroscopy	Dr. Stanley Fricke	C
Metabolic mapping of the pediatric brain	Dr. Stanley Fricke	C
Pulse Sequences and Quality Control	Dr. Stanley Fricke	C
Pulse Sequences and Coil Selection: Physics for Physicians	Dr. Iordanis Evangelou	C
Conventional MRI: Strengths and limitations for detecting brain injury		NC
More MRI Techniques		
Microstructural assessment of the injured brain: Diffusion weighted and tensor imaging		NC
Strengths and limitations of diffusion MRI for investigating the brain in health and disease	Dr. Carlo Pierpaoli	NC
Novel susceptibility weighted imaging techniques and their emerging role in pediatric brain injury	Dr. Iordanis Evangelou	NC
Pediatric high resolution morphometric brain techniques	Dr. Cedric Clouchoux	NC
Functional MRI and MRI Hardware Components	Dr. William Gaillard	NC
fMRI Principles and Applications	Dr. William Gaillard	NC
Resting functional connectivity: What is the physiologic basis and clinical application?	Dr. Nadja Kadom	NC
A new era of fast and furious MRI	Dr. Stanley Fricke	NC
Introduction to AFNI data analysis for fMRI		NC
Basic Principles of fMRI, paradigm design, and image analysis	Dr. William Gaillard	NC
Comparison of TORTOISE versus DTI studio for diffusion imaging analysis		NC
So many DTI data, so many software packages, so little time. A survival guide to DTI data processing	Dr. Carlo Pierpaoli	NC
SPM versus FSL in fMRI: Advantages and disadvantages	Dr. Madison Berl	NC

LC model and quantification of metabolic disturbances following brain injury	Dr. Stanley Fricke	NC
3D Modeling of the Brain	Dr. Cedric Clouchoux	NC
Quantification of cerebral perfusion: Where are we at?	Dr. Zarir Khademian	NC
Motion correction and high resolution reconstruction	Dr. Cedric Clouchoux	NC

Appendix 4a
INTRODUCTION TO CLINICAL RESEARCH: A TWO-WEEK INTENSIVE COURSE, 2012
Johns Hopkins University School of Medicine
Welch Center for Prevention, Epidemiology and Clinical Research
2024 E. Monument Street; Suite 1-500Q

	MONDAY July 9	TUESDAY July 10	WEDNESDAY July 11	THURSDAY July 12	FRIDAY July 13
9:00 am	<ul style="list-style-type: none"> o Introduction o Pre-Test o Clinical and Translational Research: Expectations and Goals <p>D. Ford</p>	<ul style="list-style-type: none"> o Study Design: Cross-sectional Studies <p>HC-Ch. 8 D. Ford</p>	<ul style="list-style-type: none"> o Study Design: Pilot Studies <p>C. Flexner</p>	<ul style="list-style-type: none"> o Measurement Issues in Imaging <p>R. Wahl</p>	<ul style="list-style-type: none"> o Study Design: Clinical Trials – Part I <p>HC-Ch. 10 E. Miller</p>
10:00 am	<ul style="list-style-type: none"> o Defining the Research Question <p>HC-Ch. 1,2 D. Ford</p>	<ul style="list-style-type: none"> o Confidence Intervals: Inference About One and Two Population Means (Proportions) <p>DT-pgs. 93-110 J. McGready</p>	<ul style="list-style-type: none"> o Study Design: Prospective Studies <p>HC-Chapter 7 E. Miller</p>	<ul style="list-style-type: none"> o Research Funding and Career Development <p>HC-Ch.19 M. Amey</p>	<ul style="list-style-type: none"> o Study Design: Clinical Trials – Part II <p>HC-Ch. 11 E. Miller</p>
11:00 am	<ul style="list-style-type: none"> o Measurement of Rates and Risks <p>D. Ford</p>	<ul style="list-style-type: none"> o Confidence Intervals: Inference About One and Two Population Means (Proportions)-Part II <p>DT-pgs. 135-153 J. McGready</p>	<ul style="list-style-type: none"> o Choosing a Sample Size <p>DT-pgs. 125-130 DT-pgs. 154-157 J. McGready</p>	<ul style="list-style-type: none"> o Managing Your Own Data (...If You Have To) <p>K. Carson</p>	<ul style="list-style-type: none"> o Secondary Translation <p>D. Ford</p>
12:00	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH
1:30 pm	<ul style="list-style-type: none"> o Scientific Concepts for Clinical Research <p>S. Zeger</p>	<ul style="list-style-type: none"> o Ethical Issues in Clinical Research <p>J. Sugarman</p>	<ul style="list-style-type: none"> o Study Design: Case-Control Studies <p>HC-Ch. 8 D. Ford</p>	<ul style="list-style-type: none"> o Principles of Drug Development <p>C. Flexner</p>	<ul style="list-style-type: none"> o Institutional Review Board <p>D. Ford</p>
2:30 pm	<ul style="list-style-type: none"> o Introduction to Statistical Inference <p>DT-pgs. 72-90 S. Zeger</p>	<i>SMALL GROUPS ASSIGNMENTS WILL BE DISTRIBUTED ON TUESDAY, JULY 10TH</i>			
		3:00pm-4:00 Small Groups	3:00pm-4:00 Small Groups	3:00pm-4:00 Small Groups	3:00pm-4:00 Small Groups
3:30 pm	<ul style="list-style-type: none"> o Introduction to Statistical Inference (cont'd) <p>DT-pgs. 72-90 S. Zeger</p>				

INTRODUCTION TO CLINICAL RESEARCH: A TWO-WEEK INTENSIVE COURSE, 2012
Johns Hopkins University School of Medicine
Welch Center for Prevention, Epidemiology and Clinical Research
2024 E. Monument Street; Suite 1-500Q

	MONDAY July 16	TUESDAY July 17	WEDNESDAY July 18	THURSDAY July 19	FRIDAY July 20
9:00 am	o Searching the Literature V. Goode	o Patient Reported Outcomes A. Wu	o Statistics: Prediction/Prognostics Models J. McGready	o How to Make a Bad Plot K. Bandeen-Roche	9:00- 9:30 POST-TEST
10:00 am	o Evaluation of Diagnostic Tests and Screening I HC-Ch. 12/DT-Ch. 12 D. Dowdy	o Linear Regression DT-pgs. 192-220 DT-pgs. 245-279 K. Bandeen-Roche	o Conducting a Study Safely and Efficiently at Johns Hopkins D. Ford	o Working with the Institute for Clinical and Translational Research D. Ford	PRESENTATIONS Presentations by small groups will begin at approximately 10:00am and are to be 15 minutes in length (10 minutes for presentation; 5 minutes for questions)
11:00 am	o Evaluation of Diagnostic Tests and Screening II HC-Ch.12 D. Dowdy	o Confounding: Comparing Two Groups within Strata of Confounders HC-pgs. 127-145 K. Bandeen-Roche	o Mentoring J. Clark	o How to Access Data from Clinical Systems/bio-specimen and Clinical Data D. Gumas	
12:00-1:30	LUNCH	LUNCH	LUNCH	LUNCH	
1:30 pm	o Systematic Reviews/Meta-analysis HC-Ch.13 S. Singh	o Log-linear, Logistic and Survival Regression DT-pgs. 261-263 DT-pgs. 229-244 J. McGready	o Survival Analysis – Getting Started DT-pgs. 221-228 G. Yenokyan	o Journal Editor’s Tips on Publishing Your Study E. Bass	LUNCHEON AND REVIEW OF POST-TEST
3:00	o Small Group Meeting	o Small Group Meeting	o Small Group Meeting	o Small Group Meeting	

HC - Hulley,Cummings, et al; DT - Dawson, Trapp

Appendix 4b



Institute for Clinical and Translational Research

July, 2012

To whom it may concern:

This note is written to certify that Nicole Dobson participated in the 2012 Johns Hopkins Introduction to Clinical Research Course held July 9th-20th. The course curriculum included 37 hours of direct teaching time focused on epidemiologic, biostatistical and other issues related to the conduct of clinical research, 20 hours of associated course laboratory time, and extensive reading. The course has been approved by the Curriculum Committee of the Johns Hopkins University Bloomberg School of Public Health and is approved for 6 hours of academic credit toward degrees at the Johns Hopkins University Bloomberg School of Public Health.

A handwritten signature in black ink, appearing to read "D. Ford".

Daniel E. Ford, M.D. M.P.H.
Vice Dean for Clinical Investigation
Director, Institute for Clinical and Translational Research
Professor of Medicine, Psychiatry, Epidemiology and
Health Policy and Management



Institute for Clinical and Translational Research

July, 2012

To whom it may concern:

This note is written to certify that Gerald York participated in the 2012 Johns Hopkins Introduction to Clinical Research Course held July 9th-20th. The course curriculum included 37 hours of direct teaching time focused on epidemiologic, biostatistical and other issues related to the conduct of clinical research, 20 hours of associated course laboratory time, and extensive reading. The course has been approved by the Curriculum Committee of the Johns Hopkins University Bloomberg School of Public Health and is approved for 6 hours of academic credit toward degrees at the Johns Hopkins University Bloomberg School of Public Health.

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Vice Dean for Clinical Investigation
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Professor of Medicine, Psychiatry, Epidemiology and
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Appendix 5

Children's Research Education And Career Training Program (CREAT) 2012-2013

Research Methodologies:
101 The Design of Clinical Research Studies
Instructor(s): Robert McCarter ScD, Avital Cnaan PhD, Peter Scheidt PhD
Intended Audiences
Faculty and students interested in designing research studies or in understanding study designs including their potential pitfalls
Impact of Session
Attendees will be able to select and identify appropriate designs to address particular research problems and focus attention on the vulnerable aspects of each design

Research Methodologies:
102 Meeting the Informatics Needs of Research Studies: The Children's Hospital Research Informatics System and Red Cap
Instructor(s): Robert McCarter ScD
Intended Audiences
Basic science and clinical researchers
Impact of Session
Attendees will be presented with different informatics platforms including CHRIS and Red Cap and others that addresses each of the challenges and requirements to successfully fielding a research study

Research Methodologies:
103 Application of statistics to Protocol Development (Writing Clear, Logical and Achievable Aims and Testable Hypotheses with Precision
Instructor(s): Robert McCarter ScD, Michael Spaeder MD, Avital Cnaan PhD
Intended Audiences
Faculty, Staff, Students, Residents, Post-Doctoral Fellows engaging in basic, clinical, and community research
Impact of Session
Participants will learn and discuss the skills, strategies, and vision needed to write clear, logical, and precise aims and hypotheses for grant proposals and IRB protocols that lead to successful research in the clinical and translational science era. This is not a session on the mechanics of writing grants—instead it focuses on thinking logically about research from scientific and statistical perspectives

Research Methodologies:
104 Basics of Submitting Research Protocols to the Institutional Review Board (IRB) and the Office for the Protection of Human Subjects (OPHS)
Instructor(s): MaryAnn Rossi PhD, CIP and Team
Intended Audiences
Investigators, fellows, study coordinators, and other research personnel engaged in human subjects research, especially those who are new to CNMC or new to research. This course is an introduction to the IRB, the Office for the Protections of Human Subjects (OPHS), and the protocol application process, intended for individuals who are responsible for preparing and submitting research protocol documents for IRB review.
Impact of Session
Participants will learn important concepts in human subjects research protection and information about the policies and procedures of the CNMC IRB and OPHS. Some topics include: 1) CNMC educational requirements for human

subject protections training; 2) regulatory criteria for IRB approval; 3) the distinction between Full Board, Expedited, and Exempt IRB review; and 4) requirements for protocol modifications and Continuing Review. After completing this session, participants will be able to prepare more thorough and complete IRB submissions that will facilitate the review process, thereby reducing time from submission to IRB approval.

Faculty Development:

101 What to Know About APT (Advancement, Promotion and Tenure)

Instructor(s): Naomi Luban, MD

Intended Audiences

Faculty, fellows

Impact of Session

These workshops are designed to explain the guidelines for academic promotion and tenure review. Expectations, criteria and tools to capture data that will be needed for future promotion are reviewed. Samples of successful CV's, portfolios and assembly of biographical material are discussed and provided to the participants

Faculty Development:

102 Portfolio Building Workshop II: Preparing for Tenure

Instructor(s): Naomi Luban, MD

Intended Audiences

Faculty, basic science researchers, doctoral and post-doctoral students

Impact of Session

Participants will learn key methods to build academic portfolios, understand the APT process and market their academic advancement

Faculty Development:

103 Portfolio Building Workshop II: Preparing for Tenure

Instructor(s): Naomi Luban MD, Rachel Moon MD, Mary Rose PhD

Intended Audiences

Faculty, basic science researchers, doctoral and post-doctoral students

Impact of Session

Participants will learn key methods to build academic portfolios, understand the APT process and market their academic advancement

Faculty Development:

104 Leadership Faculty Development: Enhancing Team Effectiveness: Managing Team Challenges: Competencies for Success

Intended Audiences

Faculty, fellows, residents, doctoral and post-doctoral students

Impact of Session

At the end of this session, participants will be able to 1. Describe the value of teams 2. Identify team attributes that promote or impede team success 3. Describe and analyze one team of which you are a member to identify it's strengths and weaknesses 4. Recognize individual behaviors that impact team function and how conflict can be used to advantage

Grant Training:

101 Grant and Foundation Sourcing

Instructor(s): Naomi Luban MD, Member of Children's Foundation Office

DATE	(TIME)	LOCATION	CLOSED OR OPEN
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Intended Audiences

Faculty, fellows, residents, doctoral and post-doctoral students
Impact of Session
The Grant Workshop is designed for junior faculty and any individual planning on submitting a grant who want to learn more about the NIH grant and evaluation process. Details are provided on the importance of specific aims, statistics, budget and grant presentation. This workshop augments those on electronic submission. Special attention is given to how RFA's and RFP's are developed and to foundation funding sources. On alternative years, this workshop becomes an interactive workshop on how to respond to negative reviews and finding non-NIH funding

Grant Training:
102 Abstract and Poster and Research Manuscript Submission and Review Processes
Instructor(s): Annie Colberg-Poley PhD, Vittorio Gallo PhD
Intended Audiences
Junior Faculty, residents, fellows, doctoral and post-doctoral students
Impact of Session
At the end of this session, participants will know how to submit an abstract, poster and manuscript to a medical journal, know what to expect with the review process and increase their chances of publishing successfully

Grant Training:
103 Understanding the NIH Review Process and Summary Statements
Instructor(s): Annie Colberg-Poley PhD, Vittorio Gallo PhD, CRI Leadership
Intended Audiences
Principal Investigators, Co-Investigators and Collaborators
Impact of Session
Participants will develop an understanding of the NIH Scientific Grant Review Process, the role of Study Sections, the Grant Review Criteria, and Grant Scoring System. The attendees will be introduced to useful approaches to develop improved revised grant applications

Grant Training:
104 Mock Study Section Workshop
Instructor(s): Mendel Tuchman MD, Peter Scheidt PhD, Eric Hoffman PhD, CRI Leadership
Intended Audiences
Faculty, doctoral and post-doctoral students who have or plan to submit a grant
Impact of Session
In this session, we will discuss the key factors in preparing a successful grant application and review and critique successful and unsuccessful applications

Grant Training:
105 SF 424 and PHS 398: Understanding the Pre-Award Process
Instructor(s): Monique Foxx, Stephanie Bair, Lisa Sheehy
Intended Audiences
New Investigators, Research Associates, Junior-Level Faculty, Administrative Assistants
Impact of Session
Participants will learn how to identify, prepare and submit an application for federal funding using resources available at CNMC

Grant Training:
106 Cracking the Code: Making sense of performance reports (and other strategies for managing your award at CNMC)
Instructor(s): Carmen Mendez MBA and Staff

<i>Intended Audiences</i>	
New Investigators, Research Associates, Junior-Level Faculty, Administrative Assistants	
<i>Impact of Session</i>	
Participants will learn how to take an active role in the financial management of grant awards at CNMC	

CITI Collaborative Institutional Training Initiative

CITI Good Clinical Practice Curriculum Completion Report Printed on 10/1/2012

Learner: Nicole Dobson (username: ndobson)
 Institution: Children's National Medical Center
 Contact Information Phone: 202-476-3842
 Email: nicole.dobson@usuhs.edu
 CITI Good Clinical Practice Course:

Stage 1. Basic Course Passed on 10/01/12 (Ref # 8782822)

Required Modules	Date Completed	Score
GCP Introduction	09/14/12	3/3 (100%)
Overview of New Drug Development	09/14/12	5/5 (100%)
ICH Overview	09/14/12	4/4 (100%)
FDA Regulated Research and ICH for Investigators	09/17/12	3/5 (60%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	09/17/12	3/4 (75%)
Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	09/17/12	3/3 (100%)
Investigator Obligations in FDA-Regulated Clinical Research	09/17/12	5/5 (100%)
Managing Investigational Agents According to GCP Requirements	09/17/12	5/5 (100%)
Conducting Clinical Trials of Medical Devices	09/18/12	2/3 (67%)
Informed Consent	09/18/12	4/4 (100%)
Detection and Evaluation of Adverse Events	10/01/12	4/4 (100%)
Reporting Serious Adverse Events	10/01/12	4/4 (100%)
Audits and Inspections in Clinical Trials	10/01/12	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors	10/01/12	7/8 (88%)
Completing the CITI GCP Course	10/01/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
 Professor, University of Miami
 Director Office of Research Education
 CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

CITI Human Subjects Research Curriculum Completion Report

Printed on 10/1/2012

Learner: Nicole Dobson (username: ndobson)

Institution: Children's National Medical Center

Contact Information Phone: 202-476-3842

Email: nicole.dobson@usuhs.edu

Biomedical Research:

Stage 1. Basic Course Passed on 09/14/12 (Ref # 8669891)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	02/10/10	3/3 (100%)
History and Ethical Principles	09/06/12	5/6 (83%)
Basic Institutional Review Board (IRB) Regulations and Review Process	02/10/10	4/5 (80%)
Informed Consent	02/10/10	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	02/10/10	1/4 (25%)
Records-Based Research	02/10/10	1/2 (50%)
Genetic Research in Human Populations	02/10/10	1/2 (50%)
Research With Protected Populations - Vulnerable Subjects: An Overview	02/10/10	4/4 (100%)
Vulnerable Subjects - Research Involving Prisoners	09/11/12	2/4 (50%)
Vulnerable Subjects - Research Involving Children	09/11/12	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	09/11/12	3/3 (100%)
Avoiding Group Harms: U.S. Research Perspectives	09/11/12	3/3 (100%)
FDA-Regulated Research	02/10/10	4/5 (80%)
Research and HIPAA Privacy Protections	09/11/12	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees	09/14/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	02/12/10	2/2 (100%)
Children's National Medical Center	09/14/12	no quiz

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Paul Braunschweiger Ph.D.
Professor, University of Miami

Completion Report

<https://www.citiprogram.org/members/learnersII/crbysta...>

Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

CITI Human Subjects Research Curriculum Completion Report Printed on 9/15/2012

Learner: Gerald York (username: york0011)
Institution: Children's National Medical Center
Contact Information 111 Michigan Ave NW
 Washington, DC 20010
 Phone: 2024764188
 Email: gerald.york@amedd.army.mil

Biomedical Research:

Stage 1. Basic Course Passed on 09/06/12 (Ref # 8666767)

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	05/20/12	3/3 (100%)
History and Ethical Principles	05/20/12	5/6 (83%)
Basic Institutional Review Board (IRB) Regulations and Review Process	05/28/12	5/5 (100%)
Informed Consent	05/28/12	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	05/28/12	4/4 (100%)
Records-Based Research	06/14/12	2/2 (100%)
Genetic Research in Human Populations	11/05/08	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	06/14/12	4/4 (100%)
Vulnerable Subjects - Research Involving Prisoners	09/06/12	4/4 (100%)
Vulnerable Subjects - Research Involving Children	11/05/08	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates	11/05/08	3/3 (100%)
Avoiding Group Harms: U.S. Research Perspectives	06/14/12	3/3 (100%)

FDA-Regulated Research	11/05/08	5/5 (100%)
Research and HIPAA Privacy Protections	11/05/08	2/2 (100%)
Vulnerable Subjects - Research Involving Workers/Employees	06/14/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	06/14/12	4/5 (80%)
Children's National Medical Center	09/06/12	no quiz

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 Professor, University of Miami
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CITI Collaborative Institutional Training Initiative (CITI)

Responsible Conduct of Research Curriculum Completion Report Printed on 9/15/2012

Learner: Gerald York (username: york0011)
Institution: Children's National Medical Center
Contact Information 111 Michigan Ave NW
 Washington, DC 20010
 Phone: 2024764188
 Email: gerald.york@amedd.army.mil
Biomedical Responsible Conduct of Research Course:

Stage 1. RCR Passed on 09/12/12 (Ref # 8666769)

Required Modules	Date Completed	Score
Introduction to the Responsible Conduct of Research	09/06/12	no quiz
Research Misconduct 0-1516	09/06/12	6/6 (100%)
Case Study - Truth or Consequences 1-1470	09/10/12	3/3 (100%)
Case Study Plagiarism 1-1473	09/12/12	2/2 (100%)
Case Study No News is Not Good News - 1-1469	09/12/12	3/3 (100%)
Data Acquisition, Management, Sharing and Ownership 1-1308	09/12/12	4/5 (80%)
Data Management Video Vignette Case Studies	09/12/12	no quiz
Case Study - Data Management - Share and Share Alike 1-1193	09/12/12	3/3 (100%)
Case Study - Data Management "Who Owns Research Data?" 1-1444	09/12/12	3/3 (100%)
Publication Practices and Responsible Authorship 1-1380	09/12/12	4/5 (80%)
Responsible Authorship - The Chair as an Author 1-1320	09/12/12	2/2 (100%)
Authorship and Publications - The Grateful Author 1-1235	09/12/12	4/5 (80%)

Responsible Authorship -Taking Shortcuts (All Science)	09/12/12	3/5 (60%)
Peer Review 0-1520	09/12/12	3/5 (60%)
What is Responsible Peer Review 1-1369	09/12/12	5/5 (100%)
Mentor and Trainee Responsibilities 01234 1250	09/12/12	5/5 (100%)
Mentoring Case Study: O, What a Tangled Web We Weave	09/12/12	4/4 (100%)
Mentoring Case Study: Lisa Bach's Case	09/12/12	3/3 (100%)
Mentoring Case Study: The Business of Mentoring	09/12/12	4/4 (100%)
Collaborative Research 0-1468	09/12/12	6/6 (100%)
Collaborative Research Simulation - Eight Scenarios and Resolutions	09/12/12	no quiz
The CITI RCR Course Completion Page	09/12/12	no quiz

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CITI Collaborative Institutional Training Initiative**CITI Good Clinical Practice Curriculum Completion Report**
Printed on 9/15/2012

Learner: Gerald York (username: york0011)
Institution: Children's National Medical Center
Contact Information 111 Michigan Ave NW
 Washington, DC 20010
 Phone: 2024764188
 Email: gerald.york@amedd.army.mil

CITI Good Clinical Practice Course:**Stage 1. Basic Course Passed on 09/15/12 (Ref # 8666768)**

Required Modules	Date Completed	Score
GCP Introduction	09/12/12	3/3 (100%)
Overview of New Drug Development	09/12/12	5/5 (100%)
ICH Overview	09/15/12	4/4 (100%)
FDA Regulated Research and ICH for Investigators	09/15/12	5/5 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	09/15/12	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices	09/15/12	3/3 (100%)
Investigator Obligations in FDA-Regulated Clinical Research	09/15/12	4/5 (80%)
Managing Investigational Agents According to GCP Requirements	09/15/12	4/5 (80%)
Conducting Clinical Trials of Medical Devices	09/15/12	3/3 (100%)
Informed Consent	09/15/12	4/4 (100%)
Detection and Evaluation of Adverse Events	09/15/12	3/4 (75%)
Reporting Serious Adverse Events	09/15/12	4/4 (100%)

Audits and Inspections in Clinical Trials	09/15/12	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors	09/15/12	7/8 (88%)
Completing the CITI GCP Course	09/15/12	no quiz

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Appendix 7 Principles of Pediatric Brain Injury Seminars

Title	Presenter	Completed (C) Not Completed (NC)
CNS Development		
Normal and abnormal development of the cerebellum	Dr. Adre du Plessis	C
Normal and Abnormal development of the posterior fossa structures	Dr. Adre du Plessis	C
Understanding normal brain development: Role of MRI	Dr. Gilbert Vezina	C
MRI diagnosis of normal and abnormal posterior fossa development	Dr. Gilbert Vezina	NC
Cerebral Blood Flow and Metabolism		
Normal and Abnormal Regulation of CBF and Metabolism	Dr. Adre du Plessis	NC
Brain Injury in the Preterm and Term Newborn		
Mechanisms of Brain Injury in the Preterm and Term Newborn	Dr. Adre du Plessis	NC
MRI diagnosis of brain injury in the Preterm and term infant	Dr. Gilbert Vezina	NC
Stroke in Childhood		
Mechanisms and MRI manifestations of stroke in childhood	TBD	NC
Traumatic Brain Injury (Including non-accidental injury)		
Mechanisms and manifestations of traumatic brain injury	Dr. Gerald Gioia	NC
MRI in the diagnosis and timing of traumatic brain injury	Dr. Gilbert Vezina	NC