

Department of Health and Human Services
Public Health Service

ZNS1

Review Group	Type	Activity	Grant Number
SRB-R (1)	5	R01	HD42386-02

Application for Continuation Grant

Total Project Period	
From: 09/25/2001	Through: 08/31/2006
Requested Budget Period	
From: 09/01/2002	Through: 08/31/2003

To be verified by applicant. Check information in Items 1 through 6. If incorrect, furnish correct information in Item 13.

1. TITLE OF PROJECT fmri and Sports-Related Concussion	
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code) MARION, DONALD W UNIVERSITY OF PITTSBURGH DEPT OF NEURO SURGERY-SUITE B400 200 LOTHROP ST-UPMC PRESBYTERIAN PITTSBURGH, PA 15213	4. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code) UNIVERSITY OF PITTSBURGH OFFICE OF RESEARCH 350 THACKERAY HALL PITTSBURGH, PA 15260 02-07-01P01:41 RCVD
2b. E-MAIL ADDRESS DMARION@NEURONET.PITT.EDU	5. ENTITY IDENTIFICATION NUMBER EIN/TIN Number
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT NEUROLOGICAL SURGERY	6. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL DIR, OFFICE OF RESEARCH UNIVERSITY OF PITTSBURGH 350 THACKERAY HALL PITTSBURGH, PA 15260 E-MAIL ADDRESS ornih@orserver.off-res.pitt.edu
2d. MAJOR SUBDIVISION SCHOOL OF MEDICINE	
3. ORGANIZATIONAL CODE 01 SCHOOL OF MEDICINE	

Complete the following (see instructions).

7. HUMAN SUBJECTS <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes	7a. If "Yes," Exemption no. or IRB approval date 1/28/02	<input type="checkbox"/> Full IRB or <input checked="" type="checkbox"/> Expedited Review	7b. Assurance of compliance no. M1259	8. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	8a. If "Yes," IACUC approval date	8b. Animal welfare assurance no.
9. COSTS REQUESTED FOR NEXT BUDGET PERIOD 9a. DIRECT \$ 9b. TOTAL \$		10. INVENTIONS AND PATENTS (See instructions) <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," <input type="checkbox"/> Previously reported <input type="checkbox"/> Not previously reported				
11. PERFORMANCE SITE(S) (Organizations and addresses) University of Pittsburgh Pittsburgh, PA Carnegie Mellon University Pittsburgh, PA		12a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a) Donald W. Marion, MD	AREA CODE 412 412	TELEPHONE NO. AND FAX NO. 647-0956 647-7337		
		12b. NAME OF ADMINISTRATIVE OFFICIAL (Item 6) Michael M. Crouch	412 412	624-7400 624-7409		
		12c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 15) Michael M. Crouch Director, Office of Research	412 412	624-7400 624-7409		
		E-MAIL ADDRESS offres@orserver.off-res.pitt.edu				

13. USE THIS SPACE FOR CORRECTIONS TO ITEMS 1 THROUGH 6. INDICATE THE NUMBER(S) WHERE ANSWERS APPLY.

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI / PD NAMED IN 2a (In ink. "Per" signature not acceptable.) <i>Donald W. Marion</i>	DATE 6/6/02
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 12c (In ink. "Per" signature not acceptable.) <i>Michael M. Crouch</i>	DATE 6/28/02

BUDGET JUSTIFICATION

GRANT NUMBER
5 R01 HD42386-02

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

✓ Rebecca Roush, fMRI Analyst, [] % effort: Ms Roush will coordinate the research imaging protocols and perform various data analysis and organization for the project. She will work closely with the study coordinator and co-investigators in ensuring that the overall project runs smoothly in all aspects with a focus on the acquisition, transfer, and analysis of the functional MR imaging data.

Fringe Benefits are 18.8% for faculty and 26% for staff per the University of Pittsburgh DHHS Agreement dated 3/30/01, effective 7/1/02.

CURRENT BUDGET PERIOD	FROM 9/25/01	THROUGH 8/31/02
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% = Percentage of Effort

A Subcontract to the University of Pittsburgh
to be included with a Proposal to the
National Institutes of Health
titled

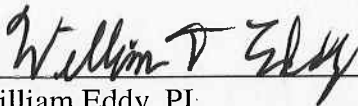
“fMRI and Sports Related Concussion”

from

Department of Statistics
Carnegie Mellon University
Pittsburgh, PA 15213-3890

Proposal Duration: 9/01/2001* – 8/31/2006

Total Amount Requested: \$253,787



William Eddy, PI
Professor, Department of Statistics

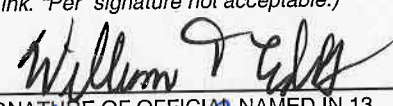



Susan Burkett, Associate Provost
Carnegie Mellon University



Michael M. Crouch, Director
Office of Research

*NOTE: CMU participation to begin project year two, i.e. 9/1/2002.

Department of Health and Human Services Public Health Services Grant Application <i>Do not exceed 56-character length restrictions, including spaces.</i>		LEAVE BLANK—FOR PHS USE ONLY.			
		Type	Activity	Number	
		Review Group		Formerly	
		Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT Fmri and Sports Related Concussion					
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (If "Yes," state number and title) Number: NS-01-007 Title: Functional MRI and Intervention for Cognitive Deficits.....					
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR			New Investigator <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		
3a. NAME (Last, first, middle) Eddy, William		3b. DEGREE(S) Ph.D			
3c. POSITION TITLE Professor		3d. MAILING ADDRESS (Street, city, state, zip code) BAKER HALL CARNEGIE MELLON UNIVERSITY 5000 FORBES AVENUE PITTSBURGH PA 15213 E-MAIL ADDRESS: bill@stat.cmu.edu			
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT STATISTICS					
3f. MAJOR SUBDIVISION COLLEGE, HUMANITIES & SOCIAL SCIENCES					
3g. TELEPHONE AND FAX (Area code, number and extension) TEL: 412-268-2725 FAX: 412-268-7828					
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		4a. Research Exempt <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes If "Yes," Exemption No. TBA		5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
		4b. Human Subjects Assurance No.		5a. If "Yes," IACUC approval Date	
		4c. NIH-defined Phase III Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		5b. Animal welfare assurance no	
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY) From 9/1/01 Through 8/31/06		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) \$0		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 7b. Total Costs (\$) \$0 8a. Direct Costs (\$) \$166,649 8b. Total Costs (\$) \$253,787	
9. APPLICANT ORGANIZATION Name CARNEGIE MELLON UNIVERSITY Address 5000 FORBES AVENUE PITTSBURGH PA 15213 Institutional Profile File Number (if known)		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input checked="" type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged			
		11. ENTITY IDENTIFICATION NUMBER EIN/TIN Number DUNS NO. (if available) 05-218-4116 Congressional District 14			
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name THOMAS M. EAGAN Title MANAGER, OFFICE OF SPONSORED RESEARCH Address 5000 FORBES AVENUE PITTSBURGH PA 15213 Tel 412-268-5835 FAX 412-268-5841 E-Mail te9b@andrew.cmu.edu		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name SUSAN BURKETT Title ASSOCIATE PROVOST Address 5000 FORBES AVENUE PITTSBURGH PA 15213 Tel 412-268-8746 FAX 412-268-6279 E-Mail sburkett@andrew.cmu.edu			
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PD NAMED IN 3a. (In ink. "Per" signature not acceptable.) 		DATE 06/19/02	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. (In ink. "Per" signature not acceptable.) 		DATE 6/19/02	

PHS 2590 OTHER SUPPORT

Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

MARION, D.W.**ACTIVE**

NS303180 - Marion (PI) 03/01/95-06/30/05 %
 NIH/NINDS \$830,493
 University of Pittsburgh Brain Trauma Research Center

This is a program project grant, which is a continuation of the University of Pittsburgh Brain Trauma Research Center grant. The focus of our investigations are in the molecular mechanisms of secondary injury with particular emphases on delayed oxidative stress, programmed cell death, the relationship of amyloid precursor protein with interleukin 1 β , the role of inducible nitric oxide synthase as an endogenous neuroprotectant, the role of mesocortical dopamine systems in causing chronic functional and cognitive deficits, and the role of poly (ACP-ribose) polymerase as a mediator of oxidative DNA damage and apoptosis. Our investigations will attempt to correlate findings regarding these molecular mechanisms in the laboratory with patients who have suffered severe traumatic brain injury through recovery of CSF and dialysis samples and brain tissue at surgery. As such, there is no overlap with the present grant.

R49/CCR310285 - Marion (PI) 09/01/98-08/31/03 %
 Centers for Disease Control \$662,337
 Grants for Injury Control Research Centers

This project is a center project sponsored by the CDC intended to address issues related to injury prevention, acute care, and rehabilitation. As Director of this Center, I coordinate research done by a group of other individuals although I do not have a specific research project of my own.

R01 NS38087 - Kochanek (PI) 07/01/99-06/30/04 %
 NIH/NINDS \$10,615
 Adenosine and Traumatic Brain Injury

This project investigates the levels of cerebrospinal fluid adenosine following traumatic brain injury in adults and children and also attempts to investigate pharmacologic manipulations at those levels. It is involving primarily basic science research. The project has no scientific or budgetary overlap with the current project.

M1999-0080 - Dixon (PI) 07/01/99-06/30/02 %
Private Support \$16,225

In this project, Dr. Dixon is developing preliminary and pilot data relative to the dopaminergic oxidative mechanisms described in his new proposal. I will serve as a consultant and have no scientific or budgetary overlap with the current proposal.

R01 NR04801 - Kerr (PI) 09/30/99-06/30/04 %
 NIH/NINR \$46,527
 The Effect of APOE on Outcomes in TBI

This project will be investigating a genetic marker (APOE) as a possible indicator of predisposition to poor outcome following severe and moderate traumatic brain injury. There is no budgetary overlap.

1 T32 HD40686 – Kochanek (PI) 09/25/00-04/30/05
NIH/NINDS \$94,003
Training in Pediatric Neurointensive Care and Resuscitation Research

%

This is a training grant that has been submitted for the training of pediatric neurointensive care and resuscitation research specialists. I will serve as a consultant and faculty member in this effort.

1 R01 HD42386 – Marion (PI) 09/25/01-08/31/06
NIH/NICHHD \$546,261
FMRI and Sports-Related Concussion

%

This study will evaluate athletes with sports-related concussions using fMRI and neuropsychological testing. We expect the result of this study to provide a physiologic and anatomic underpinning for the cognitive deficits observed after one or more concussions in different at-risk groups. Such information should enable the development of better guidelines for return to play, school, or work. The results of this study also will help determine which medications or other therapies are most likely to benefit victims of concussion in subsequent therapeutic trials.

BECKER, J. T.

ACTIVE

5 K02 MH01077-08 (Becker) 7/1/99 - 6/30/04
NIMH \$73,140
Natural History of Dementia

%

The data gathered from this project will address the question on how the HIV virus affects higher thought processes and why there is individual variation in the behavioral effects.

5 R01 MH45311-12 (Becker) 8/1/98 - 7/31/03
NIMH \$193,637
HIV-I Related Neuropsychological Abnormalities

%

The Allegheny Neuropsychiatric Survey (MH43511) investigates the neuropsychological, psychosocial, and neurological consequences of HIV infection and AIDS among community residents seeking primary medical care.

5 R01 AG15928-02 (Kuller) 9/30/98 - 7/31/02
NIA \$41,589
Cognitive Tests, ApoE, Brain MRI and Risks of Dementia

%

We propose to test the hypothesis that MRI changes, including infarct-like lesions are associated with increased risk of dementia.

1 R01 AG20098-01 (Lopez) 4/1/02 - 2/28/07
NIA \$308,210
Alzheimers Disease in Mild Cognitive Impairment

%

This study focuses primarily in early detection and modification of progression in AD and disability, and raises

the question of whether we can improve the identification of individuals in the earliest stages of AD.

1 R01 HD42386-01 (Marion)	9/25/01 - 8/31/06	%
NIA	\$367,704	
fMRI and Sports-Related Concussion		

To determine which medications or other therapies are most likely to benefit victims of concussions in subsequent therapeutic trials.

5 P50 AG05133-18 (DeKosky)	6/1/00 - 3/31/05	%
NIA	\$193,598	
ADRC--Administrative Core		

The Administrative Core provides the organizational structure and leadership for planning and implementation of all activities directed toward the fulfillment of the ADRC aims.

5 P50 AG05133-18 (DeKosky)	6/1/00 - 3/31/05	%
NIA	\$235,813	
ADRC-Clinical Core		

The clinical core will perform clinical and research evaluations at the study entry and at annual follow-up of patients with AD and related dementias and control subjects participant in the ADRC.

EDDY, W. F.
ACTIVE

1 PO 1 HD35496-1 (Minshew)	6/1/97 - 5/31/02	%
Source: University of Pittsburgh (NICHD)	\$172,076 project year five	
Title: Behavioral and fMRI Studies of Cognition and Autism		

The major goals of this project are: to provide statistical support for the various projects and to develop new, relevant statistical methods.

2-5-20412 (Thulborn)	7/1/97 - 6/30/02	%
Source: University of Illinois at Chicago (NIH)	\$52,724 project year five	
Title: Core C: Computing and Statistical Methods Component		

The major goals of this project are: to develop robust software encompassing interactive and detailed analyses of fMRI data.

DMS-9819950	1/1/99 - 12/31/03
Source: NSF	\$472,352 annual average of 1 st 3 years
Title: VIGRE-Vertical and Horizontal Integration of Research and Education in	

The major goals of this project are: to develop a joint vertically integrated program of education and research focusing on preparation for academic careers including training in both cross-disciplinary research and teaching.

Pending Support

Pending Support

OVERLAP: NONE

BOADA, F.E.
ACTIVE

R01HL64205-01(Boada)	1/18/00	12/31/02	%
National Institutes of Health		\$122,043.00	
Methodology for In Vivo 3D Triple Quantum Sodium MRI			

Normal cells maintain a relatively low intra-cellular sodium concentration (10-40mM) against a large sodium pool in the extra-cellular space. The large concentration gradient that develops across the cell membrane is critically important for...

1 R21 MH61472-01(Stenger)	5/15/00	4/30/02	%
National Institutes of Health		\$75,000.00	
Tailored RF Pulses for Reducing Artifacts in fMRI			

The purpose of this R21 proposal is to develop tailored Radio Frequency (RF) pulse methodology for the mitigation of magnetic field inhomogeneity artifacts in gradient echo (GE) functional MR imaging.

1R21CA87805-01(Boada)	7/1/00	6/30/02	%
National Institutes of Health		\$100,000.00	
Assessing Tumor Malignancy In Vivo Using Sodium MRI			

This exploratory proposal is aimed at exploring the relationship between triple-quantum filtered sodium signal intensity and tumor malignancy in vivo using a pool of high and low grade biloma patients undergoing treatment at the Pittsburgh Cancer Institute.

(Jones)	4/1/01	3/31/05	%
National Institutes of Health		\$59,273.00	
Sodium Accumulation During Ischemia			

This proposal addresses the problem posed by a stroke victim who is a candidate for thrombolysis, but whose onset time is not known. A sizeable fraction of patients fall into this category, estimated in several studies to be from 20 to 45%. Using experimental stroke models and external factors, we propose to define, understand, and validate a system to estimate the time after stroke onset.

5R01Dk49200-07(Kelley) 7/1/01
National Institutes of Health
Effects of Obesity on Muscle FFA Utilization (David Kelley)

6/30/02
\$12,797.00

5 R01 HD42386-02
%

The purpose of this research project is to study the efficacy of exercise alone and in combination with a weight loss program for improving the capability of skeletal muscle for the utilization of fatty acids in obesity.

1R01HD42386-07(Marion) 9/1/01
National Institutes of Health
fMRI and Sports-Related Concussion (Marion)

8/31/06
\$52,959.00

%

2P50 AG05133 4/1/01
National Institutes of Health
ADRC Neuroimaging Core

3/31/02
\$61,761.00

%

The Neuroimaging Core will provide support for all neuroimaging studies performed on AD and related dementias by ADRC and ADRC-associated investigators.

PENDING

Pending Support

Pending Support

Pending Support

Pending Support

cerebral artery (MCA) occlusion.

Pending Support

Pending Support

Pending Support

OVERLAP: NONE

LOVELL, M.R.
NONE

COLLINS, M.W.
NONE

FIELD, M.
NONE

ANDY STENGER
ACTIVE

2R01 NS32756-06	(Boada)	2/1/99 1/31/02	%
National Institutes of Health		\$43,261.00	
Rapid Whole-Brain Functional MR Imaging (Boada)			

This is a subcontract to the University of Michigan to enhance and evaluate methods for functional magnetic resonance imaging (fMRI) that are capable of high temporal resolution spatial resolution and whole brain coverage.

1 R21 MH61472-01	(Stenger)	5/15/00 4/30/02	%
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National Institutes of Health \$75,000.00
 Tailored RF Pulses for Reducing Artifacts in fMRI

The purpose of this R21 proposal is to develop tailored Radio Frequency (RF) pulse methodology for the mitigation of magnetic field inhomogeneity artifacts in gradient echo (GE) functional MR imaging.

5R01MH47074-08 (Stenger) 6/6/97 5/31/02 %
 National Institutes of Health \$23,618.00
 Mechanisms of Context Processing in Schizophrenia (Cohen)

This project takes an integrated approach to studying the cognitive and neurobiological disturbances associated with schizophrenia and the relation between these.

(Fiez) 7/1/00 6/30/05 %
 National Institutes of Health \$63,131.00
 Articulatory/Phonological Processes in Working Memory

1R01HD42386-07 (Marion) 9/1/01 8/31/06 %
 National Institutes of Health \$52,959.00
 fMRI and Sports-Related Concussion (Marion)

PENDING

Pending Support

Pending Support

Pending Support

Pending Support

Pending Support

OVERLAP: NONE

PROGRESS REPORT SUMMARY

GRANT NUMBER
5 R01 HD42386-02

PERIOD COVERED BY THIS REPORT

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
Donald W. Marion, M.D.

FROM
09/25/01

THROUGH
8/31/02

APPLICANT ORGANIZATION
University of Pittsburgh

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
FMRI & Sports Related Concussion

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects No Change Since Previous Submission Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals No Change Since Previous Submission Change

(SEE INSTRUCTIONS)

Has there been a change in the other support of key personnel since the last reporting period?

See other support pages included.

Will there be, in the next budget period, significant rebudgeting of funds from what was approved for this project?

No.

Will there be, in the next budget period, a change in the level of effort for key personnel from what was approved for this project?

No.

Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?

No.

Funding for the study began in September of 2001. The overall specific aims for our project are to (1) describe fMRI patterns of brain activation that typically occur with specific cognitive deficits identified using a traditional (n-back) and a new (Impact) test of neuropsychological function in victims of sports-related concussion, (2) describe typical fMRI activation associated with subjective components of sports-related concussion and post-concussion syndrome, (3) determine the effect of multiple sports-related concussion on cognitive function and fMRI activation, (4) define gender and age effects on concussion related changes in fMRI activation and cognition, and (5) correlate concussion related fMRI, cognitive, and symptomatic changes with academic performance. We plan to study 250 high school and college athletes over the next five years in order to address these specific aims.

During our first nine months of funding, our primary focus has been on the hiring of two key people: Kristen Hawn was hired in November to be the project administrator. She has a background in college athletic training and has worked for several years with one of our co-investigators, Dr. Lovell. Since starting, she has held monthly investigator meetings to work out details of the project and she has been very active in advertising our program to all of the major high schools and colleges in the region. She has spent a great deal of time developing close relationships with the trainers of all of these sports teams and has developed methods for assuring that she is notified if and when they have a concussed athlete. Ms. Hawn has also become familiar with all aspects of this study, including obtaining of the fMRI scans. She has worked out details of not only recruitment, but also

transport of patients between the testing sites. Together with the Principal Investigator (Dr. Marion), Ms. Hawn was very helpful in formulating our application for the Investigational Review Board at the University of Pittsburgh. We finally obtained approval from our IRB on January 28, 2002.

The second person we hired was Rebecca Roush. This person was hired as our fMRI Processing Technician. She recently graduated from the University of Pittsburgh with a degree in computer science and has already spent internship time working with our fMRI co-investigator, Dr. James Becker. Ms. Roush will primarily be stationed in the fMRI scanning suite and will not only be responsible for initial processing of the raw fMRI data, but also for quality assurance in the suite. She will pay particular attention to assuring that each of the activation protocols is adhered to and assure consistency not only within patients, but among patients.

We currently are in the final phases of completing the modified symbol matching activation task which will be used in conjunction with the n-back as our fMRI stimulus. Verification of the study task and comparison with the results of the n-back have already been completed. Our next step will be to test this among several normal volunteers and ultimately several concussed athletes. This will take place in the next six to eight weeks.

As of February of this year, we have enrolled four individuals, three males and one female, all who acted as controls in the study. It is not intended that these individuals or six more that we will study will be included in the final protocol since they are essentially pilot individuals who have served to help us refine our system of enrollment, psychological testing at the Sports Medicine Institute, transport to the fMRI facility, and conduct of the fMRI studies. We are working very hard, however, to finalize these protocols so that beginning on August 15th, during the football season, we will be able to enroll 2 to 4 patients per week, each week, through the end of football season and subsequent to that. We have contacted all high school and college football teams in the region and have assurances from those teams that they will, in fact, refer their patients with concussion. We will have a seasonal "kick-off" meeting and concussion conference in late July, which is an annual conference we have had for a number of years and is widely attended by athletic trainers throughout the region. We also are planning to place posters in local emergency departments to advertise our study and indicate the numbers to call. Finally, we have sent brochures to all athletic departments in the region with attachments describing our study.

In summary, progress on this proposal has been slightly slower than expected, but key elements of the study are currently in place and we anticipate that the next year will see substantial enrollment toward our specific aims.

GENDER AND MINORITY INCLUSION					STUDY TITLE		
Provide the number of subjects enrolled in the study <i>to date</i> (cumulatively since the most recent competitive award) according to the following categories. (See Page 8 for definitions.) If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations which are included in the study.					FMRI & Sports Related Concussion		
	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	TOTAL
Female					1		1
Male					3		3
Unknown							
TOTAL					4		4

Marion, Donato, w.

Inclusion Enrollment Report Table

This report format should NOT be used for data collection from study participants.

Study Title: fMRI & Sports-Related Concussion

Total Enrollment: 4

Protocol Number: _____

Grant Number: 1 RO1HD42386-01

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino	1	3		4
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	1	3		4 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	1	3		4
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*	1	3		4 *
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

GRANT NUMBER
5 R01 HD42386-02

CHECKLIST

1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS (See instructions.)

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/ certifications are provided in Section III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

- Debarment and Suspension •Drug- Free Workplace (*applicable to new [Type 1] or revised [Type 1] applications only*); •Lobbying •Non-Delinquency on Federal Debt •Research Misconduct •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690) •Sex Discrimination (Form HHS 639-A or HHS 690) •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and Human Gene Transfer Research •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

- Human Subjects •Research Using Human Embryonic Stem Cells •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy •Vertebrate Animals

3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS

F&A costs will **not** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

- DHHS Agreement dated: 3/30/01 No Facilities and Administrative Costs Requested.
- No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base \$ 320,709 x Rate applied 49.5/49 % = F&A costs \$ 158,484
 Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

- Salary and wages base Modified total direct cost base Other base (*Explain*)
- Off-site, other special rate, or more than one rate involved (*Explain*)

Explanation (*Attach separate sheet, if necessary.*):

PERSONNEL REPORT

GRANT NUMBER

5 RO1 HD42386-01

Place this form at the end of the signed original copy of the application. Do not duplicate.

All Key Personnel for the Current Budget Period

Name	Degree(s)	SSN	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
✓ Donald W. Marion	M.D.	SSN	P.I.	DOB	%
Mark R. Lovell	Ph.D.		Co-Investigator		
Michael W. Collins	Ph.D.		Co-Investigator		
James Becker	Ph.D.		Co-Investigator		
Fernando Boada	Ph.D.		Co-Investigator		
V. Andrew Stenger	Ph.D.		Co-Investigator		
Melvin Field	M.D.		Co-Investigator		
Kristen L. Hawn	M.A., ATC		Coordinator		
✓ William Eddy	Ph.D.		Consultant		
Denise Davis	B.S., R.T.	Consultant			