

Award Number: W81XWH-11-1-0831

TITLE: Application of Near Infrared Spectroscopy, Intravascular
Ultrasound and the Coronary Calcium Score to Predict Adverse
Coronary Events

PRINCIPAL INVESTIGATOR: Dr. Charles Lambert

CONTRACTING ORGANIZATION: University Community Hospital
Væ] æ Æ Ö Å H Î F H Á

REPORT DATE: October 2014

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of
the author(s) and should not be construed as an official Department of the
Army position, policy or decision unless so designated by other
documentation.

REPORT DOCUMENTATION PAGE		<i>Form Approved</i> <i>OMB No. 0704-0188</i>
<small>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</small>		
1. REPORT DATE October 2014	2. REPORT TYPE Annual	3. DATES COVERED 25-SEP-2013 to 25-SEP-2014
4. TITLE AND SUBTITLE Application of Near Infrared Spectroscopy, Intravascular Ultrasound and the Coronary Calcium Score to Predict Adverse Coronary Events		5a. CONTRACT NUMBER
6. AUTHOR(S) Dr. Charles Lambert		5b. GRANT NUMBER Y FYY P F F F F H F
E-Mail: etno.dgt@o.gtaq		5c. PROGRAM ELEMENT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University Community Hospital 3100 East Fletcher Ave Tampa, Florida 33613		5d. PROJECT NUMBER
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
		8. PERFORMING ORGANIZATION REPORT NUMBER
		10. SPONSOR/MONITOR'S ACRONYM(S)
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited		11. SPONSOR/MONITOR'S ACRONYM(S)
13. SUPPLEMENTARY NOTES		
14. ABSTRACT Final IRB approval was granted effective July 15, 2013. Patient screening, enrollment and data acquisition is ongoing. Additional co-investigators have been added to the study including James Smith, MD, Vasco Marques, MD, Mohammed Tabesh, MD, Jordan Hopkins, MD, Asad Sawar, MD, Alex Michel, MD, Faisal Shaikh, MD and Hesham Fakhri, MD. 79 patients have been screened for the study. 24 patients were subsequent screen failures. Thirteen patients have completed enrollment and imaging. One SAE, unrelated to the study, was reported to the IRB. Study operation continues as planned.		
15. SUBJECT TERMS coronary artery disease, near infrared spectroscopy, calcium scoring, intravascular ultrasound		
16. SECURITY CLASSIFICATION OF:		

			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS	UU	15	USAMRMC
U	U	PAGE U			19b. TELEPHONE NUMBER <i>(include area code)</i>

Table of Contents

	<u>Page</u>
Introduction.....	5
Body.....	6
Key Research Accomplishments.....	11
Reportable Outcomes.....	11
Conclusion.....	11
References.....	12
Appendices.....	12

Introduction

The aim of the present project is to

1. Utilize near infrared intra-coronary spectroscopy as an adjunctive technique during cardiac catheterization to identify potential vulnerable plaque morphology
2. Relate its presence to intermediate and long-term outcomes in patients defined as angina, myocardial infarction, death, congestive heart failure, stroke and need for revascularization over five years.
3. To compare near infrared intra-coronary spectroscopy data to that from coronary calcium scoring, angiographic findings and intracoronary ultrasound in predicting those outcomes in #2.

Body

Revision and review of the original protocol was followed by institutional review board approval of the protocol with final informed consent revision effective on July 15 2013.

Data for run-in patients were previously described.

Subsequently, additional co-investigators have been added to the study including James Smith, MD, Vasco Marques, MD, Mohammed Tabesh, MD, Jordan Hopkins, MD, Asad Sawar, MD, Alex Michel, MD, Faisal Shaikh, MD and Hesham Fakhri, MD.

Improved catheters and console components were obtained in January 2014 and retraining was completed.

Test calcium scoring was performed and active patient recruitment was begun.

Key Research Accomplishments

79 Patients have been screened for the study following the initial run-in patients included in the prior report:

6/12/14	Smith	RCA stent, LAD small with 70% lesion poor target, Circ too tortuous
12-Jun-14	Smith	Declined
6/12/2014	Tabesh	PreOp for surgery
6/19/14	Smith	screen failed in cath lab
6/19/14	Smith	Approached to consent enrolled
6/19/14	Smith	Approached to consent then enrolled
6/20/14	Marques	Not good candidate multiple problems
6/24/14	Smith	Cancelled cath
6/18/14	Smith	screen failed in cath lab
6/25/14	Smith	Approached to consent then screen fail in cath lab
7/9/14	Smith	Approached to consent then screen fail in cath lab
7/9/14	Smith	Approached to consent then screen fail in cath lab
7/25/14	Smith	Declined all research
7/16/14	Tabesh	No IVUS targets due to bypass grafts, small vessels and severe disease
8/6/14	Smith	
8/6/14	Smith	
8/6/14	Smith	
8/1/14	Smith	Spanish speaking only
7/30/14	Smith	screen failed in cath lab
7/31/14	Smith	extremely anxious
7/30/14	Smith	life expectancy less than 3 years
7/22/14	Marques	PreOp for surgery
7/22/14	Smith	life expectancy less than 3 years
7/21/14	Sawar	signed consent Dr Sawar decided not to use NIRS despite good targets
7/21/14	Smith	canceled due to family emergency
7/21/14	Smith	screen failed in cath lab
7/21/14	Marques	enrolled
7/23/14	Tabesh	Spanish speaking only
7/25/14	Tabesh	PreOp for surgery
7/23/14	Tabesh	at last minute MD switch to nonDOD MD
8/14/14	Tabesh	preOp for surgery
8/13/14	Marques	preOp for orthopedic surgery no CAD right heart for valve issues
8/12/14	Marques	declined due to moving in 2 weeks to Nebraska has too much going on
8/11/14	Tabesh	PreOp for surgery
8/11/14	Marques	consented for study and at last minute MD change in cath lab to nonDOD MD
8/14/14	Tabesh	life expectancy less than 3 years
8/21/14	Tabesh	life expectancy less than 3 years
8/22/14	Tabesh	PreOp for surgery
8/22/14	Marques	respiratory and valve issues, multiple medical problems
8/22/14	Marques	life expectancy less than 3 years
9/12/14	Tabesh	just prior to cath MD changed to nonDOD MD
9/10/14	Marques	just prior to cath MD changed to nonDOD MD
8/27/14	Smith	poor historian, s/p current surgery, wound center for active ulcers other complications
8/27/14	Tabesh	preOp for surgery
9/4/14	Smith	life expectancy less than 3 years, very advanced age
9/3/14	Marques	just prior to cath MD changed to nonDOD MD
9/4/14	Marques	Spanish speaking only
9/3/14	Hopkins	declined
9/10/14	Smith	advanced age, no targets for imaging due to bypass grafts and several stents
10/1/14	Hopkins	life expectancy less than 3 years very advanced age
10/3/14	Marques	no IVUS targets due to bypass grafts, stents
10/3/14	Tabesh	no IVUS targets due to bypass grafts, stents
9/30/14	Tabesh	insufficient time to consider research, discuss, read consent prior to cath
10/1/14	Hopkins	declined due to other health issues
9/18/14	Marques	very advanced age
9/22/14	Hopkins	very advanced age
10/7/14	Shaikh	no targets to image
10/22/14	Smith	no targets due to prior CABG, and small vessels
10/23/14	Smith	advanced age
10/24/14	Tabesh	no targets due to prior CABG, and small vessels
10/28/14	Marques	Not good candidate multiple problems
10/24/14	Tabesh	canceled Dwight Walker
10/20/14	Smith	stents in all vessels
10/14/14	Smith	declined
10/14/14	Marques	declined
10/14/14	Gangadharan	preop for TAVR surgery, very advanced age
10/8/14	Marques	Acute TIA
10/3/14	Marques	case done unexpectedly earlier than scheduled
10/31/14	Fakhri	case canceled
10/30/14	Smith	consented for peripheral study
10/8/14	Smith	no superuser working at all no rep on site
10/15/14	Smith	case canceled
11/4/14	Gangadharan	Spanish speaking only
11/6/14	Tabesh	existing RCA proximal stent, no CAD other vessels
11/7/14	Marques	advanced age, several med issues, visual impairment
11/12/14	Gangadharan	Spanish speaking only
11/12/14	Tabesh	life expectancy, age
11/13/14	Smith	Very advanced age
11/12/14	Gangadharan	no targets, CABG

22 Patients were subsequent screen failures:

Date of SCREEN FAIL:	Sub-I MD:	Reason for SCREEN FAIL:
6/19/14	Smith	Radial artery too small to accommodate NIRS catheter
6/26/14	Smith	RCA stent mid vessel, LAD CTO proximal in vessel, Circ too small
7/10/14	Smith	Unable to torque and advance NIRS catheter in vessel
7/10/14	Smith	no CAD
7/22/14	Smith	no CAD
7/22/14	Sawar	Md dd not want to use NIRS
7/25/14	Tabesh	CABG consult no targets to image
7/31/14	Smith	no CAD
7/31/14	Smith	no CAD
8/7/14	Smith	no CAD to image
8/11/14	Marques	just prior to cath MD changed to nonDOD MD Dr Fakhri
8/28/14	Smith	no CAD
9/3/14	Marques	disease too distal in vessels
9/11/14	Hopkins	no CAD
9/18/14	Smith	no CAD
9/30/14	Marques	severe 3 vessels disease no targets for IVUS
10/1/14	Hopkins	no disease
10/9/14	Tabesh	existing stent and in other vessels Md did not want to expose pt to anticoag isk
10/16/14	Smith	LAD stent MD said no disease on visual in other vessels
10/17/14	Gangadharan	myocardial bridging no disease to image
10/23/14	Marques	no CAD, non ischemic CM
10/30/14	Smith	prior positive coronary CT, stenosed diagonal no CAD Circ RCA LAD
11/6/14	Michel	Case scheduled for 1200, MD started at 1500, MD said he did not have time to NIRS for study
11/7/14	Tabesh	RCA totoally occluded, Circ too small, LAD too tortuous

14 Patients completed all imaging and are enrolled for long term follow-up:

6/19/14	Smith	1	RCA
6/20/14	Smith	2	RCA, LAD
6/26/14	Smith	1	RCA
7/10/14	Smith	1	RCA
7/24/14	Marques	2	LAD, CIRC
9/4/14	Smith	1	LAD
9/8/14	Hopkins	1	LAD
9/24/14	Shaikh	2	LAD, Ramus
10/6/14	Hopkins	1	RCA
10/6/14	Marques	2	LM, CIRC
10/7/14	Smith	1	RCA
10/10/14	Marques	2	LAD, RCA
10/23/14	Gangadharan	1	LAD
11/13/14	Smith	1	RAC

Reportable Outcomes

Data are being accrued.

Conclusion

Near infrared spectroscopy and simultaneous intravascular ultrasound images can be obtained safely in patients. Using these technologies make identification of vulnerable plaques possible the current study valuable as defined in the statement of work.

References

None

Appendices

6 Month Interim IRB Review



Investigator's Progress Report

Continuing Review / Interim Report /
Final Report of Research

Florida Hospital Tampa Bay Division IRB

Full Board Continuing Review Instructions:	Expedited Continuing Review Instructions:
<p>Submission deadline: All Part A & B documents due on the 1st of the month for review on the 3rd Tuesday.</p> <p>All documents are to be submitted under (2) separate Part A & B email attachments or 17 collated paper copies.</p> <p>Ensure all documents and revisions are clearly identified, and in the following order:</p>	<p>If <input type="checkbox"/> the protocol is permanently closed to the enrollment of new participants, <input type="checkbox"/> all participants have completed all research-related therapy / interventions (labs, x-rays, etc.), and the <input type="checkbox"/> research remains active only for long-term follow-up of participants; -OR- <input type="checkbox"/> No participants have been enrolled and no additional risks have been identified; -OR- <input type="checkbox"/> The remaining research activities are limited to data analysis only; your continuing review may be eligible for Expedited Review (45 CFR 46.110). Expedited submissions may be submitted at any time via Email or 3 paper copies to the IRB.</p>
<p>Final Report Instructions: If the project is complete, submit this form and check "Final Report - Termination Requested". The form must be completely filled out, and any publications and/or data analysis reports included with the submission.</p>	
<p>Part A <input checked="" type="checkbox"/> #1. - Continuing Review Application filled out completely, and signed. Please note that blanks and/or insufficient information may result in a delay of your review/approval.</p>	

Contact Information

Today's Date: 31 Oct 2014	Date of Initial Review: 17Jul2012	Date of Last Continuing Review: 13 Jun2014	Date Last Seen by the IRB: 13Jun2014	
Type of Submission:	<input type="checkbox"/> Continuing Review	<input checked="" type="checkbox"/> Interim Report	<input type="checkbox"/> Final Report – Termination requested	
Type of Review Requested:	<input checked="" type="checkbox"/> Full Review	<input type="checkbox"/> Expedited Review		
Protocol Information:	Title: <i>Proposal 10169004 - Application of Near Infrared Spectroscopy, Intravascular Ultrasound and the Coronary Calcium Score to Predict Adverse Coronary Events</i>			
	Protocol #: 5/2012	Protocol Version (current): 5/2012		
Study Type:	<input type="checkbox"/> Device	IDE #:	Phase#:	
	<input type="checkbox"/> Drug	IND #:	Phase #:	
	<input type="checkbox"/> Post Market Approval Study	<input type="checkbox"/> Registry	<input checked="" type="checkbox"/> Prospective Data Review	<input type="checkbox"/> Retrospective Data Review
	<input checked="" type="checkbox"/> Investigator Initiated Study			
	*Please describe type of trial: <i>Prospective Data Review</i>			
	<input type="checkbox"/> Other (please describe):			
Principal Investigator:	Charles Lambert, MD, PhD			
Primary Contact:	Yvonne Gopsill, RN, BSN, CCRC	E-mail:	Yvonne.Gopsill@ahss.org	
Telephone:	56517	Fax:	57574	

Current Status of Project (check only one):

Part A <input checked="" type="checkbox"/> #2.	Please summarize activity for all study types. *For data review studies, summarize the number of charts, etc, that were reviewed.
--	--

* No participants on therapy or in follow-up, no data collection being done, and no data queries being resolved.

Interim Cont Review DOD 31Oct20143

<input type="checkbox"/> Study has not yet begun		<input type="checkbox"/> No participants entered	
<input checked="" type="checkbox"/> Currently in Progress		Number of participants enrolled:	13
<input type="checkbox"/> Closed to participant enrollment (remains active)		Enrollment Summary:	
Are study interventions (labs, x-rays, etc.) complete? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		On active therapy/interventions:	13
		Long term follow-up – therapy/interventions completed:	0
		Follow-Up complete (study in data analysis only):	0
Summary of Transfer Patients:		Withdrawal Summary:	
Subjects Transferred In:		Subject withdrawn by PI:	0
Subjects Transferred Out:		Subject withdrew from study:	0
Previously reported to the IRB? <i>*If no, please summarize in comments</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Reached End Point – Exited From Study:	0
		Other: <i>Describe:</i>	n/a
<i>Note: numbers should be recorded in applicable enrollment summary category</i>		Total : <i>*Should match number of participants enrolled</i>	13
		Number of Death's	0
<input type="checkbox"/> Termination Requested – Site Closure: Study remains open, but site closed/withdrawn. Reason for Closure:			
<input type="checkbox"/> Termination Requested – Study Closure: No further subject accrual or data analysis / collection.			
Comments related to project status: <i>The study is not closed to enrollment.</i>			

Summary of Informed Consent

Part A <input checked="" type="checkbox"/> #3. Informed Consent with any proposed Tracked Changes.[†]	
<input checked="" type="checkbox"/> Informed Consent Form (no change):	<input type="checkbox"/> ICF with footer Version change only: <i>*changed to reflect the current protocol version</i>
<input type="checkbox"/> New Revised Informed Consent Form	<input type="checkbox"/> Other, (specify):
❖ If including a revised informed consent form, please provide a summary of the revisions (<i>*required</i>):	
❖ Are the informed consent revisions related to changes in the protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>*If yes, please explain:</i>	
❖ Do the informed consent changes affect patient safety? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>*Please explain:</i>	
❖ Will study participants be re-consented? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>*If yes, please describe at what point they will be re-consented:</i>	
Comments:	

Summary of Individuals Screened, Entered and Withdrawn at the Florida Hospital Tampa Bay Division site(s) only

Part A <input checked="" type="checkbox"/> #4. Summary of: Subject enrollment <i>*Required for all study types, including retrospective chart reviews.</i>	
Number of individuals screened for entry into study since the start of the project? <i>22 were screen fails, 13 enrolled</i>	35

[†] Consent changes must be easily identifiable to the RERB committee.

Number of individuals entered into the study since the start of the project?	13
Number of individuals withdrawn from the study since the start of the project? Describe the reason for withdrawal:	0
Number of individuals entered into the study since the last IRB review?	13
Number of individuals withdrawn from the study since the last IRB review? Describe the reason for withdrawal:	0
Comments:	

Summary of Protocol and Investigator Brochure

Part A #5. **Summary of:** Protocol changes, Investigator Brochure changes, etc., as applicable.
*A summary of changes is required for each item selected.

Has the protocol been revised since the last Continuing Review? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No *If yes, please provide a brief summary of the changes:	
Has the investigator brochure been revised since the last Continuing Review? <input type="checkbox"/> Yes <input type="checkbox"/> No *If yes, please provide a brief summary of the updates: <i>n/a</i>	
<i>If including a protocol and/or investigator brochure revision with the Continuing Review, please provide the following information:</i>	
<input type="checkbox"/> New Protocol Revision / Amendment Provide a summary of the revisions:	Current Version: New Version:
❖ Are the protocol revisions a result of new information that effects patient safety? *If yes, please explain:	<input type="checkbox"/> Yes* <input type="checkbox"/> No
❖ Do the protocol revisions require changes to the informed consent form? *If yes, please explain:	<input type="checkbox"/> Yes* <input type="checkbox"/> No
<input type="checkbox"/> Change in Protocol Personnel Describe change:	
<input type="checkbox"/> Study Enrollment Closure Reason for closure:	
Comments:	
<input type="checkbox"/> New Investigator Brochure Revision Provide a summary of the revisions:	Current Version: New Version:
❖ Do the updates include new information that effects patient safety? *If yes, please explain:	<input type="checkbox"/> Yes* <input type="checkbox"/> No
❖ Do the updates require changes to the informed consent form? *If yes, please explain:	<input type="checkbox"/> Yes* <input type="checkbox"/> No
Comments:	

Summary of Study Related Material

Part A #6. **Other:** Please select all applicable material reviewed/approved by the IRB, i.e., Advertising Material, Patient Retention Material, etc., as applicable, since the last Continuing Review.

<input type="checkbox"/> Advertising materials – no change	<input type="checkbox"/> Retention material – no change
<input type="checkbox"/> Manual of Procedures (MOP) – no change	<input type="checkbox"/> Instructions for use – no change
<input type="checkbox"/> CRF's – no change <i>Note: CRF's require IRB review if not standardized industry forms, such as investigator initiated forms used to collect data.</i>	
<input type="checkbox"/> Other – no change (<i>specify</i>):	

*If including new or revised material with the Continuing Review, please provide the following information:	
<input type="checkbox"/> New/Revised Advertising Material Provide a summary of the revisions:	
<input type="checkbox"/> New/Revised Retention Material(describe) Provide a summary of the revisions:	
<input type="checkbox"/> New/Revised Manual of Procedures (describe) Provide a summary of the revisions:	
<input type="checkbox"/> New/Revised Instructions for Use (describe) Provide a summary of the revisions:	
<input type="checkbox"/> New/Revised CRF's Provide a summary of the revisions:	
<input type="checkbox"/> Other, (specify)	
Comments:	

Part A <input type="checkbox"/> #7. Summary of: Serious Adverse Events, enrollment issues, risk changes, etc., as applicable.	
Number of adverse events (at this site) requiring submission to the IRB	0
Number of adverse events (at any site) requiring submission to the IRB	0
Any unanticipated problems involving risks to participants or others? Provide a brief explanation of unanticipated problems involving risk that occurred internally and/or externally, and explain risk issues that prompted Informed Consent, Protocol, or Investigator Brochure revisions: *Include any relevant reports, literature, etc.	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Any problems obtaining informed consent? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Any problems with enrollment? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Have any participants or others complained about the research? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Have any obvious, study-related benefits occurred for participants? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Have any risks or potential benefits for this research changed? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
<input type="checkbox"/> Other, (specify):	
Comments:	

Since the last IRB review, have you received any of the following types of information?

Part A <input checked="" type="checkbox"/> #8. Multi-center trial reports, Data and Safety Monitoring Board reports, Interim findings, Published literature, etc.	
Multi-center trial reports? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Data and Safety Monitoring Board reports? (please include reports that have not been previously reported to the IRB)	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Interim findings? If yes, please summarize (include relevant documents):	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Published literature? Previously submitted to the IRB? (If no, please include literature not previously reported to the IRB)	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
Any other relevant information regarding this research, especially information about risks?	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No

Interim Cont Review DOD 31Oct20143

If yes, please summarize:	
Could any of the information described above relate to the participants' willingness to continue participating? If yes, please summarize:	<input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No
<input type="checkbox"/> Other, (specify)	
Comments: <i>Study is only being conducted at this site.</i>	

Submission deadline: All Part B documents due on the 1st of the month for full board review on the 3rd Tuesday. All documents are to be submitted under separate Part B email attachment or 3 collated paper copies. Ensure all documents and revisions are clearly identified, and in the following order:	
Part B <input checked="" type="checkbox"/> #1.	"Current Version" of the Informed Consent in use, <i>showing the IRB stamp.</i> / Paper Copy = 1 Copy
Part B <input type="checkbox"/> #2.	"Clean" Informed Consent incorporating all changes and with 1.5" footer margin to accommodate new IRB stamp. <i>ONLY a current stamped version is approved for patient use.</i> / Paper Copy = 2 Copies Note: Investigator Initiated studies should include a description of the consent process in the study protocol
Part B <input type="checkbox"/> #3.	Full Versions of any and all: New full protocol incorporating all changes, New complete Investigator Brochure incorporating all changes, New complete Manual of Procedures (MOP) incorporating all changes, etc., as applicable. / Paper Copy (if revised) = 3 Full Version Copies



 Signature of Principal Investigator



 Date

Review Details

[489208-4] DOD "Application of Intracoronary NIRS, IVUS and Coronary Calcium Score to Predict Adverse Corona
Florida Hospital Tampa Bay IRB, Tampa Bay, FL

Submission Details	
Submitted To	Florida Hospital Tampa Bay IRB, Tampa Bay, FL
Submitted by	Yvonne Gopsill
Submission Date	11/03/2014
Submission Type	Continuing Review/Progress Report
Local Board Reference Number	2012-018

Review Details:

Agenda	Review Type	Board Action	Effective Date	Project Status	Expiration Date
11/18/2014 12:00 PM	Full Committee Review	Acknowledged	11/18/2014	Active	06/13/2015