Palmetto Health Administrative Research Review (PHARR) Process and Financial Conflict of Interest

RESEARCH TODAY...HOPE FOR TOMORROW | PALMETTO HEALTH

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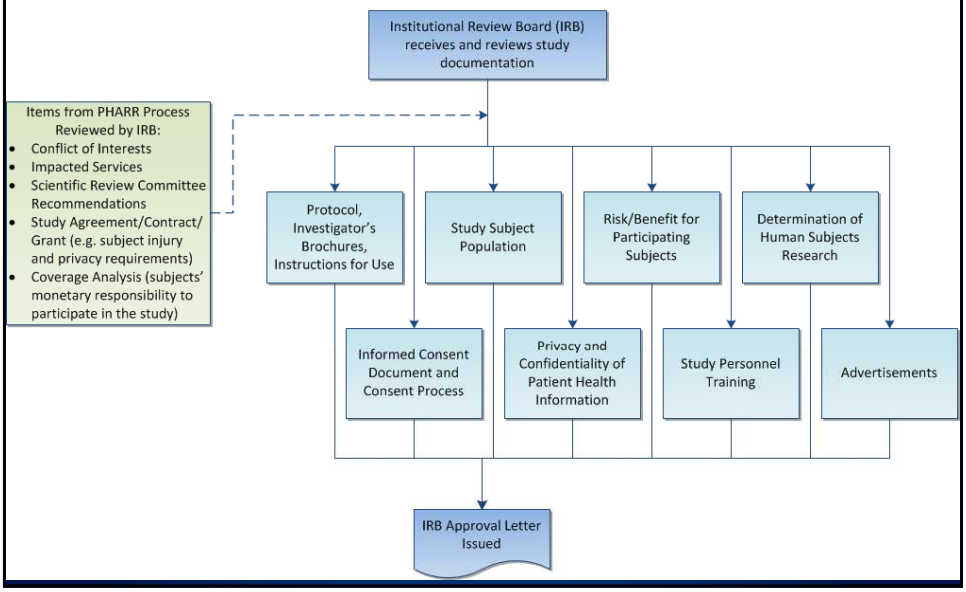
Director, Research

May 17, 2012

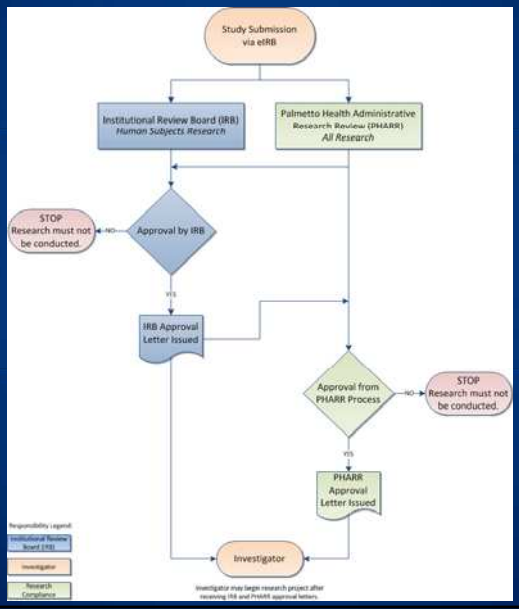
Objectives

- Introduction of Palmetto Health Administrative Research Review (PHARR) process
- Review of the PHARR form
- Review of other PHARR processes
- Review of the new Financial Conflict of Interest policy and form

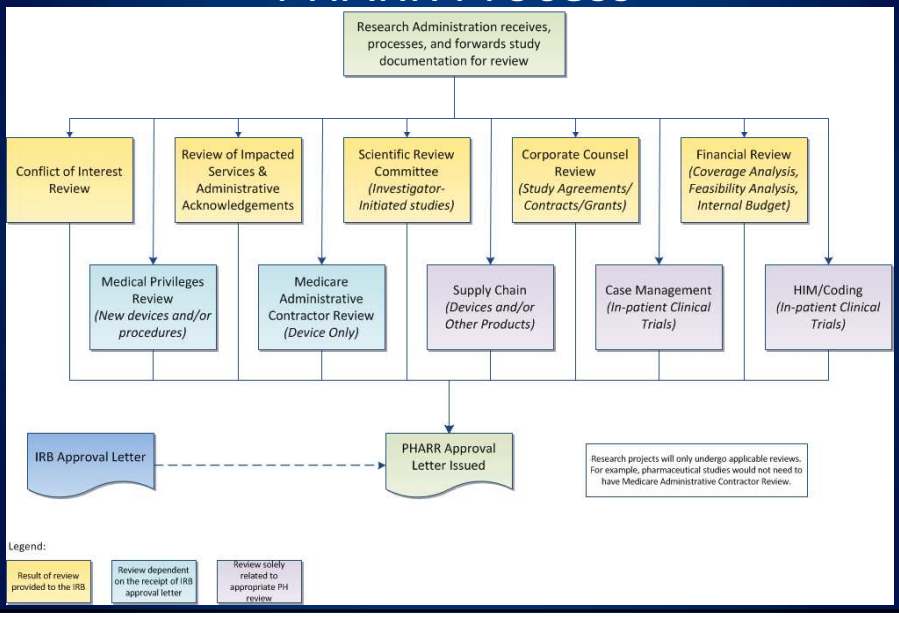
Institutional Review Board (IRB) Process



Addition of the PHARR Process

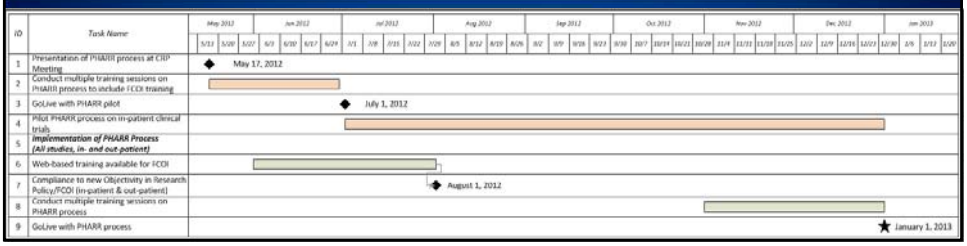


PHARR Process



PHARR Rollout

- July 1, 2012 – All new in-patient clinical trials
- August 1, 2012 – All research personnel (and their spouses and dependent children) must complete the Research Financial Disclosure Statement
- January 1, 2013 – All new studies



Research Compliance Website

- Go to www.palmettohealth.org
- Education, Residency Programs & Research
- Research Division
- Compliance

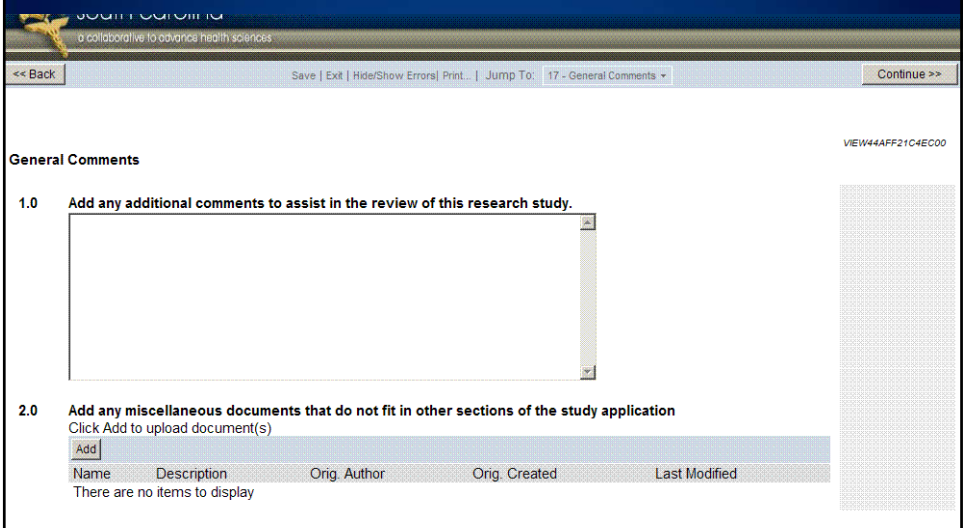
- All policies/procedures, forms, training information, etc. will be found on this website.

PHARR FORM

Overview of PHARR Form

- Must be completed and submitted into eIRB when study is initially submitted for review
- Requested attachments must also uploaded into eIRB

eIRB



- Submit PHARR form and attachments into eIRB

Study Identifiers

SECTION I. STUDY IDENTIFIERS
Short Title:
Investigator:
IRB Pro Number:
Clinical Trials Number, if applicable (8 digits, can be found at www.clinicaltrials.gov):

NIH/PHS Assurance

SECTION II. NIH/PHS PRINCIPAL INVESTIGATOR ASSURANCE *(Complete if study is funded by NIH/PHS.)*		
NIH/Award/Application Number (if known):		
Type of Submission: ☐ Application ☐ Post Submission Information	☐ Progress Report ☐ Post Award Approval Request	
If the study is funded by NIH, is PH the prime or subawardee organization?	Yes ☐	No ☐
If YES, the Principal Investigator(s) must sign the NIH/PHS Acknowledgement in Section X.		

- Skip section if study is not sponsored by NIH/PHS.
- If Palmetto Health receives a subaward from USC who is a subawardee of the prime awardee institution, mark “YES”.

Investigator-Initiated Research

SECTION III. INVESTIGATOR-INITIATED RESEARCH *(Complete if research proposal was created/written by a local investigator.)*		
Is the research likely to result in publication or presentation?	Yes ☐	No ☐
Is the research likely to lead to an invention?	Yes ☐	No ☐
Research design ☐ Observational (Check on of the following): ☐ Prospective (Example: survey research) – *Proceed to Section VII* ☐ Retrospective (Example: medical record review) – *Proceed to Section VII* ☐ Interventional (Subjects will be assigned to treatments) – *Proceed to Section IV* ☐ Interventional (Educational testing only) – *Proceed to Section VII*		

- Skip section if the study is not investigator-initiated.
- Investigator-initiated studies: protocols written by local investigators
- Type of study directs you to the next section that needs to be completed. You do not need to answer questions in the sections that are skipped.

Drug Studies

SECTION IV. DRUG STUDIES *(Complete for any studies involving drugs.)*					
If this clinical trial is a postmarketing study (Phase IV), please indicate type:					
☐ Postmarketing Requirement (PMR)		☐ Postmarketing Commitment (PMC)			
List all drugs under investigation and include the IND numbers, if applicable. Indicate whether the drug(s) are supplied by the Sponsor and whether they are supplied at no cost. *(Attach additional pages as necessary.)*					
Drug Name	IND Number	Supplied by Sponsor?		Supplied at no cost?	
		Yes ☐	No ☐	Yes ☐	No ☐
		Yes ☐	No ☐	Yes ☐	No ☐
		Yes ☐	No ☐	Yes ☐	No ☐
		Yes ☐	No ☐	Yes ☐	No ☐

- Skip if study does not involve drugs.

Device Studies

SECTION IV. DEVICE STUDIES *(Complete for any studies involving device implantation/usage.)*

Indicate type of study/device:

- ☐ Humanitarian Device Exemption (HDE)
- ☐ Investigational Device Exemption (IDE)
- ☐ Non-FDA regulated study (Sponsor initiated)
- ☐ Other, specify:
- ☐ Postmarket Surveillance Study (522)
- ☐ Post-Approval Study
- ☐ Post-Approval Extension Study

List all medical devices under investigational and their IDE, HDE, 510K, or PMA numbers. Indicate whether the device(s) are supplied by the Sponsor and whether they are supplied at no cost. Also, attach a list of product numbers for all potential devices use for the study. *(Attach additional pages as necessary.)*

Device Name (Trade/common AND classification name)	Enter Appropriate Device Number					Supplied by Sponsor?	Supplied at no cost?
	IDE Number	IDE Category	HDE	510K	PMA		
	G	A ☐ B ☐	H	K	P	Yes ☐ No ☐	Yes ☐ No ☐
	G	A ☐ B ☐	H	K	P	Yes ☐ No ☐	Yes ☐ No ☐

Will patients insured through CMS be possible recipients of the device? Yes ☐ No ☐

If NO, go to Section V. If YES AND the protocol involves an HDE or IDE or if the device requires CMS pre-approval (e.g. post approval or post approval extension studies), provide the following: (Attach additional pages as necessary)

- Skip if study does not involve devices.

Device Studies - continued

- If "YES" and requires CMS pre-approval, you will need to answer the following questions:
  - Device description narrative
  - Device support information
  - List of comparable devices
  - Similarity or variance comparison for device and comparable product
  - List of physicians implanting and their NPI numbers
  - Facility where device will be implanted
  - Specify point of service (inpatient, outpatient, clinic)
  - Indicate expected CPT, HCPCS, Revenue, and/or ICD codes for claim submission
- This information is required by Palmetto GBA to get pre-approval of the device use in Medicare patients.
- Typically, these studies will be industry-sponsored, and the sponsor will be prepared to answer these questions for you.

Medical Privileges

SECTION V. MEDICAL PRIVILEGES *(Complete if study utilizes a device OR examines a procedure/therapy)*		
If procedure/therapy, describe:		
Have you already received medical privileges (credentialing) for the use of the device/performance of the procedure/therapy?	Yes ☐	No ☐
If YES, go to Section VI. If NO, continue with the remaining questions in this section.		

- Required if the study utilizes a device or examines a procedure/therapy. Skip section if not applicable.
- Information provided in this section will be reviewed by Palmetto Health's Credentialing Committee.

Medical Privileges - continued

Is the device/procedure/therapy proven clinical efficacy and effectiveness? *(Note, most IDEs/HDEs do not have proven safety and/or efficacy.)*	Yes ☐	No ☐
If YES, explain:		
Two department chiefs agree that the participation in the study/HDE is appropriate for PH?	Yes ☐	No ☐
List the names of the two chiefs:		
Will you have co-Investigators that will also be using the device/performing the procedure/therapy?	Yes ☐	No ☐
List co-Investigators names and specialties: *(Note, these co-Investigators must be listed on the Institutional Review Board application.)*		
List other institutions/hospitals/sites participating in the study/implanting of the HDE:		
Does the procedure/therapy carry a risk greater than existing conventional procedure therapy?	Yes ☐	No ☐
Is training/education provided by the sponsor/manufacturer?	Yes ☐	No ☐
If YES, describe the training/education. *(Also, provide certificates, if available.)*:		
If NO, explain why training/education is not required:		

Research Billing

SECTION VI. RESEARCH BILLING		
If the study is funded by a non-federal entity, are the payments for the services rendered for the study compensated at fair market value?	Yes ☐	No ☐
Have you requested a waiver of the requirement for written informed consent documentation and authorization for the study?	Yes ☐	No ☐
If YES, proceed to Section VII. If NO, continue with the remaining questions in this section		

- First question – related to Stark / anti-kickback statutes

Research Billing – Coverage Analysis

Answer the following questions to determine if a Coverage Analysis is needed:		
1) Will any routine or research protocol item/procedure/service be billed to the subject/subject's insurance?	Yes ☐	No ☐
2) Will any protocol item/procedure/service be performed at PH?	Yes ☐	No ☐
If YES to either (1) or (2), a Coverage Analysis must be completed. Please refer to the Coverage Analysis Creation PGR for instructions.		

- Coverage Analysis is a tool that:
  - Ensures all costs of a clinical trial are billed to the appropriate payer
  - Assists in the creation of the study budget
  - Allows appropriate wording to be included in the consent form
  - Ensures non-profit status of the hospital is maintained
- Coverage Analysis training will be available.

Research Billing – Internal Budget/Budget Feasibility Analysis

Answer the following questions to determine if an Internal Study Budget and/or a Budget Feasibility Analysis is needed:		
1) Is this research funded and/or has a request for funding been made?	Yes ☐	No ☐
2) Is the research non-funded but utilizes Palmetto Health property, facilities, equipment, or services (impacted services as identified through the Institution Review Board process)?	Yes ☐	No ☐
If YES to (1), an Internal Study Budget and Budget Feasibility Analysis is required. If YES to (2), a Budget Feasibility Analysis is required. Please refer to the Internal Study Budget Creation and Budget Feasibility Analysis PGRs for instructions.		

- Internal Budget – anticipate the costs of performing the research
- Budget Feasibility Analysis:
  - Provides a summary of the anticipated costs associated with the conduct of the study and, if funded, the negotiated budget provided by the Sponsor.
  - Provides an assessment of the profit/loss generated by the study and to determine the in-kind items/procedures/services that Palmetto Health may be providing to conduct the study
- Additional training on these topics will be available.

Qualifying Status

Answer the following questions to determine the qualifying status for insurance coverage:		
a) Does the subject or purpose of the trial evaluate an item or service that falls within a CMS benefit category (e.g. physicians' service, durable medical equipment, diagnostic test) and that is not statutorily excluded from Medicare coverage (e.g., cosmetic surgery, hearing aids)?	Yes ☐ No ☐	Indicate CMS benefit category (e.g. Drugs and Biologics):
b) Does the study have therapeutic intent?	Yes ☐ No ☐	Indicate objective of protocol (e.g. Assess the anti-inflammatory activity of [Study Drug]):
c) Does the study enroll subjects with diagnosed diseases?	Yes ☐ No ☐	Indicate disease to be treated:
d) Is this a deemed trial? *(Please note that if the study is conducted under an IDE, it is not automatically qualified even if funded by a Federal Agency.)*	Yes ☐ No ☐	Indicate why study is deemed (e.g. study sponsored by NIH):
Deemed Characteristic / **Yes** / **No** Funded by a Federal Agency (NIH, CDC, AHRQ, CMS, DOD & VA)? ☐ ☐ Supported by centers or cooperative groups funded by Federal Agencies ☐ ☐ Conducted under an IND or has an IND exemption ☐ ☐		
e) Does the study have all seven of the following desirable characteristics?	Yes ☐ No ☐	
Desirable Characteristics / **Yes** / **No** 1) Potentially improves patient health outcomes? ☐ ☐ 2) Supported by scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use? ☐ ☐ 3) Does not duplicate existing studies? ☐ ☐ 4) Designed to answer the research question? ☐ ☐ 5) Sponsored by credible organization? ☐ ☐ 6) Compliant with federal regulations relating to the protection of human subjects? ☐ ☐ 7) Conducted according to scientific standards of integrity? ☐ ☐		
f) Is this study a qualifying trial? *(To qualify, (a)-(c) must be checked YES and either (d) or (e) must be checked YES. If this is a multi-center clinical trial, the trial's lead principal investigator should be able to verify this answer.)*	Yes ☐ No ☐	

Certifications/Assurances

SECTION VII. CERTIFICATIONS/ASSURANCES		
Is any Investigator or Research Staff presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transactions by any federal department or agency?	Yes ☐	No ☐
Has any Investigator or Research Staff within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain or performing a public (federal, state, or local) transaction or contract under a public transaction; violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements or receiving stolen property?	Yes ☐	No ☐
Is any Investigator or Research Staff presently indicted for or otherwise criminally or civilly charged by a government entity (federal, state or local) with commission of any of the offenses enumerated in the preceding statement?	Yes ☐	No ☐
Has any Investigator or Research Staff within a three-year period preceding this application/proposal had one or more public transactions (federal, state or local) terminated for cause or default?	Yes ☐	No ☐

Comments/Attachments

SECTION VIII. COMMENTS
Please include any additional information necessary for the review of the study. *(Attach additional pages as necessary.)*

SECTION IX. ATTACHMENTS	
The following items, as applicable, must be submitted:	
☐ Coverage Analysis Grid	☐ Reimbursement Guide
☐ Budget Feasibility Analysis	☐ Research Financial Disclosure Statements
☐ FDA Approval Letter (IND, IDE, HDE, 510K, or PMA)	☐ Study Agreement/Contract
☐ Internal budget including an allocation budget	☐ Training/education certificates for new device/ procedure
☐ List of device product numbers	

PI Acknowledgement/Signature

- Signature acknowledges that the principal investigator will:
  - Accept responsibility for the conduct of the project
  - Agree to submit changes the study for review
  - Agree to use the *Research Registration* form and *Request for Research Billing* form as needed
- NIH/PHS Acknowledgement
  - Application is true, complete and accurate
  - Agree that any false, fictitious or fraudulent statements may result in penalties
  - Accept responsibility for scientific conduct and reporting

Administrative Acknowledgements

SECTION XI. ADMINISTRATIVE ACKNOWLEDGMENTS

I have reviewed the protocol and other study-related documents to become familiar with the proposed study, with a critical review of risks involved. I acknowledge that this project serves a purpose within the department's goals/initiatives.

I certify that the department has the necessary resources to conduct the study.

I understand the responsibility of the principal investigator, and the necessity to follow PH research policies and PGRs throughout the conduct of the study.

Program Director *(For resident/fellow research)*

Signature: _____ **Date:** _____

Printed Name:

Department Chair *(For USC faculty research)*

Signature: _____ **Date:** _____

Printed Name:

Palmetto Health VP *(For Palmetto Health-employed staff)*

Signature: _____ **Date:** _____

Printed Name:

Administrative Acknowledgements - continued

Palmetto Health VP *(Impacted Service Area at Palmetto Health)*
Signature: _____ **Date:** _____
Printed Name:

- Obtain signature from VP over area that is most impacted by the study.
  - This ensures upper management is aware of the study in the service area and ensure resources are available for the study.
- Suggested items to share with the VP
  - Study summary
  - Impacted Services Agreements
  - Budget Feasibility Analysis
- Continue to complete the Impacted Services – these signatures of acknowledgement are in addition to the Impacted Services agreement(s).

The Review Process

- Once all reviews/approvals are complete, a final letter will be issued by the Research Compliance office.
- The Research Compliance letter will outline any additional responsibilities of the Investigator during the conduct of the study.
- The Research Compliance letter and the IRB letter MUST be received prior to starting the study.

OTHER PHARR PROCESS ITEMS

Effort Reporting

- Requirement per OMB Circular A-110
- Applicability
  - Federally sponsored research
  - Palmetto Health employed Investigators and Research Staff whose salaries are directly chargeable to the study
  - All non-employed Investigators if employer does not have effort reporting mechanism
- Complete the Effort Report Form
  - Provide effort expended on organized research, patient care, instruction and training, indirect activities, and other hospital activities
  - Monthly basis
  - Send completed form to Research-Assist@PalmettoHealth.org

Research Registration

- Provides notification to Palmetto Health entities of patient encounters (e.g. pre-registration, coding, patient accounts, and case management)
- Applicability
  - Subject encounters requiring notification: the PHARR letter will notify Investigator if notification is required
- Complete a *Research Registration* form
  - Provide appropriate patient and encounter information
  - Send completed form to either Research-Baptist@PalmettoHealth.org or Research-Richland@PalmettoHealth.org
  - Must be sent within 24 hours of the subject encounter

Request for Research Billing

- Notifies Research Compliance of a subject encounter that occurs at the hospitals (excludes physician practices) that involves any research-related items/procedures/services that are paid by the Sponsor and/or not billable to the subject
- Applicability
  - Subject encounters requiring modification of billing (i.e. charges to be removed from the subject's bill): the PHARR letter will notify Investigator if notification is required
- Complete the *Request for Research Billing* form
  - Provide appropriate subject information and the item/procedure/service rendered
  - Send completed form to Research-Assist@PalmettoHealth.org
  - Must be sent within 48 hours of the research-related item/procedure/service

Palmetto Health Administrative Research Review Policy

- Outlines the steps for Investigators to take to participate in research at Palmetto Health.
- Provides Investigators framework of the proper conduct of research.

Other Research Related Policies

- Objectivity in Research (Potential Financial Conflict of Interest)
- Publication/Presentation of Research Results
- Sponsored Research Award
- Debarment and Suspension in Research
- Research Misconduct

- Will be available on myPal/myManuals (internally) and on www.palmettohealth.org (externally)

FINANCIAL CONFLICT OF INTEREST (FCOI)

COI in the News

- Researchers Fail to Reveal Full Drug Pay
  - June 8, 2008 New York Times
  - Dr. Joseph Biederman, world-renowned Harvard child psychiatrist
  - Earned at least $1.6 million in consulting fees from drug makers from 2000 to 2007 but failed to report all but about $200,000 of this income to university officials
- Top Psychiatrist Didn't Report Drug Makers' Pay
  - October 4, 2008 New York Times
  - Dr. Charles Nemeroff, top psychiatrist from Emory University
  - Earned more than $2.8 million in consulting arrangements with drug makers from 2000 to 2007, failed to report at least $1.2 million of that income to his university and violated federal research rules

FCOI Compliance at PH

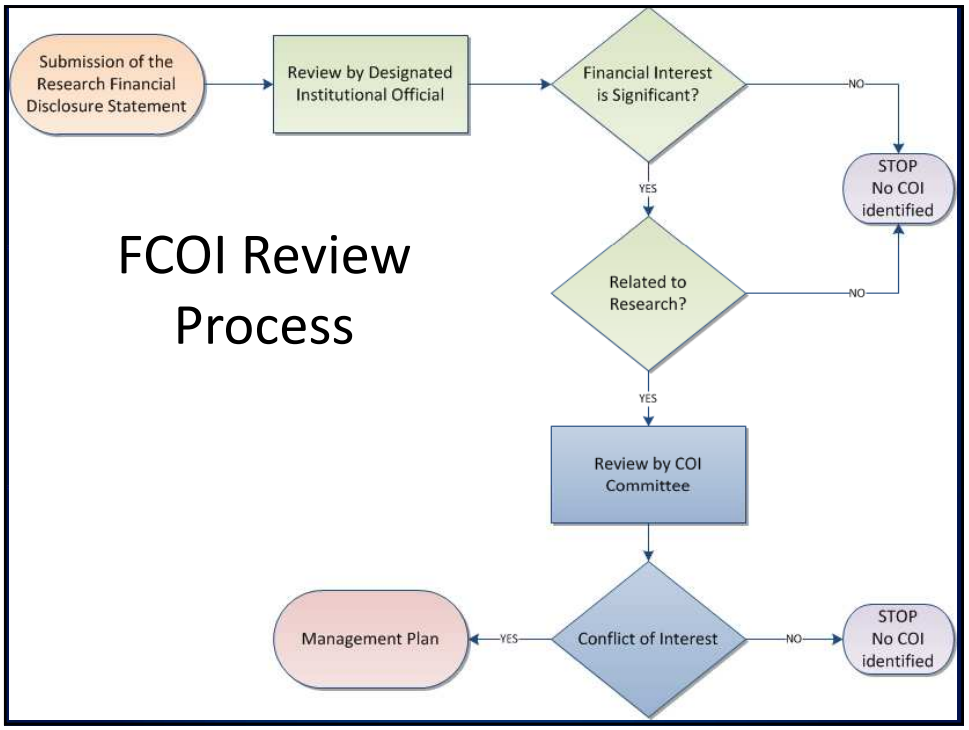
- New FCOI regulation
  - 42 CFR 50 Part F
  - Compliance date of no later than August 24, 2012
- New Palmetto Health policy
  - Objectivity in Research (Potential Conflict of Interest) Policy
  - Effective August 1, 2012
  - New Research Financial Disclosure Statement to complete

Who needs to submit

- Research Personnel
  - Project director or principal investigator
  - Any other person, who contributes to the scientific development or execution of a project in a substantive, measurable way.
- Research Personnel's spouse and dependent children

Timing of Statement submission

- Initial Research Financial Disclosure Statement
  - No later than the time of application for PHS-funded research, OR
  - At the time of study submission to the Institutional Review Board (IRB) for all other research
- Annually
- Within 30 days of discovering or acquiring a new financial interest



Significant Financial Interest (SFI)

- Any remuneration (salary or any payment for services) or equity interest in a publicly traded company that exceed $5,000 when aggregated over 12 month
- Any remuneration in a non-publicly traded company that exceed $5,000 when aggregated over 12 month
- Intellectual property rights and interest upon receipt of income related to the rights and interests
- Includes reimbursed or sponsored travel

Other Definitions

- An SFI is "related to the research" when the SFI
  - Could be affected by the funded research
  - Is in an entity whose financial interest could be affected by the research
- Conflict of Interest
  - Exists when the SFI could directly and significantly affect the design, conduct, or reporting of the research

Possible FCOI Management Plans

- Public disclosure of the FCOI
- Disclosure of the FCOI to the research participants
- Appointment of an independent monitor
- Modification of the research plan
- Change of personnel or personnel responsibilities
- Reduction of elimination of the financial interest
- Severance of relationships that create the FCOI

Palmetto Health Responsibilities

- Review of the financial interests
- Notification of the IRB and sponsor
- Post policy on external website
- Respond to any individual request for information concerning significant financial interest disclosures
- Retain records
- Provide FCOI training

Research Financial Disclosure Statement

PALMETTO HEALTH

Research Financial Disclosure Statement

This Research Financial Disclosure Statement is intended to collect information on your financial relationships, if any, that may be relevant to Palmetto Health's review of your research protocol. Investigators and other Research Personnel must complete this form and submit to Research Compliance through eIRB.

SECTION I. INVESTIGATOR/STUDY STAFF AND STUDY INFORMATION	
Your Name/Affiliation:	
Your Position on Project:	☐ Principal Investigator ☐ Co-Investigator ☐ Other, specify:
Project Title:	
Sponsor:	
Funding Type:	☐ Federal Government ☐ Private Industry ☐ Private Not-for-Profit Organization ☐ State or Local Government ☐ Internal Funding ☐ No Funding ☐ Other, specify:
Identify any business (Entity) that owns, manufactures, or licenses the technology on which the research is focused or any business that is involved in the conduct of the research (e.g. CRO, central lab, data management organization): *This business may or may not be the same as the Sponsor.*	
Do you, your spouse, or dependent children have any financial interest (e.g. remuneration, equity interest, intellectual property rights/interests, receipt of sponsored travel) potentially related to the research?	☐ YES ☐ No

If YES, provide the information listed below (Section II) for each entity in which you have a related financial interest, and attach a separate page for each entity. If NO, skip to Section III.

Research Financial Disclosure Statement - continued

SECTION II. FINANCIAL INTEREST INFORMATION	
Name of Entity:	
Type of Entity:	☐ Publicly Traded ☐ Non-publicly Traded ☐ Other, specify:
Amount of remuneration received from entity within the past twelve (12) months: *Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)*	$
Amount of equity interest in the entity: *Any stock, stock option or other ownership, as determined through reference to public prices or other reasonable measures of fair market value*	$
Are you currently entitled to receive income from the Entity due to intellectual property rights/interests? *e.g., patents, copyrights*	☐ YES ☐ No

Has the Entity reimbursed or sponsored your travel?		☐ YES ☐ No
If YES,	Indicate the purpose of the trip:	
	Indicate the destination:	
	Indicate the duration of the trip:	
	Indicate the monetary value (or approximate): $	
Are there any other situations not covered above that might possibly be affected by the research?		☐ YES ☐ No

If you answered YES to any of the above questions, please explain and provide a description of the safeguards you will put in place to protect the welfare of research subjects and ensure that the financial interest does not impact the research participant. Additional pages may be attached.

Research Financial Disclosure Statement - continued

SECTION III. SIGNATURES

I affirm that I have read Palmetto Health's policies and procedures/guidelines/rules (PGRs) related to Conflicts of Interest and agree to comply with the policies and PGRs.

I certify that the above is complete and correct in relation to the research project(s). Further, I will submit changes to this disclosed financial interest at least annually. I will also provide additional disclosures within thirty (30) days of discovering or acquiring a new financial interest.

Signature:_____ **Date:** _____

Printed Name:

Future Training Sessions

- Monday, June 4th – 10:00 AM
- Monday, June 25th – 1:30 PM
- Monday, July 9th – 10:00 AM
- Wednesday, October 17th – 2:00 PM
- November, November 12th – 1:30 PM
- Monday, December 17th – 10 AM

- Training sessions will be:
  - Approximately 1 hour in length
  - Held in 9 Med Park, Room 130
- Register for the sessions by emailing Research-Assist@PalmettoHealth.org
  - Registration is now open for any of the sessions
  - Please register for a session at least 24 hours prior to the scheduled date/time
- On-line training sessions will be available

Contact Information

General Email Mailbox
Research-Assist@PalmettoHealth.org

Rebecca Marigliano, PhD
Rebecca.Marigliano@PalmettoHealth.org
803-434-4898

QUESTIONS