Protocol Details

Basic Info

Confirmation Number:	**cibddbdg**
Protocol Number:	**832361**
Created By:	**SEBRO, RONNIE A**
Principal Investigator:	**SEBRO, RONNIE A**
Protocol Title:	**PET/CT for evaluation of benign bone lesions**
Short Title:	**PET/CT for evaluation of benign bone lesions**
Protocol Description:	**Retrospective review of benign bone lesions in patients with PET/CT to characterize these bone lesions.**
Application Type:	**EXEMPT Category 4**

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**SEBRO, RONNIE A**
Dept / School / Div:	**4452 - RA-Radiology**
Campus Address Mail Code	**4283**
Address:	**HUP** **3400 SPRUCE ST**
City State Zip:	**PHILADELPHIA PA 19104-4283**
Phone:	**215-294-9512**
Fax:	**215-615-3316**
Pager:	
Email:	**Ronnie.Sebro@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/29/2021**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**ELANGOVAN, STACEY**
Dept / School / Div:	**2100 - Health System**
Campus Address Mail Code	
Address:	**Hospital of the Univ of Penn** **Radiology Residents**
City State Zip:	
Phone:	-
Fax:	-
Pager:	
Email:	**Stacey.Elangovan@uphs.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**03/23/2019**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

None

Responsible Org (Department/School/Division):

4452 - RA-Radiology

Key Study Personnel

None

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

HRPP

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Request for HIPAA Waiver of Authorization

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Research on human data sets (e.g. medical records, clinical registries, existing research data sets, medical administrative data, etc.)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
x	**None of the above**

The following documents are currently attached to this item:

HIPAA Waiver of Authorization (petct-hipaawaiver1.docx)

Sponsors

Business Administrator

Name:	**D'ARCY, WILLIAM**
Dept / School / Div:	**4452 - RA-Radiology**
Phone:	**215-349-8423**
Fax:	**215-349-8426**
Pager:	
Email:	**DarcyW@uphs.upenn.edu**

Department budget code

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Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Objectives

Overall objectives
To characterize benign bone lesions seen on PET/CT

Background
PET/CT is a ubiquitous test used for staging and surveillance of patients with malignancy. We are trying to characterize benign bone lesions seen on PET/CT

Study Design

Design
Retrospective review of benign bone lesions seen on prior PET/CT from 01/01/2000 to 12/19/2018 Power calculations suggest that analysis of 5000 patients will give us 80% power to detect a difference with false positive rate of 0.05

Study duration
Estimated length of time to enroll all subjects: 0 days (retrospective study) Length of a subject's participation time in study: 0 days (retrospective study) Project date: 08/10/2017-08/10/2019

Characteristics of the Study Population

Target population
All patients who are treated at UPHS and evaluated with PET/CT

Subjects enrolled by Penn Researchers
5000

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment
Retrospective study. Patients will be identified from review of radiology and pathology medical records from the electronic medical record EPIC.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

N/A. Retrospective study

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
None. Retrospective review of patients who had PET/CTs and had benign bone lesions.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
Descriptive statistics (mean, max, minimum, std deviation) of clinical and demographic variables will be presented.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Subject Confidentiality
PHI will be stored on an institutionally secured & managed device. All PHI will be destroyed at the completion of study

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
No

Data Protection*

	Name
	Street address, city, county, precinct, zip code, and equivalent geocodes
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
	Telephone and fax number
	Electronic mail addresses
	Social security numbers
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Consent

1. Consent Process

Overview
This is an unfunded retrospective study which will review up to 5000 cases who were treated at Upenn over a decade. Several of these patients have moved and/or are deceased. This would be practically impossible to identify and contact all of these individuals.

Risk / Benefit

Potential Study Risks
Risks include disclosure of PHI if the UPHS IT system is hacked.

Potential Study Benefits
No direct benefits to subject as a result of study, however clinicians may now know parameters to safely ignore benign bone lesions

Risk / Benefit Assessment
Minimal risk

General Attachments

The following documents are currently attached to this item:

Cover Letter (irbbenignbonelesions.docx)

HIPAA Authorization or Waiver (petct-hipaawaiver1.docx)