Title: Optical Coherence Tomography Predictors of Functionally Significant Side Branch Compromise after Provisional Main Vessel Stenting in Bifurcation Lesion Assessed by Fractional Flow Reserve (ORBID-FFR)
PI: Annapoorna Kini, MD
NCT03115580
Document Date: January 19, 2017

Mount Sinai	Protocol Title:	Optical Coherence Tomography Predictors of Functionally Significant Side Branch Compromise after Provisional Main Vessel Stenting In Bifurcation Lesions Assessed by Fractional Flow Reserve (ORBID – FFR)
	Principal Investigator Name/Contact Info:	Annapoorna Kini, M.D./ 241-4181/ annapoorna.kini@mountsinai.org
	Primary Contact Name/Contact Info	Mary Ann Kiernan /241-7634 / maryann.kiernan@mountsinai.org Yashira Henriquez /241-0564 yashira.henriquez@mountsinai.org
	Date Revised:	January 19, 2017
	Study Number:	HSM# 16-00041/ GCO#1: 16-0204(0001)

MSSM Protocol Template HRP-503a

Instructions:

1. *Prepare a document with the following sections. Note that, depending on the nature of your research, certain sections below may not be applicable. Indicate N/A as appropriate, explaining where possible.*
2. *For any items described in the sponsor's protocol, grant application or other source documents submitted with the application, you may reference the title and page numbers of these documents rather than cutting and pasting into this document.* ***Do NOT refer to any derived documents, such as the Sample Consent document, or other internal documents required with the submission.***
3. *If you reference page numbers, attach those pages to this protocol.*
4. *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*

Brief Summary of Research (250-400 words):

Protocol Title: Optical Coherence Tomography Predictors of Functionally Significant Side Branch Compromise after Provisional Main Vessel Stenting in Calcific Coronary Artery Disease (CAD) Assessed by Fractional Flow Reserve (ORBID-FFR)

This is a single-center, randomized study in patients with stable coronary artery disease.

1) Objectives:

Research Question:

To analyze the incidence of SB compromise after provisional main vessel stenting in calcified bifurcation lesions of CAD patients, determine the incidence and OCT predictors of functionally significant SB stenosis defined as FFR ≤ 0.8 and to compare the FFR values with 3D-OCT measurements of jailed SB ostium after MV stenting.

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2) Background

Coronary artery bifurcation lesion is a common lesion subset in PCI accounting for 15-20% of the total number of interventions. Treatment of coronary artery bifurcation lesions represents a challenging area in interventional cardiology. When compared with non-bifurcation interventions, bifurcation interventions have a lower rate of procedural success, higher procedural costs, longer hospitalization and a higher clinical and angiographic restenosis. Factors contributing to this adverse outcome include limitations of angiography in assessment of side-branch (SB) disease severity and the lack of established angiographic predictors of SB patency and lumen compromise. Better understanding of the underlying plaque morphology and plaque composition may facilitate more effective treatment of bifurcation lesions.

Intravascular imaging has provided new understanding of mechanisms associated with SB compromise following bifurcation PCI. Plaque shift has been traditionally considered as the principal mechanism for side-branch compromise after main vessel intervention. Rotational atherectomy(RA) has been advocated for the treatment of bifurcation lesions, since it can effectively remove plaque with minimal injury to adjacent normal arterial segments and potentially reduce plaque shifting, the "snow plow" effect. Intravascular ultrasound (IVUS) has been used for guidance in bifurcation lesions, aiding the visualization of plaque morphology at the main vessel and the side-branches and helping the selection of stent size and length as well as the selection of stenting strategy. However, due to the low spatial resolution of IVUS, all attempts for three-dimensional visualization have only focused on visualization of the luminal contour and not on the vessel morphology or the vessel-stent interaction. Optical coherence tomography (OCT) has ~10 times higher resolution than IVUS, which allows precise evaluation of the microstructure of the vessel wall including lipid pool, fibrous cap, calcification, and thrombus. OCT has been shown to constitute a valuable tool for PCI guidance and also the utility of three-dimensional (3D) renderings for

assessing the mechanism of side-branch compromise following intervention in bifurcation lesions. The recent development of OCT with online 3D reconstruction allows the operator to obtain a 3D visualization of the lesion and may provide a unique tool for guidance during complex bifurcation PCI and potentially improve stenting results. 3D OCT has been used to visualize jailed side branches after implantation of bioresorbable scaffolds in the main branch and develop a new classification system based on the number of SB compartments. In addition, its potential clinical application in guiding the rewiring of the distal compartment of the SB ostium (jailed with stent struts after MB stenting) to minimize the risk of floating struts was demonstrated It is important to note that while OCT, 3D-OCT, and 3D-QCA (such as that used in the ORBID trial) are imaging modalities that can be used to answer important research questions, their wide-spread adoption in daily clinical practice has been very limited. Intravascular ultrasound (IVUS) is used more frequently as part of a PCI guidance strategy in daily clinical practice.

Fractional flow reserve (FFR) is a pressure-derived, lesion specific index used to determine the functional significance of coronary artery stenosis. Several studies showed that FFR is a safe and feasible method to assess the significance of an ostial SB stenosis after provisional stenting. Quantitative coronary angiography (QCA) has been shown to be unreliable in assessing the functional significance of SB after stent implantation in MV (the area under the curve 0.64, 41.5% sensitivity and 83.1% specificity) suggesting that treatment decisions for jailed SB should not be based on angiographic findings alone. A recent report demonstrated a better ability of post-PCI 3D-OCT to predict the functional significance for SB ostial lesions caused by a jailed SB outcome.

A previous study (ORBID) of 30 patients was done at Mount Sinai Hospital and aimed to identify the predictors of side branch (SB) ostial stenosis developed after provisional stenting of the main vessel (MV) using Optical Coherence Tomography (OCT). The study Showed that High lipid content of the MV lesion and a contralateral location of lipid in the bifurcation area may contribute to SBOS after provisional stenting.

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3) Setting of the Human Research

ICAHN School of Medicine at Mount Sinai and the Mount Sinai Hospital

GP 5 East Ambulatory Area

4) Resources Available to Conduct the Human Research

Given the high-volume of the Mount Sinai catheterization laboratory and its dedicated research infrastructure, patient recruitment is unlikely to pose a challenge. Mount Sinai serves a large New York City based population with extensive referrals from the Tri-State area. This will ensure our ability to screen and recruit appropriate patients. All members of the research team delegated to participate in this research protocol are adequately informed about the protocol and their trial-related duties and /or functions. The personnel listed on the HRP-211 with their Curriculum Vitae will serve to recruit patients to the study and will be adequately informed about the protocol; and their trial related duties and functions thru a site initiation visit by the sponsor after the IRB approval process; regular monthly/quarterly teleconferences and possible sponsor initiated meetings at the site or at another location.

All persons on the research team have completed CITI training, HIPPA training as well as all required research training and credentials to perform research. They are informed about the protocol, the investigational product(s), and their trial-related duties and functions.

5) Study Design

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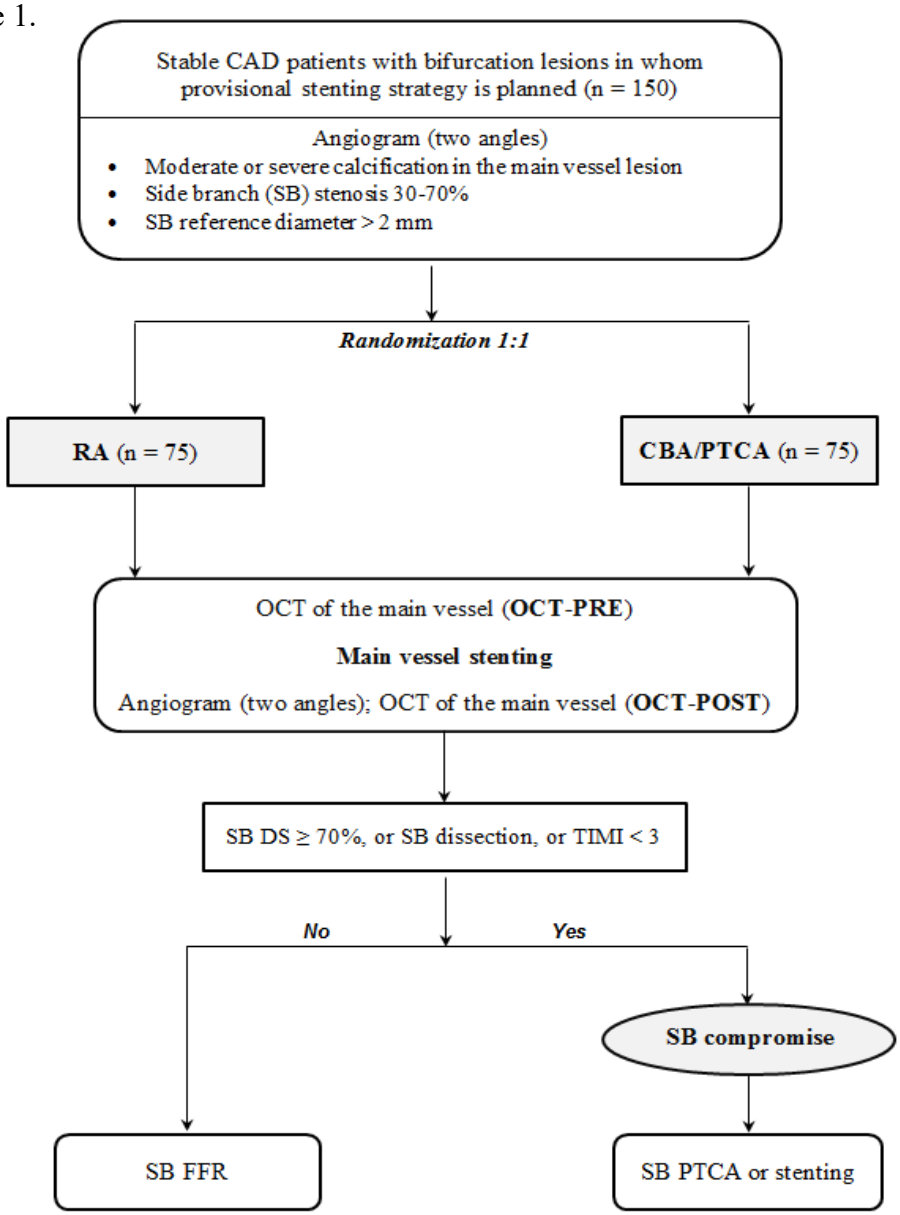
Figure 1.



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Data analysis and Statistical methods:

T-test will be used. OCT off-line image analysis. For the accurate characterization of bifurcation lesions, OCT images will be analyzed systematically at 1 mm intervals according to previously validated criteria for plaque characterization using the St. Jude Medical Offline Review Workstation as we described previously. In addition, three-dimensional OCT software (QAngio OCT, Medis) will be used to obtain the information for the side branch ostium from a single main branch pullback as described recently in a validation of cut plane analysis (Figure 2). We will also perform three-dimensional quantitative coronary angiography (3D-QCA) using QAngio XA 3D software (Medis) to obtain the measurements of bifurcation angles, stenosis, and references. This software is dedicated to bifurcation lesions and has shown to provide highly accurate assessment of lesion dimensions and geometry based on 3D reconstruction of bifurcation lesions. Offline analysis of side branch for impingement of the ostium of SB leading to acute loss in SB diameter, area, carina shift and plaque shift will be performed and 3D-OCT parameters will be correlated with SB FFR measurements.

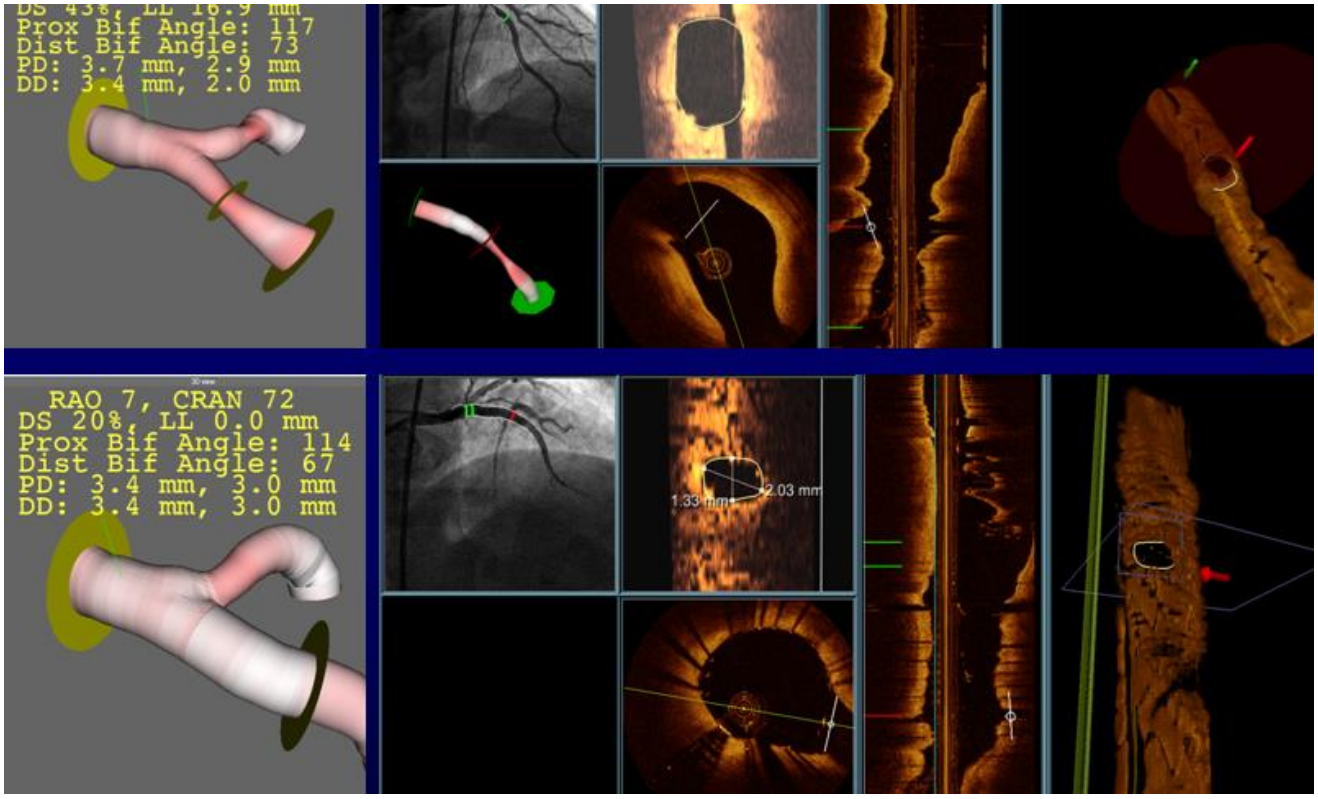

Figure 2. 3D quantitative coronary angiography (QCA) and cut-plane analysis of side branch ostium from the main branch OCT pullback for bifurcation PCI before (top row) and after (bottom row) stenting.

We assumed FFR (+) prevalence of either 20% or 25% based on previous studies. We also assumed that there would be a roughly equal proportion of patients with high and lipid levels.

Based on these assumptions, we will need at least 75 patients per EACH high lipid and low lipid groups to detect an odds ratio (OR) of 2.8.

The table below is showing the detectable OR we might have under different assumptions of the patient population assuming an equal proportion of high/low lipid level groups.

Prevalence of + FFR	Patients per group	Detectable OR with 80% power
0.2	50	3.7
0.2	75	2.9
0.2	100	2.5
0.25	50	3.5
0.25	75	2.8
0.25	100	2.4

a) Recruitment Methods

We will recruit patients referred to the interventional cardiologists involved on this study based on their medical history who require a PCI of the main vessel with drug eluting stent implantation for the treatment of stable CAD where impact on the side branch can be access. Patients will be undergoing a PCI using an angiography and OCT-guided strategy. Patients will be approached in the ambulatory unit before their procedure to obtain consent and review and confirm the inclusion and exclusion criteria of the protocol.

The PI and the research team will identify potential subjects based on their medical history. Potential patients will be approached in the ambulatory unit before their procedure to obtain consent and check the inclusion/exclusion criteria.

In all cases, the Principal Investigator, Sub-Investigator or member of the Research Team will discuss the research trial and informed consent document in full detail following Good Clinical Practices and HIPAA Laws. During the informed consent process, all of the potential subject's questions will be answered. Subjects will be given a copy of the signed

informed consent document, a copy will be placed in the subject's chart and the original copy will be stored in a secure location in the research office.

b) Inclusion and Exclusion Criteria

1. General inclusion criteria. Subjects will be enrolled in the study, if ALL of the following criteria are met

- All patients over 18 years of age presenting with stable coronary artery disease.
- Patients must have a clinical indication for coronary intervention.
- Creatinine Kinase Myocardial-Band Isoenzyme (CK-MB) must be less than or equal to the upper limit of lab normal (ULN) value within eight hours prior to the procedure

2. **Angiographic inclusion criteria**. Subjects will be enrolled in the study, if **ALL** of the following criteria are met:

- The target lesion must be a *de novo* calcified bifurcation coronary lesion that hasn't been previously treated with any interventional procedure for which provisional main vessel stenting strategy is planned after reviewing angiogram.
- The target vessel must be a native coronary artery with
    a) stenosis ≥70% and <100%, or
    b) Stenosis ≥50% and <70% with evidence of clinical ischemia via positive stress test, or FFR ≤ 0.8, or IVUS or OCT minimal lumen area ≤ 4.0 mm^2.
- The target lesion should have SB DS 30 - 70%.
- The target main vessel reference diameter must be ≥2.5 mm and ≤ 4.0 mm.
- The SB reference diameter must be > 2 mm by coronary angiogram.
- The target vessel must have a Thrombolysis in Myocardial Infarction (TIMI) flow grade 3 at baseline.

General exclusion criteria: Patient will not be enrolled in the study if ANY of the following criteria are present in the patient.

- Patients with ostial left main artery lesions or ostial right coronary artery lesions
- Female patients with child bearing potential not taking adequate contraceptives or currently breastfeeding
- Known allergy to acetylsalicylic acid or clopidogrel.
- Planned surgery within 12 months.
- History of bleeding diathesis
- Major surgery within 15 days
- Life expectancy < 12 months.
- Patients with kidney dysfunction (CrCl<30)

c) Number of Subjects

One hundred and fifty (150) consecutive patients with lesions requiring PCI of main vessel with drug eluting stent implantation for the treatment of stable CAD will be included in the study.

d) Study Timelines

This is a randomized study with one visit and no clinical follow-ups.

e) Study Endpoints

The primary endpoint is SB compromise defined as SB DS $\geq$ 70%, or dissection or TIMI < 3.

The secondary endpoints

- SB FFR after main vessel stenting and its correlation with OCT imaging parameters before PCI
- OCT predictors of SB TIMI flow reduction after main vessel PCI
- Off-line analysis of SB stenosis by 3D-OCT and its correlation with FFR; correlation between 3D-QCA measurements, 3D-OCT, and FFR data.

- Association between calcification assessment by angiography and OCT imaging.
- FFR Device Success (ability to successfully deliver FFR wire to desired SB distal segment [n/150]).
- FFR Wire Workhorse Capability (proportion of patients [n/150] in which FFR wire able to serve as rail to deliver additional interventional devices to target SB lesion).

f) Procedures Involved in the Human Research

Stable CAD patients with bifurcation lesions in whom provisional stenting strategy is planned, who have moderate or severe calcification in the main vessel lesion identified by angiography, SB stenosis 30-70% and SB reference diameter > 2mm will be enrolled in the study.

Moderate calcification will be defined as radiopaque density observed only during the cardiac cycle and typically involving only one side of the vascular wall, and severe calcification will be defined as radiopaque density noted without cardiac motion prior to contrast injection and involving both sides of the arterial wall. After completion of diagnostic angiogram and confirmation of subject eligibility, subjects will be randomly assigned to Rotational atherectomy (RA or Cutting Balloon Angioplasty (CBA)/PTCA group in a 1:1 fashion.

Patients in both groups will undergo PCI with stent implantation according to current standards of care. Lesion preparation including lesion pre-dilation, scoring or sculpting balloon angioplasty, and use of atherectomy and protection devices will be performed at the operator's discretion, followed by MV stenting. The operator will also decide in both groups about the length and size of the implanted stent. Procedural optimization, such as post-dilation or additional stent implantation will be performed based only on the angiographic findings, according to the discretion of the operator.

Optical coherence tomography (OCT) is an established medical imaging technique that uses light to capture micrometer-resolution, three-dimensional images from within optical scattering media will be performed to analyze plaque morphology, the extent and location of calcification, side branch size, angle, and ostial involvement.

Patients in both groups will undergo (standard of care) a percutaneous coronary intervention (PCI), also known as coronary angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction (MI), and multivessel coronary artery disease (CAD) with stent implantation according to current standards of care. Lesion preparation including lesion pre-dilation, scoring or sculpting balloon angioplasty, and use of atherectomy *(*a minimally invasive endovascular surgery technique for removing atherosclerosis from blood vessels within the body.) and protection devices will be performed at the operator's discretion, followed by MV stenting.

The operator will also decide in both groups about the length and size of the implanted stent. Procedural optimization, such as post-dilation or additional stent implantation will be performed based only on the angiographic findings, according to the discretion of the operator.

The Pre and post stenting OCT + FFR for side branch are the research procedures.

OCT pullback will be performed after lesion preparation before stenting (OCT-PRE) and after PCI (OCT-POST). FFR measurement in the side branch will be performed, if the coronary angiogram shows SB DS < 70%, TIMI grade 3 flow and no dissection in the side branch.

To perform FFR measurements, the pressure wire will be passed through the struts of the MV stent into the SB and FFR will be measured at least 5 mm distal to the jailed SB stenosis. Adenosine will be infused through the

femoral vein at least 140 µg/kg per minute to induce maximal coronary blood flow.

g) Specimen Banking

Not Applicable

h) Data Management and Confidentiality

Confidentiality of subject medical information will be ensured by providing unique identifiers (Subject ID) for data transmitted from the enrolling centers to St. Jude Medical Center. Designated representatives will not receive identifiable subject information.

Subject ID is a unique identifier and automatically generated in the database upon completing the baseline/enrollment electronic case report form (eCRF). This ID cannot be re-identified to a patient. The only identifying information is that data which has been entered on the eCRF.

Data generated, including Subject ID's, for the study will be stored in a limited-access file area located in KCC Room 678 and be accessible only to representatives at the study site, St. Jude Medical Center and its representatives and FDA/relevant health authorities/regulatory agencies. Limited-access file area is a secure shared drive, which only research personnel have access to. Source documents for subjects consented and subsequently enrolled will be maintained in locked cabinets within the research office. Office access is limited to research personnel.

All required data for this trial will be collected via electronic case report forms (eCRF) and securely transferred by a 21 CFR Part 11 compliant electronic data capture (EDC) system

i) Provisions to Monitor the Data to Ensure the Safety of subjects

Part I: Elements of a Data and Safety Monitoring Plan

MSSM Principal Monitor: Principal Investigator

Last Name: Kini

First Name: Annapoorna

Academic Title: Professor of Medicine/Cardiology

Department: Medicine/ Cardiology/CVI

Mailing Address: Box 1030, One Gustave L. Levy Place, NY, NY, 10029

Phone: (212) 241-4181

E-mail: annapoorna.kini@mountsinai.org

The principal monitor for this trial will be the PI since he is responsible for reporting to the IRB and Sponsor all AE/SAE. Investigators are responsible for monitoring the safety of subjects who have entered this study and for alerting the IRB and FDA to any event that seems unusual, even if this event may be considered an unanticipated benefit to the subject.

The investigator is responsible for the appropriate medical care of the subjects during the study.

The investigator remains responsible for following, through an appropriate health care option, adverse events that are serious or that caused a subject to discontinue before completing the study. The subject should be followed until the event is resolved or explained.

It is the Investigator's responsibility to classify the relationship of an adverse event as definite, Probable, possible, unlikely or not related on the Adverse Event eCRF.

j) Withdrawal of Subjects

All subjects should be encouraged to remain in the study through the duration of the follow-up period; however, if a subject decides to discontinue study participation, the reason for discontinuation must be recorded in the medical record and submitted via the electronic Case Report Form (eCRF). Subjects who discontinue participation prematurely will be included in the analysis of results (as appropriate) but they will not be replaced in the enrollment of total study subjects nor will those subjects continue to be followed by research personnel. Information previously collected on such subjects may be reviewed and monitored by research personnel and sponsoring agency to ensure compliance with protocol and data accuracy.

6) Risks to Subjects

Risks to subjects enrolled in this study include risks to subject privacy and release of protected health information (PHI). The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.

OCT and FFR are widely used in every day clinical practice. Any procedure's related adverse event will be recorded, evaluated and reported. The procedure films will be reviewed by the PI and the imaging team after the procedure for data analysis and effectiveness purposes.

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is in addition to any radiation needed for your medical care. X-rays and gamma rays from natural or medical sources can damage the genetic material (DNA) in your cells. At low doses, the body is usually able to repair the damage. Radiation risk is believed to be related to the total lifetime exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

The estimated radiation exposure that subjects will get for this research study will be 10.37mSv (an mSv is a unit of absorbed radiation). The greatest annual exposure (10.37 mSv) is projected to be in year(s) 1. This exceeds the 6.2 mSv that the average person in the United States gets each year from both natural sources like the sun, outer space, air, food and soil, as well as from medical procedures. It is less than the 50 mSv of radiation that is allowed each year for people who are exposed to radiation in their jobs.

Angiogram and angioplasty (using stent to open the blockage) will be done as standard of care. Use of this type of device is known to be associated with the following risks:

- Coronary or stent thrombosis (when a blood clot forms on the surface of a stent)
- Increased vascular and/or bleeding complications (due to a problem with blood clotting).
- Arrhythmia (irregular heart beat)
- Blood vessel rupture, which may result in a build-up of fluid around the heart
- Increased length of hospital stay
- Infection due to contamination of the stent, which may lead to thrombosis (blood clot inside a vessel), pseudoaneurysm (leaking blood from an artery), or vessel rupture (bursting).
- Spasm, thrombosis (blood clot), and/or distal embolization (obstruction) caused by implantation of the stent; stent could migrate from the site of implantation
- Rupture and life-threatening bleeding caused by excessive stretching of the artery
- Partial deployment (incomplete placement) of stents in particularly resistant lesions
- Stent dislodgment and/or migration from the target site during or after implantation

7) Provisions for Research Related Injury

In the event of injury resulting from your participation in this research study, the facilities at Mount Sinai Hospital and professional attention will be made available to you at your expense. Financial compensation from Mount Sinai will not be provided. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Annapoorna Kini at telephone number (212) 241-4181.

8) Potential Benefits to Subjects

Not Applicable.

9) Provisions to Protect the Privacy Interests of Subjects

All potential subjects are subjects are referred by their private physicians and are patients undergoing Cardiac Catherization procedures and subsequent PCI by an interventional cardiologist in the Mount Sinai Cardiac Catherization Laboratory. The private physician will be asked if a patient may be approached by a member of the study team.

Potential subjects who come to MSH the day of the procedure, or are in-patients at MSH will be approached in the unit, pre-catheterization unit or in their assigned room of the patient care unit. Only personnel directly involved with the study (investigators and research coordinators) will approach subjects for consent. It is acceptable and appropriate for members of the research team to approach prospective participants because all members of the research team delegated to participate in this research protocol are adequately informed about the protocol and their trial-related duties and /or functions.

Potential subjects will be approached for consent before the catheterization procedure. The ambulatory unit and the pre-catheterization unit are in the Cardiac Catheterization procedural preparation area. As is the case for in-patient subjects, all patients are provided with a private hospital bed for procedural preparation. We will make all efforts to give an adequate time to the subjects and subject's family to understand the trial and read the consent

form. The use of the ambulatory and pre-catheterization cath. lab areas and/or the subject's assigned room in the patient care unit during the consenting process is ideal because each subject will have a bed in a private location to discuss the details of the trial. The consenting process will always be obtained in these private locations.

This location will be an area different from the actual procedure room in which the potential subject can consider the consent as an autonomous individual, free from time constraints or a sense of obligation or dependency. Patients meeting the inclusion criteria will be informed of the trial details. This includes the protocol procedures, risk, benefits, alternative to participate, cost of procedure and follow ups, compensation, voluntary participation and privacy, etc. The patient will be encouraged to ask questions and all questions will be answered to his/her satisfaction. The patients' responsibility to keep the scheduled follow-ups will also be discussed. At this location, the patient will be given an adequate amount of time to review the consent document, discuss it with whomever they like, digest the information that has been presented to them without any element of coercion or being in any kind of anxiety provoking situation as to whether they wish to participate and make an informed decision, sign the informed consent and HIPAA consent.

10) Economic Impact on Subjects

Since a PCI procedure is the standard of care that subjects would be receiving even if they were not participating in this study, subjects will be expected to pay any copayments and insurance deductibles normally required by their insurance. This will be true for any standard follow up care that subjects receive throughout the clinical trial. Subjects will not absorb the extra cost of any procedure that is not part of their routine medical care due to their participation in this study. Some insurers have specific guidelines associated with clinical trial participation and do not pay for treatment provided as part of clinical research.

11) Payment to Subjects

Not Applicable.

12) Consent Process

All potential subjects will sign a separate Mount Sinai surgical/procedure informed consent for their Cardiac Catherization procedure on the day of their hospital visit. On the day of their procedure, and prior to signing the informed consent document, the subject's continued eligibility for the study will be reviewed. If the subject does not meet all general inclusion/exclusion criteria at this time, they will not be approached, consented and/or enrolled in the research trial.

Consent will be obtained prior to any screening procedures

After the subject has been determined to be eligible for the research trial, legally effective informed consent will be obtained from the patient. Recruiters (PIs, Sub-Investigators and Research Staff Members) will be following and will adhere to "SOP HRP-090 Informed Consent Process for Research" and "SOP HRP-091 Written Documentation of Consent"

Non-English Speaking Subjects:

Non-English speaking persons will be eligible for consent and subsequent enrollment once a PPHS/IRB approved consent document in the potential subject's native language is available for use. Non-English speaking patients will be approached for consent by the study PI, Sub-investigator or member of the Research Team that speaks the native language of the potential subject and can provide appropriate informed consent. The consenting process, timing and setting are the same as for English speaking subjects.

Several members of the research team are fluent in Spanish and would be available for the Spanish speaking subjects. In the future, if the situation warrants it, we may utilize an interpreter.

13) Process to Document Consent in Writing

Subjects will sign a separate Mount Sinai surgical/procedure informed consent for the PCI procedure.

The standard PPHS consent template will be used in this trial.

Recruiters (PIs, Sub-Investigators and Research Staff Members) will be following and will adhere to "SOP HRP-091 Written Documentation of Consent"

14) Vulnerable Populations

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
	X	*Pregnant women*
	X	*Prisoners*

15) Multi-Site Human Research (Coordinating Center)

Not Applicable

16) Community-Based Participatory Research

Not Applicable

17) Sharing of Results with Subjects

Not Applicable

18) IRB Review History

Not Applicable

19) Control of Drugs, Biologics, or Devices

Note: The IDS has its own forms that must be completed and a review process that must be followed before the IDS representative will sign off on Appendix B for submission to the PPHS.

Not Applicable.