The Florida Pancreas Collaborative (FPC): A Partnership Dedicated to the Early Detection and Prevention of Pancreatic Cancer

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Nipun Merchant, MD
Jose Trevino, MD
Outline

Rationale for studying pancreatic cancer
Project goal, aims, design, and timeline achievements
Movement towards changing state policies
Infrastructure-building and protocol standardization
Participant recruitment & biospecimen collection
Interdisciplinary team building
Collaborative abstracts, proposals, and publications
Next Steps and Future Opportunities
STUDY RATIONALE
Leading Causes of Cancer Deaths in the US

**Estimated Deaths**

**Male**
- Lung & bronchus: 85,920 (27%)
- Prostate: 26,120 (8%)
- Colon & rectum: 26,020 (8%)
- Pancreas: 21,450 (7%)
- Liver & intrahepatic bile duct: 18,280 (6%)
- Leukemia: 14,130 (4%)
- Esophagus: 12,720 (4%)
- Urinary bladder: 11,820 (4%)
- Non-Hodgkin lymphoma: 11,520 (4%)
- Brain & other nervous system: 9,440 (3%)
- All sites: 214,220 (100%)

**Female**
- Lung & bronchus: 72,160 (26%)
- Breast: 40,450 (14%)
- Colon & rectum: 23,170 (8%)
- Pancreas: 20,330 (7%)
- Ovary: 14,240 (5%)
- Uterine corpus: 10,470 (4%)
- Leukemia: 10,270 (4%)
- Liver & intrahepatic bile duct: 8,890 (3%)
- Non-Hodgkin lymphoma: 8,630 (3%)
- Brain & other nervous system: 6,610 (2%)
- All sites: 281,400 (100%)
Pancreatic Cancer is Projected to Become the 2nd Leading Cancer Killer by 2020
Estimated Number of Pancreatic Cancer Deaths and Death Rates, by State

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<td>California</td>
<td>4,390</td>
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<td><strong>41,780</strong></td>
<td><strong>12.6</strong></td>
<td><strong>9.6</strong></td>
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*Per 100,000, age-adjusted to the 2000 US standard population
-adjusted PC incidence rates in Florida, county (2003-2013)
THE TIME TO INVEST IS NOW....

→ Save lives
The urgent need for early detection and intervention strategies for pancreatic cancer (PC) is critical. Early, operable tumors are difficult to detect.

Anatomic location of the pancreas

Symptoms occur LATE in the disease process

No existing biomarkers accurately detect disease EARLY
PRIME OPPORTUNITY FOR EARLY DETECTION AND PREVENTION EFFORTS

Precursors to pancreatic cancer
Three pancreatic cancer precursors exist:

- **Pre-cancerous pancreatic cysts**
  - IPMN = intraductal papillary mucinous neoplasms
  - MCN = mucinous cystic neoplasms

The diagram illustrates the progression from normal pancreatic (duct) tissue through various precursor lesions to invasive pancreatic carcinoma.

Key lesions include:
- PanIN-1A lesion
- PanIN-1B lesion
- PanIN-2 lesion
- PanIN-3 lesion

Key conditions:
- IPMN low-grade dysplasia
- IPMN intermediate dysplasia
- IPMN high-grade dysplasia

The flow ultimately leads to **invasive pancreatic carcinoma**.
IPMN

- account for up to 40% of the ~150,000 pancreatic cysts detected incidentally each year in the USA.

- challenging to manage due to the inability to predict:
  - which lesions can be safely monitored,
  - which are likely to progress to invasion, and
  - which may have an associated invasive component.

- severity is determined by surgery & pathologic evaluation.

- Consensus guidelines exist to predict IPMN pathology based on standard clinical and radiologic features. Accurate for at least 30-70% of cases!
important opportunities for the Florida Cancer Data System (FCDS) 03-2013) to assess underestimation in # of MN cases diagnosed and reported in Florida each year.

- and moderate-grade IPMNs are non-reportable conditions.

- Establish state-wide infrastructure:
  - prospectively identify, characterize, & monitor incident IPMNs of all grades.

- Evaluate putative risk factors for & markers of PC dev’t & progression.

FCDS and DOH may change state reporting requirements for incident IPMNs.
Important opportunities for FL (cont’d)

1. Target a greater breadth of pancreas cases for enrollment.
   - early-and late-stage PC cases.
   - IPMNs and mucinous cystic neoplasms (MCNs).
   - benign conditions (chronic pancreatitis & non-mucinous pancreatic cysts).

2. Prospectively acquire, process, and store a variety of biospecimen types longitudinally.
   - Tumor tissue, though it may be suboptimal or limited for use.
   - Collect noninvasive (blood) and invasive (cyst fluid) sources of biomarkers.

3. Recruit healthy controls without a personal history of pancreatic disease as a comparison group.
   - Companions of cases
   - High-risk cohort

   - miRNAs
miRNAs (miRNAs) as attractive candidate markers of early pancreatic malignancy

gulate cancer-related pathways.
Each miRNA regulates 1000’s of genes.
markably stable in tissue and biofluids
regulated in PC vs. normal pancreas tissue to differentiate between IPMN ade and/or normal pancreas tissue.1,2,3,4,5

Plasma MicroRNAs as Novel Biomarkers for Patients with Intraductal Papillary Mucinous Neoplasms of the Pancreas

Jennifer Permutt-Weyl1,3, Dung-Tsa Chen3, William J. Fulo3, Sean J. Yodar4, Yonghong Zhang2, Christine Georgeades15, Kozim Husain2, Barbara Ann Centeno6, Anthony M. Miglioccco8, Domenico Coppola9, and Mckenze Malafa7

Abstract

Pancreatic ductal adenocarcinoma (PDAC) is one of the most fatal cancers worldwide, partly because methods are lacking to detect disease at an early, operable stage. Biomarkers for PDAC are important to improve diagnostic accuracy and aid in patient management. We aimed to evaluate the importance of miRNAs in the progression of IPMNs and PDAC and to determine whether miRNAs may be useful for early detection of IPMNs. Our primary goals were to measure the abundance of miRNAs in archived tissue samples from patients with IPMNs and normal controls and to develop novel plasma miRNAs that distinguish between IPMN patients and controls. miRNA expression profiles were used to develop an miRNA signature to evaluate 800 IPMNs, and we showed that a 50-miRNA signature distinguished 42 IPMNs cases from 24 controls (area under the curve [AUC] = 74.4; 95% CI 62.3–86.5, P < 0.002). The signature consisted of novel miRNAs and miRNAs previously implicated in pancreatic cancer that had 2- to 4-fold higher expression in IPMN than in control samples. We also generated a 5-miRNA signature that discriminated between 21 malignant (high-grade dysplasia and invasive carcinoma) and 21 benign (low- and moderate-grade dysplasia) IPMNs (AUC = 73.2; 95% CI 57.6–88.9, P = 0.005), and showed that paired plasma and tissue samples from patients with IPMNs can have distinct miRNA expression profiles. This study suggests that using a novel, cost-effective technology to develop a miRNA-based biomarker for disease may offer the greatest hope in reducing morbidity and mortality. Three noninvasive PDAC: precursor lesions (premalignant) exist: pancreatic intraductal neoplasia (PanIN), primary pancreatic neoplasms (MCN), and malignant pancreatic ductal adenocarcinoma (PDAC). PanINs are microscopic lesions, whereas MCNs and PDACs are macroscopic, and for over half of the approximately 50,000 asymptomatic patients detected annually in the general population each year by imaging (1). Once detected, endoscopic ultrasound (EUS)-guided fine needle aspirations are often performed to assess the degree of dysplasia, but imaging features and malignancies obtained from such invasive procedures do not reliably predict disease severity or progression (2). This report describes the development of a noninvasive, cost-effective technology that measures miRNAs in plasma and tissue samples from patients with IPMN and normal controls (3). The study shows that these biomarkers may be useful for early detection of IPMNs. Our results indicate that these biomarkers may be useful for early detection of IPMNs and PDAC, and may offer the greatest hope in reducing morbidity and mortality. Three noninvasive PDAC: precursor lesions (premalignant) exist: pancreatic intraductal neoplasia (PanIN), primary pancreatic neoplasms (MCN), and intraductal papillary mucinous neoplasm (IPMN); refs. 2, 3]. PanINs are microscopic lesions, whereas MCNs and IPMNs are macroscopic cysts accounting for over half of the approximately 150,000 asymptomatic pancreatic cysts detected annually in the general population each year by imaging (1). Once detected, endoscopic ultrasound (EUS)-guided fine needle aspirations are often performed to assess the degree of dysplasia, but imaging features and malignancies obtained from such invasive procedures do not reliably predict disease severity or progression (2). This report describes the development of a noninvasive, cost-effective technology that measures miRNAs in plasma and tissue samples from patients with IPMN and normal controls (3). The study shows that these biomarkers may be useful for early detection of IPMNs. Our results indicate that these biomarkers may be useful for early detection of IPMNs and PDAC, and may offer the greatest hope in reducing morbidity and mortality.
miRNAs differentiated between low-risk and high-risk IPMN cases

miR-200a-3p, miR-1185-5p, miR-33a-5p, miR-574-3p, and miR-663b

A. B.

AUC=73.2

(95% CI:57.6-88.9)

P=0.005

‘Cell cycle’ and Wnt signaling’ were among top-ranked pathways predicted
PROJECT GOAL, AIMS, DESIGN, AND TIMELINE
The Florida Pancreas Collaborative

The first state-wide multi-academic cancer center collaboration dedicated to conducting research on pancreatic cancer (PC) precursors (IPMNs), with the ultimate goal of promoting the early detection and prevention of PC.
Specific Aims

Item 1: To establish a prospective multi-center cohort of ~100 Floridians newly-diagnosed with IPMNs and other pancreatic conditions (and healthy controls) and build a comprehensive biorepository that complements existing single institution protocols.

Item 2: Demonstrate that prospectively collected blood and cyst fluid can be used to evaluate the diagnostic performance of circulating plasma and cyst fluid microRNAs in distinguishing between ‘high-risk/malignant’ and ‘low-risk/benign’ IPMNs.
To establish a prospective multi-center cohort of ~100 Floridians newly-diagnosed with IPMNs and other pancreatic conditions (and healthy controls) and build a comprehensive biorepository that complements existing single institution protocols.
RECRUITMENT EFFORTS
Eligibility

Healthy individuals 18+ without a self-reported personal history of pancreatic disease or related symptoms.

Approach to recruit and obtain written informed consent

Kimberly Quinn (MOF)  
Amber Bouton (UF)  
Dr. Suzanne Lechner (SCCC/UM)
THE FLORIDA PANCREAS COLLABORATIVE
PARTICIPATE IN PANCREATIC RESEARCH
HELP MAKE ADVANCES POSSIBLE

Doctors and researchers at Moffitt, the University of Florida, and the University of Miami are trying to develop better ways to prevent, detect, and treat pancreatic cancer and other pancreatic conditions, and we need the help of individuals with and without pancreatic conditions.

This study seeks to discover new ways to prevent, detect, and/or treat pancreatic cancer, pancreatic cysts, and other conditions of the pancreas.

You may be able to take part in this study if:

- You are a man/woman 18 years in age or older.
- You are having an evaluation of your pancreas because of some symptoms, clinical and/or imaging findings, blood work, or because you have family history of pancreatic cancer or related conditions.
- You do not have a personal history of a pancreatic condition or symptoms, but are interested in contributing to this research.

You will not need to pay for procedures performed as part of this study (blood draws).

We are collecting contact information for people who may be interested in participating in this study. Please contact Kimberly Quinn at 813-745-1060 or FPC@moffitt.org if you are interested in participating or want more information.

“Researchers, doctors, patients, friends, and families united in the prevention and early detection of pancreatic cancer and other conditions of the pancreas.”
WHERE CAN I GET ADDITIONAL INFORMATION ON PANCREATIC CANCER?
Pancreatic Cancer Action Network
www.pancan.org

National Cancer Institute
www.cancer.gov/cancertopics/types/pancreatic

American Cancer Society
www.cancer.org/cancer/pancreaticcancer/index

Moffitt Cancer Center & Research Institute
www.moffitt.org

THE FLORIDA PANCREAS COLLABORATIVE

PARTICIPATE IN PANCREATIC RESEARCH
HELP MAKE ADVANCES POSSIBLE

For inquiries about FPC, please contact us at:
FPC@moffitt.org
or
813-745-XXXX
(or toll-free at 1-800-XXXXXXX xXXXX)

Funded by:
The Florida Academic Cancer Center Alliance
http://www.floridacanceralliance.com/

The Florida Pancreas Collaborative (FPC)
A partnership dedicated to the early detection and prevention of pancreatic cancer

“Researchers, doctors, patients, and families united in efforts to prevent, detect, and treat pancreatic cancer”
INTRODUCTION

Laboratory technologies are available to support important advances in the early detection, prevention, and treatment of pancreatic cancer and other conditions affecting the pancreas, including pancreatic cysts and pancreatitis.

To help develop these research advances, it is important to collect and study biological specimens such as bodily fluids (i.e., blood) donated by individuals with and without pancreatic conditions.

Combined with information regarding age, gender, presenting symptoms, history of medical conditions, and other factors, knowledge gained through such biospecimens can change the way doctors diagnose and treat a person’s disease (Figure 1).

WHY PARTICIPATE?

• Studies based on these efforts may help us:
  - understand why some people develop cancer (or pre-cancerous conditions) and some do not.
  - understand the roles of lifestyle, genetic, and environmental factors in cancer.
  - improve the medical care of those with or at risk for pancreatic conditions.

• We will contact you about other studies for which you may be eligible to participate.

• We will update you on the newest advances in pancreatic research through periodic newsletters.

WHO CAN PARTICIPATE?

• You may be able to take part in this study if:
  - you are a male or female 18 years of age or older.
  - you are having an evaluation of your pancreas because of some symptoms, clinical and/or radiologic imaging findings, blood-work, or because you have a family history of pancreatic cancer or related conditions.
  - you do not have a personal history of a pancreatic condition or symptoms, or are interested in contributing to this research.

WHAT IS INVOLVED IF I PARTICIPATE?

• Completion of a consent form.
• Filling out a questionnaire at an initial visit and during periodic follow-up.
• Donation of biospecimens such as blood at a time that is convenient for you.
• Efforts will be made to collect samples during routine procedures.
• Providing permission for the research team to contact you regarding future studies for which you may be eligible to participate.

WHAT ARE THE BENEFITS OF PARTICIPATION?

• There may be no direct benefit to you from participation. However, the information and biospecimens you provide will be useful in learning more about the biology of pancreatic conditions.
• This new knowledge may lead to clinical testing for new ways to help people at increased risk for pancreatic cancer, as well as the discovery of new drugs for treating and preventing pancreatic conditions.

WHAT ARE THE COSTS OF PARTICIPATION?

• You will not need to pay for any procedures performed specifically for this study.
• Tests or procedures obtained as part of routine care will be your responsibility.
• Your participation is entirely voluntary. If you decide not to participate, you will not jeopardize present or future medical care or treatment.
• You may stop participation at any time.

WHAT ABOUT MY PRIVACY?

• Data collected from this study will only be used for research purposes. Results of any tests will not become part of your medical record. Results may be published in a scientific journal, but your identity will not be released.

WILL I KNOW THE RESULTS OF THIS IMPORTANT RESEARCH?

• If clinically useful information arises as a result of this study, we may contact you or a person whom you designate to discuss optional clinical tests or studies.
• We also plan to update you on new developments through a study newsletter.
## Florida Pancreas Collaborative Project Database

### MRN

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### Reason if ineligible

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### Visit Referral Reason

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### Referral Reason Notes

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### TCC Site

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### Is signed Addendum?

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### Reason for Refusing FPC

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STANDARDIZING OPERATING PROCEDURES:

- Biospecimen collection/processing/ storage
- Data collection/harmonization
## Florida Pancreas Collaborative
### Biospecimen Collection Details

<table>
<thead>
<tr>
<th>Specimen Type and Volume Requested</th>
<th>Collect From Cases/Controls</th>
<th>Timepoint(s) and Procedure(s) for Collection</th>
<th>Processing / Storage Information</th>
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</thead>
<tbody>
<tr>
<td>Men Type</td>
<td>Yes/No</td>
<td>• Residual surgical specimen (tumor &amp; normal)</td>
<td>Residual tissue processed and stored according to SOPs.</td>
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</tbody>
</table>
| Residual surgical specimen (tumor & normal) | Yes/Yes                   | • Baseline/initial visit (via venipuncture)  
• 4-6 wks post-surgery, if applicable  
• If no surgery or treatment, 1 year after baseline | Process for plasma, genomic DNA, and serum using SOPs; aliquot into 4- 0.5 mL cryovials; store at -80°C. |
| Fluid (e.g., blood)              | Yes/No                     | • At time of EUS-guided diagnostic biopsy and via aspiration from surgically resected | Use SOPs; aliquot (8-0.5 mL cryovials), store at -80°C. |
Working towards a centralized data repository

- Demographics
- Imaging details
- Clinical (presenting symptoms, medical hx)
- Captured from medical record, questionnaire, or cancer registry
- Lab values (CA 19-9, bilirubin)
- Pathology
- Epidemiologic risk factors
## Demographics

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**Lock this record for this form?**
- [ ] Yes
- [ ] No

*If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.*

**Actions:**
- Edit Instrument
- Download PDF of instrument(s)

**Buttons:**
- Save Record
- Save and Continue
AIM 2

Demonstrate that prospectively collected blood and cyst fluid can be used to evaluate the diagnostic performance of circulating plasma and cyst fluid microRNAs in distinguishing between ‘high-risk/malignant’ and ‘low-risk/benign’ IPMNs.
60 incident cases of surgically-resected, pathologically confirmed IPMNs
- 40 high-risk; 20 low-risk
- Recruited in Aim 1 (~20 from each institution).
- Banked pre-operative plasma and cyst fluid.
Methods

1. RNA & fluid preservation
2. Spike-in oligos added
3. Total RNA extraction
4. RNA integrity & concentration assessed
5. Hemolysis evaluation (plasma)
6. Measure miRNA abundance
Nanostring’s nCounter Human v3 miRNA expression Assay Codeset

The set contains: 800 human miRNAs (including the 5 candidate miRNAs);
6 positive controls; 8 negative controls;
5 human mRNA housekeeping genes

- Reproducibility and cross-site validation
- Subset of 10 samples (plasma & cyst fluid) will be evaluated at all three sites.
Data Processing, QC, and Analysis

- Background correction
- Evaluate possible contamination
- Data normalization using spike-ins
- Biological normalization using stable/invariant miRNAs

Linear models for microarray data (LIMMA) and principal component analysis (PCA) are also utilized for analysis.
# Proposed Timeline

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Recruitment and Biospecimen Collection Update

- Patients Screened N=1954
- Patients Eligible for FPC N=414
  - Pending FPC N=187
  - Consented to FPC N=200
  - Declined FPC N=27
- Blood Collected N=67
  - Blood N=48
  - Post-Op Blood N=19
  - Tissue Collected N=6
  - Cystic Fluid Collected N=8
Preliminary Diagnosis of Participants (N=200)

- Pending diagnosis: 3 (2%)
- PNET: 4 (2%)
- Family history of pancreatic cancer: 5 (2%)
- Missing Pseudocyst Information: 8 (4%)
- PDAC: 33 (17%)
- IPMN Likely: 71 (35%)
- Pancreatic cyst/lesion/mass: 50 (25%)
- Metastatic disease to pancreas: 2 (1%)
- MCN: 1
- Pancreatic aneurysm: 1
Preliminary Diagnosis of Participants with Baseline Blood Collected (N= 48)

- IPMN Likely: 17 (36%)
- PDAC: 10 (21%)
- PNET: 3 (6%)
- Pseudocyst: 4 (8%)
- Pancreatic cyst/lesion/mass/nodule: 8
- Pancreatitis: 3 (6%)
- MCN: 1 (2%)
- Metastatic disease to pancreas: 1 (2%)
- Pancreatic aneurysm: 1
Pathology of participants who have undergone surgery (N=27)

- Autoimmune Pancreatitis: 2 (7%)
- IPMN: 6 (22%)
- PNET: 2 (7%)
- Pseudocyst: 4 (15%)
- MCN: 1 (4%)
- PDAC: 8 (30%)
- Report pending: 4 (15%)
TEAM SCIENCE
Building an Interdisciplinary Team

Surgery

Oncology

Biostatistics

Immunology

IT/ Bioinformatics

Radiology

Pathology
Partnering with Patient Advocates
Pushing clinically-relevant, impactful science forward...
Long-term goal

Develop a clinical decision-making tool that has added diagnostic value in predicting IPMN pathology beyond that provided by standard radiologic and clinical characteristics.

- Low-risk IPMN (low- or moderate grade)
  - Surveillance

- High-risk IPMN (high-grade or invasive)
  - Surgery

Other text:
- non-invasive
- cost-effective
- reliable
- objective
- can easily be integrated clinically
## Abstracts, Proposals, Publications

<table>
<thead>
<tr>
<th>What</th>
<th>Where</th>
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<tbody>
<tr>
<td>Abstract (oral presentation)</td>
<td>American Association for Cancer Research (AACR)-Japan Joint Conference (Feb 2016)</td>
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<tr>
<td>Abstract (poster presentation)</td>
<td>AACR Annual Meeting (April 2016)</td>
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<tr>
<td>Proposal</td>
<td>NCI (R21) (Submitted Oct 2015)</td>
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<td>Proposal</td>
<td>American Cancer Society Research Scholars Grant (Submitted Nov 2015)</td>
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<td>Proposal</td>
<td>NCI (R01 resubmission) (To be submitted March 2016)</td>
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<td>Publication</td>
<td>under review, <em>Radiology</em></td>
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<td>Publication</td>
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Partnering to advance early detection and prevention efforts for pancreatic cancer: the Florida Pancreas Collaborative

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Team science as a necessity for making advancements in pancreatic cancer research

"Alone we can do so little; together we can do so much." This quote by Helen Keller embodies the overarching goal of transdisciplinary team science, which is to bring together investigators, community partners, and translational collaborators from various disciplines and fields to integrate concepts, theories, methods and approaches from a breadth of expertise to solve real-world problems and increase the impact of research. 

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Focusing on early detection & prevention by studying commonly detected pancreatic cancer

and incidence and death rates, pancreatic cancer is projected to surpass breast, prostate and colorectal cancer and become the second leading cause of cancer deaths by 2020 [9]. Thus, it is critical that researchers and funding agencies invest in transdisciplinary pancreatic cancer research efforts now.

KEYWORDS
• early detection • multi-institutional collaborations • pancreatic cancer
Next steps/ Future Opportunities

- Continued recruitment/ specimen collection (Aim 1)
- Start tackling Aim 2
- Projects underway
- Newsletter
- Webpage
Florida Pancreas Collaborative

Among the top causes of cancer death in the United States and Florida, pancreatic cancer is the deadliest, with a 5-year relative survival rate of 7%. This dismal prognosis is primarily attributed to the lack of early detection strategies. Based on changing demographics and incidence and death rates, pancreatic cancer is projected to surpass breast, prostate, and colorectal cancer and become the second leading cause of cancer deaths by 2020. Coinciding with the rise in pancreatic cancer incidence and mortality has been an increase in the radiologic detection of cystic lesions of the pancreas including intraductal papillary mucinous neoplasms (IPMNs). IPMNs are the most common pancreatic cancer precursors and account for 40% of the 150,000 asymptomatic pancreatic cysts detected incidentally through computed tomography (CT) or magnetic resonance imaging (MRI) each year. The only way to treat these cysts and examine severity is through surgical resection and pathological evaluation. However, pancreatic resection is associated with significant risks of morbidity (including long-term diabetes) and even mortality.
Renewal of FACCA award
- Need to continue to build a strong infrastructure

Secure extramural funding
Development and testing of new molecular and imaging markers to identify patients at high risk for PC due to genetic factors or presence of precursor lesions will be conducted by multi-disciplinary teams.

Areas:
- Identification and testing of biomarkers in bodily fluids for early detection of PDAC or its precursor lesions;
- Determine which pancreatic cysts are likely to progress to cancer; develop molecular- and/or imaging-based approaches for screening populations at high risk of PDAC;
- Conduct biomarker validation studies;
- Collect specimens longitudinally & establish a biorepository.

Deadlines: 4/26/16; 8/21/16; 4/26/17
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