Post-Acute Pancreatitis Pancreatic Exocrine Insufficiency

Rationale and Methodology of a Prospective, Observational, Multicenter Cohort Study

SUPPLEMENTAL DIGITAL CONTENT

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Initials - Patient ID

Date of Birth (Month/Date/Year)

Date of Enrollment: ☐☐/☐☐/☐☐☐☐ **(Month/Date/Year)**

Proof ID: ☐☐☐☐

APPRENTICE ID: ☐☐☐☐

PAPPEI ID: ☐☐☐☐

2. Inclusion/Exclusion Criteria, Time points

2.1 Inclusion Criteria: Include the subject if the answers to at least <u>two of the following three</u> questions are "yes"

☐ Is serum amylase or lipase of the subject elevated greater than 3× upper limit of normal?

☐ Does the subject complain of acute-onset upper abdominal pain (new pain or getting worse than baseline pain)?

☐ Does abdominal imaging studies demonstrate pancreatic edema, peripancreatic fat stranding, or complications of acute pancreatitis?

2.2 Exclusion Criteria: Exclude the subject if any of the answers to following 5 questions is "yes"

Please, record all cases that were excluded.

Is the subject less than 18 years old? ☐Yes ☐No

Is the subject, or subject's proxy, unwilling to provide consent? ☐Yes ☐No

Does the subject have known history or imaging of chronic pancreatitis (imaging findings include, but not limited to, pancreatic calcifications or atrophy)? ☐Yes ☐No

Is the subject diagnosed with exocrine pancreatic insufficiency before enrollment? ☐Yes ☐No

Did pancreatitis occur due to abdominal trauma or surgery? ☐Yes ☐No

Does the subject have pancreatic cancer? ☐Yes ☐No

☐Yes ☐No

Is the patient incarcerated? ☐Yes ☐No

Anticipated inability to follow study's protocol ☐Yes ☐No

Please write the explanation for excluding the patient if not mentioned in the above questions:

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐
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____

____

2. Anthropometric Measurements

2.1 Current Weight: ______ lbs

2.2 Height: ______ ft ______ inches

2.3 BMI (Body Mass Index) = ___________

2.4 Unintentional Weight Loss (past 6 months) Yes No

2.4.1 If answer to 2.4.1 is "YES", how much weight loss:___________

2.5 Current Waist Size: ______ (inches)

2.6 Waist-Hip Ratio: ______

(Waist circumference is measured at a level midway between the lowest rib and the iliac crest. The tape measure is in a parallel to the floor and was snugged without compressing the skin. The hip circumference is measured using the same measuring tape at its widest portion of the buttocks with tape parallel to the floor)

2.7 Mid-arm muscle circumference: ______ (inches)

3. Demographics

3.1 Age: ______

3.2 Gender (at birth): ☐Female ☐Male ☐Other

3.3 Ethnicity

☐ Hispanic or Latino* ☐ Not Hispanic or Latino

* Hispanic or Latino is a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

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3.4 Race:

☐ **American Indian/Alaska Native** (origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment)

☐ **Asian** (origin in Far East, Southeast Asia, or the Indian subcontinent)

☐ **Native Hawaiian or Other Pacific Islander** (e.g. Guam, Samoa)

☐ **Black or African American** (origins in any of the black racial groups of Africa)

☐ **White** (origin in Europe, the Middle East, or North Africa)

☐ **Unknown** (Patient does not know or refuses to select the race)

3.5 Education:

What is the highest grade or level of schooling you completed?

☐ 8th grade or less

☐ Less than high school graduate

☐ High school graduate/GED

☐ Post-high school training other college (vocational/technical school)

☐ Other, specify: _____________

☐ Associate degree/Some college

☐ Bachelor’s degree

☐ Graduate school

3.6 Which of these categories best describes your total combined family income for the past 12 months?

☐ <$25,000

☐ $25,000-<$50,000

☐ $50,000-<$75,000

☐ $75,000-<$100,000

☐ $100,000-<$150,000

☐ >$150,000

☐ I don’t know/not sure

3.7 What is your employment status?

☐ Employed for wages ☐ Student ☐ Retired ☐ Self-employed

☐ Homemaker ☐ Military ☐ Unemployed, medical reason

☐ Unemployed, non-medical reason

☐ I don’t know/not sure

3.8 What is your marital status?

☐ Married

☐ Widowed

☐ Divorced

☐ Separated

☐ Single

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☐ I don’t know/not sure

4. History of Present Illness (Acute Pancreatitis)

4.1	Date and Time of Pain Onset: (Date and best estimate of time when the characteristic upper abdominal pain of acute pancreatitis started)	☐☐/☐☐/☐☐☐☐ at ____:____
4.2	Date and Time of Presentation to the hospital (Date and best estimate of time of initial presentation to emergency room, or direct admission to hospital)	☐☐/☐☐/☐☐☐☐ at ____:____
4.3	Transfer (Applies when the patient transfers from an OSH hospital where he/she initially presented to for further management)	☐Yes ☐No
4.4	If 4.3 is yes, date and Time of admission to the Study Site:	☐☐/☐☐/☐☐☐☐ at ____:____
4.5	Date and Time of Enrollment to study:	☐☐/☐☐/☐☐☐☐ at ____:____ ☐ N/A

4.6 Acute Pancreatitis primary etiology

☐Biliary ☐Idiopathic

☐Alcoholic ☐HTG

☐Post-ERCP (If yes: Date and Time of ERCP: ☐☐/☐☐/☐☐☐☐ at ____:____)

☐Other specify: ______________

(Select the most prominent etiology. Idiopathic acute pancreatitis is confirmed when all common etiologies (gallstones, alcohol, post-ERCP, HTG, drug-induced) have been excluded; Primary hypertriglyceridemia-induced acute pancreatitis is confirmed when common etiologies have been excluded and serum triglycerides are >500 mg/Dl)

4.7 Is there a Secondary etiology? ☐Yes ☐No

4.7.1 If yes, what is the secondary etiology?

☐ Biliary ☐ Idiopathic

☐ Alcoholic ☐ HTG

☐ Post-ERCP

(If yes: Date and Time of ERCP: ☐☐/☐☐/☐☐☐☐ at ____:____

☐ Other specify: ______________

5. Patient’s Medical History and Family History

5.1 Have you previously had documented attacks of acute pancreatitis which required hospital admission? ☐Yes ☐No ☐Uncertain

If answer to question 5.1 is “NO” or “UNCERTAIN”, proceed to section 6.

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If answer to question 5.1 is "YES" answer questions 5.1.1 to 5.1.5

- **5.1.1** date of your first attack of acute pancreatitis? ______/_____/_________
- **5.1.2** How many previous hospitalizations due to attacks of acute pancreatitis have you had?

☐ 1 ☐ 3 ☐ 5 or more
☐ 2 ☐ 4 ☐ Uncertain

- **5.1.3** How long ago did you have your last attack? ______ years ______ months
- **5.1.4** During any of your previous pancreatitis attacks, was any of the following present?

☐ Organ failure ☐ Walled-off necrosis
☐ Pancreatic necrosis ☐ None of the above
☐ Fluid collection ☐ Uncertain

- **5.1.5** During any of your previous pancreatitis attacks, was any of the following needed?

☐ Intensive care unit admission
If Yes, duration of ICU stay: _______ days or ☐ Uncertain
☐ Parenteral nutrition (TPN) If Yes, duration of TPN: ______ days or ☐ Uncertain
☐ Tube feedings: _______ days or ☐ Uncertain
☐ Percutaneous, endoscopic or surgical drainage or debridement
☐ None of the above
☐ Uncertain

5.2 Past Medical History

(Data to be retrieved by the research team through interview and EMR)

5.2.1 Has the subject had any of the following conditions?

Disease	Yes	No	Uncertain
Pre-existing High triglycerides (TG >150 mg/dL)			

Baseline TG: ______ mg/dL

Disease	Yes	No	Uncertain
Diabetes			

Specify type: ☐ 1 ☐ 2
Specify treatment: ☐ Diet ☐ Oral antidiabetics ☐ Insulin

Disease	Yes	No	Uncertain
If diabetic , is there end-organ damage			

Define end organ damage: __☐ Retinopathy, ☐ Neuropathy, ☐ Nephropathy, or ☐

Brittle Diabetes____

Disease	Yes	No	Uncertain
Myocardial infarction (history, not ECG changes only)			
Congestive Heart Failure			

□□□-□□□□ □□/□□/□□□□

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Peripheral Vascular Disease (History of intermittent claudication, peripheral arterial bypass for insufficiency, gangrene, acute arterial insufficiency, untreated aortic aneurysm (>=6cm))			
Cerebrovascular disease (History of Transient Ischemic Attack (TIA), or Cerebral Vascular Attack (stroke) with no or minor sequelae)			
Hemiplegia or paraplegia (Hemiplegia means impairment in motor function of one side of the body. Paraplegia means impairment in motor function of lower extremities.)			
Dementia (Chronic cognitive deficit, e.g. Mini-Mental Status Exam(MMSE) $\leq$26)			
Chronic Pulmonary Disease (e.g. COPD, asthma, pulmonary fibrosis)			
Connective Tissue disease (e.g. lupus, rheumatoid arthritis, polymyositis, etc.)			

Specify the type of connective tissue disease: ______________________________

Peptic Ulcer Disease			
Mild liver disease (chronic liver disease with/without compensated cirrhosis. E.g. chronic viral hepatitis, steatohepatitis, autoimmune)			
Moderate or severe liver disease (decompensated cirrhosis defined by presence of ascites, encephalopathy, or history of variceal bleeding)			
Mild renal disease (creatinine>1.5 mg /dL) and less than 3 mg/dL			
Moderate or severe renal disease (creatinine > 3 mg/dL, history of renal transplantation, history of dialysis or history of uremic syndrome)			
Solid tumor without metastases (diagnosed within the last 5 years)			
Leukemia (e.g. chronic myeloid leukemia, chronic lymphocytic leukemia, acute myeloid leukemia, acute lymphocytic leukemia, polycytemia vera)			
Lymphoma (including Non-Hodgkin, Hodgkin, Waldenstrom macroglobulinemia, Multiple Myeloma)			
Metastatic solid tumor			
AIDS (defined as confirmed positive Human Immunodeficiency Virus (HIV) test plus either CD4 count < 250 or any HIV-related complications			

5.2.2 Past Surgical History

Procedure	**Yes**	**No**	**Age**	**# of times**	**Indication**
Pancreatic surgery					
Gastric bypass					
Cholecystectomy					
Gastrectomy					

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5.3 Pancreatic or Biliary imaging and intervention (to be filled at discharge)

(Data to be retrieved by the research team through interview and EMR)

5.3.1 Has the patient ever had any of the following endoscopic or surgical interventions during this admission?
(If Yes, please verify the indication(s) of endoscopic or surgical interventions)

Procedure	Yes	No	Age	# of times	Indication
Endoscopic necrosectomy					
Endoscopic drainage of collection					

5.4 Family History

Did any of the following diseases occur in first-degree family members (parents, siblings, or children)?

	Yes	No	Unknown
Acute pancreatitis			
Chronic pancreatitis			
Pancreatic cancer			
Diabetes			
Celiac disease			
High triglycerides			
Cystic fibrosis			
Exocrine Pancreatic insufficiency			

6. Drug History

All data should be collected based on patients' history BEFORE AP-related abdominal pain onset.

6.1 NSAIDs* use

☐ Yes (Taken within last 7 days prior to pain onset) ☐ Yes (Taken within last 30 days prior to pain onset) ☐ No

- If yes, how many doses have you had? ___________
- If yes, when did you have your last NSAID dose? ___________

* (NSAIDs include: ASA, Advil, Motrin, Aleve, Ascriptin, Cambia, Cataflam, Anaprox, Clinoril, Daypro, Feldene, Indocin, Tivorbex, Naprelan, Naprosyn, Voltaren, Zorvolex, Vimovo)

6.2 Statin use ☐ Yes ☐ No

□□□-□□□□ □□/□□/□□□□

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➢ If yes, when did you start it? __________

6.3 Detailed list of Drug history (Before the onset of acute pancreatitis attack)

Please write down the names of medications which were started within the last two months prior to pain onset.

Medication (Circle the medication(s) within each group when indicated)	Yes					No	Uncertain
	Started W/I 7 days	Taking W/I 30 days	Taking W/I 60 days	Daily Dose	As needed		
Pancreatic enzyme replacement therapy (e.g. Creon, Zenpep, Zymase)							
Narcotics (morphine, Dilaudid, oxycodone, oxymorphone, codeine, tramadol, other)							
Proton pump inhibitors (omeprazole, pantoprazole, esomeprazole, other)							
Antibiotics (ciprofloxacin, metronidazole, tetracycline, isoniazide, dapsone, sulfonamides, erythromycin, pentamidine, isoniazide, other)							
Steroids (oral or intravenous)							
Immunomodulators (6-mercaptopurine, azathioprine)							
HIV therapy (Lamivudine, didanoside, nelfinavir, other)							
Hormonal therapy (estrogens, carbimazole, tamoxifen, testosterone)							
Cannabis (medical)							
Olanzapine							

6.4 Vitamin/Minerals Supplements (Before the onset of acute pancreatitis attack)

Supplement	**Yes**	**No**	**If yes: Daily Dose**	**Duration**	**Uncertain**
Vitamin B12					
Vitamin K					
Vitamin A					
Vitamin E					

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Vitamin D					
Multivitamin/mineral					
Iron					
Folate					
Phosphorus					
Magnesium					

6.5 If the subject is on Multivitamin, please provide the generic name of multivitamin/mineral:
____
____

7. Social History

7.1 Alcohol

7.1.1 Have you drank more than 20 drinks, including beer, wine, wine coolers, liquor, or mixed drinks, in your life? ☐ Yes ☐No, *go to section 8.2*

7.1.2 How old were you when you first started drinking, not counting small tastes or sips of alcohol? _____ years

7.1.3 Do you currently drink alcohol? ☐Yes ☐No

7.1.4 If no, how old were you when you stopped drinking alcohol? ____years

ALL SUBJECTS

Questions 8.1.5-8.1.10 ask about your alcohol consumption during the period of maximum (most) drinking in your lifetime **(this could be consecutive or non-consecutive periods of time).**
(NOTE: It is possible that this period could be "SIMILAR TO" or "OVERLAP WITH" the "YEARS BEFORE GETTING PANCREAS PROBLEM/PANCREATITIS". Even in that case, please complete this section.)

7.1.5	How old were you when you began drinking the most (heaviest amount) alcohol in your life?	_______ years
7.1.6	How long did you drink alcohol at the heaviest level?	__ years __ months ☐ Still drinking that much
7.1.7	On the **AVERAGE** how many drinks would you have on a drinking day during the period of maximum (most) drinking?	_____ drinks/day
7.1.8	How many days a month did you drink at this level?	_____ days/month

7.1.9	What is the **MOST** number of drinks you would have in any one day?	_____ drinks/day
7.1.10	How many days a month did you drink at this level?	_____ days/month

7.1.11 How would you describe the pattern of drinking in the six months before getting pancreatitis?

☐Frequent (15 days or more per month)
☐Occasional (less than 15 days)
☐Weekend mainly
☐ Not sure
☐Binge (at least 3 days heavy drinking)
☐Special Occasions
☐Abstinent

7.1.12 How many hours or days did you have your last drink before the onset of pain?
(If you don't remember the exact time please provide an approximation)

☐Less than 12 hours
☐12-24 hours
☐24-48 hours
☐ Not sure
☐48-72 hours
☐3-7 days
☐More than 7 days

7.2 Smoking

7.2.1 Have you smoked 100 cigarettes or more in your life? ☐ Yes, *continue* ☐ No, *go to question 7.3*

7.2.2	What age did you start smoking cigarettes?	_____ years
7.2.3	Do you currently smoke cigarettes?	☐Yes ☐ No
7.2.4	If former smoker, at what age did you quit smoking cigarettes?	_____ years
7.2.5	On average, how many cigarettes do /did you smoke per day? (if less than 1 per day on average, enter '1')	_____ cigarettes/day
7.2.6	How many total years have you smoked cigarettes on a regular basis? (Please do not include years when you quit for 6 or more months)	________years ______months

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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8. Exocrine Pancreatic Insufficiency (EPI) GI Symptom Tracker

These questions are about your current symptoms, as you perceive them. If you are not sure of how to answer, choose the response that seems closest to your situation. After answering the questions below:

8.1 During the past two weeks, how often have you:

	Almost Always	Often	Sometimes	Never
8.1.1 Had frequent diarrhea?				
8.1.2 Had greasy/oily stools? (indicated by oil droplets which float in the toilet water, stools that may have white or yellow fat in them or stools that float)				
8.1.3 Had difficult to flush stool?				
8.1.4 Had foul-smelling stool?				
8.1.5 Had loose stools?				
8.1.6 Felt bloated?				
8.1.7 Had excessive gas?				
8.1.8 Had abdominal pain?				
8.1.9 Had to rush to the bathroom in the middle of the night?				
8.1.10 Been bothered/concerned by eating fatty or greasy foods?				
8.1.11 Been bothered/concerned by using a public bathroom?				
8.1.12 Been bothered/concerned by having to stay on the toilet for a long time?				
8.1.13 Been bothered/concerned by skip a meal?				
8.1.14 Been bothered/concerned by have a poor appetite because of GI problems?				
8.1.15 Been bothered/concerned by miss daily activities due to GI-related problems?				

- **8.1.16** During the past week before admission, how many stools did you have per day?
  ☐0-1 ☐2-3 ☐4-5 ☐6 or more

- **8.1.17** Usually what is the consistency of your bowel movements?
  ☐ Solid ☐ Soft ☐ Liquid

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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9. Exercise

Godin Leisure-Time Exercise Questionnaire

9.1 During a typical 7-Day period, how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
a) **STRENUOUS EXERCISE** (HEART BEATS RAPIDLY) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	
b) **MODERATE EXERCISE** (NOT EXHAUSTING) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	
c) **MILD EXERCISE** (MINIMAL EFFORT) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	

9.2 During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

☐ Often ☐ Sometimes ☐ Rarely ☐ Never

10.. Dietary Habits

10.1. In general, how healthy would you rate your overall diet?

☐ Very healthy
☐ Fairly Healthy
☐ Healthy
☐ Poor

10.2 Which of the following best describes your typical diet?

☐ Omnivore (no specific restriction with regard to meat protein or vegetable choice)
☐ Vegetarian (vegetables and some animal products such as eggs and milk)
☐ Strict vegan (only vegetable products)- no eggs, milk, or animal related products
☐ Pescatarian (eats fish, but no other animal products)
☐ Other

10.3 Do you consider your diet to be?

☐ Low fat
☐ About average in fat
☐ High in fat
☐ I don't pay attention to fat content

10.4 In the past 30 days, how often did you:

	Very often	Often	Not Often	Not a consumer
Take probiotics, prebiotics, or food supplements?				
Eat or drink items that frequently/may contain probiotic including (eg. yogurt, kefir, sauerkraut, kimchi, kombucha)?				
Eat red meat such as beef, pork, ham, or sausage? Do not include chicken, turkey or seafood?				
Eat processed meat, such as bacon, lunchmeats, or hot dogs?				
Eaten starch (bread, pasta, etc.)?				

□□□-□□□□ □□/□□/□□□□
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Drink regular soda or pop that contains sugar?				
Drink coffee or tea?				
Drink sweetened fruit drinks, sports or energy drinks, such as G/Q/6, Kool-Aid, lemonade, Hi-C, cranberry drink, Gatorade, Red Bull or Vitamin Water?				
Consume dairy products such as milk, cheese, and yogurt?				
Eat meals prepared away from home in places such as restaurants, fast food places, food stands, grocery stores, or from vending machines?				
Eat chocolate or any other types of candy?				
Eat fruit and drink natural fruit juice?				

10.16 How many servings of fruits or vegetables do you eat per day?
□ 5 or more □ 3 or 4 □ 1 or 2 □ I rarely eat fruit and vegetables

10.17 In the past 30 days have you restricted or removed foods from your diet with lactose or other carbohydrates for malabsorption, bloating or diarrhea?
□Yes □Not a consumer
□No

10.18 About how much water would you estimate that you drink per day (a medium sized glass of fluid is about 8 ounces)? ________ glasses = ________ ounces

10.19 About how much fluid in the form of juice would you estimate that you drink per day (a medium sized glass of fluid is about 8 ounces)? ________ glasses = ________ ounces

10.20 About how much coffee or tea would you estimate that you drink per day (a medium sized glass of fluid is about 8 ounces)? ________ glasses = ________ ounces

10.21 About how much fluid in the form of water, juice, coffee, tea, or milk would you estimate that you drink per day (a medium sized glass of fluid is about 8 ounces)? ________ glasses = ________ ounces

11. Quality of Life Questionnaire (SF-12)

This survey asks for your views about your health during the last 4 weeks before your abdominal pain from pancreatitis started. This information will help you keep track of how you feel and how you are able to do your usual activities. Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities and if so, how much?

	Yes, limited a lot	Yes, limited a little	Not limited at all
11.1.1 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			

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11.1.2 Climbing several flights of stairs			

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
11.1.3 Accomplished less than you would like					
11.1.4 Were limited in the kind of work or other activities					

During the past 4 weeks, how much of the time you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
11.1.5 Accomplished less than you would like					
11.1.6 Did work or other activities less carefully than usual					

11.1.7 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not at all
- ☐ A little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
11.1.8 Have you felt calm and peaceful?					
11.1.9 Did you have a lot of energy?					
11.1.10 Have you felt downhearted and blue?					

11.1.11 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11.2 Depression

Over the last two weeks, how often have you been bothered by any of the following problems?

	Not at All	Several Days	More Than Half the Days	Nearly Every Day
11.2.1 Little interest or pleasure in doing things				
11.2.2 Feeling down, depressed or hopeless				

11.2.3 Trouble falling or staying asleep, Or sleeping too much				
11.2.4 Feeling tired or having little energy				
11.2.5 Poor appetite or overeating				
11.2.6 Feeling bad about yourself-That you are a failure or have let yourself or your family down				
11.2.7 Trouble concentrating on things such as Reading the newspaper or watching television				
11.2.8 Moving or speaking so slowly that Other people could have noticed? Or the Opposite-being so fidgety or restless That you have been moving around				
11.2.9 Thoughts that you would be better off dead or of hurting yourself in some way				

12. Quality of Life Questionnaire (PROMIS Global Health Scale)

10.1 Please respond to each item by marking one box per row.

	Excellent	Very good	Good	Fair	Poor
In general, would you say your health is:					
In general, would you say your quality of life is:					
In general, how would you rate your physical health?					
	Excellent	Very good	Good	Fair	Poor
In general, how would you rate your mental health, including your mood and your ability to think?					
In general, how would you rate your satisfaction with your social activities and relationships?					
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)					

12.2 To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

☐Completely
☐Mostly
☐Moderately
☐A little
☐Not at all

12.3 In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?

☐Never
☐Rarely
☐Sometimes
☐Often
☐Always

12.4 How would you rate your fatigue on average?

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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☐None
☐Mild
☐Moderate
☐Severe
☐Very severe

12.5 How would you rate your pain on average?

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
No pain									**Worst pain imaginable**

Completed by:

Name: ___________________________________ **Date: _________**

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

Initials Patient ID Date of Birth (Month/Date/Year)

Date of Enrollment: ☐☐/☐☐/☐☐☐☐ **(Month/Date/Year)**

Proof ID: ☐☐☐☐

APPRENTICE ID: ☐☐☐☐

PAPPEI ID: ☐☐☐☐

1. Contact and Follow-up Information

1.1 Is the follow-up data collected? ☐ Yes ☐ No

1.1.1 If answer to question 1,1, is "NO", indicate the reason:

☐ Patient refused follow-up ☐Patient follow-up completed via phone

☐ Patient deceased

Date of death: ☐☐/☐☐/☐☐☐☐

Cause of death: ___________________

1.2 Follow-up time-point: ☐3Month ☐12 Month

1.3 How was the follow-up data collected? ☐Outpatient Visit ☐Inpatient Visit ☐Phone Interview

1.4 Date of follow-up data collection: ☐☐/☐☐/☐☐☐☐

2. Pancreatitis Recurrence and Complications

2.1 Re-admission to hospital

2.1.1 Since the last contact have you been re-admitted to the hospital? ☐ Yes ☐ No

If yes, how many times: _________

	Date	Recurrent Acute Pancreatitis	Other medical impression	Length of hospital Stay
First Re-admission				
Second Re-admission				
Third Re-admission				

2.1.2 If you had readmissions due to recurrent acute pancreatitis, how many of recurrent acute pancreatitis attacks did you have since the last study contact? _____________

2.1.3 Since the last study contact, have you gone to emergency room for pancreatitis-related symptoms including upper abdominal pain, nausea/vomiting, inability to have oral intake, fever due to pancreatic infection, tubal feeding problems, etc.? ☐Yes ☐No

2.1.4 Did you undergo any pancreas imaging since last visit? ☐ Yes ☐ No

- **2.1.4.1** Which imaging method was applied during this admission?
  ☐ ERCP ☐ MRI ☐ EUS
  ☐ Contrast-Enhanced CT ☐ Non-Contrast-Enhanced CT ☐ RUQ US

  If yes, Date of this imaging: ☐☐/☐☐/☐☐☐☐
  Where was this imaging performed? ___________________________
- **2.1.4.2** Is the imaging report available? ☐ Yes ☐ No
- **2.1.4.3** Are the films available? ☐ Yes ☐ No
- **2.1.4.4** What were the reported findings in radiology?

☐ Normal pancreas
☐ Interstitial Edematous Pancreatitis
☐ Pancreatic necrosis
☐ Peripancreatic necrosis
☐ Irregularities of the main pancreatic duct and its side branches
☐ Pancreatic atrophy
☐ Calcifications/Pancreatic duct stone
☐ Pancreatic fluid collection

- **2.1.9** Extent of pancreatic necrosis (if present)? ☐ <30% ☐ 30-50% ☐ >50%

2.1.5 Were you admitted in ICU setting? ☐ Yes ☐ No
If yes, how long did you stay in ICU? ________(days)

2.2 Emergency Room visits (without admission)

2.2.1 Since the last study contact have you had any emergency room visits for that did not result in admission: ☐Yes ☐No

If yes, how many times have you visited the emergency room: ________
Please give dates and reason:

	Date of ER visit	Chief Complaint
ER visit #1		
ER visit #2		
ER visit #3		

2.2.2 Were any of the ER visits due to pancreatitis-related symptoms including upper abdominal pain, nausea/vomiting, inability to have oral intake, fever due to pancreatic infection, tubal feeding problems? ☐ Yes ☐ No

2.3 NJ Tube (for three-month follow-up only)

2.3.1 Were you discharged from hospital with NJ tube? ☐ Yes ☐ No

If answer to question 2.3.1 is “YES”, answer questions 2.3.2 to 2.3.4.

2.3.2 When was the NJ tube removed? ☐☐/☐☐/☐☐☐☐

2.3.3 For how long did you have the NJ tube? _________________

2.3.4 Were there any complications due to the NJ tube? ☐Yes ☐No
If yes, please specify: ______________________________

2.4 Diabetes

2.4.1 Do you have Diabetes? ☐Yes ☐No ☐Not Sure
2.4.2 When were you diagnosed?
☐>10 years ago ☐1-10 years ago ☐ Within last 12 months
2.4.3 Was it diagnosed before/during or after your first pancreatitis attack?
☐Before ☐During ☐After

2.4.4 When was your diabetes diagnosed?
☐ Before I was enrolled to PAPPEI study
☐ After enrollment to PAPPEI, during follow up period

2.4.5 How is it being treated?
☐Diet only ☐Insulin ☐Pills ☐ Uncontrolled

2.5 Pancreatic Exocrine Insufficiency (EPI)

2.5.1 Since the last study contact, were you diagnosed with pancreatic insufficiency (diarrhea for which your doctor might have prescribed a pancreatic enzyme supplements, such as Creon)? ☐ Yes ☐ No ☐ Not sure

If EPI is diagnosed:

- **2.5.1.1** What was the date of diagnosis ☐☐/☐☐☐☐
- **2.5.1.2** How was the exocrine insufficiency documented by (check all that applies):
  ☐Clinical signs (Steatorrhea) ☐Quantitative: 24 hour stool fat excretion
  ☐Fecal Elastase (<200 mcg/gm stool) ☐Unknown

2.5.2 Are you currently taking pancreatic enzymes supplements (i.e. Creon)? ☐Yes ☐No

If on pancreatic enzymes answer questions 2.5.2.1 to 2.5.2.5:

- **2.5.2.1** How many enzymes does your healthcare provider tell you to take with:
  Every meal _______ Every snack ____
- **2.5.2.2** When are you taking your enzymes?
  ☐Before meal ☐ During meal ☐ After meal
- **2.5.2.3** What dose of pancreatic enzyme did your health care provider tell you to take with every meal?

☐ 6000 IU ☐ 12000 IU ☐ 18000 IU ☐24000 IU
☐ 36000 IU ☐ 48000 IU ☐ 72000 IU

- **2.5.2.4** Complete the table below regarding administration of enzymes:

During the past two weeks, how often did you:

	Almost Always	**Often**	**Sometimes**	**Never**
Feel bothered by taking enzymes in front of others?				
have GI problems (stomachache, loose stools, etc.) due to missed enzymes?				
Forget to bring your enzymes when eating out?				
Forget to take your enzymes?				

2.5.3 Exocrine Pancreatic Insufficiency (EPI) GI Symptom Tracker

The questions 2.5.3.1 to 2.5.3.3 are about your current symptoms, as you perceive them. If you are not sure of how to answer, choose the response that seems closest to your situation.

2.5.3.1 During the past two weeks, how often have you:

	Almost Always	Often	Sometimes	Never
1. Had frequent diarrhea?				
2. Had greasy/oily stools? (indicated by oil droplets which float in the toilet water, stools that may have white or yellow fat in them or stools that float)				
3. Had difficult to flush stool?				
4. Had foul-smelling stool?				
5. Had loose stools?				
6. Felt bloated?				
7.. Had excessive gas?				
8. Had abdominal pain?				
9.. Had to rush to the bathroom in the middle of the night?				
10. Been bothered/concerned by eating fatty or greasy foods?				
11. Been bothered/concerned by using a public bathroom?				

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐
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12. Been bothered/concerned by having to stay on the toilet for a long time?				
13. Been bothered/concerned by skip a meal?				
14. Been bothered/concerned by have a poor appetite because of GI problems?				
15. Been bothered/concerned by missing daily activities due to GI-related problems?				

2.5.3.2 During the past week, how many stools did you have per day?
☐0-1 ☐2-3 ☐4-5 ☐6 or more

2.5.3.3 Usually what is the consistency of your bowel movements?
☐solid ☐soft ☐liquid

2.6 Interventions

2.6.1 Did the patient have cholecystectomy during follow up period? ☐ Yes ☐ No
If "YES", define the date of cholecystectomy: ☐☐/☐☐/☐☐☐☐
2.6.2 Did you have any other GI-related surgery? ☐Yes ☐No
If "YES", please mention the type of surgery you had:

2.7 Metabolic Bone Disease

Since our last contact, was the patient diagnosed with any of the following diseases?
☐ Osteoporosis ☐ Osteomalacia
☐ Other Please specify:____________________________
Please verify the date of diagnosis: ☐☐/☐☐/☐☐☐☐
☐ None
☐ Uncertain

2.8 Comorbidities

Since the last visit/contact, has the patient been diagnosed with any of the following organ/systemic diseases?
☐ Cardiovascular disease ☐ Pulmonary disease ☐ Autoimmune disease
☐ Renal disease ☐ Liver disease ☐ Cancer
☐ Other Please verify: _________________________________

☐☐-☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

Center Initials Patient ID Date of Birth (Month/Date/Year)

Please verify the date of diagnosis: ☐☐/☐☐/☐☐☐☐

☐ None of the above

☐ Uncertain

3. Diet and Lifestyle

3.1 What is the patient's current weight? _________ lbs

3.2 What was patient's average weight (1 year ago)? ________lbs

3.3 Unintentional weight loss in the past 6 months: _________ Ibs

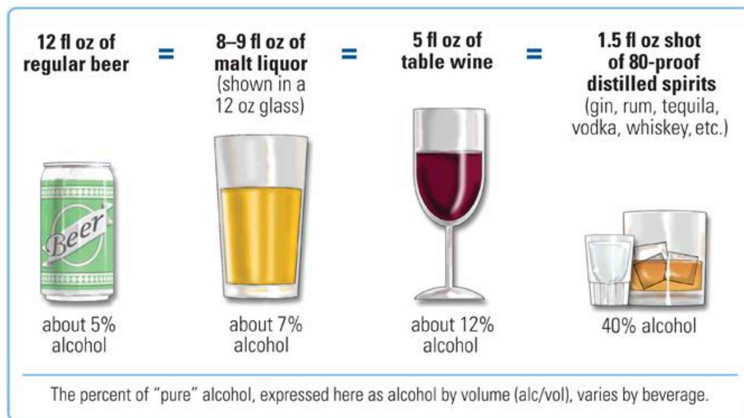
3.4 Midarm muscle diameter: _______(inches)

3.5 What is the current waist size: __________ (inches)

3.6 Waist to hip ratio: ________

3.7 Alcohol

NOTE: In the U.S., a single drink serving contains about 12 grams of ethanol or "pure" alcohol. Although the drinks below are different sizes, each one contains the same amount of pure alcohol and counts as a single drink.



3.7.1 Have you ever consumed more than 10 alcoholic drinks in your lifetime? ☐Yes ☐No

3.7.2 If Yes, do you currently drink alcohol? ☐Yes ☐No

3.7.3 If No, when did you quit? ☐☐/☐☐☐☐

3.7.4 If you currently drink alcohol, on a drinking day, how many drinks do you consume? _____

3.7.5 If you currently drink, how many days per week do you drink? ________ out of 7

3.7.6 Since our last contact has your alcohol intake?

☐ Increased ☐ Decreased

☐ Stayed about the same ☐ Stopped

3.8 Smoking

3.8.1 Have you ever smoked more than 100 cigarettes in your lifetime? ☐ Yes ☐ No

3.8.2 If "YES", do you currently smoke? ☐ Yes ☐ No

3.8.3 If "NO", when did you quit? ☐☐/☐☐☐☐

3.8.4 If you currently smoke, how many cigarettes do you smoke per day? ________

3.8.5 Since our last contact has your smoking habit?

☐ Increased ☐ Stayed about the same

☐ Decreased ☐ Stopped

3.9 Drug History

All data should be collected based on patients' history BEFORE AP-related abdominal pain onset.

3.9.1 NSAIDs* use

☐ Yes (Taken within last 7 days prior to pain onset) ☐ Yes (Taken within last 30 days prior to pain onset) ☐ No

- If yes, how many doses have you had? __________
- If yes, when did you have your last NSAID dose? __________

* (NSAIDs include: ASA, Advil, Motrin, Aleve, Ascriptin, Cambia, Cataflam, Anaprox, Clinoril, Daypro, Feldene, Indocin, Tivorbex, Naprelan, Naprosyn, Voltaren, Zorvolex, Vimovo)

3.9.2 Statin use ☐ Yes ☐ No

- If yes, when did you start it? __________

3.9.3 Detailed list of Drug history (Before the onset of acute pancreatitis attack)

Please write down the names of medications which were started within the last two months prior to pain onset.

☐☐-☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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Medication (Circle the medication(s) within each group when indicated)	Started W/I 7 days	Taking W/I 30 days	Taking W/I 60 days	Daily Dose	As needed	No	Not sure
Narcotics (morphine, Dilaudid, oxycodone, oxymorphone, codeine, tramadol, other)							
Proton pump inhibitors (omeprazole, pantoprazole, esomeprazole, other)							
Antibiotics (ciprofloxacin, metronidazole, tetracycline, isoniazide, dapsone, sulfonamides, erythromycin, pentamidine, isoniazide, other)							
Steroids (oral or intravenous)							
Immunomodulators (6-mercaptopurine, azathioprine)							
HIV therapy (Lamivudine, didanoside, nelfinavir, other)							
Hormonal therapy (estrogens, carbimazole, tamoxifen, testosterone)							
Chemotherapy (Cytarabine, ifosfamide, all-transretinoic acid, L-asparaginase, capecitabine, other)							
Cannabis (medical)							
Olanzapine (Zofran)							

3.9.4 Vitamin/Minerals Supplements (Before the onset of acute pancreatitis attack)

Supplement	**Yes**	**No**	**If yes: Daily Dose**	**Duration**	**Not sure**
Vitamin B12					
Vitamin K					
Vitamin A					
Vitamin E					
Vitamin D					
Multivitamin/mineral					
Iron					
Folate					
Phosphorus					
Magnesium					

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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3.9.5 List of Medications which **were started** within the last two months:

____

____

3.10 Exercise

Godin Leisure-Time Exercise Questionnaire

3.10.1 Do you exercise at all? ☐ Yes ☐No

If yes, during a typical 7-Day period, how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time (write on each line the appropriate number).

	Times Per Week
a) **STRENUOUS EXERCISE** (HEART BEATS RAPIDLY) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	
b) **MODERATE EXERCISE** (NOT EXHAUSTING) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	
c) **MILD EXERCISE** (MINIMAL EFFORT) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	

3.10.2 During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

☐ Often ☐ Sometimes ☐Rarely ☐Never ☐ Not sure

3.11. Dietary Habits

3.11.1 What sort of nutrition did you have when you were discharged from the hospital?

☐☐-☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐
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☐ Oral ☐ Enteral ☐ TPN

3.11.2 If Enteral or TPN, how long did you stay on this diet after discharge?
☐ 1 week ☐ 4 Weeks ☐ >6 Weeks
☐ 2 Weeks ☐ 5 Weeks
☐ 3 Weeks ☐ 6 Weeks

3.11.1 Since our last contact have there been any changes in your diet (check all that apply)
☐ Reduced calories ☐ Reduced Fat intake
☐ Increased Fruit/vegetables ☐ Stayed the same

3.11.2 In general, how healthy would you rate your overall diet?
☐ Very healthy ☐ Fairly Healthy
☐ Healthy ☐ Poor

3.11.3 Which of the following best describes your typical diet?
☐ Omnivore (no specific restriction with regard to meat protein or vegetable choice)
☐ Vegetarian (vegetables and some animal products such as eggs and milk)
☐ Strict vegan (only vegetable products)- no eggs, milk, or animal related products
☐ Pescatarian (eats fish, but no other animal products)
☐ Other

3.11.4 Do you consider your diet to be?
☐ Low fat ☐ High in fat
☐ About average in fat ☐ I don’t pay attention to fat content

In the past 30 days, how often:

	Very often (+1×/day)	Often (2-6×/WK)	Not often (-2×/WK)	Not a consumer
3.11.5 Did you take probiotics, prebiotics, or food supplements?				
3.11.6 Eat or drink items that frequently/may contain probiotic (eg. yogurt, kefir, sauerkraut, kimchi, kombucha)?				
3.11.7 Eat red meat such as beef, pork, ham, or sausage? Do not include chicken, turkey or seafood				
3.11.8 Eat processed meat, such as bacon, lunchmeats, or hot dogs?				
3.11.9 Eaten starch (bread, pasta, etc.)?				
3.11.10 Did you drink regular soda or pop that contains sugar?				
3.11.11 Did you drink coffee or tea?				
3.11.12 Did you drink sweetened fruit drinks, sports or energy drinks, such as G/Q/6, Kool-Aid, lemonade, Hi-C, cranberry drink, Gatorade, Red Bull or Vitamin Water?				
3.11.13 Did you consume dairy products such as milk, cheese, and yogurt?				

☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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3.11.14 Did you eat meals prepared away from home in places such as restaurants, fast food places, food stands, grocery stores, or from vending machines?				
3.11.15 Did you eat chocolate or any other types of candy?				
3.11.16 Did you eat fruit and natural fruit juice?				

Very often: more than once a day**, often:** 2-6 times per week**, not often:** less than 2 times per week

3.11.17 How many servings of fruits or vegetables do you eat per day?

☐ 5 or more ☐ 3 or 4 ☐ 1 or 2 ☐ I rarely eat fruit and vegetables

3.11.18 In the past 30 days have you restricted or removed foods from your diet with lactose or other carbohydrates for malabsorption, bloating or diarrhea?

☐Yes ☐Not a consumer

☐No

3.11.19 About how much fluid in the form of water, juice, coffee, tea, or milk would you estimate that you drink per day (a medium sized glass of fluid is about 8 ounces)?

____ounces water,____ounces juice, ____ounces coffee/tea

____ounces total fluid intake

4. Pain and Disability (Related to GI Complaints/Symptoms)

4.1.1 Have you had any abdominal pain the last 7 days? ☐**Yes** ☐**No**

If yes, how severe is the pain on a scale from 0 to 10? ______

4.1.2 Have you experienced any nausea in the last 7 days? ☐Yes ☐No

4.1.3 Have you experienced any vomiting in the last 7 days? ☐Yes ☐No

4.2 Since the last study contact, how would you best describe your abdominal pain:

☐ No pain at all

☐ I am usually free of abdominal pain

☐ I have episodes of mild to moderate pain

☐ I have constant mild to moderate pain

☐ I have constant mild pain plus episodes of severe pain

☐ I have constant severe pain that does not change

4.3 How often do you have episodes of pain?

Severe pain **Mild-Moderate pain**

_____ bouts in a month _____ bouts in a month

4.3.1 If you have bouts of abdominal pain attacks, how long do the episodes last?

☐ Less than 6 hours ☐ 6-12 hours ☐ 12-24 hours
☐ 1-3 days ☐ More than 3 days ☐ I have constant pain

4.4 During the FOLLOW-UP period, in your opinion, has the abdominal pain problem:
☐Improved ☐ Remained the same ☐ Worsened
☐ Resolved ☐ Had no pain previously ☐ Not sure

4.5 Which pain medication do you take?
Please verify the dose and the frequency you take these medications.

Pain Medication	Dose (mg/day)	Frequency (How Often)	GI-related (yes/no)	Other reasons of pain

4.6 Do you currently work or attend school? ☐Yes ☐No

4.6.1 <u>If answer to question 4.6 is "YES",</u> how many work days or school days have you missed in the last month due to abdominal pain? _____ days/past 30 days

4.7 Are you on disability or unemployed because of your abdominal pain?
☐Yes ☐No If yes, since when ☐☐/☐☐☐☐ (month/year)

4.8 Are you on disability or unemployed due to reasons other than abdominal issue?
☐Yes ☐No If yes, since when ☐☐/☐☐☐☐ (month/year)

□□□-□□□□ □□/□□/□□□□

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5. Quality of Life Questionnaire (SF-12)

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities and if so, how much?

	Yes, limited a lot	Yes limited a little	Not limited at all
5.1 Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
5.2 Climbing several flights of stairs			

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5.3 Accomplished less than you would like					
5.4 Were limited in the kind of work or other activities					

During the past 4 weeks, how much of the time you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5.5 Accomplished less than you would like					
5.6 Did work or other activities less carefully than usual					

5.7 During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- ☐ Not at all
- ☐ A little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

These questions are about how you feel and how things have been with you during the past time 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks.

	All of the time	Most of the time	Some of the time	A little of the time	None of the time

☐☐-☐☐☐-☐☐☐☐ ☐☐/☐☐/☐☐☐☐

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5.8 Have you felt calm and peaceful					
5.9 Did you have a lot of energy?					
5.10 Have you felt downhearted and blue					

5.11 During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc).

☐All of the time
☐Most of the time
☐Some of the time
☐A little of the time
☐None of the time

5.12 Depression
Over the last two weeks, how often have you been bothered by any of the following problems?

	Not at All	Several Days	More Than Half the Days	Nearly Every Day
5.12.1 Little interest or pleasure in doing things				
5.12.2 Feeling down, depressed or hopeless				
5.12.3 Trouble falling or staying asleep, Or sleeping too much				
5.12.4 Feeling tired or having little energy				
5.12.5 Poor appetite or overeating				
5.12.6 Feeling bad about yourself-That you are a failure or have let yourself or your family down				
5.12.7 Trouble concentrating on things such as Reading the newspaper or watching television				
5.12.8 Moving or speaking so slowly that Other people could have noticed? Or the Opposite-being so fidgety or restless That you have been moving around				
5.12.9 Thoughts that you would be better off dead or of hurting yourself in some way				

6. PROMIS Global Health Scale

Please respond to each item by marking one box per row.

	Excellent	Very good	Good	Fair	Poor
6.1 In general, would you say your health is:					
6.2 In general, would you say your quality of life is:					
6.3 In general, how would you rate your physical health?					

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6.4 In general, how would you rate your mental health, including your mood and your ability to think?					
6.5 In general, how would you rate your satisfaction with your social activities and relationships?					
6.6 In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)					

	Completely	Mostly	Moderately	A little	Not at all
6.7 To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?					

In the past 7 days…

	Never	Rarely	Sometimes	Often	Always
6.8 How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?					

	None	Mild	Moderate	Severe	Very Severe
6.9 How would you rate your fatigue on average?					

6.9.1 How would you rate your pain on average?

1 2 3 4 5 6 7 8 9 10

No Pain Worst imaginable pain

Completed by:

Center	Initials	Patient ID		Date of Birth (Month/Date/Year)

Name: ___________________________________ **Date:** _________

PAPPEI Study Lab Procedures

Sample Protocol for Clinical and Research Blood and Stool Samples

Sample Collection Time Points

Samples will be collected at these time points. Please make sure your IRB is reflective of the blood volumes.

	Baseline	3 month Follow Up Visit	12 month Follow Up Visit
Blood Clinical Labs (15 tests)	X	X	X
Blood Research			
2 red non-additives (serum)	X	X	X
1 lavender EDTA (DNA)	X	X only if missed at baseline	X only if missed at baseline & 3 month visit
Stool (clinical and research)			
EZ Sampler (for fecal elastase)	X	X	X
Snap container	X	X	X
DNA/RNA Shield	X	X	X

Clinical Labs

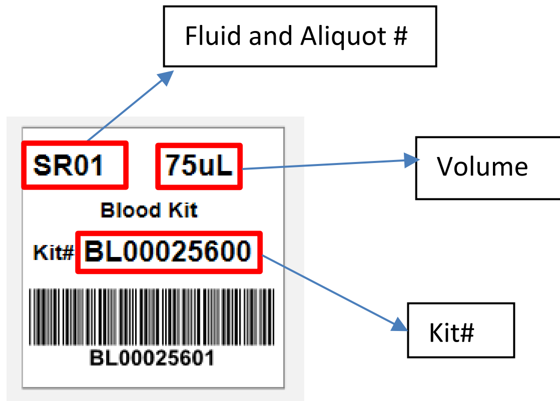
Priority	CHARGE DESCRIPTION	Tube Type	Volume needed per test (SR/PL)	Results expected	Reference Range Age	Reference Ranges
VERY	Fecal Elastase & 72 hr					
1.1	ALBUMIN PNL	1 light green PST (or gold SST)		within 4 hours	15Y	3.4-5.0 g/dL
1.2	PRE ALBUMIN			within 4 hours	20Y	18-38 mg/dL
1.3	VITAMIN B 12 TEST			within 4 hours	ALL	211-911 pg/mL
1.4	FOLATE SERUM			within 4 hours	ALL	>5.0 ng/mL
1.5	FE			within 4 hours	Gender	Male = 45-182 ug/dL ; Female = 28-170
1.5	TIBC			within 4 hours	ALL	250-420 ug/dL
1.5	Ferritin			within 4 hours	ALL	10 - 282 ng/mL
1.6	PHOSPHORUS SERUM			within 4 hours	15Y	2.5-4.6 mg/dL
1.6	MAGNESIUM			within 4 hours	15Y	1.6 - 2.3 mg/dL
2	HEMOGLOBIN GLYCOSYLATED (A1C)	1 lavendar EDTA	full	Overnight	All	4.3 - 6.1 %
3	Retinol Binding Protein	1 gold SST serum	250uL	run on Tuesdays and Fridays and reports within 4 days	Adult	1.5-6.7 mg/dL
4	Vitamin D (D2, D3, total)	1 plain red	500uL	Overnight	All	25-100 ng/mL
5.1	VITAMIN A LEVEL		500 uL	2x per week	20Y	30.0-80.0 ug/dL
5.2	VITAMIN E LEVEL	1 plain red serum (wrap in foil)		2x per week	18Y to 45Y	45Y = 5.2-7.4 ug/mL ; 35Y = 5.1-13.7 ug/mL ; 25Y= 5.8-15.1 ug/mL ; 18Y =4.3-19.0 ug/mL
6	CBC/Diff/Platelet	1 lavendar EDTA	full	within 4 hours		
7	PT PROTHROMBIN TIME (Protime and INR)	1 light blue Na Citrate	full	within 4 hours	16Y	Protime 11.2 - 15.1 sec INR 0.8 -1.2 ratio

Here is a chart of all clinical lab tests along with priority. All other columns are an example of University of Pittsburgh's clinical workflow.

Research Blood

PAPPEI Labels

Here is an example of the labels for the serum and DNA (buffy Coat) tubes (see Figure below).



Here is a picture of a kit for one patient at one time point.

Research blood (serum and DNA) will be collected at three time points: Baseline, 3 month and 12 month visits. Serum tubes will be collected at all three time points and EDTA (DNA) will only be collected one time at baseline. If EDTA (DNA) cannot be obtained at baseline, it will be collected at the 3 or 12 month visits.

Serum Processing (Red Non-additive Blood Tubes)

1. Draw two red non-additive blood tubes. Mix blood thoroughly after draw and leave red top blood tubes **upright at room temperature for at least 45 minutes** (this allows the clot to form). Tubes can be refrigerated after the 45 minutes until centrifugation.
2. Centrifuge at 1200 *g* (rcf) for 10 minutes at room temperature with NO brake. (This can be done at the same time as the plasma step).
3. Use one 15 mL conical tube and transfer serum (upper layer) from both tubes using the transfer pipet tip and mix only if both are not hemolyzed (not reddish).

   Leave approximately ¼ inch to avoid red blood cell contamination. Serum should be free of hemolysis. If the sample is hemolyzed (reddish in color), aliquot the non-hemolyzed sample first, and then finish with the hemolyzed sample. If both samples are hemolyzed, combine into one conical, mix and aliquot. Hemolysis is defined as any ruptured red blood cell contamination or red tinted serum. If a gel-like mass is present, pierce gently with a pipette tip and re-centrifuge for 5 minutes at same speed in step 2.
4. Aliquot the serum from the conical tube in numerical order (ex: SR01, SR02, SR03..etc) into the red capped vials as follows:

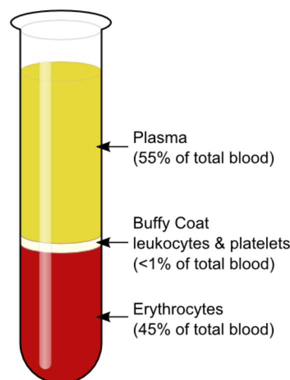
Vial #s	Volumes
SR01-06	75 uL
SR11-16	165 uLs
SR17-20	265 uLs
SR21 & up	515 uLs

   Make sure all aliquots have the volume specified on the tube. If extra serum, do not place in new tube, increment it in the few previous tubes

5. Record all data in the sample ID Sheets. Freeze serum specimens below –70ºC no more than **4 hours** after the blood draw. Serum aliquots can be temporarily stored on wet ice until able to freeze at –70ºC or colder.

DNA (Buffy Coat) Processing (Lavender EDTA Blood Tubes)

1. Centrifuge at 1200 *g* for 10 minutes at RT. This spin can be performed at the same time as step 4 for processing the serums. The slow brake enables the buffy coat to separate for easier processing. If your centrifuge doesn't have "no brake", please use the slowest brake. After centrifugation, the sample should separate into 3 layers: top layer is the plasma, middle thin white layer is the buffy coat and the bottom layer is the red blood cells.



2. Using a transfer pipet, pipet off plasma leaving the last ¼ inch and discard. Then using the same transfer pipet, transfer the entire white buffy coat into the bar-coded 15 mL conical tube labeled "BUFFY1 coat." To get the entire buffy coat, **you will need to take the remaining plasma and**

the top half of red blood cells. If you are not sure you got **ALL** of the WBCs and remaining red blood cells, take everything that is left in the tube.

3. Freeze serum specimens below –70ºC no more than **4 hours** after the blood draw. Buffy Coats (WBC) can be temporarily stored on wet ice until able to freeze at –70ºC or colder.

Storage

All cryovials (serum and urine) and DNA conical tubes can be stored in the same 81 place white box. Please place samples in box starting at top left to top right and so on. You will have one box per patient. It is okay to combine patients into one box as long as it is properly labeled.

Stool Protocol

Stool will be collected for testing fecal elastase for pancreatic function as an indicator for Exocrine Pancreas Insufficiency. Additional stool will be saved and may be used in the future for microbiome related studies.

Every patient will be given a stool kit with three different collection storage methods. Upon collection, they will ship the samples to University of Pittsburgh. The Easy Sampler will be stored in the freezer and batch shipped to Joli Diagnostics for fecal elastase testing. The snap container and the DNA/RNA Shield will be used for future research.

Materials (provided)

1. EZ Sampler (ALPCO # 58EZSAMPLER)
2. Snap containers (LACONS 150600)
3. DNA/RNA Shield fecal collection tube (Zymo cat# R1101)
4. 2 instant ice packs
5. Insulated shipping container (Therapak 56442)
6. Instructions for the patient on how to collect and ship samples to University of Pittsburgh
7. UPS Shipping label
8. UPS label pouch

Patients will be instructed to ship within 24 hours of collection.
If applicable, here are storage conditions for each of the collection tube types

Stool Tube Type	Storage Temperatures
EZ Sampler	keep in fridge (4°C)
Snap containers	keep frozen (-20°C)
DNA/RNA Shield fecal collection tube	keep cold (4°C)