Cholecystostomy Data Collection

Subject ID

Site

○ VMC - Vidant Medical Center - Greenville, NC

Age

(Numeric entry only.)

Gender

○ Male
○ Female

Previous History of Biliary Complaints

○ Yes
○ No

Comments

Number of Previous Presentations

(Inpatient, observation or emergency.)

Comments

Duration of Current Symptoms

(Approximate number of days.)

Comments

Indication for Cholecystostomy

○ Age
○ Comorbid Conditions
○ Delayed Presentation
○ Other
(Choose most appropriate.)

Comments

Admission to Cholecystostomy

(In days.)

Imaging from Admission to Cholecystostomy

☐ Ultrasound
☐ CT
☐ HIDA Scan
☐ MRI
☐ None

Comments

Cholecystostomy to Discharge

(In days.)

Length of Stay

(In days.)

ICU stay

○ Yes
○ No

Length of ICU Stay

In-Patient Mortality

○ Yes
○ No

Discharge Disposition

○ Home
○ SNF/LTAC
○ Inpatient Rehab
○ Other

Comments
Cholecystostomy Plan on Discharge

- Bridge to Surgery
- Cholecystostomy as Definitive
- Removed Prior to Discharge
- Yet to be Determined

Comments

__________________________________
# Past Medical History

## Significant Neuro History
- **Yes**
- **No**

### Neuro History
- CVA/TIA with last 6 months
- Dementia
- Other Significant Neurological History

### Comments

## Significant Cardiac History
- **Yes**
- **No**

### Cardiac History
- CAD
- MI/ACS within last 6 months
- CABG
- Stent
- CHF
- A Fib
- Other Significant Cardiac History

### Comments

## Significant Pulmonary History
- **Yes**
- **No**

### Pulmonary History
- COPD
- Home Oxygen
- OSA
- Pulmonary HTN
- Other Significant Pulmonary History

### Comments

## Significant Renal History
- **Yes**
- **No**

### Renal History
- Acute Kidney Injury
- CKD
- Dialysis
- Other Significant Renal History

### Chronic Kidney Disease Stage
- Stage 2
- Stage 3
- Stage 4
- Stage 5

### Comments

## Significant Gastrointestinal History
- **Yes**
- **No**

### GI History
- Pancreatitis
- Crohns/Ulcerative Colitis
- Diverticulitis
- Cirrhosis
- Ascites
- Other Significant GI History

### Comments
Child-Pugh
- Class A
- Class B
- Class C

Comments
__________________________________

Significant Endocrine History
- Yes
- No

Endocrine History
- Diabetes
- Chronic Steroids
- Other Significant Endocrine History

Insulin Dependent
- Yes
- No

Comments
__________________________________

Significant Hematological History
- Yes
- No

Hematological History
- Bleeding Disorder
- Blood Thinner Therapy
- Other Significant Hematological History

Blood Thinner Name
__________________________________

Comments
__________________________________

Significant Other History
- Yes
- No

Other History
- Transplant
- HIV
- Current Pregnancy
- Malignancy
- Other Significant History

Weeks Pregnant
__________________________________

Malignancy Location
__________________________________

Comments
__________________________________

Recent Abdominal Surgery (within the last 6 weeks)
- Yes
- No
(Answer "yes" only if surgery is within the last 6 weeks.)

Abdominal Surgery Detail
- Stomach
- Gastric Bypass
- Pancreas
- Spleen
- Small Bowel
- Colon
- Liver
- Other Significant Abdominal Surgery

Comments
__________________________________
### Index Admission

#### Admission Labs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>White Blood Count</td>
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<td>Creatinine</td>
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<tr>
<td>Total Bilirubin</td>
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<tr>
<td>AST</td>
<td></td>
</tr>
<tr>
<td>ALT</td>
<td></td>
</tr>
<tr>
<td>Lactate</td>
<td></td>
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<tr>
<td>INR</td>
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<tr>
<td>Blood Cultures</td>
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<td>Blood Culture Results</td>
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#### Admission Physiology

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<tr>
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<tbody>
<tr>
<td>Heart Rate</td>
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<tr>
<td>Systolic Blood Pressure</td>
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<tr>
<td>Diastolic Blood Pressure</td>
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<tr>
<td>MAP</td>
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<tr>
<td>Respiratory Rate</td>
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<tr>
<td>Temperature</td>
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<tr>
<td>Ventilator Support</td>
<td>Yes</td>
</tr>
<tr>
<td>PaO2</td>
<td></td>
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<tr>
<td>FiO2</td>
<td></td>
</tr>
<tr>
<td>Vasoactive Requirement</td>
<td>Yes</td>
</tr>
<tr>
<td>Vasoactive Agent</td>
<td>Dopamine</td>
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<tr>
<td>Comments</td>
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<tr>
<td>Day of Intervention Labs</td>
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<td>--------------------------</td>
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<td>ASA Physical Classification</td>
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<table>
<thead>
<tr>
<th>Comments</th>
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</table>
### Other Index Admission Information

<table>
<thead>
<tr>
<th>Tokyo Guidelines Severity Assessment</th>
<th>Grade I (Mild)</th>
<th>Grade II (Moderate)</th>
<th>Grade III (Severe)</th>
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</thead>
<tbody>
<tr>
<td>Comments</td>
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<table>
<thead>
<tr>
<th>Operations During Index Admission</th>
<th>Cholecystectomy</th>
<th>Wash Out Procedure</th>
<th>Homeostasis Procedure</th>
<th>PTC/ERCP</th>
<th>Other Procedure(s)</th>
<th>None</th>
</tr>
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<tbody>
<tr>
<td>Comments</td>
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<table>
<thead>
<tr>
<th>Percutaneous Interventions During index Admission</th>
<th>Catheter Exchange</th>
<th>Catheter Replacement</th>
<th>Abscess Drained</th>
<th>Biloma Drained</th>
<th>Angioembolization</th>
<th>None</th>
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</thead>
<tbody>
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<td>Comments</td>
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</table>
# Cholecystostomy Outcomes

## Post Index Admission

<table>
<thead>
<tr>
<th>Related Hospitalization up to 90 Days After Index Discharge</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Reason for Readmission(s)</td>
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<td></td>
</tr>
<tr>
<td>Recurrent acute cholecystitis</td>
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<td></td>
<td></td>
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<tr>
<td>Other</td>
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</tbody>
</table>

(Choose all that apply.)

Comment

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### Outcomes

- Cholecystectomy
- Cholecystostomy Replaced/Maintained
- Cholecystostomy Discontinued
- Death

Comment

---

### Cholecystectomy

- Laparoscopic
- Open
- Conventional

Comment

---

## Related Hospitalization 91-180 Days After Index Discharge

<table>
<thead>
<tr>
<th>Yes</th>
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Comment

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### Outcomes

- Cholecystectomy
- Cholecystostomy Replaced/Maintained
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- Death
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<tr>
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<tbody>
<tr>
<td>Cholecystectomy</td>
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<tr>
<td>○ Laparoscopic</td>
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<tr>
<td>Related Hospitalization 181-270 Days After Index Discharge</td>
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<tr>
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<td>Related Hospitalization 271-365 Days After Index Discharge</td>
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(Choose all that apply.)
Cholecystectomy

- Laparoscopic
- Open
- Conventional

Comment
Researchers at East Carolina University (ECU) and Vidant Medical Center study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

**Why am I being invited to take part in this research?**

You are being invited to take part in this research because you have been diagnosed with a biliary disease. Biliary disease can affect the gallbladder which is a sack under the liver that holds bile and the bile duct which is a tube that carries bile. The decision to take part in this research is yours to make. You are under no obligation to take part. By doing this research, we hope to clarify future research questions and learn the best approach to treating biliary disease. If you volunteer to take part in this research, you will be one of about 50 people to do so.

**Are there reasons I should not take part in this research?**

You should not participate in this research if you are under age 18.

**What other choices do I have if I do not take part in this research?**

You can choose not to participate. Choosing not to participate will not change the care you receive. This research is observation only.

**Where is the research going to take place and how long will it last?**

The research will be conducted at Vidant Medical Center. You will need not be required to do anything during the study. There is no amount of time that you will be asked to volunteer for this study.

**What will I be asked to do?**

You will be asked to give permission for the collection of information about your health. The information will come from what is recorded in your medical record.
The information includes:

- Demographics
  - Age
  - Gender
  - Days from admission to intervention for your biliary disease
  - Days of symptoms
- Medical conditions
- Previous hospitalizations
- Vital signs
- Medications
- Laboratory results
- Diagnostic test results
- Management and treatment of your biliary disease
- Admissions/ED visits related to biliary disease after cholecystostomy

**What might I experience if I take part in the research?**

We don’t know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you but the information gained by doing this research may help others in the future.

**Will I be paid for taking part in this research?**

We will not be able to pay you for the time you volunteer while being in this study.

**Will it cost me to take part in this research?**

It will not cost you any money to be part of the research.

**Who will know that I took part in this research and learn personal information about me?**

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- People designated by Vidant Medical Center;
- If you are a patient at ECU or Vidant, a copy of the first page of this form will be placed in your medical records.

**How will you keep the information you collect about me secure? How long will you keep it?**

Your data and the identifying information will be kept at least six years. To keep your information safe and private, your written information will be kept in a locked filing cabinet in a locked office until such time as it is shredded. Electronic information will be stored on the Department of Surgery’s password-protected server. Information that does not have identifying information will be entered into an electronic database on a secure server. In this database, your information, but not your identity, may be used for research in the future.
Title of Study: Prospective Multi-Institutional Evaluation of the Management of Cholecystostomy

What if I decide I don’t want to continue in this research?
You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Who should I contact if I have questions?
The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator, Dr Nathaniel Poulin at 252-847-4299 (days, between 8:00 am - 5:00 pm).

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days, 8:00 am - 5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971 and the Vidant Medical Center Risk Management Office at 252-847-5246.

Are there any Conflicts of Interest I should know about?
The Principal Investigator, research staff have no conflicts of interest associated with this study.

Where will research data be conducted?
The members of the research team will conduct the research study at East Carolina University, Vidant Medical Center and any location in the Vidant Health System where you may receive follow-up care.

When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization. In order to complete the research project in which you have decided to take part, the research team needs to collect and use some of your PHI as described below.

What types of protected health information (PHI) about me will be used or disclosed?
- Medical/clinic records
- Lab, Pathology and/or Radiology results
- Records generated during this study

Who will use or disclose my PHI?
- Principal Investigator
- Other members of the research team
- Other investigators involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.

Who will receive my PHI?
- Research investigators to conduct and oversee the research project
- Principle Investigator and research team members to participate in the various research activities
- FDA or other regulatory agencies to provide regulatory oversight
- UMCIRB to provide continuing review of the research project
- Institutional officials in connection with duties for monitoring research activity

Consent Version Date: 2 Nov 2015
Title of Study: Prospective Multi-Institutional Evaluation of the Management of Cholecystostomy

- Other providers involved in your care during research procedures, outpatient/inpatient stays during which research is being performed, or physician office visits during which research is being performed.

We will share only the PHI listed above with the individuals/agencies listed above. If we need to share other PHI or if we need to send PHI to other individuals/agencies not listed above, we will ask for your permission in writing again.

How my PHI may be released to others?
ECU and VMC are required under law to protect your PHI. However, those individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it and may share your PHI with others without your permission, if permitted by the laws governing them.

What if I do not sign this form?
You will not be eligible to participate in this study if you do not sign this Authorization form.

How may I revoke (take back) my authorization?
You have the right to stop sharing your PHI. To revoke (or take back) your authorization, you must give the Principal Investigator your request to revoke (or take back) your authorization in writing. If you request that we stop collecting your PHI for the study, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or affect payment, health plan enrollment or benefit eligibility. PHI collected for the research study prior to revoking (or taking back) your Authorization will continue to be used for the purposes of the research study.

Are there restrictions on access to my PHI?
You will not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

How long may the PHI about me be used or disclosed for this study?
Research information continues to be looked at after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

If you have questions about the sharing of PHI related to this research study, call the principal investigator Dr. Nathaniel Poulin at phone number 252-847-4299. Also, you may telephone the University and Medical Center Institutional Review Board at 252-744-2914. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at Vidant Medical Center at 252-847-3310 or the Privacy Officer at East Carolina University at 252-744-5200.

I have decided I want to take part in this research. What should I do now?
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
Title of Study: Prospective Multi-Institutional Evaluation of the Management of Cholecystostomy

- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

<table>
<thead>
<tr>
<th>Participant's Name (PRINT)</th>
<th>Signature</th>
<th>Date</th>
</tr>
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</table>

I am familiar with this person and his/her wishes. I am, therefore, giving permission for __________________________ [print participant’s name] to take part in this research because I believe it is the choice he/she would make, if able.

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<thead>
<tr>
<th>Legally Authorized Representative (PRINT)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

**Person Obtaining Informed Consent:** I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person’s questions about the research.

<table>
<thead>
<tr>
<th>Person Obtaining Consent (PRINT)</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate page views needed to complete your submission. If a question is not applicable to your study, you may state this as your response. Please read the help text located on the right side of the page throughout this application.

1.0 * Study Name (Short):
Cholecystostomy

2.0 Study Name (Long):
Prospective Multi-Institutional Evaluation of the Management of Cholecystostomy

3.0 * Summary of Research in Lay Terms:
Biliary diseases are among the most frequently encountered general surgery conditions. The spectrum of disease is broad. There has been much focus recently on the acute management of patient with biliary colic and acute cholecystitis and the trend has been toward earlier intervention. Yet patients who are frail or acutely critically ill are often managed with cholecystostomy. There are few studies available that describe the indications and management of patients with cholecystostomy. The published literature is largely retrospective case series of relatively few patients and largely reflects single institution experience. From these studies it is clear that there is no standard in management of these complicated patients; some patients initially treated with cholecystostomy may undergo cholecystectomy during the same admission, while others are managed with cholecystostomy indefinitely.

The aim of this study is largely descriptive; defining the clinical burden, indications, and management of cholecystostomy. As there is no standard of care, the information gained will be the foundation upon which to design future studies.

4.0 * Principal Investigator:
Nathaniel Poulin

5.0 Faculty Supervisor (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)

6.0 Study Coordinator or Contact Individual:
Kimberly Guillemette

7.0 Contact Individual(s) (if different from Study Coordinator or Principal Investigator):

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Organization</th>
<th>Profile</th>
<th>IRB Certification Renewal Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard</td>
<td>Michael</td>
<td>Surgery, Department of Surgery</td>
<td>Michael Bard's Profile</td>
<td>7/4/2018</td>
</tr>
<tr>
<td>DeLa'O</td>
<td>Connie</td>
<td>Surgery, Department of Surgery</td>
<td>Connie DeLa'O's Profile</td>
<td>5/15/2018</td>
</tr>
</tbody>
</table>

There are no items to display.

8.0 Sub-Investigators:

http://epirate.ecu.edu/app/Doc/0/7PGO24PDKPUKHA4OB1MPD62L70/fromString.html
**Study Staff Roles and Responsibilities**

1.0  
*Click on the UPDATE button beside each person’s name to provide the responsibilities for each study staff member:*

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nathaniel Poulin</td>
<td>Principal Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management, Collects data/specimens, Communicates with IRB, Prepares Study initiation activities, Enters patient data into electronic research records, REDCap</td>
</tr>
<tr>
<td>Kimberly Guillemette</td>
<td>Study Coordinator or Contact Individual</td>
<td>Screens potential participants, Obtains Informed Consent, Enters data on paper research records, Data management, Communicates with IRB, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Trains research team members, REDCap</td>
</tr>
<tr>
<td>Eric Toschlog</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
<tr>
<td>Claudia Goettler</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
<tr>
<td>Mark Newell</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
<tr>
<td>Brett Waibel</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management</td>
</tr>
<tr>
<td>Michael Bard</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
<tr>
<td>Connie DeLa'O</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
<tr>
<td>Cassandra Reynolds</td>
<td>Sub-Investigator</td>
<td>Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records</td>
</tr>
</tbody>
</table>

**IRB Researcher Training Records**

The following information is taken from your researcher profile.

1.0  **Principal Investigator’s Training**
IRB CITI Modules Completion Date:
5/4/2015

IRB CITI Modules Renewal Deadline:
5/4/2018

2.0 Study Coordinator IRB CITI Modules Renewal Deadline:
6/2/2018

3.0 Other Relevant Training:

ID: UMCIRB 15-000864  View: 1.3 Study Funding Information

Study Funding Information

Legacy Sponsor Information:
Department Name
There are no items to display

1.0 * Select the appropriate funding type for this study:
Funding Type
☐ Federal Funding
☐ Industry
☐ Non-Profit
☐ State or Local Funding
☐ Internally Funded (ECU)
☐ Other University or College
☐ No Funding
☐ Other
☐ International Funding

If other, provide the name of the type of funding source:

2.0 * Does the research include any monetary inducements, compensation or reimbursement for participation in this research study?

☐ Yes  ☐ No

If yes, add the payment schedule or provide specific information in the text box below:
Name  Version  Document
There are no items to display

Information about Monetary Incentives:

3.0 Will the sponsor/funding agency reimburse the participant for any items or procedures or supply any items at no cost involved in this research study?

☐ Yes  ☐ No
If yes, add written documentation of the items that will be reimbursed or supplied by the sponsor or supply this information below.

Name  
Version  
Document

There are no items to display

Sponsor Provisions:

ID: UMCIRB 15-000864  
View: 1.4 Conflict of Interest

Principal Investigator (PI)
Disclosing Real or Perceived Conflict of Interest

The Principal Investigator (PI) must answer the following questions:

1.0  * Do you or your immediate family have a total financial interest consisting of royalties, salaries or other payments, ownership of stocks or other interest?
   - Yes  
   - No

2.0  * Do you or a member of your immediate family act as a consultant, have an executive position or serve as a board member of the research sponsor or its holdings?
   - Yes  
   - No

3.0  * Do you plan or hold any claims to intellectual properties, licenses or pending patents on technology that will result from conducting this research study?
   - Yes  
   - No

4.0  * Will you receive any incentives or bonuses based on the number or speed in which you enroll human subjects?
   - Yes  
   - No

5.0  * Will you or any key personnel receive any incentives or bonuses, based on the outcome of the research study?
   - Yes  
   - No

If yes to any of the above, provide details regarding the financial or intellectual relationship:

6.0  * Is this a sponsored/funded project?
   - Yes  
   - No

7.0  * Is there a conflict of interest?
   - Yes  
   - No

ID: UMCIRB 15-000864  
View: 1.41 Research Personnel Conflict of Interest

Research Personnel Conflict of Interest

1.0  * Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest
1.0 Select the Research Facilities where this study will be conducted locally:
   - Name
     - Physicians East, PA
     - Orthopaedics East, Inc.
     - Carolina East Medical Center
     - Vidant East Carolina Health-Beaufort, Inc.
     - East Carolina University
     - Vidant Medical Center
     - Albemarle Hospital Authority
     - Vidant Duplin Hospital
     - Vidant Bertie Hospital
     - Vidant Chowan Hospital
     - Vidant Edgecombe Hospital
     - Vidant Health Access, Inc.
     - Vidant Surgicenter Services of Pitt, Inc.
     - Vidant Roanoke Chowan Hospital

2.0 Other Study Locations (if not captured in the list above):
   - Name
   There are no items to display

3.0 * Is this a multi-site study being conducted at other sites nationally or internationally?
   - Yes
   - No

4.0 * Describe the research setting, listing any safeguards in place for participant safety:
   This is a prospective study examining current practice. Our goal is to use multi-institutional trials
groups established by the Eastern Association for the Surgery of Trauma (EAST), and the American
Association for the Surgery of Trauma (AAST) as a platform to conduct this project. We will utilize
REDCap through ECU for data collection. REDCap is a secure, HIPAA-compliant, web-based
application for building and managing online research surveys and databases. This will facilitate
other sites as well as our own to enter de-identified data. There is minimal risk to patients outside of
disclosing PHI. To decrease this risk no identifiers will be contained on data collection tools.

5.0 Upload letter(s) of support/agreement from the research facility/site(s) unless research
   will be conducted at ECU or Vidant Medical Center.
   - Name
   - Description
   There are no items to display
6.0 * Will an external IRB act as the IRB of record for this study?  ☐ Yes  ☐ No

Multi-Site Study

1.0 * Is the coordinating center at this institution?
   ☐ Yes  ☐ No

2.0 If no, what is the location of the coordinating site? (If there is no coordinating site, enter N/A)

ID: UMCIRB 15-000864

Required Reviews

1.0 * Requested Review Type:
   - Exempt
   - Expeditied
   - Full IRB Review

2.0 Required Department Approvals:
   - Department/School: Surgery, Department of
   - College/School: Brody School of Medicine
   - Division/Institution: Health Sciences

3.0 Research Type:
   - Clinical Investigation
   - Qualitative Research
   - Quantitative Research

ID: UMCIRB 15-000864

Expedited Qualification

If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidelines.

1.0 * Select all that apply:
   Question
1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering the age, weight, and health of subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

(a) hair and nail clippings in a nondisfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;

(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt)

ID: UMCIRB 15-000864

Study Summary

1.0 * Expected Start Date:
7/1/2015

2.0 Expected End Date:
6/30/2017

3.0 * Describe the study objectives.
Primary aim: Understand common indications for cholecystostomy, and management of patients after cholecystostomy.

Secondary aims: Define a safe, and potentially cost effective treatment algorithm for the management of patients with cholecystostomy.

4.0 * Describe the rationale for the type of research design chosen for this study.
This is a prospective observational study, designed to prospectively record data on patients who are managed according to institutional patient management protocols.

5.0 * Describe the uncertainty to be addressed by this research study (this is the research question).
The aim of this study is largely descriptive; defining clinical burden, indications, and management at a number of institutions. As there is no standard of care, the information gained will be the foundation to build prospective studies on.

6.0 * Describe the current state of knowledge surrounding the research questions to be addressed in this study. Include any relevant citations to support your discussion (if not already included in the protocol).
Patients who are frail, present in delayed fashion, or are acutely critically ill are often managed with cholecystostomy. There are few studies available that describe the indications, and management of patients with cholecystostomy.

7.0 UPLOAD your study protocol or grant application here. A protocol is required for review by the convened IRB committee.

For student projects, UPLOAD your professional paper proposal, thesis, or dissertation proposal.

8.0 If applicable, UPLOAD your Clinical Investigator's Brochure:

Recruitment Methods

1.0 * Select recruitment methods used on this study:

- Advertising such as flyers, letters, or ads (newspaper, TV, radio)
- Email Campaign (provide language to be used in email)
- Web Site (provide language to be used on website)
- Phone Solicitations
- Referral by independent source
- Pre-existing relationship with participants
- Selected from pre-existing records
- **Selected from investigators clinic/patient population**
- Treating provider will share PHI of potential participants with study team (also requires Application for Alteration of Authorization form)
- Treating provider shares contact information of study team with potential participants to allow self-referral, no PHI is shared and no form required.
- Social Media (Facebook, Twitter, Blogs, Forums, etc)
- Other

2.0 Specify if "other" methods were selected above or if further explanation of your choice above is needed:

3.0 If recruitment will use PHI from a designated health care component of ECU or Vidant Health, please describe how the PI and/or study team members are affiliated with that health care component (check all that may apply).

1. PI and/or members of the study team are workforce members of a designated health care component of ECU
2. PI and/or members of the study team are workforce members of Vidant Health

If any study team member accessing or using PHI for recruitment is not a workforce member of the health care component from which the PHI will be accessed, or as noted above in Question 1.0, please upload the Application for Alteration of Authorization for Recruiting by Research Team Members Who Are Not Health Care Component Workforce Members.
There are no items to display

4.0 Upload all recruitment documents or scripts that need approval:
There are no items to display

Methods & Procedures: Behavioral Methods/Data Collection

1.0 Select all behavioral/data collection methods and procedures which apply to this study:

- Surveys/Questionnaires
- Interview/Focus Groups
- Videotaping/Audio Recording/Photography
- Intervention or Experimental Procedure
- Public Observation
- Standardized/Non-standardized tests
- Deception
- Creating a Databank
- Use of Existing Datasets
- Teacher Inquiry
- Chart Review
- Other social science or social-behavioral procedures

Methods & Procedures: Bio-Medical Research

1.0 Select all appropriate Bio-Medical methods and procedures for this study:

- Investigational Drugs & Biologics
- FDA Approved Drugs & Biologics
- Investigational Medical Devices/Humanitarian Use Devices
- Approved Medical Devices (being used according to their FDA approval)
- Randomization
- Placebo or No-Treatment Arm
- Washout of Previous Medications
- Diagnostic Radiation
- Therapeutic Radiation
- Substance Abuse Treatment (with medication)
- Sterile Surgical/Invasive Procedures
- Venipuncture
- Genetic Testing
- HIV Testing
1.0 Specify the organization/site at which the data/specimens will be banked:

Name

- Carolina East Medical Center
- Vidant East Carolina Health-Beaufort, Inc.
- Physicians East, PA
- Orthopaedics East, Inc.
- East Carolina University
  - Vidant Medical Center
  - Albemarle Hospital Authority
  - Vidant Duplin Hospital
  - Vidant Bertie Hospital
  - Vidant Chowan Hospital
  - Vidant Edgecombe Hospital
  - Vidant Health Access, Inc.
  - Vidant Roanoke Chowan Hospital
  - Vidant Surgicenter Services of Pitt, Inc.

2.0 Other storage site:

3.0 * How long will the samples and/or data be maintained and/or stored?
Six years past closure of the study.

4.0 * Who will have oversight over the stored samples and/or data?
Nathaniel Poulin MD

5.0 * Will you allow participants to request the samples/data in this study be destroyed?
- Yes
- No
6.0 If you answered "No" above, please explain why participants will not be able to withdraw samples/data or ask that they be destroyed:
The consenting process discloses that "PHI collected for the research study prior to revoking (or taking back) your Authorization will continue to be used for the purposes of the research study." Data collected up to the point that a participant notifies the researcher that they do not want to continue participating will be retained.

7.0 * Will cell lines be developed?  

8.0 * Will a commercial product be developed?  

9.0 Please attach the Standard Operating Procedures and forms that will be used for the bank.

ID: UMCIRB 15-000864  
View: 4.15 Prospective Collection of Data/Specimens

Prospective Collection of Data/Specimens

1.0 * Please provide a description of the data and/or samples to be collected:
Demographics
- Age, gender, race
- Days from admission
- Days of symptoms
Comorbid conditions
- ASA class
- Immunosuppression, CAD, CHF, AKI, CKD, Diabetes, cancer, COPD
- Previous history of biliary complaints
- Previous admissions/ED presentations for biliary disease
Physiology at time of cholecystostomy
- Vital signs (temp, HR, RR, BP)
- Ventilator
- Vasoactive drugs and dose
- Labs (HCT, WBC, Plt, ALT, AST, Total bilirubin, direct bilirubin, Lipase, Cr, Lactate, pH)
Pre-intervention testing
- US
  o Presence of stones, wall thickness, pericholecystic fluid
  o CBD stones
  o CBD dilation
- HIDA
- Nonfilling of gallbladder
- Dyskinesia
- Biliary obstruction
- EUS
  o choledocolithiasis
- MRCP
- CT
Management variables
- Presence of gallstones
- Cholangiogram
  o Days from cholecystostomy to cholangiogram
  o Impact on management
  - cholecystostomy removal without cholecystectomy
  - cholecystectomy (lap vs open vs lap to open)
  - cholecystostomy exchange
Outcomes
- Mortality at 1 year
- Management at 1 year
- Admissions/ED visits related to biliary disease after cholecystostomy
- Days with cholecystostomy
- Operative morbidity (enterotomy, abscess, leak, bleeding, ect)
- Cholecystostomy morbidity (tube dislodgement, bleeding, abscess, ect)

2.0  * Please describe the tests or analyses to be performed on any research samples/specimens:
NA

3.0  * Sample/Specimen Collection Method:
Name
No samples/specimens used in this research. Data collection only.

4.0  * Will the analysis to be done on any samples/specimens possibly result in the discovery of any genetic information related to the participant's (or his/her relatives') health or susceptibility to a disease or condition currently or in the future?
  ○ Yes  ○ No

Costs Related to Participation

1.0  * Select all categories indicating costs which participants or their insurance companies will be responsible for:
Name
☐ Participants will have no costs associated with this study
☐ Study Related procedures which would be done under standard care
☐ Study related procedures not associated with standard care
☐ Administration of drugs-devices
☐ Study Drugs or Devices
☐ Other

2.0  If study participants or insurance companies will assume costs for this study, describe the procedures, drugs, or devices for which the participants must assume costs:

Study Population

1.0  * Indicate what your primary targeted population will be:
  Study Population
  ☐ Children (participants under 18 years of age)
  ✓ Adults (18 years of age and older)
  ☐ Normal Volunteers
  ☐ Employees
  ☐ Students
  ✓ Inpatient Patients
2.0 * Indicate the inclusion criteria for enrollment:
Patients with calculous or acalculous cholecystitis treated with cholecystostomy

3.0 * Indicate exclusion criteria for enrollment:
Patients under the age of 18 and prisoners are excluded.

4.0 * Provide justification if this study excludes a population who might benefit.
NA
to emphasize the voluntary nature of participation?  ☐ Yes  ☐ No

4.0  Describe your plan to receive approval for the patients participation from their attending physician (if not listed as an investigator on this study).

5.0  If you plan to approach patients of other attending physicians who are not participating as investigators in this study and you know who these physicians will be, you should obtain their signatures on the Attending Physician Signature Form and upload that document here:

ID: UMCIRB 15-000864  View: 5.9 Study Population Summary

Study Population Summary

1.0  * What is the maximum number of participants you plan to recruit for this site?

90

2.0  If this is a multi-site study, indicate the projected total participant accrual:

700

3.0  Provide any additional comments regarding proposed number of participants:

4.0  * Justification for Sample Size:
It is estimated that 700 participants will provide a baseline for evaluating current treatment, areas where additional research may be necessary and a direction for exploring that research.

5.0  * Describe the safeguards in place to protect the rights and welfare of any vulnerable participants enrolled in this research study.
Children and prisoners are excluded. Participants may revoke consent at any time.

ID: UMCIRB 15-000864  View: 6 Risk/Benefit Assessment-Risks

Risk Assessment-Safeguards

1.0  * Risk classification for this study (select one).

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i).

☐ Minimal Risk
☐ Greater than Minimal Risk

2.0  * Risks, Discomforts and Potential Harms: Describe the risks/discomforts associated with each research related intervention as well as risk related to data privacy and confidentiality. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility. Risk associated with participation in the study is a breach of confidentiality. This risk is remote.

3.0  * Describe the safety precautions that will be taken to minimize the above risks/harms: Data will be stored on the Trauma Department's PirateDrive.

4.0  * Will a federal Certificate of Confidentiality be obtained for this study?:  ☐ Yes  ☐ No
If yes, please attach the Certificate of Confidentiality:

5.0 * Describe any additional safeguards in place to manage illegal, significantly intimate or potentially embarrassing information gathered in this research study.
No additional safeguards will be undertaken as the data set collected will be limited.

6.0 * Include steps to handle information that may require mandatory reporting to officials (e.g., child abuse or neglect), reportable health problems (e.g., HIV/AIDS, hepatitis), or information that requires seeking professional assistance (e.g., expression of intent to harm one's self or others).
NA - Information that requires mandatory reporting will be handled as the standard of care.

7.0 * If the research study involves HIV testing, describe the plans for pre/post test counseling, partner notifications, referrals for care and any other related considerations.
NA

8.0 * Outline the mechanism for reporting Unanticipated Problems to the IRB, participants or others for this study.
There is a remote potential of breach of confidentiality which would be reported to the IRB and Risk Management within 24 hours of discovery.

ID: UMCIRB 15-000864 View: 6.1 Risk/Benefit Analysis-Potential Benefits and Alternatives

Risk/Benefit Analysis-Potential Benefits and Alternatives

1.0 * Describe any potential for direct benefits to participants in this study:
There are no direct benefits for participation.

2.0 * Describe any potential benefits to society:
This study will describe current practices, and may give some insight to optimal care; resulting in fewer complications, and lower cost. In this way there would be a benefit to patients in the future.

3.0 * Alternatives to Participation: If applicable, describe alternatives (research or non-research) that are available to participants if they choose not to participate in this study.
NA

4.0 * Risk/Benefit Analysis: Justify why individuals should participate in this research study based on the risk/benefit ratio (relative to non-participation and/or alternatives).
This study could influence the standard of care for treatment resulting in better outcomes, fewer complications and lower costs. This has the potential to benefit patients at a future date.

ID: UMCIRB 15-000864 View: 7 Informed Consent Determination

Informed Consent

1.0 * Indicate the types of consent that will be involved in this study (check any or all that apply):

- [x] Written/signed consent by participant
- [x] Written/signed consent by a legally authorized representative (for an adult)
- [ ] Written permission for a child by a parent or legal guardian
ID: UMCIRB 15-000864 View: 7.1 Consent Forms & Process of Consent

Consent Forms & Process of Consent

1.0 There are several different types of consent form templates provided. Please follow the instructions below to complete the process.

Instructions:
1.1) Download the applicable consent form template to your machine and modify this where applicable.

- Consent Template: Consent Letter for Expedited Survey Research
- Consent Template: Consent Paragraph for Exempt Survey Research
- Consent Template: More Than Minimal Risk Research
- Consent Template: No More Than Minimal Risk Research
Genetic Testing Addendum
Language for Use in a Sponsor's Consent Template
Minor Assent Template
Parent Consent to Use Child's Data for Research Purposes

* 1.2) Upload consent forms, assent forms, or information sheets here:
Name | Modified | Version
--- | --- | ---
ICF Chole Version 23sep2015.docx | 11/23/2015 4:15 PM | 0.02

1.3) If available, upload sponsor templates:
There are no items to display

2.0 * Describe how, when, and where the consent process will be initiated:
Consent will occur with the patient, if appropriate and coherent, or the patient’s legally authorized representative after diagnosis is determined. Consent will occur in the patient's room or treatment area. When consent is received from the LAR, due diligence will be given to consenting the patient when the patient is able to participate in the consent process.

3.0 * For those team members obtaining consent, describe how they have been trained to consent potential participants and how they have the appropriate expertise to address concerns/questions of potential participants related to this study:
All members of the research team are specifically trained on obtaining informed consent through their practice or a research professional fully trained on the GCP of informed consent.

4.0 * Describe the process to minimize undue influence and coercion during the consent process:
Undue influence and coercion will be minimized by the consenting professional by stressing that participation is strictly voluntary and will in no way influence the care received. This will occur both verbally and in writing.

5.0 * Outline procedures for obtaining informed consent from participants with limited or low literacy:
Participants or LARs with limited or low literacy will have the consent read to them verbatim employing the technique of teachback to ensure understanding.

6.0 * Describe the process for determining cognitive impairment or other conditions that may make a participant more vulnerable:
Participants must be alert and oriented without overwhelming pain or stress to give consent. Otherwise, an alert and oriented LAR who is not suspected of being under the influence mind altering substances will be allowed to consent.

7.0 * Describe the process for identifying the legally authorized representative and the process to debrief and subsequently obtain consent from the study participant, when feasible:
This will occur per Vidant Medical Center policy.
## Data Privacy & Confidentiality

### 1.0 * Choose the option that applies to your research study (check all that apply):*

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**Upload all applicable HIPAA documents:**

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There are no items to display.

### 2.0 * Where will you obtain the data for this research study?*

Medical Records

**If other, specify:**

### 3.0 * Describe how the identity of individuals research data and/or specimens will be recorded (check all that may apply):*

Identified (Data will be linked directly to individuals via the use of one or more of the 18 HIPAA identifiers including initials, date of birth, etc.--if a master key is being kept, "Identified" should be selected.)

**If other, specify:**

If identity is coded, describe how the code is created (random, sequential, computer generated, etc) and give an example:

### 4.0 List all categories of data to be collected for this research study (e.g., Name, Date of Birth, Age, Disease status, etc) or upload your data collection sheet below:

**Demographics**
- Age, gender, race
- Days from admission
- Days of symptoms

**Comorbid conditions**
- ASA class
- Immunosuppression, CAD, CHF, AKI, CKD, Diabetes, cancer, COPD
- Previous history of biliary complaints
- Previous admissions/ED presentations for biliary disease

**Physiology at time of cholecystostomy**
- Vital signs (temp, HR, RR, BP)
- Ventilator
- Vasoactive drugs and dose
- Labs (HCT, WBC, Plt, ALT, AST, Total bilirubin, direct bilirubin, Lipase, Cr, Lactate, pH

**Pre-intervention testing**
- US
  - Presence of stones, wall thickness, pericholecystic fluid
  - CBD stones
  - CBD dilation
  - HIDA
  - Nonfilling of gallbladder
o Dyskinesia
o Biliary obstruction
- EUS
o choledocolithiasis
- MRCP
- CT

Management variables
- Presence of gallstones
- Cholangiogram

o Days from cholecystostomy to cholangiogram
o Impact on management
- cholecystostomy removal without cholecystectomy
- cholecystectomy (lap vs open vs lap to open)
- cholecystostomy exchange

Outcomes
- Mortality at 1 year
- Management at 1 year
- Admissions/ED visits related to biliary disease after cholecystostomy
- Days with cholecystostomy
- Operative morbidity (enterotomy, abscess, leak, bleeding, ect)
- Cholecystostomy morbidity (tube dislodgement, bleeding, abscess, ect)

If applicable, upload data collection sheet:
There are no items to display

5.0 * Where will the paper and electronic research data be stored? Please specify the physical location (building and room number), length of time it will be stored and how it will be secured to protect confidentiality:
Paper forms including consents will be stored in a locked filing cabinet in the locked office of the study coordinator (2ED-220).
Electronic data will be stored on the Trauma department’s secure Pirate Drive. Data will be stored for 6 six years after the close of the study.
Redcap will be used to create and design the data collection component of the project using secure web authentication. Redcap allows export of data to common data analysis packages.

6.0 * Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.
No one other than study personnel will have access to the data.

ID: UMCIRB 15-000864 View: 8.2 Data Privacy & Confidentiality for Coded or Identified Data

Data Privacy & Confidentiality

1.0 * If coded or identified data will be released, specify the persons/agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality:
No identified data will be released. Deidentified data will be entered into the REDCap database.

2.0 * Describe what will happen to the data or data set when the study is completed. Please indicate your plans for the destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable:
After the necessary time has passed in order to follow up on readmissions and ED utilization, the data set will be stripped of identifiers at the earliest opportunity.

3.0 * If audio/video recordings or photographs will be used, specify your plans for de-identifying or anonymizing the material. Indicate when and how these will be destroyed.
4.0 * If the participants' data or samples from this study will be used for other research studies in the future, please describe the type of data that will be used and how their privacy will be protected.

Future research may utilize the deidentified data entered into the REDCap database.

ID: UMCIRB 15-000864

Data Safety Monitoring Plan

1.0 * Check the one box below that most accurately reflects the plan for data and safety monitoring for this study.

Name
- The study will be monitored only by the study investigators and/or sponsor.
- The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).
- A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.

2.0 If this study will be monitored by individuals not associated with this study and there is no formal DSMB, provide the names of those individuals.

NA

3.0 Describe the clinical criteria for withdrawing any individual participants from the study due to safety or toxicity concerns.

NA

4.0 Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns.

NA

5.0 Are there any plans to perform an interim efficacy analysis?

- Yes  ☐ No

6.0 If you answered Yes, please describe the plans to conduct an interim analysis.

ID: UMCIRB 15-000864

Institutional Ancillary Approval

Based on your answers to the following questions, you may need to answer additional questions.

1.0 * Will this study generate or require the use of protected health information (PHI) or medical records by any ECU research team member at the research location?

- Yes  ☐ No

2.0 * Will this study require the use of medical records at Vidant Medical Center (or any other Vidant facility)?

- Yes  ☐ No
3.0  * Will this study utilize clinical areas within ECU Physicians, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at ECU/BSOM?  ○ Yes  ○ No

4.0  * Will this study involve inpatient or outpatient units/staff at a Vidant Health facility, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at a Vidant Health facility?  ○ Yes  ○ No

5.0  * Will this study take place at the Leo W. Jenkins Cancer Center (LJCC)?  ○ Yes  ○ No

ID: UMCIRB 15-000864  View: Spring 2012 11.1 Use of Protected Health Information at ECU/BSOM

Use of Protected Health Information at ECU/BSOM

1.0  HIPAA designations chosen for this study:

Name

HIPAA Authorization has been incorporated into the research consent document
Review ECU protected health information to prepare for research (upload form below)
Review Vidant protected health information to prepare for research (upload form below)

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There are no items to display

Note the following information:

1. Research access to medical records will be view only.
2. The legal medical record for VMC is the imaged medical record.
3. A researcher must have and maintain the appropriate UMCIRB and HIPAA approvals prior to requesting or accessing any protected health information from the medical records system.
4. The researchers will follow all established ECU policies for the conduct of research and use of protected health information.
5. For each record accessed, an Accounting of Disclosure must be completed.

Questions?
Contact ECU HIPAA Privacy Office at (252) 744-5200.

Information Technology Security for Protected Health Information at ECU/BSOM

1.0  * Will the records you use or collect in preparation for your study or any time during your study (inclusive of any temporary collection) contain any of the 18 Personal Identifiers as specified by HIPAA Privacy? (Check all the Personal Identifiers contained
in the data you plan to use or collect:

- Patient Names
- Medical record numbers
- Date of Birth/Death/treatment/admission/discharge/diagnosis/age (if older than 90) or any other element of date (except year) which is directly related to the individual

Note: If any of the 18 Personal Identifiers are utilized then the research data is considered PHI (Protected Health Information) and subject to HIPAA privacy regulations.

ID: UMCIRB 15-000864  View: Spring 2012 11.6 Use of Protected Health Information at ECU/BSOM

Information Technology Security for Protected Health Information at ECU/BSOM

1.0 Do you plan to de-identify the PHI data prior to final analysis for this study by removing the 18 identifiers as required by HIPAA?
   - Yes

Note: All PHI Data use and storage requirements must be followed until the point of de-identification.

2.0 Will PHI data be stored electronically, on paper, or both?:
   - Both

Specify if not applicable:

3.0 If storage of PHI is on paper: please provide location(s) of paper storage and security controls (lock and key, restricted access, etc.):
   - Paper storage will be in the study coordinator's locked office in a locked filing cabinet. The office is located at 2ED-220.
   - Note: HIPAA requires a minimum of 6 years for paper retention as specified by HIPAA Privacy #004. If NIH, federal regulations, or Industry Sponsor requires a longer period, you must adhere to those retention policies.

4.0 If storage of PHI is in electronic form: please provide location(s) and storage device(s) below:
   - ECU Departmental Folder in Pirate Drive
   - List Other storage locations or devices:

Note: the storage location(s) and device(s) must be from the ITCS HIPAA Acceptable Storage Device List. Please review the device list in order to fully understand specific requirements for each storage device.

5.0 Please provide the name AND the contact information for the appointed HIPAA Administrator for all electronic PHI for this study.:  
   - Nathaniel Poulin, MD 600 Moye Blvd Greenville, NC 27834 252-847-4299
   - Note: For EPHI stored at ECU, the appointed administrator must be a full-time ECU faculty or staff member. Failure to appoint an Administrator is a violation of University Policy.

6.0 Will the electronic or paper PHI data be shared with entities external to ECU as part of this study (including medical imaging, film, audio/video recordings, etc)?
   - Yes ☐  No ☑

If yes, please list all external entities, contact information, location(s) and business justification(s):
Note: It will be necessary to complete a HIPAA Privacy review if data is transferred external to the University.

7.0 It is ECU policy that all PHI data is backed up regularly to ensure against data loss. What will be the method used back up the electronic PHI data?:
If initial research data is already stored on your Departmental Pirate drive, check here. Pirate drive is backed up automatically and no action is required on your part.

List Other backup storage location(s):

Note: ECU data should be stored on ECU issued computers. Cloud Hosted storage solutions (e.g. Dropbox, MyPCBackup, Mozy, etc.) are not appropriate options. Contact IT Help Desk if you need assistance for options other than Pirate Drive or encrypted hard drive.

8.0 Do you plan to store de-identified PHI data any differently from the methods already listed above?:
Yes
If yes, please explain:
Deidentified data will be entered into REDCap.

9.0 Do you plan to have the ability to re-identify your data in the future (if a master key is being kept, this should be "yes")?:
No

Note: If YES, the re-identified data will contain PHI data and will be considered a HIPAA System under HIPAA Security Regulations. IT Security must be notified immediately when data is re-identified. Contact ITSecurity@ecu.edu to report re-identification. Failure to report the re-identification of data is a violation of University Policy.

10.0 How will the ECU owned PHI data be destroyed once it is no longer necessary to be retained?
Indicate how data will be destroyed if paper or electronically stored.:
Paper- Cross-cut shredder
Electronic- Deletion from Piratedrive or other ITCS Computer

If Other, please describe:

ID: UMCIRB 15-000864

Use of Medical Records at Vidant

Based on your answers to the following questions, you may need to answer additional questions.

1.0 HIPAA designations chosen for this study:
Name
HIPAA Authorization has been incorporated into the research consent document
Review ECU protected health information to prepare for research (upload form below)
Review Vidant protected health information to prepare for research (upload form below)

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Note the following information:

1. Research access to medical records will be view only.
2. The legal medical record for Vidant is the imaged medical record.
3. A researcher must have and maintain the appropriate UMCIRB and HIPAA approvals prior to requesting or accessing any protected health information from the hospital medical records system.
4. The researchers will follow all established Vidant policies for the conduct of research and use of protected health information.

Questions?
Contact Vidant Health Information Management Services or Vidant Privacy Office/Research Compliance Office of Audit & Compliance

11.4 PCMH Inpatient/Outpatient Services

Based on your answers to the following questions, you may need to answer additional questions.

1.0 Will this study involve ionizing radiation?: ☐ Yes ☐ No

What are the type and frequency of tests using ionizing radiation, which are a part of the protocol?

List the tests that are using ionizing radiation which are not routine services. Routine services are services that are generally available to Medicare Beneficiaries.

Questions?
Contact Radiation Safety

2.0 Will this study involve Special Medical Services (Endoscopy, Bronchoscopy, Respiratory, Urodynamics, Neurophysiology)? ☐ Yes ☐ No

Questions?
Contact Special Medical Services

3.0 Will this study involve patients receiving Rehabilitation Services including any diagnostic studies?: ☐ Yes ☐ No

Choose whether this study will take place in the inpatient or outpatient areas of PCMH:
Choose the location or service that will be involved:
Name
There are no items to display

If Inpatient Rehabilitation, will the research protocol be conducted during the patient's therapy times, which are held 7 days of the week between the hours of 8:00 and 4:00 pm (there are strict standards from CMS regarding the number of therapy hours our patients must receive)?

- Yes
- No

Questions?
Contact Rehab Services at (252) 847-8906

4.0 Will this study utilize investigational or other devices, materials or supplies? (Yes / No)

Confirm that the mechanism for tracking investigational devices has been established with the services required for the research study. If there has been no established mechanism contact Materials Management at (252) 847-4240:

Describe how the investigational devices and related supplies for this research will be ordered.

Describe how the investigational devices and related supplies for this research will be received into the hospital.

Describe how and where the investigational devices and related supplies for this research will be stored.

Identify who will have access to the investigational research devices and related supplies and how access by unauthorized individuals will be prevented.

Questions?
Contact Materials Management

5.0 Is there any medical equipment involved in this study? (Yes / No)

Will it be attached or possibly come in contact with the patient during the study?

- Yes
- No

Has it been tested by a "Nationally Recognized Testing Laboratory" such as UL?

- Yes
- No

*Any electrical medical instrumentation used in this study that comes in contact with the patient, must be checked by the PCMH Biomedical Department prior to the start of the study.

Questions?
Contact PCMH Biomedical Department

6.0 Will this study utilize the PCMH laboratory? (Yes / No)
Will there be any laboratory tests performed as part of this study that will not be billed to the patient’s hospital account?  ○ Yes  ○ No

Will there be any specimens collected from the patient that will require testing or examination at an outside laboratory?  ○ Yes  ○ No

Does this study require the PCMH Microbiology laboratory to perform susceptibility studies on investigational drugs?  ○ Yes  ○ No

Will hospital pathologists or pathologist assistants be asked to collect or examine tissue specimens as part of this study?  ○ Yes  ○ No

Will stored tissue (block or slides) be examined as part of this study?  ○ Yes  ○ No

Note the following information:
1. The PCMH laboratory is prepared to support research by performing all tests that are part of our standard test menu.
2. The PCMH laboratory is not prepared to collect, prepare, store or transport specimens to central laboratories as part of this study.
3. Requests for laboratory testing performed at PCMH which are not routine services (generally available to Medicare Beneficiaries) should be submitted on special forms obtained in the laboratory Outreach office at (252)847-4222.
4. Note that any individual mailing biological materials from the institution must have received the appropriate training and certification or its equivalent. For additional questions call (252) 744-2237.

Questions?
Contact PCMH Lab

7.0 Will this study involve medications?  ○ Yes  ○ No

Are the drugs investigational?  ○ Yes  ○ No

Are the drugs FDA approved but being used for an unapproved indication?  ○ Yes  ○ No

Will the drugs be dispensed to the patient in the hospital, outpatient hospital department, or from a clinic or private office setting?

Are the drugs being charged to the patient or supplied free of charge by the sponsor?

Is there a contract with the Investigational Drug Pharmacist to receive, store and dispense the drugs under investigation?  ○ Yes  ○ No

Questions?
Contact PCMH Investigational Drug Coordinator at (252) 847-5723

8.0 Will this study involve inpatient or outpatient units or staff within PCMH?  ○ Yes  ○ No

Identify the target units for the study patients (inpatients) and indicate whether the appropriate floor managers have been contacted regarding the impact on those floors’ resources. Target units include those receiving patients with cholecystitis treated with cholecystostomy. Floor managers have not been contacted as floor resources will not be impacted by the study.
Identify any nursing outpatient department and/or procedure areas that will be involved with the study (AMU, ASU, Chest Pain Unit, ARU, Healthsteps, Cath Lab, COU, EP Lab, PACU, etc).: N/A

Describe the extent in which the nursing staff will be involved with the research study (i.e. in delivering, administering, or monitoring of the investigational test article).: N/A

Describe the plans for educating the nursing staff and attach any relevant educational materials below:
Nurses will be informed that a patient they are caring for is to be consented for a research study in order not to disrupt care. At that time the nurse will be informed that nursing staff will not participate in the delivery, administration, monitoring, or collecting of any study information/activity.

Upload any relevant educational materials:

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Identify any consulting or support services that will be required specifically for the research: N/A

Describe the impact that the research will have on the participant’s length of stay:
There is no impact on length of stay.

Describe the impact that the research will have on the nurses’ routine, e.g., if there will be a potential increase in the length of time to perform their normal responsibilities as a result of any research related procedures.
There is no impact expected on the nurses’ routine. Every effort will be made to avoid interfering with the delivery of care.

Questions?
Contact PCMH Human Protection Administrator

9.0

Will this study require obtaining data from existing databases at PCMH (or other UHS facility)? Yes ☐ No

List Dept(s) where the data will be obtained from and indicate whether the department manager has been contacted:

Questions?
Contact PCMH Human Protection Administrator

10.0 Will any clinical services be performed as part of this study (including those services paid for by the sponsor)? Yes ☐ No

This section, as well as the Financial Services Review Form, must be completed if any clinical services will be performed as part of the study even if all of those services will be paid for by the sponsor.

Confirm that the mechanism for direct billing has been established with the services required for the research study. If there has been no established mechanism contact the following:
Pharmacy (252) 847-5723, Radiology (252) 847-5260, Laboratory (252) 847-4946, Other Services (252) 847-0778 or (252) 847-5244, Investigational Device Service Codes (252) 847-0778 or (252) 847-5244.
Contact PCMH Finance to negotiate pricing for all services except Pharmacy and Lab.

What is the turnaround time for payment of the claim?

Who is responsible for payment of the claims

What is the billing address and contact person for claims payment?

If a medical device study, upload a copy of the FDA letter confirming the category.

Upload Financial Services Review Form:

Note: The research participant list (enrollees) needs to be emailed to PCMH Finance.

Questions?
Contact PCMH Finance

Additional Material

Please upload any other items for review and approval if not already uploaded on a previous page of this application. Additional Items for IRB Review and Approval:

Name
Version
Document

There are no items to display

Final Page

If you have completed your application, click "Finish" to finalize and exit the application. This action does NOT submit the application for review, it just means you have finished editing the application at this particular time.

For those studies that are being submitted for review and approval by the UMCIRB:

1. All research personnel/team members must login to ePIRATE and click the "Agree to Participate" button before ePIRATE will allow a study to be submitted.
2. A submission may only be submitted to the UMCIRB by the Principal Investigator. To do this, the Principal Investigator must login and click the "SUBMIT STUDY" button under My Activities for this Study ID: UMCIRB 15-000864.

For those studies that are being submitted for acknowledgment of the use of an external IRB:

1. Research personnel/team members are not required to "Agree to Participate" before ePIRATE will allow a study to be submitted.
2. A submission may be submitted by any listed team member. To do this, the team member must login and click the "SUBMIT STUDY" button under My Activities for this Study.

You can track the ongoing status of your submission by logging into the study workspace.

Please wait until you receive your final approval/acknowledgement notice prior to beginning your study and feel free to contact the UMCIRB with any questions or concerns.