

Study Interview Application (Version 1.0)

1.0 General Information

***Please enter the full title of your study:**

Current Diagnosis and Management of Pancreatic Injuries - Western Trauma Association Multi-Center Trial

***Please enter the short title you would like to use as a reference.**

Diagnosis and Mgmt of Pancreatic Inj - WTA
 * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Please identify the Research Type?

Emergency and Trauma

Please identify the Study Phase:

--none--

2.0 Add Department - Research Site(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
<input type="radio"/>	Scripps - Scripps Clinical Research Services
<input type="radio"/>	Scripps - Trauma Services

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Biffel, Walter

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

B) Research Support Staff

Schaffer, Katie Brown, MPH, CCRP, CSTR
 Study Coordinator

3.3 *Please add a Study Contact:

Schaffer, Katie Brown, MPH, CCRP, CSTR

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

4.0

Study Interview

Interview Tips:

- *All questions that require answers are preceded by an asterisk (*). After completing a section click on the 'Save and Continue to Next Section' button in the upper right. If you miss a required question, an error box will appear and the field you missed will be indicated in red.*
- *You do not have to complete this interview all at one time. If you wish to stop in the middle, any sections you have completed AND SAVED will be saved as a 'Draft' version. You can return to this 'Draft' version by going to the My Studies area of Study Assistant.*
- *If you are entering a long block of text copied from another source that requires editing, it will be easier to paste this into MS Word on your desktop and do the editing there, then paste into the text box or text editor within this application.*
- *If you want to go back to a prior section in the interview do NOT use the 'Back' button in the upper right or the 'Back' button in your browser. Click on the section you wish to go back to in the 'Sections' menu on the left. If the 'Sections' menu on the left is not visible, then use the 'Back' button in the upper right. If you do accidentally click on the 'Back' button you will go the Submissions section for your study. Click on the 'Application' link under 'Protocol Items' to return to the interview.*
- *Help for completing some sections will appear on the right side of the interview. Put your cursor over the bubble containing a question mark and click on the link that pops up to view HELPFUL TIPS.*
- *When calling or emailing with questions about or problems with this interview please refer to the section title in addition to the section number.*

4.1 *How do you want your Institution, Department, Division, etc. to appear on official IRB Approval Notices?

Scripps Memorial La Jolla Trauma Service

5.0 Independent IRB

5.1 *Are you using a Central/Independent IRB? (If Yes, be sure to attach the IRB application, sponsor protocol, investigational drug brochure and approved consent/assent forms.)

Yes No

6.0 HDE/HUD

6.1 *Is this a Humanitarian Use Device Registry (HUD)?

Yes No

7.0 Exempt/Waived Research

7.1 *Do you think this research may be Waived under 45 CFR 46.102(f) as 'Not Human Subjects' research?

[FOR CLARIFICATION/QUESTIONS, CALL THE IRB OFFICE BEFORE YOU COMPLETE THIS SECTION: 858-652-5500]

Examples that may be Waived include:

- Use of human derived materials that are purchased from a commercial source
- Use of unidentifiable tissue or serum from a biorepository

(Note: Using or deriving Human Stem Cell lines cannot be waived.)

Yes No

If Yes, please explain:

7.2 (Reminder: If you answered 'Yes' to Waived, please answer 'No' to Exempt.)

*Do you think your study may be Exempt from IRB review? (This category is usually only applicable to basic scientists at the Research Institute. If you are not sure, select No. If you are using blood from the Normal Blood Donor service or using or deriving human stem cells, your study is NOT exempt.)

Yes No

If Yes, please explain in detail:

8.0 TSRI Normal Blood Donor Services

8.1 *Is your ONLY use of human subjects obtaining blood from the TSRI Normal Blood Donor program?

Note: If you are obtaining any other specimens, answer No.

Yes No

9.0 Care Line/Co-Management Committee

9.1 *Has your proposal been endorsed by a Scripps Health Care Line or Co-Management Committee?

Yes No

9.2 If NO, please indicate why not:

10.0 Tissue/Blood from Scripps (Patients/Employees) OR Outside of Scripps

10.1 *Are you obtaining blood or tissue from Scripps employees or patients? (May require informed consent.)

IF USING THE NORMAL BLOOD DONOR PROGRAM, OR IF THIS IS A CLINICAL TRIAL, ANSWER "NO".

Yes No

If Yes, please describe:

10.2 *Is your only use of human subjects obtaining blood, tissue, saliva, etc. using collaborators outside of Scripps Health or TSRI? [Check "NO" if your study involves any intervention with human subjects such as drugs, devices, interviews, questionnaires, etc.]

Yes No

If Yes, please describe:

11.0 Privacy of Health Information and Confidentiality of Data

11.1 *Will the research involve obtaining individual patient authorization (via patient consent) to use and /or disclose Protected Health Information? (If No, you must apply for a Waiver of Authorization from the IRB.)
(Important: If you plan to use Protected Health Information, you must either obtain written authorization from the individual/patient/subject OR request a Waiver of Authorization from the IRB. If you apply for a Waiver, you will also need to provide a description of the data you plan to use. This description can be provided by using the Confidential Data Request form, available on the Scripps intranet.)

Yes No

12.0 Privacy of Health Information and Confidentiality of Data - No Patient Authorization

12.1 Check all categories that apply to the research data:

- Retrospective
- Paper Records
- Electronic Records
- Deceased
- N/A: No Identifiable Data to be Accessed

12.2 *Do you already have download of the data or the patient population you will need for this study?

Yes No

If Yes, where did you get the data/patient population?

12.3 Description of the desired data population

***Date Range of Data Population: (Note: For retrospective chart review, the end date MUST precede the current date.)**

***From: (Beginning date)**

01/01/2010

***To: (End Date)**

03/26/2018

Date Range is Not Applicable

Estimated number of data records (if known):

100

***Sites:**

- Encinitas
- Green
- Home Health
- La Jolla
- Mercy San Diego
- Mercy Chula Vista
- Scripps Clinic (Specify below)
- Scripps Coastal Medical Center (Specify below)
- Other (Specify below)

Specify:

13.0 Privacy of Health Information and Confidentiality of Data - Sending Externally

13.1 *Will data be sent to an external, third-party recipient outside of Scripps? (Note: If Yes, specify recipient in the Confidential Data Request Form.)

Yes No

If data will be stored on a Secure Scripps Network drive, please provide drive and folder location:

14.0 Privacy of Health Information and Confidentiality of Data - Detail

14.1 *Do you plan to use Scripps Health medical records or patient data to identify potential subjects? (Note: If Yes, you need to complete a Confidential Data Request form [CDR]. Refer to Scripps policy.)

Yes No

14.2 *What provisions have been made to maintain the confidentiality of the subject's data and/or samples? (Important: Identifiable medical information may NOT be stored on non-Scripps electronic devices such as smartphones, laptops, tablets, personal computers, etc. NEVER email any personal identifiers such as name, MR#, etc.)

Limited access - IRB must be aware of anyone who has access to identifiable data

- Stored in secure folder on the Scripps network
- Research numbers will be assigned. Identification code will be kept separately from the data
- Password-protected database
- Other

If Other, please explain:

**14.3 *Will Non-Scripps personnel need to access any Scripps Information Systems to complete the research?
(Important: Any non-Scripps personnel will require orientation, employee health screening, name badge and IS coordination. They must also go through a vendor/volunteer process before accessing any Scripps data. Policy S-FW-EC-1157 is on the Scripps intranet.)**

Yes No

If Yes, list anyone who will have access to the data that is NOT part of the study staff or sponsoring organization.

**14.4 *Is there any specific hardware, software and/or transmission of data beyond the standard eCRF?
(This would include sponsor- required laptops or software to be loaded onto Scripps PCs, laptops or assets.)
If Yes, please complete the Request for Software Installation or Third Party Application Service Provider (ASP) form.
(Note: Modems are not acceptable.)**

Yes No

15.0 Research Sites and Administrative Review

15.1 *Is this a multi-center trial?

Yes No

If Yes, are you the Principal Investigator or Program Director for the multi-center trial?

Yes No

If Yes, (you are the Principal Investigator or Program Director), list all non-Scripps sites.

The following trauma hospitals have expressed interest to participate in this study, pending IRB approval: UC San Francisco, UC Davis, Emory University, Denver Health, VCU Medical Center, University of Oklahoma Health Services, Oregon Health and Science, University of Pennsylvania, University of Texas Houston, Indiana University

15.2 How will any Non-Scripps sites send data to Scripps Health?

De-identified data will be sent to Scripps Health via a tracked mailing process. De-identification guidelines will be followed to protect the privacy of all participants by disassociating the clinical information gathered from the information specific to the trial participant. This is done by removing or recoding, direct and indirect, identifiers in the data. The following types of identifiers are examples, such as those identified by HIPAA, that should be considered for removal or recoding to prevent the risk of association of a participant to his/her data.

15.3

What steps have been implemented to verify the integrity of Non-Scripps data prior to loading it into the Scripps network? (Answer is required if Scripps PI is acting as lead site for multi-center study.)

Research data will be reviewed by Scripps Trauma research staff prior to data entry into a HIPAA-compliant, password protected database. Access is limited to the PI and Study Coordinator from Scripps Trauma research. Individuals listed on the IRB protocols of each participating site will have access to their own data prior to sending to Scripps.

15.4 *Is the research a project of Scripps Health or the Scripps Research Institute (TSRI)?

- Scripps Health - (Conducted by Scripps employees, agents or in Scripps facilities)
- Scripps Research Institute - (Conducted by TSRI employees, agents or in TSRI facilities)

15.5 *Indicate the sites(s) at which data will be collected and/or analyzed. (Select all that apply.)

- MD Office
- Outside - Non Scripps Health
- Scripps Cancer Center (SCC) - Network
- Scripps Cancer Center - Mercy
- Scripps Cancer Center - Green
- Scripps Clinic - Carmel Valley
- Scripps Clinic - Mission Valley
- Scripps Clinic - Rancho Bernardo
- Scripps Genomic Medicine (STSI)
- Scripps Clinic - Torrey Pines
- Scripps Green Hospital
- Scripps Memorial Hospital - Encinitas
- Scripps Memorial Hospital - La Jolla
- Scripps Mercy Hospital - San Diego
- Scripps Mercy Hospital - Chula Vista
- TSRI - Florida
- TSRI - Normal Blood Donor Service (NBDS)
- Scripps Radiation/Oncology
- Scripps Proton Center
- TSRI - The Scripps Research Institute
- Whittier Institute
- Scripps Clinical Research Center
- Other

If Other, enter site name.

15.6 Non Scripps and other collaborative research sites.

Please identify additional locations or facilities not listed above.

If using other sites, do they require additional IRB review?

- Yes No

If Yes, what is the status of this other IRB review?

- Not yet submitted

- Pending
- Approved

16.0 Scripps Health Review

16.1 *Does this study involve any Scripps Health facility or Scripps Health patients?

- Yes
- No

17.0 Scripps Health Review Detail

17.1 *Is this study Investigator-Initiated? (A protocol designed by the investigator, even if it is supported by commercial funds.)

- Yes
- No

17.2 *What is the anticipated benefit to future patients or healthcare providers?

There is no direct benefit to participants. Injuries to the pancreas present a significant challenge, in diagnosis as well as management. The infrequency of these injuries has resulted in a lack of experience among practicing trauma surgeons and a dearth of data guiding management. Describing the evolution in practice among trauma surgeons the past 8 years with regard to the diagnosis and management of pancreatic injuries will lead to a greater understanding and potentially improve diagnosis and management of these injuries in the future.

17.3 *What is the anticipated benefit of this research to Scripps Health as an organization or to the patients who receive care from Scripps Health?

Injuries to the pancreas present a significant challenge, in diagnosis as well as management. The infrequency of these injuries has resulted in a lack of experience among practicing trauma surgeons and a dearth of data guiding management. Describing the evolution in practice among trauma surgeons the past 8 years with regard to the diagnosis and management of pancreatic injuries will lead to a greater understanding and potentially improve diagnosis and management of these injuries in the future, including patients who receive care from Scripps Health.

17.4 *The topic of this study relates to which of the following: (Select all that apply.)

- Cost of Care
- Preventing hospital admission/Preventing readmission
- Care across the continuum
- Publicly reported quality metrics
- Nurse sensitive quality indicators
- Never-events
- Value based purchasing/Core Measures
- Strategic plan, goals or objectives
- Board reported quality metrics
- Patient satisfaction
- Delay to treatment
- Hospital acquired infection
- Mortality
- Patient safety
- Medication management and/or safety
- Decreased labor/staff time
- Improved operational efficiency

- Regulatory readiness
- Workplace or workforce safety
- Healthcare literacy
- General Wellness Monitoring
- Other

If Other, please explain:

18.0

Clinical Trial

18.1 *Is your project a Clinical Trial?

The NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Yes No

18.2 If not a clinical trial, does your project involve testing an assay or device of any sort?

Yes No

18.3 *Will your project involve informed consent from individual subjects?

Yes No

18.4 If this is a Clinical Trial, what is the NCT number that identifies the trial on www.clinicaltrials.gov?

Note: All clinical trials must be registered in a national database at www.clinicaltrials.gov. Each trial is assigned a unique registry number, the "NCT" number, which begins with NCT followed by an 8-digit number. We must have this number to be able to identify clinical trials ongoing at Scripps, as required by Scripps Health leadership. For commercially-sponsored studies, get the number from the sponsor; for investigator-initiated studies, ask the Principal Investigator or search the clinical trials database to find it.

-
- N/A
 - NCT Not Listed

If NCT number is not listed, explain why:

19.0 Study Plan - Details

19.1 Research Methods - Include the Schedule of Events or provide a precise description of the data collection methods. (Attach the Schedule of Events to the Initial Review Submission Form, if applicable)

This is a retrospective review of patients with traumatic pancreatic injuries. Patients managed between January 2010 and March 2018 will be enrolled. The time periods before (January 2010- December 2013)

and after (January 2014-March 2018) publication of the WTA algorithm will be compared. Standardized data will be collected, allowing analysis of demographic data, injury data, and outcomes. See attached data collection tool.

Inclusion: Adult patients diagnosed with pancreatic injuries Grade III-IV. Also Gr I or II with pancreas-related complications, and a total N of those grade injuries for denominator.

Exclusion: Patients with incomplete data.

Primary outcomes: Length of stay; Pancreatic fistula/abscess; Mortality. Pancreatic fistula is defined /graded based on ISGPF 2016 update.¹⁶ Drain output of any measurable volume of fluid with amylase level >3 times the upper limit of institutional normal but without other significant clinical effect is termed "biochemical leak." Categorization as grade B is based on a change in the postoperative management; drains either left in place >3 weeks or repositioned through endoscopic or percutaneous procedures; angiographic procedure for bleeding; or signs of infection without organ failure. Grade C postoperative pancreatic fistula refers to those that require re-operation or lead to single or multiple organ failure, or mortality attributable to the pancreatic fistula

Secondary outcomes: Missed ductal injury; delayed pancreatic fluid collection; delayed pancreatic intervention.

Data collected will include the following elements: Subject # Year of Admission, Age and Gender, Trauma Center Level, Mechanism of Injury, Injury Severity, Major Associated Injuries, Indications for immediate exploratory laparotomy procedure, date and time of operative procedures, radiological imaging findings, pancreas grade of injury, presence of peripancreatic Fluid, presence of pancreatic duct injury, ERCP, Cholangiopancreatography, Pancreatography, Pancreatic Injury description, drainage type and position, feeding tube placement, ICU and Hospital length of stay, discharge disposition and Complications including peripancreatic abscess, pancreatic fistula and delayed pancreatic pseudocyst.

20.0 Waiver of Informed Consent

20.1 *Are you requesting to waive informed consent?

Yes No

21.0 Waiver of Informed Consent Detail

21.1 *Explain why you think the research involves no more than minimal risk to subjects.

This is a minimal risk study since no PHI except age will be collected. All information will be de-identified prior to upload into the database. No intervention or treatment will be administered and the variables collected are those generated during treatment.

21.2 *Explain how waiving informed consent will not adversely affect the rights and welfare of the subjects.

The collection of these data will not impact the treatment received in any way. This is a retrospective data collection. All data will be de-identified prior to upload into the database.

21.3 *Explain why the research could not be carried out without the waiver or alteration.

The collection of these data will not impact the treatment received in any way. This is a retrospective data collection. All data will be de-identified prior to upload into the database. There will be no direct interaction with study participants. All data will be collected through abstraction from the medical record. Obtaining informed consent would require interaction with study participants.

21.4 If appropriate, do you plan to give additional pertinent information to subjects after participation?

There will be no direct interaction with study participants. No additional pertinent information will be given to subjects after participation.

22.0 Waiver of Privacy Rule Authorization

22.1 *Are you requesting to waive individual Privacy Rule authorization?

Yes No

23.0 Waiver of Privacy Rule Authorization Detail

23.1 If protected health information will be used or disclosed, and you have applied to waive informed consent, provide the following information to be considered for a Waiver of Authorization. The use or disclosure of the protected health information involves no more than minimal risk to the privacy of individuals, based on the adequacy of the following.

(For more info, hold your mouse over the Help bubble to the left and click on the link that appears.)

*Describe your plan for protecting data from improper use and disclosure. *NOTE: *The protected health information may only be used or disclosed as described in this application.*

Access of PHI is only necessary when patients are identified for inclusion in the study. No PHI will be collected except age. All information will be de-identified prior to upload into the database. Database is on a secure network, password protected with limited access.

*Explain when identifiers will be destroyed.

No PHI will be collected except age. All information will be de-identified prior to upload into the database.

*Explain why you think the research could not practicably be done without waiver.

Accessing PHI is needed to identify patients to include in study sample. No PHI will be uploaded into the database.

*Explain why you think the research could not practicably be conducted without access to and use of protected health information.

Accessing PHI is needed to identify patients to include in study sample. No PHI will be uploaded into the database.

24.0 Surveys and Questionnaires

24.1 *Does the project involve the use of Surveys, Questionnaires or Interviews?

Yes No

25.0 Study Population

25.1 *Briefly describe your targeted population. (Patients with a condition or disease, healthy control subjects, etc.)

Adult patients diagnosed with pancreatic injuries Grade III-IV. Also Gr I or II with pancreas-related complications,

25.2 *Explain rationale for using human subjects.

Objectives would not be met without the use of data from human subjects. The objective of this study is to analyze the diagnosis and management practices of traumatic pancreatic injury among trauma centers to help establish best practice guidelines. Injuries to the pancreas present a significant challenge in diagnosis and management and the infrequency of these injuries has resulted in a lack of experience

among practicing trauma surgeons. This study will provide an review of practice and help determine the evolution of this practice among trauma centers.

25.3 *Age

Age Range Not Applicable

Enter the specific age range for study population.

From:

To:

25.4 *Gender

- Male
 Female
 Both male and female

25.5 *How many subjects are you planning to enroll at this institution/site?

70

If this is a chart review, indicate the number of charts: *(If this is not a chart review, enter 0.)*

150

If necessary, provide explanation below.

All patients with traumatic pancreatic injury treated at Scripps La Jolla trauma center during the study period will be identified. Pancreatic grade of injury will be determined and those meeting inclusion criteria based on grade of injury and presence of pancreas-related complications will be studied.

25.6 *How many subjects will be enrolled at ALL sites? (Include Scripps and NON-Scripps)

250

If necessary, provide explanation below.

Study population goal for this multi-center study is 250. Populations differ at each trauma center and, due to the rarity of this injury, cases meeting inclusion criteria will vary at each trauma center. 5-10 study participating study sites will be needed in order to reach our study population goal of 250.

25.7 To achieve your needed number of subjects, how many subjects do you estimate will need to give informed consent? (Allowing for screen failures)

0

25.8 *Justification for the number of subjects required:

Based on our trauma patient census and frequency of pancreatic injury cases, we estimate to identify

approximately 70 cases at our Level II trauma center. If we have 5-10 Level I and Level II trauma centers participating in this study, we should reach our study sample goal.

25.9 Please check all potentially vulnerable populations that are included:

** Regulated*

- Children / Minors (subjects less than 18 years) *
- Pregnant Women *
- Prisoners *
- Economically or educationally disadvantaged persons
- Non-ENGLISH speaking
- Diminished mental capacity
- Physically disabled
- Students
- Scripps Health Employees
- Scripps Research Institute Employees
- Other

If other, describe.

If including vulnerable subjects, explain why. Explain what safeguards are included to protect against coercion or undue influence.

No specific population or subgroup will be excluded.

25.10 Inclusion Criteria

*Use the link below to add inclusion criteria.

Order Number	Criteria
1	Patients treated at Scripps Memorial Trauma Service with a traumatic pancreatic injury
1	Admission to Scripps Memorial Trauma Service Jan 1, 2010 - Mar 26, 2018

25.11 Exclusion Criteria

*Use the link below to add exclusion criteria.

Order Number	Criteria
1	Trauma patients with a pancreatic injury Grade I or Grade II without any pancreas-related complications

25.12 Provide justification for inclusion or exclusion of any group (gender, race, ethnicity or other):

No specific population or subgroup will be excluded.

25.13 Subject Debriefing

Describe any debriefing procedure(s).

Not applicable.

*When will participants be given experimental results and the key to any study blinding? (If not known, request this information from the Sponsor.)

Not applicable.

26.0 Nursing, Allied Health and Health Services Research

26.1 *Is this Nursing, Allied Health or Health Services Research ?

(Note: Health Services research is the study of the organization, delivery and financing of health care. Some projects of this type may be considered Quality Assurance, Quality Improvement or Process Improvement but NOT research.)

Yes No

27.0 Funding Source (If you are a Principal Investigator receiving a Federal funded grant for collaborative sites to conduct Human Subjects Research, contact the IRB office. You will need to submit IRB documents from the collaborating institution.)

IMPORTANT: If ANY funding for this project is coming from a Federal source (federal agency, federal government, National Institutes of Health, National Science Foundation, US military - such as Department of Defense, etc.), the source(s) MUST be entered in this section.

27.1 *Is this study funded by a commercial sponsor?

Yes No

27.2 *Is this study funded by a grant?

Yes No

*Is this an SCMG grant?

Yes No

If this study is funded by a grant, are you the PI receiving the grant?

Yes No

If you are the PI receiving the grant, will any other projects in the grant use human subjects?

Yes No

*If you are the PI for the entire grant, and checked 'Yes' to 'Human Subjects', please submit a copy of the entire grant.

27.3 *Status of funding:

Please select one.

- Applied/Pending
- Approved
- Not Applicable

27.4 Sponsor Protocol Number:

27.5 Grant Number:

**27.6 *Granting Agency/Sponsor (You can select more than one agency.)
(If your agency is not in the list, click on the help bubble to the right.)**

If Departmental Funds are being used, click on 'Private' and choose 'Departmental Funds'.

***Note: All studies must have an identifiable source of funding or they cannot be reviewed. Fill in the matrix below.**

	Sponsor	Funding	Protocol Control	Data Coordination	Monitoring	Auditing	Pass Through Funding
Commercial							
Federal or State							
Private	SCRIPPS MEMORIAL TRAUMA SERVICE	■	■	■	■	□	□
CRO							
Department funds	No funding necessary	■	■	■	□	□	□

27.7 Proposed Funding Date - BEGIN

27.8 Proposed Funding Date - END

27.9 Are part of or all activities in this proposal funded by a training grant?

- Yes
- No

