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**HRP-503C – MEDICAL RECORD REVIEW ONLY PROTOCOL**

**(2016-1)**

**Protocol Title:** Retrospective observational trial of the management of acute necrotizing pancreatitis

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**Version Date: 7/14/2017**

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| **INSTRUCTIONS** |
| This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:**1. Use this protocol template for a Medical Record Review Application only. Additional templates for other types of research protocols are available in the system Library.
2. If a section or question does not apply to your research study, type “Not Applicable” underneath.
3. Once completed, upload your protocol in the “Basic Information” screen in IRES IRB system.
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## Section I: Research Plan

**Requests for medical records should be made through JDAT as described at** <http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx>

1. **Will information be collected from sources other than YSM or YNHH** (including Yale-New Haven Health System partners, e.g., Greenwich Hospital, Bridgeport Hospital)?

NO [ ]  YES [x]  (IRB approval from those sites may also need to been obtained)

If **Yes**, is it from international sources? NO [x]  YES [ ]  (this may require that you coordinate with that facility for access to the records).

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested and describe the research plan and possible risks and benefits.

Acute pancreatitis is a common condition with the potential to cause significant morbidity and mortality. Most patients with acute pancreatitis suffer only a mild attack, without local or systemic complications as defined by the Atlanta criteria. Approximately 20% of patients, however, will suffer a severe attack with associated morbidity and a mortality rate between 17% and 39%. Patients with severe pancreatitis can develop pancreatic necrosis.] In 40% to 70% of these patients, the pancreatic necrosis will become infected. Infected pancreatic necrosis requires adequate debridement and drainage via surgical or radiologic means. Failure to adequately control infected pancreatic necrosis results in an almost 100% mortality because of overwhelming organ failure. It is generally considered that delayed rather than early intervention is preferable in those with pancreatic necrosis. It is also widely accepted that sterile necrosis in the absence of significant symptoms does not require routine debridement, but most authorities still recommend urgent debridement for infected necrosis, as delays to intervention are associated with increased mortality. Techniques for management of infected pancreatitis include radiology-guided drain placement with or without serial debridement, minimal access techniques via laparoscopy or endoscopy and open surgical necrosectomy. To date, there are few studies evaluating the current management of infected pancreatic necrosis in the United States. We proposed a multicenter retrospective observational trial using database support provided by the American Association for the Surgery of Trauma. The purpose of the study is to define current practice and inform best practices. As this is a retrospective observational study, there are no risks to patients. However, if a best practice can be identified, with reductions in complications and mortality, the study will benefit future patients with the disease.

1. **Probable duration of study:** (Please state the expected duration of the project, including all data analysis activities). Participating institutions will identify patients treated at their institution between January 2007 and January 2017.
2. **Estimated number of records to be reviewed:**  200 total, 20-30 at Yale New Haven Hospital
3. **Criteria for inclusion/exclusion**: Patients who are at least 18 years old with acute pancreatitis complicated by pancreatic necrosis for inclusion in the study.
4. **Does the PI or any other member of the research team have a direct existing clinical relationship with the subjects whose records will be reviewed?**

 [ ]  Yes, all subjects

 [x]  Yes, some of the subjects

 [ ]  No

If yes, describe the nature of this relationship: The PIs will have had a treating physician relationship with some if not all of the patients at Yale New Haven Hospital.

1. **Nature of the data** (check applicable and answer the associated questions):

[x]  **Retrospective** (data already in existence)

Dates of the medical records that will be reviewed: January 2007 to January 2017.

[ ]  **Prospective** (records that will be created in the future)

Dates of the medical records that will be reviewed: Write here to Write here

[ ]  **Both retrospective and prospective**

Dates of the medical records that will be reviewed: Write here to Write here

If at all **prospective,** consider whether verbal or signed consent should be obtained.

Should consent be obtained? Yes [ ]  No [ ]

If consent is to be obtained, see **Appendix I** for required additional questions.

1. **Information collected and recorded from medical records.**
2. List all data to be recorded from the chart (i.e., MRN, name, diagnosis). Only those items listed on this application may be requested from JDAT. Note that only the minimum information necessary to conduct the research should be used.

Patient protected health information will be collected at Yale New Haven Hospital to facilitate appropriate chart review. The Yale patients will be anonymized prior to submission to the central data repository. Patient demographics, laboratory values, imaging study results, etiology of pancreatitis, timing, method and number of interventions, antimicrobial therapy and duration, complications including multisystem organ dysfunction (MODS), length of ICU and hospital stay, and long-term need for insulin, oral hypoglycemics and pancreatic enzyme replacement will be collected. Sepsis will be defined per the Society of Critical Care Medicine (SCCM) criteria and MODS will be classified using the modified Marshal scoring system [25].

Statistical analysis will be performed with SAS 9.4 (SAS Corp., Cary NC) and if applicable as a two sided test on a 5% level of significance. Chi square analysis and Fisher’s exact test will be used to evaluate qualitative parameters. For analysis of quantitative parameters, the Mann-Whitney-U test will be used. Hierarchical multivariable logistic and log-linear regression analysis will be performed to control for confounders on outcomes including mortality, morbidity and length of stay.

Data collection points:

Patient identifiers: Yale patients only (to be de-identified prior to submission to central data repository

* Name
* MRN
* Date of birth

Patient demographics: age, gender, BMI

Major comorbidities

Etiology of pancreatitis (alcoholic, biliary, iatrogenic, drug related, hypertriglyceridemia related or idiopathic)

Duration of symptoms at diagnosis

Microbiology data from pancreatic tissue and blood,

Components of the SOFA score at presentation and 48 hours.

Presence or absence of sepsis

CT imaging findings: at presentation and at first identification of necrosis, location, percentage involvement of the pancreas, percentage with evidence of infection (gas), approximate volume of necrotic tissue

Number and timing of catheter-based interventions

Number and timing of endoscopic based interventions

Number and timing of laparoscopic based interventions

Number and timing of open necrosectomy

Complications: As defined by the National Surgical Quality Improvement Program

Pancreatic insufficiency (defined as need for enzymatic supplementation) or new onset diabetes defined using insulin or oral hypoglycemic at 1, 3, 6 and 12 months post discharge (if available)

Outcomes: Mortality, discharge disposition (home, rehabilitation, skilled nursing facility, morgue), ventilator days, ICU and hospital length of stay.

1. Identify the type of medium that will be used to record the information and the plans for maintaining confidentiality and security of the data. Investigators at individual sites (including YNHH), as treating physicians, will have access to their patients’ identified data. All sites will input deidentified data into the American Association for the Surgery of Trauma’s multi-institutional trials data collection tool. This site is a secure data site which meets all regulatory requirements. Access to the deidentified data will be limited to the PIs for the duration of the study. Thereafter, other researchers may apply for access to the entire data set for further study. Patient protected health information will not be collected: all data will be anonymized at the participating institution. Participating institutions will be identified from the membership of the American Association for the Surgery of Trauma. Contributors will be required to conform to their own institutional IRB requirements for participation.
2. Indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored. The data will be stored in perpetuity for ongoing research. The data becomes the property of the American Association for the Surgery of Trauma, as one of their approved multi-institutional trials. All data inputted into their system is deidentified prior to upload but the contributing institution.

***Note****: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unencrypted moveable media.  Identifiers and code keys must be stored in a secure manner, e.g., Yale network servers.  All portable devices must contain encryption software, per University Policy 5100.  If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url* [*http://its.yale.edu/egrc*](http://its.yale.edu/egrc) *or email* *it.compliance@yale.edu*

1. **How will the data and/or identifiers be destroyed when no longer needed for research purposes?** If it will not please explain why data must be retained, for how long and how it will be kept secured.

The AAST Multi-Institutional Trials data collection tool is housed at Infotech Systems Management, a company out of San Diego, CA. The security measures that Infotech employ are:

1. The database server is located behind a firewall and is not accessible from the internet

2. Data stored on the database server is encrypted by AES using a 256-bit key

3. Data transmitted between the web server and the end use is encrypted by 128-bit SSL encryption. Besides the above measures, only the Primary Investigator, which is approved by the Multi-Institutional Trials Committee of AAST, can view the data for their study. Data inputted into the data collection tool is stored indefinitely and may be used by other research projects if approved by the MIT Chair. Additionally, housed data will only be directly accessed by individuals with approved IRBs and the data is de-identified. There is no IRB that has jurisdiction over the data collection tool as AAST owns the data collection tool and all data that is inputted. Only approve studies or research projects are eligible to use the data collection database.

## Section II: Consent and HIPAA Authorization Waivers

 **If you are requesting a Waiver of Consent/Waiver of HIPAA Authorization, complete the following (if not requesting a waiver, state N/A and fill out questions in Appendix I):**

* 1. Does the research pose greater than minimal risk to subjects? Yes [ ]  No [x]
	2. Will the waiver adversely affect subjects’ rights and welfare? Yes [ ]  No [x]
	3. Explain why the research could not practicably be carried out without the waiver.

The ten-year span of retrospective data, coupled with the high mortality rates of the disease process, make consent of individual patients impossible.

* 1. Are there any plans to provide subjects with additional pertinent information after their records have been reviewed? [x] No [ ] Yes

 If yes, how will pertinent information be returned to subjects, if appropriate at a later date? Write here

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the “accounting for disclosures log”, by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer*.*

**The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.**

***Waiver of signed consent:*** (Verbal consent from subjects will be obtained. Note that an information sheet may be required.) [ ]  N/A

 **For a waiver of signed consent, address the following:**

* Would the signed consent form be the only record linking the subject and the research?  **YES** [ ] **NO** [ ]
* Does a breach of confidentiality constitute the principal risk to subjects? **YES** [ ] **NO** [ ]

 **OR**

* Does the research pose greater than minimal risk? **YES** [ ]  **NO**[x]
* Does the research include any activities that would require signed consent in a non-research context? **YES** [ ]  **NO** [x]

**APPENDIX I: Consent Considerations**

***If consent will be obtained (verbal or written), please address the following:***

1. **Process of Consent/Assent:** Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects’ independent decision-making.

Write here

1. **Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent:** Indicate how the personnel obtaining consent will assess the potential subject’s ability and capacity to consent to the research being proposed.

Write here

1. **Documentation of Consent/Assent:** List the documents that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given to subjects.

Write here

**Non-English Speaking Subjects:** Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. Translated copies of all consent materials must be submitted for approval prior to use.

Write here

As a limited alternative to the above requirement, will you use the short form\* for consenting process if you unexpectedly encounter a non-English speaking individual interested in study participation and the translation of the long form is not possible prior to intended enrollment? YES [ ]   NO [ ]

**Note\*** If more than 2 study participants are enrolled using a short form translated into the same language, then the full consent form should be translated into that language for use the next time a subject speaking that language is to be enrolled.

Several translated short form templates are available on the HRPP website (yale.edu/hrpp) and translated HIPAA Research Authorization Forms are available on the HIPAA website (hipaa.yale.edu). If the translation of the short form is not available on our website, then the translated short form needs to be submitted to the IRB office for approval via modification prior to enrolling the subject.  ***Please review the guidance and presentation on use of the short form available on the HRPP website.***

**If using a short form without a translated HIPAA Research Authorization Form, please request a HIPAA waiver in the section above.**