

Standard Operating Procedures and their Effect on Confidence Levels.

Master of Science (Clinical Research Management)

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Luke Bailey, B.S.

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Luke Bailey, B.S.

APPROVED:

Major Professor

Committee Member

Committee Member

Chair, Department of Biomedical Sciences

Dean, Graduate School of Biomedical Sciences

Standard Operating Procedures
and their Effect on Confidence Levels.

INTERNSHIP PRACTICUM REPORT

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Luke Bailey, B.S.

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Chapter 1. Introduction

I. Summary

This practicum sought to study whether the systematic creation of a set of Standard Operating Procedures (SOP) for the Department of Emergency Medicine (DEM) at University of Texas Southwestern (UTSW) would increase research staff confidence in their ability and improve knowledge of resources. We wished to determine also faculty confidence in research staff before and after SOP creation. The term SOP and its use came to prominence in the mid 20th century as a descriptor for a systematic method to ensure consistency and efficiency in task completion in organizations. An SOP is any document that seeks to standardize, through plain and instructive language, a common process or task in an organization to ensure the quality and uniformity of the outcome or product of said task or process. The DEM at UTSW was recently created as its own department when it split off from under the umbrella of the Department of Surgery and did not have any documented standardized processes in place regarding research administration actions and procedures. This could have been hindering the ability of the staff to operate efficiently, consistently, and correctly. For this project, the clinical research staff and faculty of the DEM of UTSW were surveyed regarding their confidence levels before and after a

set of administrative SOPs were systematically developed to evaluate the success of aforementioned SOPs. Before creating the SOPs, the staff and faculty were consulted on which SOPs they felt were most needed and, based upon the outcome of these consultations, creation of those SOPs were prioritized accordingly. Then, after looking at SOPs for similar or identical processes from other departments, they were collaboratively created with input and insights of research staff and faculty from these other departments. It was hypothesized that having SOPs would increase research staff confidence, increase efficiency, and increase accuracy in the completion of their duties, as well as increase faculty confidence in research staff. A statistical analysis of the seven pre-SOP research staff responses with six post-SOP research staff responses and 22 pre-SOP faculty responses with 15 post-SOP faculty responses yielded no significant associations. However, the mean response improved for all but one question of the faculty and research staff surveys. Considering the limitations of the present study, including a limited sample size and limited time window for completion, future studies with improved design are needed to further evaluate the impact of SOPs. But valuable however, is the confirmation by the present study that involvement of personnel to whom SOPs apply is not only valuable and preferred, it is essential to ensuring that they are applicable and useful.

CHAPTER II INTERNSHIP SUBJECT

BACKGROUND AND LITERATURE

When taking on any repetitive project, task, or duty, efficiency and accuracy can be optimized if a standardized and well thought out approach is utilized. In this way, unnecessary

steps are avoided, problems are anticipated and prevented before they occur, and high-quality work can be delivered in a thorough and consistent manner. In most modern organizations, this is achieved by utilizing suitable SOPs.

An SOP is a recorded set of unambiguous directions to handle a certain scenario, or, more formally, a “method of controlling a practice in accordance with predetermined specifications to obtain a desired outcome.” [1] Although the method of having a specific methodology for approaching different situations and work scenarios is certainly not a recent development, the term, ‘Standard Operating Procedure’ is a relatively new one. SOPs are widely used across all types of businesses, especially large ones, as well as in hospitals, government, manufacturing, and military organizations. [2] The vast prevalence of SOPs lends credence to their usefulness. Specifically, in clinical research an SOP is defined as “detailed, written instructions to achieve uniformity of the performance of a specific function.” [3] This definition was put forth by the International Council of Harmonization (ICH), an organization founded in 1990 which seeks to bring uniformity of good clinical practice to the development of new drugs through clinical trials. Following ICH protocol is not legally mandated in the US, but nevertheless these are official guidelines designated by the United States Food and Drug Administration (FDA).

Despite the need for efficiency and timeliness within a research administrative setting, SOPs are not presently widely used within administrative aspects of clinical research, but their use in these administrative aspects is growing. [4] In contrast to this, SOPs are widely used and required by sponsors of clinical trials and contract research organizations (CROs), to ensure that quality assurance and quality control systems are adequate. In fact, the ability of an organization

to adhere to study SOPs is one of the qualifying factors for selection in a clinical trial. [5]

One of the barriers for implementation and design of an SOP is that there can be a negative connotation and reception to them. This is partly due to the fact that SOPs are a form of micromanagement and can be viewed as too restrictive and rigid, and they do generally decrease flexibilities and freedom in the workplace. However, a recent study concluded that the relationship between intrinsic motivation and the requirement to follow SOPs could actually be positive in the right conditions. [6] The authors, then went on to suggest that the best way to ensure SOPs are well received and even could be motivating is to ensure employee participation in the creation of the SOPs. [6] There must also be an explicit and clear need for an SOP, clearly understood by the workforce for whom they are to be created. For example, it would be clear that an organization's members would be open to SOPs if they frequently complained about not knowing how to handle common issues or about worrisome inconsistencies in the organization's product(s) or service(s). Also, ideally, an organization should be in a relatively stable state, i.e not going through a management or employee overhaul, making big changes to its production, drastically redefining its mission or purpose Since this project seeks to create most of the UTSW DEM SOPs from scratch, DEM employee participation will not only be sought, it will be necessary.

There are many elements that are characteristic of a well-made and useful set of SOPs. It is important for SOPs to be written in clear and plain language to ensure ease of use and clarity of instructions. When addressing how many or what specific SOPs need to be developed, there is no universal standard answer that could be utilized. This is because SOPs essentially are an insight into how an institution operates and all institutions are inherently different. An SOP

serves to limit areas of confusion, inefficiencies, or contradictions in the operations of the institution for which it is written. [7] Also, while writing SOPs, it is important to remember that they should be serviceable to the people to whom they apply, and not simply written in a way that would, for example, appease a potential auditor, or satisfy a sponsor. [8] It is critical that there is a specific and set process to update SOPs because standards and procedures will change over time as well as the structure of the institution for which they are written. Relatedly, there must be a review and approval process for new SOPs as well as a designated “owner” and storage site for them. [9] A study in 2014 evaluating the quality of the European League of Rheumatism’s (EULAR) recommendations, which were made utilizing SOPs that were published in 2004, found that while the recommendations still had utility, they did need updating. [10]

A SOP should ideally have a purpose beyond simply stating what is done, which in of itself, is not useful in every case or situation. It should only be created for areas which are prone to error or misunderstanding and written in a way that efficiently aids its users. It should serve as a guide to quickly train new employees. Upon a lengthy review of articles Gidey Amare similarly concluded that “standard operating procedure[s], if realized and materialized as a component of an effective management system, helps cultivate transparent functions; implement error prevention measures and facilitate corrective actions and transfer knowledge and skill.”

[11]

SPECIFIC AIMS

Aim #1: Standardize and streamline administrative processes by developing SOPs to increase the ability of the Research Division Staff to operate efficiently.

Aim #2: Measure research staff confidence in their ability to complete tasks and efficiently move the departments studies along from start to finish pre- and post- SOP creation.

Aim #3: Measure DEM faculty confidence in research division staff to effectively manage and carry out their studies pre and post SOP creation.

Rationale: Creation of SOPs may increase confidence of research staff and faculty confidence in the staff.

SIGNIFICANCE

During this project, I worked with the members of the Research Division of the DEM at UTSW as well as the faculty to streamline administrative processes utilizing SOPs which will help improve their ability to perform research efficiently and within a Good Clinical Practice (GCP) environment. Once implemented, the project may provide a good foundation of accurate and efficient SOPs which the department can rely upon as well as update and build on in the future. Additionally, it will benefit the department by making the site more attractive to future sponsors as a research site because administrative SOPs have been implemented. There is currently a committee at UTSW with the goal of developing an institutional level set of SOPs for research administration. [4] The product of this project is intended for review before the committee for their consideration to provide a foundation for future administrative SOP development.

MATERIALS AND METHODS

1) Site of the practicum

For this practicum, I served as a Clinical Research Intern for six months in the Department of Emergency Medicine at The University of Texas Southwestern UTSW in Dallas, TX. I developed a set of SOPs pertaining to administrative management of research for the department. The Clinical Research Division of the department (not including the numerous faculty) currently consists of 8 full time staff members. They are Shannon McNabb, the Clinical Research Manager, Khushbakht Bakhshi, a Grants and Contracts specialist, Mario Puente, a Clinical Study Coordinator, Riley, a newly hired Clinical Study Coordinator, Pamela Owen, a research Associate, Paula Arrelano-Cruz, a Clinical Program Coordinator, Dixie Climer, a Research Nurse, and David Gallegos, a Data Specialist. Pamela, Paula, Dixie, and David are all part of the personal research team of Dr. Ahamed Idris (the departmental Director of Research) and work in a separate building with him.

The department is a large and active one. It currently has 100+ active protocols, 25 of which are sponsored studies in some stage of development and 8 which are actively enrolling. 4 of the protocols are closed to new enrollment, but follow up is being performed. Many of the studies require coordination with other teams within the institution. For example, Access, a study that exclusively involves patients that are resuscitated from ventricular tachycardia arrest, must be coordinated with EMS directors, EMS coordinators, and rapid response teams.

2) Population

The two populations involved in this project were: (1) the Clinical Research Staff, and (2) the faculty of the Department of Emergency Medicine at UTSW. The Clinical Research Division

of the department has 8 staff members, while there are over 90 physician faculty, of which around 25% participate in research.

3) Surveys

A survey was given to both the faculty and research staff before and after the SOPs were in place for a total of four surveys. The surveys employed an ordinal scale which was Likert in nature and consisted of five to ten questions each. The Survey of the Clinical Research Staff (Figure A) measured Staff confidence to complete research administrative tasks efficiently and correctly. The survey of the Faculty (Figure B) evaluated Faculty confidence in the Clinical Research Staff to complete research efficiently and correctly.

Figure A. Research Staff Survey

Disclaimer: This survey is anonymous, voluntary, and purely for research purposes.

Instructions: Please circle the number corresponding to your response for each question.

1- strongly disagree 2- somewhat disagree 3- Neutral 4- somewhat agree 5- strongly agree

1. I have all of the tools and resources I need to conduct tasks assigned to me without undue difficulty or burdensome communications.

1	2	3	4	5
---	---	---	---	---

2. I explicitly know all of the steps to perform my main responsibilities to the department.

1	2	3	4	5
---	---	---	---	---

3. If I am required to take over another staff member's responsibilities temporarily I am confident in my ability to perform them correctly.

1	2	3	4	5
---	---	---	---	---

4. I explicitly know what documentation or forms I need for every step of my main responsibilities to the department.

1	2	3	4	5
---	---	---	---	---

5. The amount of time it takes for me to communicate issues to the correct person or entity is acceptable.

1	2	3	4	5
---	---	---	---	---

6. I have all of tools and resources I need to fulfill all of my main responsibilities to the department.

1	2	3	4	5
---	---	---	---	---

7. My communications within the department is efficient and timely.

1	2	3	4	5
---	---	---	---	---

8. The way I have been trained to perform my job responsibilities is the most efficient way to do them.

1	2	3	4	5
---	---	---	---	---

8

9. I am confident that my work is completed in a timely manner and per departmental expectations.

1	2	3	4	5
---	---	---	---	---

10. I am confident in my knowledge of procedures relating to the management of clinical research within my role to the department.

1	2	3	4	5
---	---	---	---	---

Total Score _____

Figure B. Faculty Survey

Disclaimer: This survey is anonymous, voluntary, and purely for research purposes.

Instructions: Please circle the number corresponding to your response for each question.

1- strongly disagree 2- somewhat disagree 3- Neutral 4- somewhat agree 5- strongly agree

1. The staff of the research division has all of the tools and resources that they need to efficiently manage and carry out research for the department.

1	2	3	4	5
---	---	---	---	---

2. The average amount of time it takes for a communication or request to be answered or performed by the research division is adequate.

1	2	3	4	5
---	---	---	---	---

3. I am likely to continue my current level or increase my involvement with research.

1	2	3	4	5
---	---	---	---	---

4. The research division is capable of and equipped to quickly develop new hires into proficient and independent workers.

1	2	3	4	5
---	---	---	---	---

5. I am satisfied with the performance of the research division of the department.

1	2	3	4	5
---	---	---	---	---

Total Score _____

4) SOP creation

Creating a departmental level set of SOPs required a systematic approach as well as collaboration with both the research staff and faculty. Initially, a master SOP was created. (See figure D below) Such a document ensures uniformity and clarity as well as a set process to add to or update any new SOP's. Predictably, one of the main components of this document is a common template for SOPs. Attention was subsequently shifted to the operations set of SOPs. A preliminary list of SOPs most desired by members of the research staff and faculty was created through conversations and discussions at team meetings. From a list of 50 SOPs, ten were identified for prioritization (see the table below.) Next the purpose, scope, prerequisites, responsibilities, and procedure of each SOP were defined one by one.

-----**Figure C. Master SOP**-----

Master Standard Operating Procedure

1. Purpose

This standard operating procedure (SOP) will describe the method and provides a template for creating new administrative SOPs as well as maintaining, reviewing, and revising old ones.

2. Scope

This SOP will provide a foundation for and promote consistency in administrative practices and duties performed by staff of the Clinical Research Division of the Department of Emergency Medicine (DEM) at the University of Texas Southwestern (UTSW.)

3. Prerequisites

None

4. Responsibilities

The Clinical Research Manager

- Owns the set of SOPs for the department and keeps a file of all prior versions of SOPs
- Reviews the departments SOPs on a biannual basis
- Responsible for revising SOPs on an as needed basis if circumstances relating to the SOP change

DEM faculty and clinical research staff

- Responsible for notifying the Clinical Research Manager if there are deficiencies in current administrative processes that have SOPs or if there are processes that could benefit from a new department SOP

Clinical Research staff/Clinical Research Manager

- Responsible for the creation of new SOPs as needed

5. **Procedure**

5.1 **Identifying the need for SOPs**

The creation of new SOPs should be spurred and prioritized by the needs of the department, faculty, and research staff.

5.2 **Writing the SOP**

The appropriate individuals knowledgeable in the subject of the SOP should be involved and the level of detail need should be determined. The responsible individuals covered by the SOP or a designated individual will complete a draft of the SOP. The draft will then be reviewed for clarity and accuracy by the Clinical Research Manager or another designated individual. The attached template may be used.

5.3 **Format:**

Title: The title should be indicative of the main concept of the SOP but not be more than 10 words.

1. **Purpose:** Describes the goals and intent of the SOP.
2. **Scope:** Brief list or statement in regard to whom the SOP applies.
3. **Prerequisites:** Outlines previous training needed to perform duties outlined in the SOP.
4. **Responsibilities:** Clearly states the specific responsibilities of each of the people or groups of people to whom the SOP applies.
5. **Procedure:** A clear and concise step-by-step description of the activities necessary for correct completion of duties and tasks to which the SOP applies.
6. **Forms or Attachments:** Materials needed to complete the tasks outlined by the SOP. This can include checklists, forms, or any additional information that may be needed.

In this corner the policy number, effective date, revised date, and review date will be listed

5.4 Implementation

After the SOP is finalized and approved, the Director of Research or the Clinical Research Manager should ensure that all appropriate individuals are aware of the new SOP and have access to it. Training, if applicable, should also be performed and documented.

5.5 SOP revisions and retention

Each SOP is reviewed every two years for possible updates needed because of changing regulations, laws, or institutional norms. A copy of the revised SOP will be posted on the O-drive and website. The new SOP will be effective 60 days after the revisions have been announced. The research staff should destroy any paper or electronic copies of the old SOP in a timely manner consistent with the organization's Records Retention Schedule. The Clinical Research Manager will keep an electronic copy of the past revisions of SOPs for record keeping purposes.

6. Forms or Attachments:

Attached is a template for new SOPs.

Table A. List of SOPs with table showing those created. (top ten bolded and underlined.)

<u>Potential SOP list</u>	<u>SOPs Created</u>
<u>1. Vetting new studies</u>	1. Master SOP
2. Recruitment process	2. Legally Authorized Representatives
3. Slicer/Dicer	3. Study Start Up
4. CDA process	4. Site Initiation Visit
5. Pre-Site selection Visit (regulatory documents needed)	5. Site Qualifying Visit
6. Cost analysis	6. Serum Collection and Processing
7. Budget and contract negotiation	7. Informed Consent
<u>8. IRB application processing</u>	8. Completion of Case Report Forms
9. Funding proposal through SPA	9. Invoicing
10. Site approval	10. Training and Credentialing of Research Coordinators
11. Site initiation visit/SQV	11. Reporting Research Unanticipated Problems and Reportable events
12. Manual of operations	12. Study Closure and Record Retention
<u>13. Study start-up checklist</u>	13. Lab Management
<u>14. Invoicing</u>	14. Team Member Responsibilities
15. Prescreening on EPIC and maintaining a log (with template)	15. Billing for Procedures and Orders Performed for a Research Study
16. Research credentialing steps	16. Patient Screening in EPIC
17. Informed consent process	17. EIRB submission
<u>Potential SOP List</u>	<u>SOPs Created</u>

<p><u>18. Onboarding for new hires</u></p> <p>19. Study brochures for potential subjects</p> <p>20. Who reviews IND safety reports and when to report to the IRB</p> <p><u>21. Study close out check list</u></p> <p>22. Faxing and emailing with PHI</p> <p>23. IATA Training</p> <p>24. Biomedical waste training</p> <p>25. HIPPA privacy safeguards</p> <p>26. Electronic medical record</p> <p>27. Record retention, storage, and destruction</p> <p>28. Freezer monitoring</p> <p>29. Subject payment</p> <p>30. Grants management</p> <p>31. Data management and quality assurance</p> <p>32. Electricity failure in the lab</p> <p>33. Biohazard waste disposal</p> <p>34. Annual lab equipment calibration</p> <p>35. O drive paperless file sharing</p> <p>36. Dress code</p> <p>37. Effort tracking</p> <p>38. Administration of study drugs</p> <p>39. Differentiating research studies from quality improvement projects</p> <p><u>40. Parkland Site Review and approval process</u></p> <p><u>41. Research team responsibilities</u></p> <p><u>42. Training and education for individuals conducting research</u></p> <p>43. Research equipment</p> <p><u>45. Reporting research unanticipated problems and adverse events</u></p> <p>46. Participant recruitment and enrollment</p> <p>47. Access for visiting research monitors and reviewers</p> <p>48. Clinical trials billing – investigational drugs</p> <p>49. Clinical trials billing – Devices</p> <p>50. Research data request and management</p> <p>51. PHS financial conflict of interests in research</p> <p>52. Research misconduct</p> <p>53. Human subject protection plan</p>	<p>18. HIPAA privacy safeguards</p> <p>19. Regulatory Files</p>
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Below is the process that was followed to create an SOP:

- 1) A draft SOP was first created based on prior knowledge gained from working in the department, previous education, and research.
- 2) Then, in collaboration with the Clinical Research Manager and the appropriate research staff, the drafts were edited and adjusted before being finalized.
- 3) Some of the SOPs which require more complicated processes, a Time and Motion approach was taken to gather all of the necessary information to create the SOPs. A time in motion approach is where you film or otherwise objectively record a process, such as timing steps.
- 4) Finally, The SOPs were individually brought before The Clinical Research Manager then Dr. Ahamed Idris, the Research Director of the DEM, for final approval.

There were a few exceptions for very routine tasks, such as freezer monitoring and hazardous material management protocols; these were adjusted from a similar SOP from another department at UTSW or an institutional level resource.

As mentioned earlier, there will be a process for updating and creating new SOPs. The SOPs will be reviewed every two years and new SOPs can be created from the template provided by the Master SOP document (Figure C.) The original SOPs will be owned by the Clinical Research Manager, and copies will be available to all of the research staff on shared electronic drives and on the soon-to-be created departmental intranet.

5) Data Analysis

At the end of the project, after the post SOP surveys were collected, the pre- and post-SOP confidence/knowledge of both the research staff and the faculty were compared. As there are only eight people on staff in the Clinical Research Division it would be most appropriate to use the Wilcoxon signed rank test. The hope was that there would be enough responses from the research faculty, of which there are a little more than 90, before and after the SOPs to be able to do a statistical test with more power, but regression to a Cochran-Armitage Trend Test was necessary due to a low number of respondents. A two-sided .05 significance level was considered statistically significant.

RESULTS

Neither the faculty or research staff pre and post SOP surveys varied significantly. Of the Research staff, 7 responded to the Pre-SOP survey while 6 responded to the Post-SOP survey. A Wilcoxon signed rank test was used for the research staff and a P- value varying from .15 to .75 was obtained for each question. For the faculty an unpaired test was utilized and a P-value varying from .07 to .69 was obtained utilizing a Cochran-Armitage test for trend across each question. Although there was no significant data point or trend in any of by data sets it is pertinent to note that the mean response improved for every question (**except Question #1 on Table C**) after the SOPs were presented.

Table B. Research Staff survey results

Research Staff Question #	Pre – SOP Mean	Post SOP Mean	Wilcoxon Signed Rank P
1	3.83	4.33	.44
2	3.83	4.17	.75
3	3.67	4.17	.50
4	3.67	4.17	.50
5	3.50	4.50	.15
6	3.83	4.33	.53
7	4.16	4.66	.25
8	3.50	4.33	.31
9	4.17	4.50	.63
10	4.00	4.33	.68

Table C. Faculty Survey results

Faculty Question #	Pre – SOP Mean	Post SOP Mean	Cochran- Armitage Trend
1	3.41	3.40	.50
2	3.54	3.66	.69
3	3.66	4.43	.07
4	3.18	3.40	.34
5	3.31	3.46	.58

DISCUSSION

Even though the data did not reach significance, there are things to learn from the study and there were limitations and biases that are worth mentioning and pertinent for future studies to avoid. There were several limitations and biases inherent with assessing the quality of a new set of SOPs which could not be controlled for within the context of the present project and its timeframe. One of the most significant limitations was the low sample size. There are only seven clinical research staff around 25 faculty (out of around 90 total) that participate in research. Unfortunately, there is also a profound lack of prior research regarding SOPs. Particularly, I was unable to find a single paper involving administrative SOPs. Another significant limitation is that the time period from when the SOPs were first put in place, to when confidence was measured for the second time was very short. It is possible that confidence only changed minimally simply because not enough time has elapsed for the staff to become accustomed to the new SOPs or for the faculty to notice a difference. In fact, due to the delayed release of the SOPs to the department for use, none of the research staff or faculty actually used the SOPs before the second survey; rather they were just provided with list of the completed SOPs and copies of the drafts of them to consider. Also, low faculty participation in the confidence survey was encountered. Per Ms. McNabb, only about 25% of the faculty actively participate in research on a regular basis. [4] Therefore, the remaining 75% may have ignored the request due to a lack of a personal stake in, or even involvement with research. A third potential limitation/confounding factor may have been the common workplace phenomenon that people can be resistant to change. As noted earlier, the impact of this may be reduced by involving the research staff in the creation of the SOPs. Most institutional endeavors to establish SOPs are typically lengthy and involve a

large number of staff. From 2011-2012 , Cincinnati Children's Hospital Medical Center (CCHMC) sought to improve the quality of its clinical data management with SOPs. To do this, they developed a tiered system in which a team of 16 staff members developed the SOPs before a team of eight faculty members then a team of three external experts reviewed them. The product of this team, working for ten months, resulted in twelve finalized and implemented SOPs across the entire hospital. [7] This project was smaller and primarily sought to design and implement a startup set of administrative SOPs for a single division of a department within an institution. Similarly to their project, meetings with different groups and individuals were held in the department to review SOPs that applied directly to them or affected their work. Based on the experience and results of this project, future studies and/or SOP startup initiatives would benefit from a design similar to Cincinnati Children's Hospital's method. That is, a committee or other group of individuals would be designated to develop and enact a systematic process based on the experience of individuals in the group as well as prior efforts within the institution, as well as outside of it. Lastly, known biases were avoided as far as was reasonably possible. Leading question bias was minimized by ensuring that the survey questions were not worded to suggest that a particular response was sought. Observer expectancy bias was minimized by administering the survey anonymously and online.

CONCLUSIONS

When designed and utilized in an appropriate and systemic manner, standard operating procedures can be a great boon for any organization. They can ensure uniformity of quality for numerous common procedures as well as prevent costly, inefficient, unethical, or even dangerous

mistakes. For this practicum, I sought to evaluate whether a set of SOPs for a department that had none would increase the confidence of the Faculty in the research staff and the staff's confidence in their ability and in their resources. Unfortunately, none of the results showed statistically significant data. However, it is pertinent to note that although no significant difference was found, the mean response improved for every single question except one after the SOPs had been presented to the faculty and staff.

Future studies regarding this topic can draw a good deal of insight from this project as well as ways in which similar future studies could be improved. Obviously, it would be expedient for future studies to try to utilize a larger sample size in order to lend more power to the study, as well as look at a larger time window for implementation of the SOPs. Specifically, it would be more appropriate and telling if future studies could compare confidence after SOPs have been presented and actually been in use for at least a few months rather than just presenting them. The research staff and faculty had a much more positive response when their advice or input on the SOPs was elicited and they were involved in the process.

APPENDIX:

SOPs Created: (just the bodies of procedures are included, not the official SOPs):

Master Standard Operating Procedure

6. **Purpose**

This standard operating procedure(SOP) will describe the method and provides a template for creating new administrative SOPs as well as maintaining, reviewing, and revising old ones.

7. **Scope**

This SOP will provide a foundation for and promote consistency in administrative practices and duties performed by staff of the Clinical Research Division of the Department of Emergency Medicine (DEM) at the University of Texas Southwestern (UTSW.)

8. **Prerequisites**

None

9. **Responsibilities**

The Clinical Research Manager

- Owns the set of SOPs for the department and keeps a file of all prior versions of SOPs
- Reviews the departments SOPs on a biyearly basis
- Responsible for revising SOPs on an as needed basis if circumstances relating to the SOP change

DEM faculty and clinical research staff

- Responsible for notifying the Clinical Research Manager if there are deficiencies in current administrative processes that have SOPs or if there are processes that could benefit from a new department SOP

Clinical Research staff/Clinical Research Manager

- Responsible for the creation of new SOPs as needed

10. **Procedure**

5.1 Identifying the need for SOPs

The creation of new SOPs should be spurred and prioritized by the needs of the department, faculty, and research staff.

5.2 Writing the SOP

The appropriate individuals knowledgeable in the subject of the SOP should be involved and the level of detail need should be determined. The responsible individuals covered by the SOP or a designated individual will complete a draft of the SOP. The draft will then be reviewed for clarity and accuracy by the Clinical Research Manager or another designated individual. The attached template may be used.

5.3 Format:

Title: The title should be indicative of its main idea but not too lengthy.

7. Purpose: Describes the goals and intent of the SOP.

8. Scope: Brief list or statement of to whom the SOP applies.

9. Prerequisites: Outlines previous training needed to perform duties outlined in the SOP.

10. Responsibilities: Clearly states the specific responsibilities of each of the people or groups of people that the SOP applies to.

11. Procedure: A clear and concise step by step description of the activities necessary for correct completion of duties and tasks the SOP applies to.

12. Forms or Attachments: Materials needed to complete the tasks outlined by the SOP. This can include checklists, forms, or any additional information that may be needed.

In this corner the policy number, effective date, revised date, and review date will be listed

5.4 Implementation

After the SOP is finalized and approved by the Director of Research or the Clinical Research Manager should ensure that all appropriate individuals are aware of the new SOP and have access to it. Training, if applicable, should also be performed and documented.

5.6 SOP revisions and retention

Each SOP is reviewed every two years for possible updates needed because of changing regulations, laws, or institutional norms. A copy of the revised SOP will be posted on the O-drive and website. The new SOP will be effective 60 days after the

revisions have been announced. The research staff should destroy any paper or electronic copies of the old SOP. The Clinical Research Manager will keep an electronic copy of the past revisions of SOPs for record keeping purposes.

6. Forms or Attachments:

Attached is a template for new SOPs.

Approved By:

Dr. Ahamed Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

**Legally Authorized Representative (LAR) and
Exception from Informed Consent (EFIC)**

11. Purpose

This policy and procedure applies to all human subjects' research involving divisionally impaired or otherwise incompetent adults.

12. Scope

This SOP applies to anyone in the Department of Emergency Medicine (DEM) who screen and/or enroll patients who are mentally impaired in studies

13. Prerequisites

Research credentialing

Must be named on IRB application as study personnel

14. Responsibilities

Research Study Coordinators are responsible for knowing when LAR procedure or

EFIC procedures are IRB approved and must be used and properly implement it. This policy is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct research on problems that are unique to persons who have an impaired decision-making capacity.

5. Procedures

Ordinarily, an investigator must obtain informed consent directly from prospective research subjects. When the prospective research subject is an adult whose own consent would not be legally effective because s/he lacks the capacity to give or communicate comprehending informed consent, then research may be conducted only with the consent of the potential subject's parent, guardian or legally authorized representative (the "LAR"), which is also known as "surrogate consent." Adults are presumed to have capacity to give informed consent for research. In the absence of indications to the contrary, such capacity can be assumed without further evaluation or documentation. The UTSW IRB may waive the requirement for obtaining LAR consent if the research meets the provisions for waiver in 45 CFR 46.116(d)(1-4). Assent (affirmative agreement) is required if the subject is able to give it. However, the IRB may waive the requirement to seek assent if the subject is not competent to give it. Decision-making impairments may be permanent, temporary, progressive, or fluctuating. Depending upon the population and the research, the IRB may require periodic re-assessment of decision-making ability during the study. If consent is initially provided by a LAR and the subject regains decision-making capacity, the IRB may require the investigator to obtain consent from the subject using standard consent procedures. If so, the consent provided by the LAR is no longer considered valid for continued participation in the research. In some research, such as longitudinal studies involving progressive disorders or aging populations, enrolled subjects may be initially competent to provide consent but progressive or intermittent disorders may lead to decisional impairment during the research. The IRB considers whether it would be appropriate for the investigator to discuss during enrollment whether the prospective subjects should designate someone to serve as a LAR, should the subject's decision-making ability become compromised during the research.

Assent

Assent is an affirmative agreement by an individual not competent to give legally valid informed consent (e.g. person with limited mental capacity) to participate in research. The IRB determines whether assent is required. If assent is determined appropriate in decisionally impaired adults, and/or incompetent adults, the individual should be given an explanation, at a level appropriate to the individual's condition, of the procedures to be used, their meaning in terms of discomfort and inconvenience, and the general purpose of the research. Documentation of assent is required. Generally, assent is documented by having the individual sign the consent form in the designated signature section.

The IRB may waive its requirements for obtaining or documenting assent appropriate in decisionally impaired adults, and/or incompetent adults, if the IRB determines:

- The research involves no more than minimal risk to the participants; and
- The waiver will not adversely affect the rights and welfare of the participants; and
- The research could not practicably be carried out if assent was required; and
- When appropriate, pertinent information is provided after participation

Consent via a LAR

The Research Study Coordinator (RSC) may obtain consent by a LAR only in situations where the prospective subject is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination that a subject is incompetent or has an impaired decision-making capacity must be made by a legal determination or a determination by the practitioner (e.g., a psychiatrist or licensed psychologist may be consulted if based on mental illness diagnosis). This determination may be made independently, in consultation with another qualified individual or after appropriate medical evaluation it is determined that the prospective subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time. The IRB may require investigators to conduct a preliminary competency assessment whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects. The RSC advises the LAR of his/her role and responsibilities in serving as the decision-maker for the subject. The investigator also advises the LAR that it is his/her obligation to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what he/she thinks is in the incompetent person's best interest. If feasible, the RSC explains the proposed research to the prospective subject even when the LAR gives consent. For subjects whose decision-making capacity may fluctuate and either regain capacity to consent or those with decreasing capacity to give consent, a re-consenting plan may be necessary.

Exception from Informed Consent (EFIC) Emergency Research

Federal regulations allow an IRB to approve research that involves patients in life-threatening conditions without requiring that informed consent be obtained, and they also allow the use of an investigational device or drug in patients with life-threatening conditions, though with a list of requirements that must be met.

Legally authorized representative (LAR)

Under Texas law, the consent must come either from the legal guardian of the subject, or, in the case of research that is part of medical treatment, from the subject's health care agent:

- The appointed guardian or
- The person to whom the subject has given a durable power of attorney, which must include the authority to make health care decisions

In the absence of either of the above, a LAR from the following list, in order of priority, who is available after a reasonably diligent inquiry, may consent on behalf of the patient:

- The patient's spouse (including a common law spouse)
- An adult child of the patient who has the waiver and consent of all other qualified adult children of the patient to act as the sole decision-maker
- A majority of the patient's reasonably available adult children
- The patient's parents; or
- The individual clearly identified to act for the patient by the patient before the patient became incapacitated, the patient's nearest living relative, or a member of the clergy

Competence

Competence is a legal term that should not be confused with decision-making capacity. Someone who has been judged legally incompetent to handle their finances may still be able to make a meaningful choice about participating in research.

Informed Consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in Research or to undergo a diagnostic therapeutic or preventive procedure. For the purposes of contrast, "Consent," is voluntary agreement without mention of whether full knowledge was imparted or understanding took place and "Legally Effective Informed Consent" is obtained when a subject or a subject's legally authorized representative as outlined in 45 CFR 46 (Common Rule) agrees to participate. Informed Consent is obtained only after the prospective subject is provided sufficient opportunity to consider whether or not to participate. Informed consent nor legally effective informed consent can be obtained from a subject with Diminished Autonomous Decision-Making Capacity (DADMC) for research purposes. Surrogate Consent or Legally Authorized Representative (LAR) is obtained in such a case.

Legally Effective Informed Consent is consent of a subject, or if the subject is incapacitated, incompetent, or has impaired decision-making capacity, then the consent of the subject's Legally Authorized Representative (LAR) or surrogate as outlined in 45 CFR 46 (Common Rule). It is not always required that Informed Consent to participate

in research be given by the legally authorized representative if another form of Surrogate Consent is available such as family member consent depending on applicable state law, institutional policy and the determination of the IRB.

Someone who is:

- Incapacitated
- Incompetent, or
- has Impaired Decision-Making Capacity

cannot give legally effective informed consent for research purposes. Surrogate Consent or Legally Authorized Representative (LAR) is obtained in such a case.

REFERENCES

21 CFR 50

21 CFR 5645 CFR 46

45 CFR 146

46 CFR § 46.116(d)(f)

21 CFR § 50.24(a)

21 CFR § 50.23(a)

Texas Probate Code, Chapter XIII, § 767(a)(4)

The Texas Medical Consent Act, codified at Title 4 Tex. Health & Safety Code, Section 313.004(a)

Title 2, Health & Safety Code, §§ 166.151-166

Title 2, Texas Family Code § 31.001

Title 2, Texas Family Code § 31.003

Title 4, Texas Health and Safety Code § 313.004

Title 9, Tex. Health & Safety Code § 773.008(1)(2)

CONTACT FOR FURTHER INFORMATION

Human Research Protection Program Office

HRPP@UTSouthwestern.edu

214-648-3060

Approved By:

Dr. Ahamed Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Study Startup

15. Purpose

The purpose of this SOP is to act as a guide to ensure all of the appropriate steps are completed and approvals are requested prior to launching a new study.

16. Scope

This SOP applies to anyone in the Department of Emergency Medicine (DEM) who participates in getting research off the ground and seeks to promote consistency, accuracy, and efficiency in the process to start new studies.

17. Prerequisites

Velos and eIRB training modules

18. Responsibilities

Principal Investigator: a,b,n,o,s

Clinical Research Managers: c,e,f,g,h,I,m,n

Grants and Contracts Specialist: b,d,j,l

Research Study Coordinators: n,o,p,q,r,t,u

19. Procedures

- a) A faculty member is contacted by a sponsor to see if we are interested in participating in a multisite study.
- b) Once the faculty member expresses interest in being a site PI, the sponsor will send us a Confidentiality and Data Use Agreement (CDA) or a Nondisclosure Agreement (NDA), which is to be uploaded into eAgreements.
 - a. Enter in database: date CDA received from sponsor, date uploaded to eAgreements, contract ID# assigned by eAgreements, who it was assigned to, date language was approved by UTSW, date sent to sponsor for review, date executed, date activated
- c) Once the CDA is executed, it is followed by a feasibility survey. The Clinical Research Manager or any staff member with access to SLICER DICER will do a query on the targeted

subject pool and provide the sponsor with feedback on our numbers. For example, we see blank number of seizure patients come through the ED annually. Do queries for both Clements and Parkland hospitals.

- d) After the sponsor has deemed us a feasible site, they will send the full protocol for review. If we agree that we can operationalize the protocol, the Site Qualifying Visit (SQV) is the next step. The SQV can be conducted over the phone or in person, but is usually done in person. This is when the sponsor sends representatives to visit the site. They will want to meet with the PI (typically for one hour) and the research team (typically all day), give a presentation on the study, and gather regulatory documents that must be prepared beforehand. These documents include the PI's current biosketch, medical license, lab certifications, equipment calibration dates, and signing the DOA log. A member of the research division will be responsible for giving them a tour of the lab and the EDs. After the conclusion of the SQV the department must wait until they determine if UTSW will be confirmed as a performance site.
- e) After being confirmed as a study site, the study is to be submitted into Velos.
Log onto Velos <https://velos.swmed.edu/velos/jsp/ereslogin.jsp>
 1. Click MANAGE
 2. Under STUDIES, click NEW
 3. Complete the summary page
 4. E-signature (always 1234) and submit
 5. Record the Velos # provided by the system
- f) Now, from Velos, push the study into eIRB:
 1. Click on the tab named STUDY STATUS
 2. Click the blue link ADD NEW STATUS
 3. Organization = UTSW Medical Ctr and Affiliates
 4. Status Type = IRB
 5. Study Status = IRB – Submission Initiated
 6. Status Valid From = choose today's date
 7. E-signature (always 1234) and submit
 8. It may take up to 15 minutes for the study to appear in eIRB. If it does not appear, your title may be too long.
- g) Log into eIRB
<https://eresearch.swmed.edu/eIRB/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity%5BROID%5BAC482809EC03C442A46F2C8EEC4D75D3%5D%5D>
Complete the appropriate forms on eIRB
 - There are templates available for Informed Consent and HIPAA authorization forms.
 - It is important to note that PMH mandates that the following phrase be in every HIPPA authorization form for studies using them as a site: *“Medical information collected during this study and the results of any test or procedure done may be included in your medical record and this information may be available to health care providers and authorized persons including your insurance company.”*
 - For EFIC studies, you must submit your plan for community outreach which must be approved before you can implement the plan.
 - If parkland is being used as a site IRB approved informed consent forms and HIPAA authorization forms must be translated into Spanish. Parkland bills us for this service. If you know parkland will be used as a site early on be sure to have this cost listed in your budget as a start-up fee. The form for language translation services can be found here:

- h) It must then be determined if a study needs to be sent to other committees for approval. Examples include:
- SHUR, a radiation committee which reviews any study that involves imaging
 - Cancer Committee
 - Information System Acquisition Committee (ISAC)
 - Biosafety Committee needed if you will be transporting biohazards to a lab
- i) Before the budget can be completed, a coverage analysis should be requested via Velos. You need to upload the consent form along with the request for the coverage analysis. The following should be included in the budget:
1. Coverage Analysis \$3000
 2. IRB fees (initial review \$3000, continuing reviews \$1500)
 3. Pharmacy fees for drug storage, dispensing fees, etc.
 4. Translation Services
 5. Personnel are not usually included on the budget of an industry sponsored study. It is generally just start up and close out fees along with how much they will pay per enrollment. After the study is done and all invoicing is completed, the PI is to pay back the DEM for the time/effort of the research staff [Research Manager can tell PI the amount of hours each staff member worked on the project]. If there are funds remaining, the PI is to move the remainder into a consolidated funds acct (CFA) and is encouraged to donate a small percentage to the Research Division's CFA to support future unfunded research.
 6. Indirect fees: 30% for industry, 26% for federal if off campus, 62% for federal if on campus
 7. Enter in database:
 - i. The direct cost for year 1, the indirect cost for year 1, the total cost for year 1
 - ii. The direct cost for the total project period, the indirect cost for total project period, the total cost for the total project period
- j) Clinical Trial Agreement (CTA): Contracts cannot be executed until there is IRB approval.
- a. Enter in database: date CDA received from sponsor, date uploaded to eAgreements, contract ID# assigned by eA, who it was assigned to, date language was approved by UTSW, date sent to sponsor for review, date executed, date activated
 - b. If we are subcontracting with other sites, these contracts cannot be processed until the main contract is activated.
 - c. If the study is industry sponsored, an Award ID will automatically be generated by the Office of Post Awards (OPA) following activation of the contract. A funding proposal must be created in eGrants for federally funded studies.
- k) Other support: For each study, enter the following into the database so the PI can update their Other Support page
1. Contract or a grant, grant # if a grant
 2. Name of PI
 3. Start and end date of project period
 4. Calendar month dedicated to project
 5. Sponsor name
 6. Annual direct costs
 7. Title

8. Goals
- l) Next, Site approval must be requested via Velos.
 1. forms
 2. Jump to form performance site review form and click GO
 3. fill out the form, change form status to READY FOR SUBMISSION and submit
 4. Go to study status tab
 5. Click on ADD NEW STATUS
 6. In the Organization box, pick your performance site (Parkland or Clements)
 7. Change status type to PERFORMANCE SITE
 8. Change study status to PERFORMANCE SITE SUBMITTED
 9. Mark the date
 10. Esign and submit
 11. Site approval won't be granted prior to IRB approval
- m) Log into eGrants
https://eresearch.swmed.edu/eIRB/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge_entity.Entity%5B0ID%5BAC482809EC03C442A46F2C8EEC4D75D3%5D%5D
 1. Complete the forms for the funding proposal and enter the budget information
 2. Attach the budget justification
 3. You should get an email stating that the account for the funds has been set up along with a project ID#, Award#, etc
 4. Enter in database: FP#, date submitted in eGrants, date of approval, project ID#
- n) Next, the site initiation visit (SIV) will take place. This usually will involve one or two representatives of the sponsor coming to the site, or possibly just a telephone call, if they have already toured the site at the SQV. The purpose of this visit is to train the research staff to implement the study. Only those who participate in the training will be able to participate in the study.
- o) Next, site training must take place. You must first give the physicians and nurses notification of the study and sometimes you will actually need to train the faculty and nurses. If this is needed, they must sign a training log. TEMRAPPERS may also be utilized so they can page or otherwise notify us of potentially eligible patients.
- p) The research coordinator(s) for the study must ensure all supplies are on site and inventoried. They must also ensure the devices (if any) are charged.
- q) At this point study packets can be made. Every study packet should include 2 copies of the consent and HIPPA forms (one for the DEM and one for the subject), and all data collection sheets.
- r) Once the sponsor has notified us that we are an activated site, prescreening can begin. Prescreening is typically done through EPIC but waivers of consent and authorization must be granted by the IRB for the specific purpose of prescreening for eligibility.
- s) For EFIC studies, public disclosure in English and Spanish is required before launching. We must have opt out bracelets or dog tags in stock in case community members call to opt out of the study. Before placing the newspaper ads, it must be approved by the Communications Department. You must also have the information relating to the distribution of publication or source that the ad is in to report to the IRB. For example, you can find online that the Dallas morning news has 271,900 subscribers and a weekly audience (newspaper and online) of 1.5 million.
- t) If the study is a clinical trial, involving a drug, device, or intervention, it must be registered on the clinicaltrials.gov website. It is the responsibility of the main site to register and list all the subsites of a multicenter trial. Check to ensure we are listed as a site.
- u) **YOU MAY BEGIN SCREENING AND ENROLLMENT ACTIVITIES AS APPROVED BY THE IRB.**

20. Forms or Attachments

Attached is a checklist for starting new studies.

Approved By:

Dr. Ahamed Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

**Site Initiation Visit (SIV)
SOP**

1. Purpose

To allow sponsors to meet with the study team (PI, Sub-I, Research Study Coordinators, Research Manager, Pharmacy, Nursing)

2. Scope

All research personnel involved in Department of Emergency Medicine (DEM) related sponsored projects.

3. Prerequisites

Basic knowledge of the study by reviewing the protocol. Should know both hospitals' Emergency Department (ED) layout so can give the sponsor a tour of the ED and have them meet with Pharmacy.

4. Responsibilities

Each time a sponsor requests an SIV, one will be scheduled with an experienced coordinator. This coordinator will block sufficient time to allow the sponsor to tour the campus, meet with Pharmacy, and meet with the Research Study Coordinators, Research Manager, and PI/Sub-I.

5. **Procedures**

- A. Notify the DEM administrative office when your site initiation visit will take place. If need be, the DEM office can assist with whom to contact in various departments to set up interviews with the Sponsor's representative.
- B. Schedule time with the Sponsor's representative and the requested team members including the PI, Pharmacists, and any other department personnel that may be used during the course of the study (i.e., Infusion Clinic, Pathology Lab, Imaging Staff, etc.)
- C. Prior to the visit, request any materials the sponsor will be going over at the SIV so you can review these before the visit.
- D. If the sponsor's representative requires paperwork or documentation before the visit, provide this in a timely manner before the visit.
- E. The sponsor typically provides formal protocol training at this visit. Pre-load the presentation prior to the start of the meeting and ensure all those in need of training are present and sign the training log.
- F. A tour of the appropriate clinics, departments, and sites is to be completed.
- G. Exchange contact information prior to the conclusion of the visit.
- H. If contacted after the visit, provide any additional information the Sponsor's representative requires as quickly as possible.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Site Qualifying Visit (SQV) SOP

1. Purpose

To allow sponsors to assess whether there is a commitment and ability to conduct a study at UTSW

2. Scope

Any research personnel involved in DEM sponsored projects

3. Prerequisites

Part of the research team for particular study

4. Responsibilities

Each time a sponsor requests a SQV, one will be scheduled with the PI and study team members. Sufficient time must be blocked to allow the sponsor to tour the campus, our clinical research lab, the ED(s) and pharmacy if applicable.

5. Procedures

- I. Reconcile schedules among the sponsor's representatives, the PI and all other study team members.
- J. Schedule a conference room.
- K. Send out a calendar invite to all involved.
- L. Prior to the visit, request a copy of any powerpoints they would like to present so that they can be pre-loaded before the meeting.
- M. If the sponsor's representative requires paperwork or documentation before the visit, provide this in a timely manner before the visit.
- N. The Sponsor will ask a number of questions to determine UTSW's ability and desire to participate in the study. Under promise. Over deliver.
- O. A tour of the appropriate clinics, departments, and sites will be completed pointing out the benefits of selecting UTSW as a study site.
- P. Exchange contact information prior to the conclusion of the visit.
- Q. Send an email the following day
- R. If contacted after the visit, provide any additional information the Sponsor's representative requires as quickly as possible.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Specimen Collection and Processing SOP

1. Purpose

To maintain the integrity of the biological samples, while ensuring the safety of the coordinator collecting and processing the specimens

2. Scope

All research personnel involved in Department of Emergency Medicine (DEM) research projects

3. Prerequisites

Universal Precautions Training
Hazardous/Dangerous Goods Training
International Air Transport Association IATA

4. Responsibilities

It is the responsibility of all DEM personnel to collect and handle all biological specimens according to Universal Precautions and process them according to IATA regulations.

5. Procedures

- S. Coordinators should identify the subject as the correct subject for which the sample is being collected.
- T. Using Universal Precautions, the specimen should be collected per the Sponsor's specifications (i.e. tube size, amount to be collected, tube type, etc.)
- U. The specimens should be processed and handled according to the Sponsor's specifications (i.e., placed on ice, frozen, spun down at a particular speed on a centrifuge, shipped ambient, etc.)
- V. All Coordinators must be IATA certified and are responsible for renewing this certification every two years.
 - 1) Certificates proving training should be forwarded to the Clinical Research Manager.
 - 2) It is your responsibility not to allow your certification to expire.
 - 3) Upon completion of re-certification, your new certificate should be forwarded to the Clinical Research Manager.
 - 4) Coordinators should keep an electronic copy of their certificates on their computers.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

HIPAA Privacy Safeguards SOP

1. **Purpose**

To provide tips on how to safeguard Protected Health Information (PHI)

2. **Scope**

All research personnel involved in Department of Emergency Medicine related projects.

3. **Prerequisites**

Good Clinical Practice Training, Human Subject Protections Training, and HIPAA Research Training

4. **Responsibilities**

It is the responsibility of all research personnel in the Department of Emergency Medicine to actively take steps and demonstrate practices to protect PHI of human research subjects.

5. **Procedures**

A. Know and understand patient HIPAA privacy rights.

Patients have the right to:

1. access and receive copies of records (including electronic copies)
2. request corrections to the record
3. receive and acknowledge Notice of Privacy Practices
4. request confidential communication from staff
5. request restrictions to the record
6. request a list of record releases
7. receive notification following a breach of unsecured health information

B. Protected Health Information (PHI) is identifiable health information in any format. You are responsible to Protect PHI defined as:

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Phone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code (note this does not mean

- the unique code assigned by the investigator to code the data)
- C. Use Caution regarding conversations involving PHI while on the phone or in a reception or waiting area that might be overheard by unauthorized persons. Do not leave messages containing PHI on patient's answering machines.
 - D. Do not access the electronic medical records of friends, family, or co-workers unless the need for access is job-related. Access is based on your job responsibilities and role. Do not access your own medical record. Only use MyChart to access your record.
 - E. Use and disclose only the minimum amount of PHI necessary to do your job.
 - F. Ask the subject if they will allow you to discuss their PHI with family or friends who have accompanied them to the ED. Get their permission first.
 - G. Limit subject's private information on computer screens in areas that may be visible to the public.
 - H. Do not post any PHI on social media sites such as Facebook, Twitter, and blogs.
 - I. Make sure that your computer passwords are not accessible, and you log off the computer when not in use. Do not share your log-in ID or password with anyone!
 - J. File away all papers promptly, lock up PHI in your desk drawers, overhead cabinets or rolling offices.
 - K. Collect printed materials from the printer promptly if they contain PHI.
 - L. The subject's written HIPAA authorization is required before you disclose PHI outside of UT Southwestern Medical Center.
 - M. Always dispose of PHI in shredders or shred-it-boxes.
 - N. Only store PHI on UTSW issued and encrypted computers, laptops, and flash drives.
 - O. Know how to access the HIPAA Privacy policies, procedures, and associated forms. They are located on the Intranet on the Office of Compliance page.
 - P. Know who to contact if you suspect or know of a violation, contact the Office of Compliance. Compliance Hotline 1-877-507-7139, utsouthwestern.net/hotline

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Informed Consent Process SOP

1. Purpose

To describe how to properly perform the informed consent process with research participants that are being recruited by Department of Emergency Medicine (DEM) study coordinators.

2. Scope

All research personnel involved in consenting for DEM studies

3. Prerequisites

CITI Training
Research Credentialing
Site approval for study
IRB-approval letter for study
IRB approved Informed consent form
IRB approved HIPAA Authorization form

4. Responsibilities

It is the responsibility of all DEM research personnel, to properly perform the informed consent process to ensure that every individual approached about a study given the opportunity to make an informed decision about participating.

5. Procedures

- A. Be familiar with the IRB approved Informed Consent Form (ICF) and the study protocol.
- B. Ensure privacy when discussing the ICF with the subject.
- C. Illiterate subjects that cannot comprehend the written ICF are to be consented via oral presentation of the consent form with a witness present.
- D. Cognitively impaired subjects must have a legal guardian present, who can decide in the best interest of the subject. (*See LAR SOP.*)
- E. Ensure the subject is eligible to participate by reviewing the inclusion and exclusion criteria with the clinical treatment team and the patient.
- F. Do not perform any study procedures prior to the completion of the consenting process.
- G. Ensure the subject, LAR or designee has been informed that refusing to
- H. participate in research, investigation, or clinical trials, or discontinuing participation at any time will not jeopardize his or her access to care, treatment, and services unrelated to the research.
- I. Give a copy of the ICF and the HIPAA Authorization to the subject in a language they understand and review and discuss all sections of the ICF in detail – including: study procedures, risks and benefits as well as protection of confidentiality and privacy.
- J. Give the subject adequate time to read the consent form and HIPAA document.
- K. Ensure that the possibility of coercion and undue influence is minimized.
- L. Encourage the subject (and representative [if applicable]) to ask questions and clarification throughout the process.
- M. After satisfactory discussion of all questions and concerns, the subject and/or representative initial all applicable sections and sign, date/time the signature page of both the ICF and the HIPAA Authorization.
- N. The research personnel is required to print, sign, date/time the ICF behind the subject.
- O. Give a copy to the subject for their personal files and file the signed ICF and signed HIPAA Authorization in the appropriate study binder.

- P. Any time changes are made to the ICF or the HIPAA Authorization, all subjects previously consented may need to be re-consented with the current version (unless changes include: study team member change or correction of typographical errors). The IRB will inform you when this is required.
- Q. Documentation of the informed consent process needs to be made in the study files to ensure compliance with federal regulations. The attached file can be used as documentation of this process.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Completion of Case Report Forms

1. Purpose

To maintain all study related source documentation or case report forms (CRFs) in an organized and consistent manner.

2. Scope

All research personnel involved in Department of Emergency Medicine (DEM) sponsored projects.

3. Prerequisites

CITI Training: Sponsor Required Training, Good Clinical Practice, HIPAA Research, and Human Subject Protections
Research Credentialing
Study specific training
Listed on Delegation of Authority Log
Electronic access to database (REDCap, etc.)

4. Responsibilities

It is the responsibility of all DEM personnel to complete all study related CRFs correctly and completely, as well as maintain CRFs and source documentation for each study.

5. Procedures

All data collected is to be maintained in the study subject's file as outlined below.

- W. Paper CRFs and source documentation will be stored in a double locked manner (i.e., behind a locked door and in a locked desk, cabinet or bookcase) when not in use.
- X. During each study visit, the subject CRFs, records, and source document will be updated accordingly and within the timeline specified by the sponsor.
- Y. If no timeline is mandated by the sponsor, the CRFs should be completed within 48 hours after the subject's study visit.*
- Z. CRF binders should be organized in the following format:
 - 1) The study subject's original Informed Consent Form and HIPAA Authorization are to be kept in CRF/Source Document binder unless specified otherwise to the IRB.
 - 2) All study data, CRFs, and applicable items will be filed according to study visit. This information includes but is not limited to:
 - a. Medication logs
 - b. Adverse events
 - c. Lab reports
 - d. Reportable events
 - e. Study specific notes
 - f. EPIC print outs

*Note: Many sponsors do not have paper CRFs but rely on a paperless Electronic Data Capture (EDC). The same rules apply to EDC records as do CRFs.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Invoicing

21. Purpose

The purpose of this SOP is to act as a guide for carrying out invoicing and related duties for the department.

22. Scope

This SOP applies to anyone in the Department of Emergency Medicine (DEM) who is responsible directly for invoicing, have duties relating to it, or have oversight of it.

23. Prerequisites

Velos and PeopleSoft training

24. Responsibilities

Principal Investigator:

Clinical Research Managers:

Grants and Contracts Specialist:

Research Study Coordinators:

25. Procedures

5.1 Steps for paying an invoice:

1. Dr. Idris likes us to generate the invoice in accord with the subcontract and # of completed cases confirmed by the Sponsor (sample attached)
 - a. List each case#
 - b. They can't be paid for anything that is not on the subcontract
2. Obtain Dr. Idris' signature on invoice to confirm that is what we owe for that Q
3. Send to our contact at the sub and request PI signature to confirm that is all we owe them for that Q
4. Upon return from sub, forward to subawards@utsw.edu with instructions to pay the invoice from SL# 49C0093701 (cc SPAoutreach@utsw.edu with instructions not to close the ticket until the payment has been confirmed)

Payment can't be made if the following holds true:

- There is a negative balance in any budget category within the subledger
 - Encumbrance of salaries – Ginger Tran
 - Rebudget the categories. Move more funds into M&O or subk – Billy Pritchett
- The subcontract has not been fully executed for that time frame on the invoice – Jose Granados

5.2 How to check the balances of a sub ledger:

- 1) Log into Peoplesoft via explorer only
- 2) Click link for Peoplesoft Financials
- 3) Click link for UT Southwestern Custom
- 4) Click link for PI All Funds Report
- 5) Go into Report ID box and remove the letters RPT at the end, hit enter on keyboard
- 6) Go down to search results and click link for DKKPIFND
- 7) Click the tab for Query Prompts

- 8) Enter Dr. Idris' UTSW employee ID # in the box for Prompt Value on all 3 pages = 58880
- 9) Click save
- 10) Click link for nVision Report Request
- 11) Click run report
- 12) Click drop down box for Type and select email
- 13) Click ok
- 14) Wait for report to be emailed to you

5.3 How to find an award ID in peoplesoft

- 1) Go to PS Financials
- 2) Grant
- 3) Grants Portal
- 4) Project Information
- 5) Project Detail
- 6) Type the project ID (the middle 6 digits of the SL#) into the Project field in the Grants Portal pages
- 7) Put the 2 leading zeros in front of the 6 digit project #.
- 8) Hit search

5.4 How to get a Budget overview

- 1) Budget overview
- 2) Add a new value
- 3) Name it
- 4) Click add
- 5) "GM_CH" in ledger GRP box
- 6) click glass
- 7) click link
- 8) take out % and but in SL# twice
- 9) save

5.5 How to get a list of checks received for a study

1. Sign into PS
2. Go to PS Financials
 - a. Grants
 - b. Grants Portal
 - c. Transaction Inquiries
 - d. Invoice and Payment Inquiry
3. Enter 20100 Office of Post Award for the Business unit
4. Enter the Award ID (starts with OPA or SPA)*
5. Date selection "as of date"
6. Choose today's date on the calendar
7. The name of the study should pop up next to the award # you entered
8. Hit search
9. Look in box for Payments received
10. Export to excel by clicking on the blue grid above with the red arrow in the top left corner

***How to find the Award ID:**

- 1) PeopleSoft Financial
- 2) UT Southwestern Custom
- 3) Oas Help
- 4) Click on the second tab "PeopleSoft to OAS"
- 5) Enter SL# and hit GO

In the box labeled "OAS and PeopleSoft Values" click on the second tab "Grants and Projects"

5.6 How to pay Subawards on Dr. Idris' studies:

1. A check is received by the sponsor
2. Dr. Idris prepares a spreadsheet of how much each sub is owed per quarter
3. Prepare an invoice for each sub with cases confirmed by study coordinator and listed on invoice
4. Send to Dr. Idris for his signature
5. Send to study coordinator to sent to sub for site PI signature
6. Upon return of signed invoice, check balance in SL, clear out negative balances as needed (Billy Prichett)
7. Send invoice to subawards@utsw.edu, cc Dr. Idris and study coordinator

5.7 How to query Actuals on Parkland Systems:

- Explorer browser must be used
- Log on to PeopleSoft
- Go to UT Custom
- GL Summary Reports

Journals Tab (last tab)

Enter SL#

Hit Go

Hit grid to export to excel spreadsheet

SL Summary Tab (1st tab)

Hit the blue link on the right for Budget Overview

Hit search

- 1) Enter GM_CH as Ledger Group hit microscope search button next to it (if SL starts with #5)
Delete % sign and enter SL # twice
- 2) Hit search at top
- 3) Hit grid to export to excel

Or

- 1) Enter KK_DEPT (if SL starts with #2) and hit microscope search button next to it
- 2) Delete % sign and enter SL # twice
- 3) Hit search at top
- 4) Hit grid to export to excel

5.8 How to run an encumbrance report:

- 1) PS
- 2) HCM
- 3) UT Department Reports
- 4) Encumbrance detail report
- 5) Hit search
- 6) Click a link
- 7) Put in Project #
- 8) Click run
- 9) Ok
- 10) Process monitor
- 11) Hit refresh until run status changes from queued to processing then success
- 12) Click link go back to encumbrance detail report
- 13) Report management
- 14) Admin tab
- 15) Change status to posted and Hit refresh

5.9 Steps for paying an Invoice on TXA:

1. Dr. Idris likes us to generate the invoice in accord with the subcontract and # of completed cases confirmed by the Sponsor (sample attached)
 - a. List each case#
 - b. They can't be paid for anything that is not on the subcontract
2. Obtain Dr. Idris' signature on invoice to confirm that is what we owe for that Q
3. Send to our contact at the sub and request PI signature to confirm that is all we owe them for that Q
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- 6) Go down to search results and click link for DKKPIFND
- 7) Click the tab for Query Prompts
- 8) Enter Dr. Idris' UTSW employee ID # in the box for Prompt Value on all 3 pages = 58880
- 9) Click save
- 10) Click link for nVision Report Request
- 11) Click run report
- 12) Click drop down box for Type and select email
- 13) Click ok
- 14) Wait for report to be emailed to you

6. Attachments:

Attached is a template for an invoice checklist and an example of a filled-out checklist.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

HIPAAA privacy safeguards

26. Purpose

The purpose of the SOP is to provide tips on how to safeguard Protected Health Information (PHI)

27. Scope

This SOP is for all research personnel involved in DEM related projects.

28. Prerequisites

Good Clinical Practice Training, Human Subject Protections Training, and HIPAA Research Training

29. Responsibilities

It is the responsibility of all DEM personnel to actively take steps and demonstrate practices to protect PHI of research subjects.

30. Procedures Adapted from a privacy Tip Sheet created by the office of Compliance at UTSW

- Q. Know and understand patient HIPAA privacy rights. Patients have the right to i) access and receive copies of records (including electronic copies), ii) request corrections to the record, iii) receive and acknowledge Notice of Privacy Practices, iv) request confidential communication from staff, v) request restrictions to the record, vi) request a list of record releases, and vii) receive notification following a breach of unsecured health information.
- R. Protected Health Information (PHI) is identifiable health information in any format. You are responsible to Protect PHI
- S. Use Caution regarding conversations involving PHI while on the phone or in a reception or waiting area that might be overheard by unauthorized persons. Don't leave messages containing PHI on patient's answering machines.
- T. Do not access the medical record of friends, family, or co-workers unless access is job-related. Access is based on your job responsibilities and role. Do not access your own medical record. Only use MyChart to access your record.
- U. Use and disclose only the minimum amount of PHI necessary to do your job.
- V. Ask if your patients will allow you to discuss their PHI with family or friends who accompany them to the clinic or hospital. Get their permission first.
- W. Limit patient information on whiteboards, X-ray boxes, or computer screens in areas that may be visible to the public.
- X. Do not post any PHI on social media sites such as Facebook, Twitter, and blogs
- Y. Make sure that your computer passwords are not accessible, and you log off the computer when not in use. Do not share your log-in ID or password with anyone!
- Z. File away all papers promptly, lock up PHI, and lock all doors before you leave an area at night.
- AA. Compare and verify any PHI before releasing it to patients or others.
- BB. In most cases, obtain a patient's written authorization before you disclose PHI outside of UT Southwestern Medical Center unless there is an established treatment relationship.
- CC. Always dispose of PHI in shredders or shred-it-boxes.
- DD. Know how to access the HIPAA Privacy policies, procedures, and associated forms. They are located on the Intranet on the Office of Compliance page

EE. Know who to contact if you suspect or know of a violation, contact the Office of Compliance.
Compliance Hotline 1-877-507-7139 utsouthwestern.net/hotline

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Clinical Research Lab Management

31. Purpose

To act as a guide to ensure that all members of the clinical research division team are aware of, observe, and practice safe and efficient lab practices.

32. Scope

Any staff of the Department of Emergency Medicine who utilizes the clinical research lab F2.100.

33. Prerequisites

None

34. Responsibilities

A copy of this document should be available for reference in the clinical research lab.

35. Procedures

A. Freezer Monitoring

- If the -80°F freezer varies by plus or minus 10°F, the Central Data Acquisition Services (CDAS) will notify the Clinical Research Manager.

- The Clinical Research Manager or delegate will check on the freezer and move all stored samples to the back-up freezer in G8.212. [Research staff should check monthly to verify that they can still access the G8 lab with their badges. If not, contact the current Lab Manager in the Department of Surgery.]
- Monthly temperature logs are sent to Clinical Research Manager via email from Facilities Management. They are to be:
 - Saved
 - Printed out and placed in study binders for each study that utilized the - 80°F freezer.
- In case of a power outage: As soon as power loss is sensed, the electrical load will be immediately transferred to the backup generators (tested monthly for at least 30 minutes) which will begin to supply power to the freezers instantly.
- In the case of an emergency: contact the physical plant CDAS at 214-648-3375.

B. Hazardous Waste Management Program

Hazardous materials include explosives, flammable and combustible substances, poisons, and radioactive materials.

These materials can cause death, serious injury, long-lasting health effects, and property damage.

Know where the nearest safety shower is located: _____

Know where the nearest eyewash fountain is located: in the hallway directly across from Lab F2.100.

1. How to Handle a Hazardous Materials Release/Spill:

Minor chemical spill inside a building:

- Isolate and secure the spill area.
- Warn others in the immediate area.
- Wear appropriate personal protective equipment (goggles or face shield, gloves and lab coat).
- Use appropriate kit to neutralize and absorb inorganic acids and bases. For other chemical, use appropriate kit or absorb spill with vermiculite, dry sand or paper towels. Collect residue, place in container, label container and call

Environmental Health & Safety (214) 648-2250.

- Clean spill area with detergent and water.

Major chemical spill inside a building:

- Immediately call University Campus Police 214-648-8311
- Alert people in the surrounding area to evacuate
- Attend to injured or contaminated persons and remove them from exposure. In case of personal contamination, remove affected clothing and flush contaminated skin with water for at least 15 minutes. Seek medical attention immediately.
- Close doors to affected areas as you leave
- Have person with knowledge of incident and laboratory assist emergency personnel to proper location upon arrival.

Outside a building:

- Isolate and secure the spill area.
- Warn others in the immediate area.
- Call 911 and give the location and type of material spilled, if assistance is needed.
- Do not wash spilled material into a storm drain.
- Meet with and assist emergency response personnel.

If someone is injured:

- Assist with emergency eyewash/shower, as needed.
 - [eye wash station must be flushed for 30 minutes once a month]
- Provide first aid for all serious injuries.
- Call 911 and give the location and type of material involved.
- Remove and bag contaminated clothing if you can do this without harming the victim.
 - Obtain a Material Safety Data Sheet (MSDS) for the material involved. An MSDS, developed by a chemical manufacturer or distributor, provides information about the contents, characteristics, physical hazards, and health hazards associated with the chemical.

How to Handle a Biological Spill:

Major Spill:

Qualified as any spill that is a) Large scale spills outside of primary containment

(e.g. Biosafety Cabinet) b) Spills/Leaks in high speed centrifuges, incubators, pressurized equipment, and/or c) Any high impact spill or aerosol generation involving human pathogens.

- 1) Assess spill area including: affected surfacing, equipment and PPE or exposed areas of your body, as well as other persons in the immediate area.
- 2) Alert people in the immediate area of spill as well as EH&S (214) 648-2250. Cordon off area to prevent entry.
- 3) Remove any Contaminated PPE and re-don fresh PPE prior to initiating any cleanup procedures.
- 4) Leave area for 30 minutes to allow aerosols to settle.
- 5) Absorb (Do not wipe) any casual moisture before application of 10% bleach solution to spill area as well as the absorbent material. (solution should be in contact with spill for at least 15 minutes).
- 6) Decontaminate all equipment with 10% bleach solution or appropriate disinfectant as described by the manufacturer.
- 7) Using Tongs or nitrile gloves remove the absorbent materials and place in a biological waste box or autoclave bags.
- 8) Reapply bleach solution or disinfectant to area, absorb and discard into provided waste bags, boxes, or containers.
- 9) Request disposal through EH&S or sterilize via autoclave.
- 10) Report the incident to your supervisor and EH&S
- 11) Contact Occupation Health to receive a medical consultation regarding potential exposure.

Minor Spill

Qualified as small scale spills (<10mls) or spills that are rapidly absorbed by protective linings or diaper paper.

- 1) Assess spill area including: affected surfacing, equipment, and PPE or exposed areas of your body, as well as others in the immediate area.
- 2) Alert people in the immediate area of spill.
- 3) Cover the spill with absorbent paper. Cordon off to prevent entry into affected area.
- 4) Absorb (Do not wipe) any casual moisture before application of 10% bleach solution to spill area as well as the absorbent material. (solution should be in contact with spill for at least 15 minutes).
- 5) Decontaminate all equipment with 10% bleach solution or appropriate disinfectant as described by the manufacturer.
- 6) Wearing Nitrile gloves, remove the absorbent paper and place in an autoclave bag. Autoclave all spill generated waste.
- 7) Clean spill area with detergent and water.

C. Medical Waste Pickup

The following site is attended to by UTSW's Office of Safety and Business Continuity and can be used to request pickup of sharps, bio-waste, chemical waste, pharmaceutical waste, etc:

- <https://www.utsouthwestern.net/intranet/administration/safety/safety-programs/requests/>

-Please note that you do not need to sign in, you must simply click the link to request pickup then enter the number of boxes needing collection and how many boxes you will need them to supply.

-Pickup will occur 48-72 hours after the request is received

Carlos Vaccaro 2146458349

Office of Safety and Business Continuity Main office 214-648-2250

Environmental Health and Safety 214-648-2250

D. Fire Safety

Help prevent fires!

1. Check that all heat or flame producing equipment /appliances are turned "off" before you leave.
2. Keep work areas clean.
3. Do not use flammable liquids near sources of ignition.
4. Store all flammable liquids in approved flammable storage cabinets.
5. Do not overload electrical outlets.
6. If equipment trips a breaker or blows a fuse, report it to FIRE SAFETY at x82250

Never Ignore a Fire Alarm! If the fire alarm is going off:

1. Evacuate the building using the nearest exit stairwell (follow the "EXIT" signs). DO NOT USE ELEVATORS.
2. Close doors behind you as you leave (to help contain the fire.)
3. Do NOT re-enter the building unless cleared by University Police or Fire Safety Staff.

In the Event of a Fire

1. Alert others in the immediate area.
2. Call 911 and activate the building fire alarm system (pull station).
3. Extinguish the fire or evacuate the building. Any attempt to extinguish a fire should be made by trained personnel only, otherwise, evacuate the building.

Always report a fire, even a small one, to fire safety at x82250

Never return a used fire extinguisher to its original location – call fire safety at x82250 For a Replacement.

E. Blood / Bodily Fluid Exposure

1. Wash hands and any other affected skin area with soap and water. Flush eyes and mucus membranes with water as soon as feasible for 15 minutes.
2. Call the Blood-borne pathogen exposure Pager at 214-588-6263.
3. Contact your supervisor to report exposure.
4. Alert EH&S (214) 648-2250 and Occupational Health Department (214 645-5300 to report exposure.
5. Go immediately to the Occupational Health Department.

Staff will:

- i. Arrange for completion of paperwork including first report of injury and incident report.
- ii. Draw appropriate labs.
- iii. Conduct risk assessment, including nature and degree of exposure.
- iv. Implement plan of care and follow up.

Note: Medical Students receive initial care through Student Health Services located 8th floor Aston (58690)

F. Sharps Management

Special note needs to be made concerning the management of sharps. Materials in this waste stream pose the greatest risk of injury and infection to personnel. It is of the utmost importance that materials that can cause lacerations or puncture wounds be appropriately managed.

All needles, scalpel blades, razor blades, Pasteur pipettes, broken glass, or glass slides contaminated with infectious material need to be discarded promptly into rigid sharps containers. Approved sharps containers are rigid plastic, labeled with the biohazard symbol, and capable of being sealed closed. Sharps must never be discarded into plastic bags or thin walled containers or discarded into regular trash or waste.

When sharp containers are $\frac{3}{4}$ filled they must be sealed and a pick-up request must be submitted through the EH&S website. These containers will be packed into medical waste boxes for incineration. Do not empty filled sharps containers into medical waste boxes. The filled containers must be disposed of intact.

G. General Lab safety and compliance:

The following is a reference guide produced and maintained by the Office of Safety and Business Continuity and should be used by and staff member who uses the lab to ensure that proper protocols are being observed and as a reference for and questions or concerns. If there is any confusion or questions they should be directed to the Office of Safety and Business Continuity at 214-648-2250. Please note that some sections have been omitted because they are not applicable considering the department's

current lab and it's uses of it.

Laboratory Safety Survey Reference Guide

Laboratory safety surveys are conducted on a routine basis by The Office of Safety and Business Continuity (OSBC) in all of the biomedical research and clinical laboratories at UT Southwestern. The focus of the surveys is to ensure that general safety, fire safety, chemical safety, biological safety, and physical safety practices are followed. The following reference guide outlines mandatory institutional safety and health standards as well as basic recommendations covering good laboratory practices. The following descriptions are intended to assist employers in providing a safe workplace for employees, students, and visitors. In order to keep the contents of this guide up-to-date with institutional policy, current regulations, and best practices, OSBC may periodically revise this document. If you have any questions or concerns please contact The Office of Safety and Business Continuity at 214-648-2250.

I. General Safety

Housekeeping

Maintaining a clean and orderly workplace reduces the risk for work-related accidents (e.g. slips, trips, falls, etc.), injuries (e.g. cuts, needlesticks), and exposures (e.g. surface and equipment contamination). Additionally, organization and routine cleaning practices reduce the potential for sample, culture, and stock contamination.

Food or Drink in the Laboratory

University policy prohibits storage and consumption of food and drink within laboratories.

Safety Sign

According to NFPA 400.6.1 8.1.3, posting of appropriate safety signs near the entry doors to our campus laboratories ensures both UT Southwestern personnel and emergency responders are aware of the hazardous materials stored and utilized in these areas. These safety signs shall not be obscured, shall be legible, and shall not be removed. **The Office of Safety and Business Continuity will place and update these signs as needed.**

Safety Showers/Eye Washes Clearance

In the event of an emergency, functional and certified safety showers and eye washes must be readily available to all laboratory personnel. These may be located directly in the laboratory or within the hallway corridor. According to the ANSI Standard and the Americans with Disability Act (ADA), safety showers/eye washes must have sufficient clearance to allow immediate access and use at all times.

Fabric Chairs in Laboratory

According to the UT Southwestern Biosafety Manual and the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, laboratories are designed to be easily cleaned and decontaminated, including chairs. Chairs used in laboratory areas must be made of non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

Fire Sprinklered Rooms - 18" Ceiling Clearance

No object may be stored within 18 inches of the ceiling, including storage along facility perimeter walls. This 18-inch clearance ensures compliance with NFPA 13.8.5.5.2.1.

Non-Fire Sprinklered Rooms – 24” Ceiling Clearance: No object may be stored within 24 inches of the ceiling, including storage along facility perimeter walls. This 24-inch clearance ensures compliance with NFPA 1.10.18.3.1.

Appropriate Personal Protective Equipment (PPE) Available

According to Texas Health and Safety Code Title 6 Subtitle D Chapter 502.0017(b) and the UT Southwestern Biosafety and Chemical Safety Manuals, principal investigators and department supervisors are required to provide employees and students with appropriate PPE. The minimal PPE required when working in research laboratories: gloves, lab coats, and eye protection.

Laboratory Personnel Wearing Personal Protective Equipment (PPE)

According to the UT Southwestern Biosafety and Chemical Safety Manuals, laboratory personnel must wear, at a minimum, a laboratory coat, gloves, and eye protection when engaged in any laboratory research activities (e.g. lab bench, fume hood, tissue culture hood, microscope station, etc.). Additional PPE (e.g. respirators, cryo-gloves, etc.) may be required based on the workplace, the hazard, and/or how the hazard is manipulated (e.g. aerosol production, etc.).

Personnel Attire Not Appropriate for Laboratory Operations

According to the UT Southwestern Biosafety and Chemical Safety Manuals, laboratory personnel must wear clothing appropriate for the workplace. Personnel must ensure pants or skirts/dresses cover the legs down to the ankles and shoes cover the complete foot up to the ankle.

Laboratory Personnel Wearing UT Badges

University Policy (SEC-153) indicates that the UT Southwestern identification badge provided by the institution must be worn in a readily visible location at all times while on campus.

Compressed Gas Cylinders

According to NFPA 55 regulations, all gas cylinders must be secured and also capped when not in use.

Equipment to Promote Proper Laboratory Hygiene Available

According to the UT Southwestern Biosafety Manual, the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, and the Bloodborne Pathogen 29 CFR 1910.1030, in BSL-1 and BSL-2 laboratories where sinks are present, a sink must be identified for hand washing. Personnel must have access to liquid handwashing soap to facilitate proper handwashing following the removal of gloves and prior to leaving the lab. Hand sanitizer must be available in BSL-2 laboratories that do not have sinks.

Plumbing Fixtures

Leaking faucets and drain lines can create an opportune environment for bacteria and mold to grow, increasing the risk for unwarranted exposures. Additionally, the presence of water can create a slip/trip/fall hazard. Please contact Physical Plant to evaluate any potential leaking pipes or drains.

Adequate Lighting

Poor lighting can create a hazardous working environment by limiting what personnel are able to see; therefore, it is important for all light fixtures to be working properly. Please contact Physical Plant to replace or repair nonfunctional light fixtures.

Egress Pathways: According to the NFPA and UT Southwestern Fire and Life Safety Manual, a minimum of three feet (36 in) must be maintained in walkways for proper egress during emergencies. All items must be kept to a minimum within laboratory bench bays, hallways, and walkways.

Electrical Panels

According to OSHA and NFPA standards, electrical panels cannot be blocked. Please remove the obstruction.

Appropriate Use of Power Strips (relocatable power taps)

The inappropriate use, overloading, and daisy-chaining of power strips/surge protectors can cause electrical fires. According to the National Electric Code and OSHA, power strips cannot be used as a substitute for fixed wiring structures (e.g., the use of a power strip as an extension cord is not allowed). Additionally, power strips and extension cords cannot run under doorways, through ceiling tiles, or along walkways.

Emergency Shutoff Devices

According to the UT Southwestern Chemical Safety Manual, emergency shutoff valves must be visible, readily accessible, and capable of being reached quickly for operation without removing obstacles.

UV Light Safety Sign

Ceiling-mounted UV light systems used to decontaminate laboratory surfaces pose a significant exposure risk to personnel who may enter the room when these systems are active. To inform personnel that a location has a ceiling-mounted UV light system and to warn personnel to not enter the room when UV lights are active, safety signage must be posted. **The Office of Safety and Business Continuity will place and update these signs as needed.**

II. Chemical Safety

Chematix Chemical Inventory System

According to university policy EHS/SBC-202, all laboratories are required to maintain a real-time inventory of stored hazardous chemicals. The Office of Safety and Business Continuity operates an online chemical inventory system called Chematix and can assist laboratories with the implementation of their hazardous chemical inventories within this system. Please contact the Chemical Safety Program by submitting a request at the following link:

<http://utsouthwestern.net/intranet/administration/safety/safety-programs/chemical/chematix.html>

Chemicals Properly Labeled

According to the Texas Health and Safety Code Title 6 Subtitle D Chapter 502 Section 502.007, labels on stock containers of hazardous chemicals must not be removed or defaced and must conform to the OSHA standard. Secondary containers must be labeled with at least the identity appearing on the Safety Data Sheet (SDS) and the appropriate hazard warnings.

Old Peroxide-Forming Chemicals

According to the UT Southwestern Chemical Safety Manual, many chemicals form potentially explosive peroxides upon storage. It is best-practice to date these chemicals when they are first received and when opened. Please contact the Chemical Safety Program at ChemicalSafety@UTSouthwestern.edu for assistance.

Flammables Stored in Flammable Cabinet

According to NFPA 45 rules, all flammable liquids not in immediate use must be stored in a flammable cabinet that meets the construction design defined in NFPA 30 (2000).

Proper Segregation of Hazardous Chemicals

According to NFPA regulations, all hazardous chemicals must be stored according to their hazard classification. Please segregate hazardous chemicals accordingly. For more information, please refer to the UT Southwestern Chemical Safety Manual.

- **Oxidizers:** Oxidizers must be stored separately from flammable liquids and reducing agents, and cannot be stored on wooden shelves. Oxidizers, with the exceptions of nitric and perchloric acids, also cannot be stored with corrosives. Please store oxidizers separately from incompatible chemical classes and in a proper cabinet (metal, plastic, or resin).

- **Corrosives:** Corrosives must be stored separately from flammable liquids and oxidizers. Additionally, acids and bases must be physically segregated from each other (in separate storage bins) if they are kept in the same cabinet. Please store corrosives separately from incompatible chemical classes and ensure acids and bases are physically separated.

- **Nitric and Perchloric Acid:** Nitric and perchloric acids are oxidizers which, like other oxidizers, cannot be stored with flammable liquids or reducing agents and cannot be stored on wooden shelves; however, they can be stored alongside standard corrosives unlike other oxidizers. Nitric and perchloric acid must be stored within plastic secondary containers to prevent further incidents in case of a spill or leak. Please store nitric and perchloric acid separately from incompatible chemical classes, in a proper cabinet (metal, plastic, or resin), and within secondary containment.

Hazardous Waste Containment

According to the UT Southwestern Chemical safety Manual, all waste containers storing hazardous waste must be stored in secondary containment. Secondary containment must have sufficient holding capacity to contain the entire contents of the largest waste container.

Reuse of Chemical Containers for Hazardous Waste

Empty chemical containers can be reused to collect hazardous waste if the containers are compliant with EPA regulations. Hazardous waste chemicals collected must be compatible with the container itself and with any remaining residuals of the original product. Laboratory personnel must deface the original product label and mark the container with the words "Hazardous Waste" plus the container contents.

Hazardous Waste Containers Capped

According to EPA regulations, all containers containing hazardous waste must be capped at all times except when hazardous waste is being added to or removed from the containers.

Chemical Spill Kit

According to the UT Southwestern Chemical Safety Manual, all contiguous laboratory areas that utilize hazardous chemical materials must have a chemical spill kit. The spill kit contents must include materials capable of absorbing, neutralizing, and inactivating hazardous materials in the event of a spill. The location of the spill kit must be labeled and unobstructed.

Chemical Fume Hood Free of Excessive Storage

According to the UT Southwestern Chemical Safety Manual, storing excessive amounts of chemicals, waste included, or equipment inside the fume hood may restrict the airflow required for proper function.

Chemical Fume Hood Annual Verification

The Office of Safety and Business Continuity verifies fume hoods on an annual basis. If a fume hood fails verification a warning sign explaining why the fume hood failed verification will be placed on the fume hood sash. **The Office of Safety and Business Continuity will contact Physical Plant to re-evaluate the unit airflow, and will re-test the unit.**

III. Biological Safety

Biosafety Cabinet (BSC) Certification

According to the UT Southwestern Biosafety Manual and OSHA 29 CFR 1910.01030(e)(2)(iii)(B), biosafety cabinets must be certified annually according to the NSF 49 Standard. Biosafety cabinets must also be certified when installed, moved, or repaired.

Biosafety Cabinet (BSC) Work Surfaces

According to the UT Southwestern Biosafety Manual and the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, to reduce the potential for spills and exposures, all BSC work surfaces and sub surfaces must be routinely decontaminated, cleaned, and free of excessive storage.

Biosafety Level 2 (BSL-2) Laboratory Doors Remain Closed (Tissue Culture Room)

According to the UT Southwestern Biosafety Manual and the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, access to a BSL-2 laboratory must be restricted and the door must remain closed.

Biosafety Level 2 (BSL-2) Laboratory Door Sign (Tissue Culture Room)

According to the UT Southwestern Biosafety Manual and the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, a Biohazard Door Sign must be posted on all entry doors to BSL-2 laboratories.

Medical Waste Properly Managed

According to the UT Southwestern Biosafety Manual, all medical waste (e.g., bulk unprocessed human and animal tissue) must be properly packaged and stored prior to collection. Please correct the following items:

- **Medical waste boxes/bags:** Laboratory personnel must use The Office of Safety and Business Continuity-provided medical waste boxes and bags to hold solid medical waste.

- **Filling medical waste boxes/bags:** When 75% full, medical waste bags must be tied shut by laboratory personnel, placed in the provided medical waste box, and the box must be properly closed prior to onsite storage.
- **Medical waste storage:** Laboratory personnel should promptly submit a medical waste pick-up request following the generation of a full medical waste box.
- **Medical waste storage in public hallways:** At no time should medical waste be stored in public hallways.

Autoclave Waste Properly Managed

According to the UT Southwestern Autoclave Use and Verification Manual, all autoclave waste must be properly packaged, stored, and treated prior to disposal. Please correct the following items:

- **Autoclave waste containers:** Autoclave waste containers selected to hold solid biological waste must be composed of autoclave-safe material and leak-proof.
- **Autoclave waste bags:** To ensure the proper treatment and disposition of autoclave waste, appropriate autoclave waste bags must be used. Bags used for autoclave waste must be marked for autoclave treatment and be orange or translucent. At no time can red bags be used for onsite autoclave waste treatment.
- **Filling autoclave waste bags:** When 75% full, autoclave waste bags must be sealed by laboratory personnel prior to autoclave treatment.
- **Autoclave waste bag storage:** When autoclaves are not immediately available, biological waste must be properly stored until an autoclave is available. Laboratory personnel must place sealed autoclave waste bags in autoclavable bins, store the waste in areas under their control, and ensure the waste is promptly treated when an autoclave becomes available.
- **Autoclave waste storage in public hallways:** At no time should autoclave waste be stored in public hallways.

Sharps Properly Managed

According to TCEQ and the UT Southwestern Biosafety Manual, sharps must be properly managed in all laboratory areas.

- **Metal Sharps:** This includes needles and blades. Place in a commercially purchased sharps container. These must be provided by each laboratory. Never attempt to retrieve items from a sharps container. Do not place sharps in plastic bags or other non-sharps containers.
- **Plastic Sharps:** This includes plastic disposable pipettes and pipette tips that have not been in contact with any biological material. Place in a sturdy cardboard box lined with a plastic bag. Once full, seal securely and label "TRASH".

Aspiration Flasks in Secondary Containment

According to the UT Southwestern Biosafety Manual, aspiration flasks stored on the floor must be in secondary containment. This secondary containment must have sufficient holding capacity to contain the entire contents of the flask.

Aspiration Flasks/Tubing Properly Managed

According to the UT Southwestern Biosafety Manual, aspiration flasks and associated tubing must be maintained to prevent the growth of mold and other biological contaminants.

Aspiration Flasks Properly Labeled

Aspiration flasks used to collect liquids from infectious cultures must be properly labeled with the word “waste” and a biohazard sticker. **The Office of Safety and Business Continuity will place these labels as needed.**

House Vacuum System Protection

According to the UT Southwestern Biosafety and Chemical Safety Manuals, a Polytetrafluoroethylene (PTFE) 0.45µm filter, or equivalent, must be attached in line with the vacuum spigot to prevent house line contamination. This includes all aspiration flasks. VacuGuards containing PTFE filters can be purchased through UT Southwestern General Stores, item numbers 5801 or 5802.

Centrifuges Properly Maintained

According to the UT Southwestern Biosafety Manual, clean centrifuges reduce the risk of exposure. Spills or leaks that have previously occurred within a centrifuge can later become aerosolized leading to exposure.

Incubators Properly Maintained

According to the UT Southwestern Biosafety Manual, clean incubators reduce the risk of exposure. Spills or leaks that have previously occurred within an incubator can lead to uncontrolled growth of mold, bacteria, and fungi.

Proper Surface and Equipment Disinfectants Available: According to the UT Southwestern Biosafety Manual and the Biosafety in Microbiological and Biomedical Laboratories 5th Edition, the proper use of disinfectants will reduce biological contamination on laboratory surfaces, equipment, and reusable supplies. By reducing this contamination, the risk of exposure is reduced. Common laboratory disinfectants include alcohols, bleach, and quaternary ammonium compounds.

Biological Spill Materials: According to the UT Southwestern Biosafety Manual, biological spill materials must be present to all contiguous laboratory areas that utilize biological materials. The spill material contents must include materials capable of absorbing, neutralizing, and inactivating biological materials in the event of a spill.

Active Water Baths Properly Maintained

According to the UT Southwestern Biosafety Manual, water baths in use must have a sufficient amount of water to prevent the basin from drying out.

Inactive Water Baths Properly Maintained

According to the UT Southwestern Biosafety Manual, water baths with dry basins must be unplugged.

Cryostat and Microtome Safety Sign

The use of cryostats and microtomes in the laboratory presents a laceration hazard which can result in an exposure to bloodborne pathogens or other infectious materials. The Office of Safety and Business Continuity (SBC) provides and posts safety signage near these instruments to remind laboratory staff of this potential injury and exposure risk. **The Office of Safety and Business Continuity will place and update these signs as needed.**

Hazardous Chemicals Stored in an Environmental Room

According to the UT Southwestern Chemical Safety Manual, hazardous chemicals cannot be stored in an environmental room (i.e., warm/cold rooms). Hazardous chemicals may be utilized in small quantities for experimental procedures in environmental rooms. Please contact the Chemical Safety Program at ChemicalSafety@UTSouthwestern.edu for assistance.

Mold Present in Environmental Rooms

According to the UT Southwestern Biosafety Manual, preventing the unintentional growth of mold in environmental rooms (i.e., cold/warm rooms) is essential to protecting research personnel, equipment, and supplies. When mold infestation is severe, room decontamination should be considered. Please contact the BioSafety Program at BioSafety@UTSouthwestern.edu for assistance (fees apply).

Shaking Incubator Flask Holders/Clamps Properly Maintained: Culture spills related to improperly seated or secured flasks can expose laboratory personnel to infectious materials, damage circulating shakers, and contaminate surfaces and warm rooms. Please inform staff members to properly secure flask clamps to the incubator's circulating stage and to utilize the appropriate clamps for each flask's size.

Recommendation for Proper Storage in Environmental Rooms (i.e. Cold/Warm Rooms)

Paper based products (e.g. cardboard) and porous materials (e.g. styrofoam) can harbor and facilitate the growth of mold. The storage of these materials in environmental rooms can lead to mold infestations which can contaminate experiments and expose personnel. The Office of Safety and Business Continuity recommends the removal of these materials from the identified environmental rooms.

- **Note:** Manufacturer-supplied cardboard boxes, designed for cold storage, can be stored in cold rooms and refrigerators. These boxes have special coatings that will delay the growth of mold.

Recommendations for Labeling Equipment with Biohazard Stickers: Labeling laboratory equipment utilized to cultivate, manipulate, and store infectious agents or materials ensures laboratory personnel are aware that this equipment may harbor these agents or materials.

- **Note:** Laboratory equipment identified for the above purpose was not labeled with biohazard stickers. The OSBC can provide you with additional stickers to label equipment identified for this purpose. Please contact the BioSafety Program at BioSafety@UTSouthwestern.edu for assistance.

Serum collection

From The Early Detection Research Network (EDRN)

For Collection of Serum

GENERAL REQUIREMENTS

- Gloves must be worn at all times when handling specimens. This includes during removal of the rubber stopper from the blood tubes, centrifugation, pipetting, disposal of contaminated tubes, and clean up of any spills. Tubes, needles, and pipets must be properly disposed of in biohazard containers, in accordance with institutional requirements.
- Universal precautions and OSHA (Occupational Safety and Health Administration) and institutional requirements (<http://www.osha.gov/SLTC/biologicalagents/index.html>) should be followed, including gloves, eye protection or working in a biosafety cabinet for blood processing.
- All equipment (storage, shipping, and centrifuge) must be labeled as biohazard.
- It is important to take steps to prevent hemolysis in these samples. A vacutainer is recommended. If a needle is used, a 21 gauge needle is recommended.

SERUM COLLECTION

Supplies

Red Top Vacutainer (NOT SST tubes) (for example, BD vacutainers catalog#366430)

Centrifuge with swinging bucket rotor

15 ml polypropylene conical tubes (for example, Corning 430052, Fisher cat #05-538-53D)

Sterile cryovials with writing surface (for example, Simport T311-2 or Fisher #05-669-57)

2ml, 5ml and 10ml pipettes (for example, Fisher cat #13-678-11C, 13-678-11D, 13-678-11E)

Disposable transfer pipettes (for example, Fisher cat #13-711-20)

Automatic pipet aid

Small ice bucket

Serum Separation Procedure

1. Filled red top blood collection tubes ("vacutainers") should sit upright after the blood is drawn at room temperature for a minimum of 30 to a maximum of 60 minutes to allow the clot to form.

Note: Use red top (serum) tubes (silicon-coated)—no additives and not SST (serum separator tubes). These tubes, without additives, allow the red blood cells to form a clot. The clot also includes white blood cells, platelets etc. After centrifuging, the clot is at the bottom of the tube, and the serum is on top of the clot). The red top tubes do not have to be full to be used.

2. Centrifuge the blood sample at the end of the clotting time (30-60 minutes) in a horizontal rotor (swing-out head) for 20 minutes at 1100-1300 g at room temperature. If the blood is not centrifuged immediately after the clotting time (30 to 60 minutes at room temperature), the tubes should be refrigerated (4°C) for no longer than 4 hours.

Warning: Excessive centrifuge speed (over 2000 g) may cause tube breakage and exposure to blood and possible injury. If needed, RCF for a centrifuge can

be calculated. For an on-line calculator tool, please refer to:

<http://www.changbioscience.com/cell/rcf.html>

3. Use pipette to transfer the serum (Recommendation: do not pour!). If more than one tube is drawn, pull the serum from both tubes into a 15 ml conical tube and mix. Pipette serum into the labeled cryovials, filling the vials in sequential order. Aliquot volume is recommended to be 100 µl or 250 µl. Close the caps on the vials tightly. This process should be completed within 1 hour of centrifugation.

Note: Be very careful not to pick up red blood cells when aliquoting. This can be done by keeping the pipet above the red blood cell layer and leaving a small amount of serum in the tube.

4. Check that all aliquot vial caps are secure and that all vials are labeled.

5. Place all aliquots upright in a specimen box or rack in an -80°C or colder freezer. All specimens should remain at -80°C or colder prior to shipping. The samples should not be thawed prior to shipping. (Serum will be shipped on dry ice. Refer to SOP for "Shipping" instructions.)

Data points

1. Is the serum hemolyzed? If yes, sample cannot be used.
2. Date and time of blood collection
3. Number and volume of aliquots prepared
4. Date and time into -80°C
5. Date and time of shipping
6. Any freeze-thaw that occurs with a sample for any reason
7. Any variations or deviations from the SOP, problems, or issues

Notes

- Sterile, disposable droppers, pipetman, pipet aid, eppendorf repeater are examples of ways to aliquot. Depends on size of aliquots, volume of plasma, and volume of aliquots.
 - Serum should not undergo freeze-thaw cycles, so choose aliquot volume carefully.
 - Freezers need to have a back up generator or other emergency system
- Options: Create emergency management plan, such as moving to a new freezer or adding dry ice in the event of a freezer failure.

Approved By:

Dr. Idris, Director of Research

Study Closure and Record Retention

36. Purpose

To notify the IRB of the closure of a study and how to retain study related records.

37. Scope

This SOP is for all research personnel involved in DEM related projects.

38. Prerequisites

Velos and eIRB training

39. Responsibilities

It is the responsibility of DEM personnel to close out completed studies and to retain their records appropriately under the UTSW Records Retention Policy

40. Procedure

A. Procedure for Study Closure

When a research project has been completed, a report must be submitted to the IRB to provide a final report of the project. The Notice of Study Closure should be completed and submitted via the eIRB system when all of the following apply:

- All subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing),
- All subject specimens, records, and data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained),
- No further contact with enrolled subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary),
- Analysis of subject identifiable data is no longer necessary (i.e., subjects' records will no longer be required or all data/specimens have been de-identified. This includes review of source documents by study sponsors, and
- If the study is industry-sponsored, the sponsor or sponsor's representative has agreed the study may be closed at this site.

Within 30 days of the study's ending, a notice of study closure must be created using the activity "Edit Notice of Study Closure," and submitted by the study PI using the activity "Submit Notice of Study Closure" in the main study workplace, eIRB. Before closing the study via eIRB, the investigator and research personnel should be sure that all paperwork for the study is in order and complete. This includes reporting all Adverse Events prior to

study closure.

Note: Studies that remains active only for long-term follow-up of subjects are considered active and must receive annual continuing review.

B. Records Retention

Please review the Records Retention Policy for UTSW

<http://www.utsouthwestern.net/intranet/administration/policy-library/handbook/chapter-08/fss-201-records-management-and-retention.html>

C. For More Information

Records Retention Website

<http://www.utsouthwestern.net/intranet/administration/materials-management/records-retention/>

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Specimen Collection and Processing

41. Purpose

To maintain the integrity of the biological samples, while ensuring the safety of the coordinator collecting and processing the specimens.

42. Scope

This SOP is for all research personnel involved in DEM related projects.

43. Prerequisites

International Air Transport Association IATA Hazardous/Dangerous Goods Training, and Universal Precautions training

44. Responsibilities

It is the responsibility of all DEM personnel to collect and handle all biological specimens according to Universal Precautions and process them according to IATA regulations.

45. Procedures

AA. Coordinators should identify the subject as the correct subject for which the sample is being collected.

BB. Using Universal Precautions, the specimen should be collected per the Sponsor's specifications (i.e. tube size, amount to be collected, tube type, etc.)

CC. The specimens should be processed and handled according to the Sponsor's specifications (i.e., placed on ice, frozen, spun down at a particular speed on a centrifuge, shipped ambient, etc.)

DD. All Coordinators must be IATA certified and are responsible for renewing this certification every two years.

- 5) Certificates proving training should be forwarded to the DEM administrative office.
- 6) The DEM administrative office will keep your training certificates on file and will notify you several months before your certification expires.
- 7) Upon completion of re-certification, your new certificate should be forwarded to the DEM office.
- 8) Coordinators should keep a copy of their certificates on file in their regulatory binder.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

EIRB New Study Submission

46. Purpose

To protect the rights, welfare, and safety of research subjects of at UTSW.

47. Scope

This SOP applies to all research personnel involved in DEM related projects.

48. Prerequisites

EIRB and Velos classroom training

49. Responsibilities

Every study must be approved by the UTSW IRB prior to implementing any study related activities. The IRB will send a final approval letter and approved Informed Consent/HIPAA authorization via the eIRB system.

50. Procedures

When completing the IRB application in eIRB, please refer to the instructions of the IRB website.

- A. Review the protocol. The eIRB application must be based on a “final” version of the protocol.
- B. Please refer to your eIRB and Velos training material on how to submit your application.
- C. Prepare the Informed Consent document. The sponsor should provide a template consent form in your start up package. The consent must be in the UTSW format. If portion is not optional, you will need to use the DNA consent form template. You can contact the IRB office for any questions regarding which consent to use.
- D. Prepare a separate HIPAA authorization. A template can be found @ <http://www.utsouthestern.edu/research/research-administration/irb/new-study-submission/index.html>
- E. Once you have put the Consent an HIPPA authorization in UTSW format, you must submit this to the Sponsor for their approval prior to submission to the IRB.
- F. If you have Sub-Investigators or Co-Investigators on the study, they must agree to participate in the study before the application can be submitted to the IRB. Instructions for this can be found in your eIRB/Velos training book.
- G. Once your application is completed, the PI will need to submit the application.
- H. Upon review of the application, the IRB will send out stipulation. All IRB stipulations

- I. must be addressed immediately.
- J. Any changes to the consent form or HIPAA authorization must be IFRST submitted back to the Sponsor for their approval before re-submitting to the IRB.
- K. A detailed memo outlining the changes you have made must be uploaded in Supporting Documents when you return the application to the IRB.
- L. A copy of the approval letter, stamped consent and HIPAA authorization must be sent to the sponsor after approval.
- M. In Velos, you will need to complete a Performance Site Review Form. This also includes if you are only consenting subjects at that site. A separate form will need to be completed for each site you are utilizing (PHHS,CMC, UTSW, etc.)

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Patient screening in EPIC

1. Purpose

The purpose of this SOP is to act as a guide for screening patients in EPIC.

2. Scope

This SOP applies to anyone in the Department of Emergency Medicine (DEM) who participates in screening patients for studies.

3. Prerequisites

- 1. EPIC training
- 2. Parkland credentialing, Clements credentialing
- 3. Study specific training

4. Responsibilities

Research Study Coordinators: Screening and enrolling patients is one of the responsibilities of research coordinators.

Data Specialists: Data specialists are sometimes also tasked with screening and enrolling patients.

5. Procedures

- N. This department often has multiple Research Study Coordinators and Data Specialists on payroll at once of varying tenure. If you are a newer hire, a more tenured coordinator or data specialist can be a great resource or in absence of that the Clinical Research Manager.
- O. Before you can begin screening for a study you must ensure that you have gone through the specific training for that study.
- P. Next, and connected to the prior step, you must know and understand the inclusion and exclusion criteria for your study. It may be helpful, especially if you are responsible for screening for multiple studies at one, to carry around notecards with the purpose, I/D criteria, and other relevant information for each study you are enrolling in. Some studies have extensive and/or highly specific I/E criteria which can be difficult to memorize.
- Q. The next thing you have to consider is where your patients are by asking yourself things like: Is the study only involve Parkland, Clements, or both? Are you looking for admitted patients or patients in the observation unit? L/M pod patients?
- R. You must consider how you are going to look for them and how you are going to find them. The most efficient way to pre-screen people through EPIC will vary from study to study. For some studies EPIC is not used initially for pre-screening. For example, there are studies that utilize pagers to notify us of lab findings that meet inclusion criteria, EPIC alerts, or protocols where physicians and/or RNs are used to identify eligible patients for us. It will be useful to organize or change your EPIC track board tabs based on what information you are looking for in order to consider patients for different studies.
- S. It is important to consider if enrollment or eligibility is time sensitive. If it is, this can be used to further optimize prescreening techniques. For example, if an inclusion criteria is that that to be eligible a patient must be discharged from the ED in 24 hours it would not be helpful to prescreen or screen a patient who has been in the department for 22 hours and has just had an additional round of labs and a CT ordered. Once you have gotten a better feel for how long it takes for various labs/radiology to result, dispositions, procedures, and other common ED events it will become easier to plan out and discern which patients have the greatest change of falling in the need time windows.
- T. The most efficient way to keep a patient log is through excel. This also ensures that it cannot be lost. Make sure that the study or sponsor does not require you to use a specific screening log. The screening log must be kept up to date daily and be kept on

- U. the O drive and/or in the source document binder.
- V. It is important to remember that not everything will be available right away, and mentally keeping track of patients you have pre-screened as well as patients in the log itself is necessary as you wait for RN/physician decisions, dispositions, laboratory results, medication orders, procedures, patient events, etc. that will determine if a patient is eligible for enrollment.
- W. Every time you open a chart (go into any physician or RN notes, including triage note) it must go into the screening log. Considering this, it is important to balance your pre-screening and screening efforts. Obviously, the more patients whose charts you open the more potentially eligible patients you will find. But, it is far more efficient to use pre-planned techniques and monitor the track boards to choose which patients to open a chart on. For example: It would be expedient to automatically open a chart on someone that has already been dx with mild CHF when all other labs and studies are negative for a study testing a home medication to treat CHF while it would be better to wait and see if a BNP is drawn if someone has only been triaged with “worsening SOB over a few days” as the CC but the provider has not seen them yet.
- X. Typical minimum data points for a screening log: Date, screening exclusion/inclusion met/not met, primary dx, primary chief complaint, MRN, gender, name, enrolled/not enrolled.
- Y. TEMRAP research associates can be used to help screen when possible by having them ask RN’s, providers, and patients questions. Other than the student leaders, they do not have access to EPIC and are not permitted to look at patients charts or EPIC.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Billing for Procedures and Orders Performed for a Research Study

6. Purpose

The purpose of this SOP is to describe the current procedure to place the correct order for a procedure or order mandated and paid for by a study. The procedure needs to be associated with the order so that it can be properly billed to the study, sponsor, or appropriate entity. An epic update has added question titled “Bill to Research Study” is now available in all procedure orders allowing a procedure to be properly linked with the study they are performed for.

7. Scope

This SOP is for all research personnel involved in DEM related projects.

8. Prerequisites

Sponsor Required Training, Good Clinical Practice, HIPAA Research, and Human Subject Protections Training, EPIC training

9. Responsibilities

It is the responsibility of all DEM personnel to follow this procedure to ensure that procedures separate from standard of care that are done for Research Studies are properly billed to that study.

10. Procedures

From Order entry or Meds & Orders section

1. Search for an order and open the order composer. In the search field for “Bill to Research Study”, type [Study ID] and press Enter.
2. Notice that the full study name appears in the field. If the study number does not exist, a study selection window will display.
The question response is not restricted in any way, so any study could be selected. Ensure that the correct study is selected before signing the order.
3. If you need to enter the Account Code, it can be typed into the comments field to the right of the study selection field.

From a Beacon Treatment Plan

Orders in Beacon Treatment Plans will also contain the “Bill to Research Study” question. If the order has multiple questions, the Bill to Research Study question will be at the bottom of the list.

11. Attachments

Please see attached Tip Sheet provided by the Office of Clinical Research Services for EPIC screenshots demonstrating the process above.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

Regulatory Files

12. Purpose

To maintain and house all study related documents in compliance with FDA and ICH guidelines. Additionally this procedure will help insure they are organized in a consistent manner.

13. Scope

This SOP applies to all research personnel involved in DEM related projects.

14. Prerequisites

Sponsor required training, Good Clinical Practice, HIPAA Research, and Human Subject Protection Training

15. Responsibilities

It is the responsibility of all DEM personnel to maintain and update regulatory files throughout the course of the study.

16. Procedure

- Z. Coordinators will keep an up-to-date Regulatory binder or database file (on O-drive) with all required regulatory documents. Oftentimes a sponsor will provide a table of contents or even a whole prepared binder to utilize. If this is not provided use the following as well as the attached table of contents example as a guide.

These include, but are not limited to:

1. 1572 forms (if an FDA study)*

2. PI and CO-I signed and dated CVs
3. CAP and CLIA certifications (if laboratory samples being done locally)
4. Delegation log
5. Latest investigator brochure (if a drug study)
6. Correspondence to and from the Sponsor (this includes e-mails, faxes, letters, documented phone calls, and notes to file)
7. Screening log
8. Enrollment log
9. Drug dispensation logs (if not using Investigational Drug Services [IDS])
10. Reportable Events and Adverse Events
11. Any documents required by the Sponsor.

AA. Records will be kept in reverse order with most recent version on the top

BB. At minimum, the binder should be updated once a month.

CC. The binder should be made available to the monitor at all monitor visits

DD. Once the binder has begun to accumulate patient information it must be stored utilizing the "double lock" strategy. I.E behind a locked or badge access door and in a locked cabinet.

*obtain the latest version at www.FDA.gov. Enter information per sponsor guidelines. The PI should sign and date. Original should be forwarded to sponsor and copy maintained in the binder. DO NOT throw away older versions. All versions need to be maintained during the study.

Approved By:

Dr. Idris, Director of Research

Shannon McNabb, Clinical Research Manager

Effective Date

DAILY JOURNAL

Week one:

Day 1, Tuesday 5/29/18:

-Today was both exciting and overwhelming. It was great getting to meet everyone but like most new jobs it was a lot to take in. I also sat in on the weekly department meeting at 11AM. During it Dr. Idris, the director of emergency medicine research, reviewed 17 of the department's studies, their status, and the steps being taken to advance them by the various members of the team. Holy and Mario also took me on a tour of parkland from 1-2PM. I also took the time today to email my committee members and set up a doodle for a potential time and date for the first meeting. Lastly, unfortunately, I Miguel and I are not credentialed yet so I cannot start doing any real work for them.

Day 2, Wednesday 5/30/18:

-Today was a little interesting off the bat because I got lost trying to get into the department from a different route, I can see why Fed-ex has apparently had issues before. Holy, Miguel, and I had lunch with Dr. Idris that was quite informative and enjoyable. I learned more about what was expected of me, current events in the field of medicine, and about possibly doing a project that involves creating a SOP resource binder for the department as there is not one. I also toured Clemmons around 3pm. I am still waiting to get credentialed.

Day 3, Thursday 5/31/18:

-Today I worked more on my applications in the morning. I also filled out a resource sheet for Holy. Around 1PM I attended the weekly meeting with the director, Dr. Pierce. During it we went over the status of all studies and I learned more about how the team operates and works together to ensure all the research projects are moving forward. During the meeting, a topic was discussed that I might be able to do a project on. We were discussing what would be the best way to educate residents and ED staff about the studies we are doing and help them keep them in mind so everyone can be on the same page. I could utilize several different strategies and use some metric to compare knowledge of the studies between different groups. The team also went over a stack of potential new hires for the two-open clinical research coordinator positions. This was a great opportunity for me to see what a research department (and specifically this one) are looking for in applicants to CRC positions. I am still awaiting credentialing.

Day 4, Friday 6/1/18:

-There was one more potential patient for the HF study and Holy let Miguel and I come watch the process of screening a patient and seeing if they have an interest participating prior to the longer official informed consent process. Unfortunately, he declined to be in the study within a minute of walking into the room. I left early to go to UNThsc to get a TB test. I am still awaiting credentialing

Week 2

Day 5, Monday 6/4/18:

-I got into the office around 930 after getting my TB test read in FW. I had a lot of free time today so I worked on and was able to submit my TMDSAS application. After that, I worked on my secondary applications. I also spent a good amount of time perusing sites on how to read chest XRAYs and abd CTs. I am still awaiting credentialing so I am able to start helping the team with ongoing studies.

Day 6, Tuesday 6/5/18:

-I mostly worked on my applications during the morning because I was the first one in the office and still have not been credentialed. I also just by chance met Dr. Ray Fowler, who is the EMS chief at UTSW. He states that there is a massive database of MI patients and that no one has extracted and done anything with CHF data from it. This is another potential project I could pursue. Next, I went to the weekly 11AM team meeting with Dr. Idris. Unfortunately, one of the studies, Energize, might have to close because window for enrollment is closing. I also offered to contact students for one of Dr. Idris's studies to avoid the ethical issue of asking students who are working for him to be a part of his study. The study is an exempt study because it is an anonymous non-human study looking at strictly data. Specifically, waveforms on defibrillator with ventilation. Dr. Idris also spoke a lot about the AHA funding a project to create a national database that collects data form EMS and hospitals that can achieve a 85-90% match rate.

Day 7, Wednesday 6/6/18:

-I finally got my ID badge today and a UTSW email today. Unfortunately, the appropriate access has still not been connected to the badge and is pending a long with my logins for UTSW and parkland hospital systems among other credentialing. There was a full department meeting at 12:30 that I went to. Miguel and I also went to Parkland with Mario for a few hours. He worked on screening patients and during the process taught us about the screening process and navigating EPIC. I am still awaiting credentialing.

Day 8, Thursday 6/7/18:

-I am still awaiting credentialing! I started to look through the Neuroscience translational research binder's sections involving funding to see what a section on obtaining funding would look like should I make one for the department. I also observed Holy go through the full process of consenting of a patient when one of the people she screened agreed to be in the study. I also again attending the weekly team meeting with Dr. Diedrich. At the end of the meeting she engaged Miguel and I on the progress of our projects and our settling into the department. She suggested one option for my project could be a prospective experiment on what is the best way to keep residents informed of studies is. Holy also obtained a copy of the list of grand rounds schedule for June. She discovered that the attendance for them are entirely open to anyone who works for UTSW and encouraged us to attend any that interest us if they do not interfere with any of our other duties or commitments to the department.

Day 9, Friday 6/8/18:

-I am unfortunately still awaiting credentialing. Again, there was not a lot for me to do today so I perused some research on emergency medicine and reviewed some old lectures from my

physiology class during MedSci. Again, I worked on my secondary applications some. Hopefully I am credentialed next week so I can start formal training and begin to work for the department as well.

Week 3:

Day 10, Monday 6/11/18:

-I Observed Holy screen and consent another patient for the Guided HF study in the morning. Shannon McNabb, the Clinical Research Manager for the department, has returned from being out of office and Miguel and I got to meet her. She is going to be our primary on site mentor/boss. Miguel and I spent most of the afternoon sorting through the piles of TEMRAP surveys and filing them. We then met with Shannon from 4-530 to discuss expectations as well as the progress of our practicum.

Day 11, Tuesday 6/12/18:

I took the Dart today from home and was quite proud that I was able to navigate my way from the Parkland parking garage to UTSW Emergency Medicine Department and only got lost once. In the morning Miguel and I finished filing the TEMRAP data and I read over the thesis of a UNThsc student who did their project on SOPs six years ago. Again, I attended the weekly 11AM meeting. Below are notes of the studies that are active or somewhere post or pre-active.

1. For MATH, too many are already on blood thinners or are anticoagulated also some have been admitted for other reasons. PI is working to increase visibility.
2. ORTHO Vitros IRB approved working with Parkland to obtain site approval but also waiting on amendment awaiting approval by the IRB.
3. STAGO TRUST (blood collection DDIMER ASSAY to exclude DVT and PE) Mario is going to revise ICF and then get sponsor's okay before submitting to our IRB Mario to submit protocol to our IRB as well- under review 6/5/18.
4. ENERGIZE (Phase 2 RCT for treatment of hyperK with zirconium cyclosilicate) awaiting order sets. Study will close in September or October.
5. ECHO (sub study with ECHOs) Completed sending ECHOS, awaiting payment.
6. ACCESS (post arrest immediate vs later cath) Start projected for end of June. Need to notify public via newspaper ad about the study. Link to opt out. Dr. Idris will ask IRB about possibility of social media post which would be free, question posed by Shannon. Also awaiting interventional cardiologist training date, research staff training will happen last.
7. HOBIT (SIREN) (HBO for TBI)
8. BOOST III (SIREN) ICP and brain p)2 based interventions for TBI) final protocol received.
- 9- AWARE II (Obs study of the relationship between the quality of brain resuscitation consciousness, neuro. IRB stipulations addressed and resubmitted to the IRB.
10. Adasuve (phase 4 drug study) (assess safety of the drug on patients with agitation associated with Schizophrenia or bipolar disorder) **Study is being withdrawn** but working on invoicing.

11. AURORA (obs study) (improve the understanding, prevention and treatment of posttraumatic neuropsychiatric sequelae) IN IRB review, PI is now DD.
12. ICECAP (SIREN) under review at NIH.
13. ADHF with systolic dysfunction drug study Enrollment through 12/18. Can't enroll yet due
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to pending protocol amendment, awaiting sponsors ICF prior to submission.
14. High Sensitivity Troponin Needs some direction Consent drafted for approval, waiting on contract to start submission.
15. Ventilation during continuous chest compression Submitted to sponsor UTSW approved May 2018.
16. Multicenter ventilation study (determine relationship of ventilation during CPR with outcome. Uploading data files, will analyze data.
17. Bio impedance and amplitude with tidal volume.
18. Ventilation study in the MICU relationship of bio impedance and amplitude with tidal volume. Submitted protocol to UTSW IRM as exempt, awaiting to hear back.
19. DFW cardiac arrest registry (streaming EMS and hospital data to match files) protocol under development.
20. Transformative emergency dispatch for multifold survival increase

Shannon also made notes on a previous CRM student who did their thesis on start-up activities for a research study as guidance for my project.

Day 12, Wednesday 6/13/18:

I spent a good amount of time working on my secondary applications. I also worked on my proposal and project summaries over SOPs. I also observed Holy consent another patient for the guided HF study. Lastly, I researched and tried to find what some other Department's administrative SOPs looked like.

Day 13, Thursday 6/14/18:

I spent a good amount of time today putting together a table of contents for the SOP binder. In the afternoon, I visited UTSW's surplus warehouse to see if there were any suitable chairs to replace the ones currently in the lab so that we could be code compliant (the ones currently there are have fabric seats and backs.)

Day 14, Friday 6/15/18:

I put an email together for Dr. Idris emailing a poster to the TEMRAP students to see if they were interested in participating in the ventilation waveform study. I also spent a good about of time today working on secondary applications. Lastly, I started working on my project summary and a PowerPoint for the committee meeting next week.

Week 4:

Day 15, Monday 6/18/18:

I worked more on the project summary and on the tentative table of contents for a SOP binder. I also worked on my secondary applications. I also watched Holy consent another patient. I am still waiting to get credentialed. Additionally, I worked on the PowerPoint and project summary for the first committee meeting later this week.

Day 16, Tuesday 6/19/18:

I have been credentialed for Parkland!! I worked some more on the table of contents for the SOP binder and my secondary applications. I also worked on my project summary and PowerPoint for the first committee meeting.

Day 17, Wednesday 6/20/18:

I was sick today and did not come into the office. I finalized the PowerPoint and project summary for the first committee meeting tomorrow.

Day 18, Thursday 6/21/18:

The pre-proposal committee meeting was today. I thought that it went pretty well and all of my committee members had great suggestions. In the afternoon, I worked on my proposal. It is really hard to find good sources to cite just for my proposal, but I will keep working on it.

Day 19, Friday 6/22/18:

I spent all day today working on my proposal. I am still finding it difficult to find any good articles to cite on research administration but will keep looking. Holy also taught me more about screening patients for studies.

Week 5:

Day 20, Monday 6/25/18:

I spent all day today working on my proposal. I also took some time to email the Emergency Medicine research staff and faculty to ask for their opinion on what needs to be made into an SOP.

Day 21, Tuesday 6/26/18:

I spent most of today working on my proposal. I also have started to receive responses from the faculty and staff on what they would like to see become SOPs. I have started a simple tally on the list of SOPs to determine which one to start first once I have more responses. Additionally,

around 2 I attended a presentation on active shooters given by UTSW PD. Lastly, in the afternoon I met with the department's biostatistician regarding my project. She agreed that I will probably need to use a Wilcoxon ranked sum test for both the research staff and faculty.

Day 22, Wednesday 6/27/18:

I spent most of the morning working on my proposal. I also started working on a SOP for making administrative SOPs for the department or in other words a template to promote consistency and longevity of the SOPs. Holy, Mario, and I went to lunch and we discussed the difficulties with ongoing projects. Energize is still having trouble because the person tasked with creating the order set has still not created it. This is problematic because the time window of the study closes at the end of this year and while UTSW only seeks to enroll 5 patients, the inclusion exclusion criteria are expected to be limiting. I worked on my proposal some more in the afternoon before leaving the office.

Day 23, Thursday 6/28/18:

I again spent most of the day working on my proposal. I also worked on my secondary's. I again attended the weekly Dr. Diercks meeting with the research team. We went through all of the departments ongoing, pending, and recently completed studies. Lastly, I started to work on creating a SOP for creating SOPs for the department, a key component to standardizing the process and ensuring longevity and effectiveness of my project.

Day 24, Friday 6/29/18:

I made corrections and additions to my proposal per Dr. Cross's suggestions. I also had the pleasure of having lunch with Dr. Fowler, the EMS director, and then shadowed him on his ER shift in the afternoon. During the lunch, we discussed the application process as well as current events in the field of medicine. It was a very interesting shadow shift. It was very intriguing to see how a county teaching hospital operates. Parkland is also pod based which is quite different from the acuity based system that THR, the hospital system I scribe for, uses. There were also several interesting cases including someone that likely has cutaneous T-cell lymphoma and a crush injury resulting in a Chopart joint separation, which is essentially when the arch of the foot is broken.

Week 6:

Day 25, Monday 7/2/18:

Dr. Cross has provided suggestions for revisions to my proposal. I spent all day making those revisions and beefing up my proposal.

Day 26, Tuesday 7/3/18:

In the morning, I worked more on beefing up my proposal. I then went to the Weekly Dr. Idris meeting at 11AM. We went over all of the departments studies and what steps were being taken to advance them,.

Day 27, Wednesday 7/4/18:

Today was the 4th of July, I did not go into work.

Day 28, Thursday 7/5/18:

I did not feel well today so I worked on my proposal from home.

Day 29, Friday 7/6/18:

Dr. Cross has obtained a deadline extension for my proposal and it is now due on the 13th. I worked more on the proposal trying to find more sources for the background section. I also fleshed out and reorganized the summary section to provide a few sentences of coverage for all other sections.

Week 7:

Day 30, Monday 7/9/18:

I attended velos, eIRB, and EPIC screening and enrolling classes which ran from 8AM-12PM. In the afternoon, I worked more on the Master SOP, and submitted my project to UTSW's eIRB. I also finalized the survey questions for the research staff and faculty which can be given before and after the SOPs are in place and sent them to Shannon for her consideration. Shannon requests some edits and revisions to the survey and subsequently approved them.

Day 31, Tuesday 7/10/18:

I attended the weekly Dr. Idris meeting which started at 10:30AM this time because the last one ran over. We finished around 12PM. There was also an interesting new study that Dr. Idris mentioned that he was contacted about to see if the department had any interest in participating in. It involves prehospital treatment of acute seizure with a non-IV drug. This has the potential to be a highly beneficial study because it can often be quite difficult to get IV access on an actively seizing patient.

Day 32, Wednesday 7/11/18:

I spent the morning working on the Master SOP. I attended a full department meeting at 1:30PM. Colby, the department head, brought up a lot of interesting issues, some of which actually relate to my project. He brought up that one of the faculties biggest complaints and one of the departments biggest internal issues is the inundation of faculty and staff with emails as well as

inefficient communication patterns. He stated that a plan was in the works to set up a weekly “need to know” communication containing pertinent updates. I could incorporate this idea into a SOP. I also continued to work on secondary applications some. Shannon has already provided with some comments on my proposal and I have begun to take those in to consideration.

Day 33, Thursday 7/12/18:

I continued to make revisions to my proposal in the morning. I then attended the weekly Dr. Diercks meeting at 1PM. We went through all of the departments studies to bring everyone up to speed and plan how to move each one forward. I also reached out to various members of the clinical research staff again to ask for prioritization of SOPs. Lastly, I worked some more on a master SOP and started to work on a SOP for a study start-up check list.

Day 34, Friday 7/13/18:

My proposal has been approved! I have given a draft of a master SOP to Shannon for her to consider. I have also sent Shannon a draft of the proposal for UTSW’s IRB and we worked together to refine it then send it to the eIRB.

Week 8:

Day 35, Monday 7/16/18:

I completed the master SOP today but have asked Joanie, the administrative Manager of the Department, if I could meet with her regarding how she would like to see the SOP’s standardized.

Day 36, Tuesday 7/17/18:

I have started working on the study startup checklist SOP. I also spent several hours going through parkland pathways training which is required for Parkland EPIC access.

Day 37, Wednesday 7/18/18:

I spent more time completing the parkland pathway modules. I also Meet with Shannon for 2 hours regarding the SOPs and how she would like several of them to go/be made.

Day 38, Thursday 7/19/18:

I attended the weekly Dr. Idris Meeting at 11AM we went over all of the department’s ongoing studies and what every member of the team was doing to move them forward.

Day 39, Friday 7/20/18:

I worked some more on the study startup checklist. I then met with Joanie so she can show me some of the non-administrative SOPs that the department has so that I could use the same or similar format.

Week 9:

Day 40, Monday 7/23/18:

I worked on the team member responsibilities SOP and have sent a draft to Shannon for her consideration.

Day 41, Tuesday 7/24/18:

I went back to working on the study start up SOP. Shannon has asked me to adapt and add onto an existing ideal study timetable to be more relevant and complete in regard to the department.

Day 42, Wednesday 7/25/18:

I continued to work on the ideal study timetable. I also worked some on the team member responsibilities SOP

Day 43, Thursday 7/26/18:

I continued to work on the ideal study timetable. I worked some on my secondary applications.

Day 44, Friday 7/27/18:

I was sick and did not go into work this day.

Week 10:

Day 43, Monday 7/30/18:

I continued to work on the ideal study timetable and team member responsibilities SOP.

Day 44, Tuesday 7/31/18

I went to the Dr. Idris meeting today which ran from 11AM to 1:30PM. We went over all of the departments studies, what stage they are in, and what is being done to move them along through the process. I sent out an email with a link to the confidence survey to the to the research staff today. I also started working on the invoicing SOP.

Day 45, Wednesday 8/1/18

I continued to work on the ideal study time table. I also emailed Paula, the department's Clinical Research Coordinator today. Shannon has directed me to work with her to start working on a SOP for invoicing.

Day 46, Thursday 8/2/18:

I continued to work on the ideal study timetable and invoicing SOP today. Paula has gotten back to me and provided be with a lot of great resources to create an invoicing SOP, including her personal notes from when Shannon trained her as well as examples of invoices.

Day 47, Friday 8/3/18:

I spent most of today working with on the SOP for invoicing and the study timetable.

Week 11:

Day 48, Monday 8/4/18

I worked on the SOP for Site initiation visit today.

Day 49, Tuesday 8/5/18

I started the SOP for reportable events. I started the SOP for patient screening in EPIC

Day 50, Wednesday 8/6/18

I started an SOP for study closure.

Day 51, Thursday 8/9/18

I have completed my secondary applications! I started the SOP for Billing for Procedures and Orders Performed for a Research Study

Day 52, Friday 8/10/18

I worked on and finished the SOP for patient screening in EPIC

Week 12:

Day 53, Monday 8/11/18

I worked on and finished the SOP for study closure

Day 54, Tuesday 8/12/18

I worked on an SOP for the site qualifying visit. I started the SOP for training and credentialing for research coordinators.

Day 55, Wednesday 8/13/18

I did an inventory count for Shannon of a box of blood sample kits for the VITROS study.

Day 56, Thursday 8/14/18

I transcribed the research staff survey into a survey monkey survey and sent it out today.

Day 57, Friday 8/15/18

I completed the SOP for Billing for Procedures and Orders Performed for a Research Study

Week 13:

Day 58, Monday 8/16/18

I started the SOP for Serum collection and processing.

Day 59, Tuesday 8/17/18

I Started an SOP for Informed consent. I worked on and finished the SOP for reportable events.

Day 60, Wednesday 8/18/18

Day 70. Thursday 8/19/18

I finished the SOP for serum collection and processing.

Day 71, Friday 8/20/18

I started the SOP for case report forms. I completed the SOP for training and credentialing of research coordinators.

Week 14:

Day 72, Monday 8/21/18

I worked more on and completed the SOP for informed consent.

Day 73, Tuesday 8/22/18

Per Shannon's request I have started to work on an SOP for legally authorized representative from a prior SOP that Holy started but did not finish.

Day 74, Wednesday 8/23/18

I continued to work on the LAR SOP.

Day 75, Thursday 8/24/18

Day 76, Friday 8/25/18

I continued to work on the LAR SOP. I finished the SOP for completion of case report forms.

Week 15:

Day 77, Monday, 8/27/18:

I worked on a draft of the layout of my practicum report and sent it to my major professor, Dr. Cross. Shannon made some additional requests for and sent the study timetable back to me to work on some more and I spent a good amount of time doing that.

Day 78, Tuesday, 8/28/18:

I Attended the weekly Dr. Idris meeting. We reviewed the status of all of the Departments studies and what was being done to move them forward. I also transcribed the faculty survey into a survey monkey and sent it out via email. Shannon has also started me on a new project where I will be transferring data into a spreadsheet on a new software.

Day 79, Wednesday 8/29/18:

I began working lab management SOP.

Day 80, Thursday, 8/30/18

I continued to work on the lab management SOP. I contacted Jose Rodriguez, an employee within the office of Safety and Business Continuity, regarding what they look for to qualify that a lab on UTSW is in compliance. He sent me a reference guide and a survey checklist that they utilize. I will incorporate these into the SOB. I also worked some on my practicum report.

Day 81, Friday 8/31/18

My scribing shift when way over time and I did not get any sleep after getting off at 4AM the night before so I did not go into work today. I worked on the lab management SOP from home though.

Week 16:

Day 82, Monday 9/3/18:

Today was Labor Day and I did not go into work.

Day 83, Tuesday 9/4/18:

I attended the weekly Research meeting, facilitated by Dr. Idris. We went over all of the departments studies and discussed what individual members of the team are doing to move them forward. I then worked on SOPs. Confirmed the defense date. I then attended the monthly ED department staff meeting from 1:30PM to 2:30 PM. The big topic of discussion during the meeting was project reboot for PeopleSoft which has been long coming and will help to streamline and improve many of the processes utilized through PeopleSoft by individuals and teams across the entire institution. Colby also brought up that 3 years ago the department had a 4 million in debt fiscal year compared to 2019 where we are on track to have a \$700,000 surplus. The department is also working to fill a content producer position to communication within the department and to the outside world. I emailed the Department Administrator, Colby regarding what he would like to see in place for Effort tracking. Started doing some research on effort tracking.

Day 84, Wednesday 9/5/18:

I spent a few hours working on my final practicum report draft. I also communicated with Mario and have set up a time tomorrow where I can watch him and hopefully get the info I need to create an SOP for EPIC screening and log maintenance. It unfortunately will take too many hoops to jump through to make it worthwhile for me to help out Shannon with the new spreadsheet. I also helped Mario dispose of a large number of sets of unused paperwork from the lab that pertained to a study that which has passed.

Day 85, Thursday 9/6/18:

I got to work early and went with Mario to the ED where he screened patients and talked with me about the process for a about an hour and a half. I took notes then started to develop and SOP for screening from those notes and our conversations.

Day 86, Friday 9/7/18

I attended the TEMRAP abridged introduction to the IRB which lasted for an hour and a half. I then continued to work on the patient screening in EPIC SOP. I also spent a good amount of time working on my practicum report.

Week 16:

Day 87, Monday 9/10/18

Day 88, Tuesday 9/11/18

I compiled the faculty data in an excel spreadsheet then passed out the staff survey to the remaining members who have not taken it at the Weekly Dr. Idris meeting. We went over all of the ongoing studies and what is being done to move them forward. Heart walk data entry

Day 89, Wednesday 9/12/18

I worked on my practicum draft.

Day 90, Thursday 9/13/18

Practicum

Day 91, Friday 9/14/18

I worked on my Practicum draft today.

Week 17:

Day 92, Monday 9/17/18

At Shannon's request I attended Dr. Dierks lecture on Women in Medicine

Day 93, Tuesday 9/18/18

I filled out the intent to defend from and started to send it around to my committee members

Day 94, Wednesday 9/19/18

Filled out intent to defend , converted it to a PDF and

Thursday

Office of clinical research personnel start up

Resource for PI, research coordinators and research RNs

The goal is to homogenize coordinator quality at UTSW

Eventually will be expanded to PI and research RN

Working to give coordinators a voice and maybe work on salaries

Working on maybe establishing a mentorship or training program

Work on continuing education

Streamlining credentialing processes to all three instructions

Pay disparities , market survey and working to bring

Day 95, Friday 9/20/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Week 18:

Day 96, Monday 9/24/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 97, Tuesday 9/25/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 98, Wednesday 9/26/18

Started working on my PowerPoint presentation to use for my public and private defense. I also continued to work on my practicum report.

Day 99, Thursday 9/27/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 100, Friday 9/28/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Week 19:

Day 101, Monday 10/1/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 102 Tuesday 10/2/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 103 Wednesday 10/3/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 104, Thursday 10/4/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 105, Friday 10/5/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Week 20:

Day 106, Monday 10/8/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 107, Tuesday 10/9/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 108, Wednesday 10/10/18

Day 109, Thursday 10/11/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 110, Friday 10/12/18

Week 21:

Day 111, Monday 10/15/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 112, Tuesday 10/16/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 113, Wednesday 10/17/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 114, Thursday 10/18/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 115, Friday 10/19/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Week 23:

Day 116, Monday 10/22/18

Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 117 Tuesday 10/23/18

Worked on my practicum report. Worked on my practicum report. Worked on standardizing the format and proofreading the set of SOPs.

Day 118, Wednesday 10/24/18

I worked all day on my practicum report and send it back to Dr. Cross as she wanted to make some final comments on it before I send it to the rest of the committee.

Day 119, Thursday 10/25/18

I left today to go on a hunting trip with some friends in south Texas. I worked on final edits from Dr. Cross's comments on the car ride.

Day 120, Friday 10/26/18

I woke up, finished the final few edits, and emailed the finalized practicum report to Dr. Cross and the rest of my committee.

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