Official Study Title: Pediatric Intubation Simulations with Bougie

Document Title: Study Protocol with Statistical Analysis Plan

NCT number: Pending

Document date: 10/05/2026

Qualification for Exempt Review

1. General Exempt Exclusions

Read each statement below and check any statement if true for this study. If ANY of the following statements are true, this study does not meet exempt criteria and you should complete HRP-UT901 Standard Protocol Form instead.

☐ The study is aimed at involving prisoners.

☐ The study is FDA-regulated (unless exemption #6 is selected). *This includes the use of drugs, medical devices, etc.*

☐ The research involves deception or incomplete disclosure AND participants will not be prospectively agreeing to participate in a study that involves deception. *i.e. Participants are not provided with complete information about the study procedures OR are misled about the purpose of the study*

☐ The study involves more than minimal risk to subjects. *Participants are likely to experience more physical, emotional, or mental stress/discomfort than they do in the course of daily life or a routine medical or psychological exam.*

STOP – If any of the above are checked, submit HRP-UT901.

2. Exempt Determination Categories

All of the research activities MUST fit within one or more of the exempt categories listed in this table. Review these categories, then check the box(es) in item 2a below to select all activities applicable to this study.

Category 1: Research on Education/Teaching	*Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.* ***This includes most research on regular and special education instructional strategies, and research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.***
Category 2: Interviews, Surveys, Public Observations	*Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.* ***Only adults can participate in surveys/interviews and children cannot be subjects of research involving surveys/interviews (i.e. no private, identifiable information about children can be collected).*** *Observations of public behavior may include children if the investigators do not interact nor participate in the activity being observed.* *Note: Behavior is considered public when it occurs in spaces that are open/accessible to the general public (e.g., roads, public squares, parks, beaches) where individuals could reasonably expect their behavior might be observed or recorded without their explicit permission.*
Category 3: Benign Behavioral Interventions (BBIs)	*Benign Behavioral Interventions (BBIs) are limited to procedures involving communication or interpersonal contact with the subject, the performance of a cognitive, intellectual, educational or behavioral tasks, or manipulation of the subject's physical, sensory, social, or emotional environment.* ***Data collection is limited to verbal or written responses, or audiovisual recordings. Physiological measurements/readings beyond audiovisual are not permitted (e.g. use of sensors such as heart rate monitoring, activity trackers, eye tracking that involves infrared or other physical sensors, etc.).*** *BBIs must be brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Deception is permitted if participants are aware the research involves deception and they prospectively agree to participate.* ***Only adults can participate in category 3 research.***
Category 4: Secondary Use	*Secondary use of data and/or specimens originally collected for other purposes.* *NOTE – if the study ONLY meets exempt category 4 and there will be no contact with participants, it is recommended to complete the HRP-UT903 - Secondary Use Protocol Form instead.*
Less Common Categories:	

Category 5: Public Benefit/Service	*Federally supported/conducted research and demonstration projects of public benefit or service programs.* ***The study MUST have specific funding/support from a federal agency, and that agency must specify that the study qualifies for this exempt category.***
Category 6: Taste and Food Tests	*Taste and food quality evaluation and consumer acceptance studies.*

2a. Study Activities

After reviewing the table above, check all research activities applicable to this study. ***If your study involves activities that are not listed below, submit HRP-UT901 Standard Protocol Form.***

☒ Category 1: Research on Education/Teaching/Classroom Management

☐ Category 2: Focus Groups or other group interviews with adult participants only
(no private, identifiable data about children collected)

☒ Category 2: Interviews/Surveys with adult participants only
(no private, identifiable data about children collected)

☐ Category 2: Observation of public behavior

☐ Category 3: Benign Behavioral Intervention (BBI) with adult participants only

☐ Category 4: Secondary use of data /specimens originally collected for other purposes

☐ Category 5: Federally supported/conducted public benefit study *(rare)*

☐ Category 6: Taste/Food quality tests *(rare)*

Study Information

Study Title

Include the study title below.

Pediatric Intubation Simulations with Bougie

3. External Time Limitation

Generally, the IRB will review applications in the order in which they are received. When possible, the IRB can assign higher priority to research with externally-imposed urgency that is beyond the control of the researcher (example: grant deadlines, research responding to a sudden or emerging event, etc.).

Completing this section provides the IRB with information but does not guarantee priority review is possible or that a requested deadline can be met. Researchers are encouraged to communicate with the IRB as soon as possible when there is an urgent situation (ideally before submitting the IRB application), and we will do our best to accommodate requests, as possible: https://research.utexas.edu/ors/human-subjects/get-help/

Are you requesting the IRB consider priority review due to an *externally-imposed* deadline or time limitation affecting this submission?

☒ No

☐ Yes → *If yes, briefly describe the urgency or deadline below, including the reason for it:*

4. Is the research taking place at or using data from any of the following:

Knowing when UT's external clinical partners are involved helps inform IRB review and reporting.

☐ None of these

☐ Health Discovery Labs

☐ Central Health

☐ CommUnity Care

☒ Ascension locations → *Submit a request to the Seton Site Approval Tool (SAT) and upload the confirmation email that states the request has been submitted in UTRMS under "Other Documents." Please note, we do NOT need the final approval letter (you will not receive SAT approval until after IRB approval is granted). If you encounter issues or have questions about SAT, please reach out to siteapproval@seton.org.*

5. Study Purpose/Hypotheses/Research Questions

Please briefly describe the study purpose and hypotheses/research questions in the box below.
As noted in the instructions on page 1, ***if you are requesting a "Not Human Subjects Research" determination, please stop completing this form*** *and instead go to our Not Human Subjects Research (NHSR) Determination Tool. If you require an official IRB determination of NHSR, follow the instructions in the tool to submit a PDF of the tool results instead of this form.*

Difficulty in pediatric airway management is associated with significant morbidity and mortality, including cardiac arrest and neurologic injury (Nishisaki et al., 2013; Graciano et al., 2014). Proficiency with airway management tools is essential for pediatric emergency medicine providers. The bougie, a flexible introducer used to facilitate endotracheal intubation, is widely used in adult airway management but has been less studied in pediatric populations.

Due to ethical and practical limitations, there is limited opportunity to study airway interventions in pediatric patients using randomized designs (Prekker et al., 2023). Simulation-based training provides a safe and effective method to teach and evaluate skills for high-acuity, low-frequency procedures such as pediatric intubation (Elendu et al., 2024).

The purpose of this study is to evaluate the use of simulation-based training for bougie-assisted intubation in pediatric emergency providers. Our research question is: ***Does simulation-based bougie training improve provider competence and confidence in managing difficult pediatric airways?***

Study objectives include:

- To assess baseline experience, comfort, confidence, and utilization of bougie-assisted intubation
- To evaluate the effect of simulation-based bougie training on provider confidence and competence in performing bougie-assisted pediatric intubation
- To assess retention of provider confidence at 6 months following simulation-based training

Elendu, C., Amaechi, D. C., Okatta, A. U., Amaechi, E. C., Elendu, T. C., Ezeh, C. P., & Elendu, I. D. (2024). The impact of simulation-based training in medical education: A review. *Medicine*, *103*(27), e38813. https://doi.org/10.1097/MD.0000000000038813

Graciano, A. L., Tamburro, R. F., Thompson, A. E., Fiadjoe, J. E., Nadkarni, V. M., Nishisaki, A., & NEAR4KIDS Investigators. (2014). Incidence and associated factors of difficult tracheal intubation in pediatric intensive care units. *Critical Care Medicine, 42*(3), 731–740. https://doi.org/10.1097/CCM.0000000000000033

Nishisaki, A., Turner, D. A., Brown, C. A., Walls, R. M., Nadkarni, V. M., & National Emergency Airway Registry for Children (NEAR4KIDS) Investigators. (2013). A national emergency airway registry for children: Landscape of tracheal intubation in 15 pediatric intensive care units. *Critical Care Medicine, 41*(3), 874–885. https://doi.org/10.1097/CCM.0b013e3182746736

Prekker, M. E., Bjorklund, A. R., Myers, C., Harvey, L., Horton, G. B., Goldstein, J., Usher, S. C., Reardon, R. F., Robinson, A., Strobel, A. M., & Driver, B. E. (2023). The pediatric bougie for the first tracheal intubation attempt in critically ill children. *Annals of Emergency Medicine*, *81*(6), 667–676. https://doi.org/10.1016/j.annemergmed.2023.01.016

6. Procedure Description

The description below should cover all research activities involving participants (or their data), including the following details:

- *Research measures/tests/data collection tools that will be used.* ***Upload surveys, interview guides, assessments, questionnaires, and any other data collection tools that will be used to UTRMS-IRB in the "Other Attachments" section.***
- *Research interventions and activities, including the stimuli/tasks/instructions that participants will see, hear, or experience as part of their participation.* ***Upload intervention materials (including videos, audio files, handouts, photos, scripts, etc.) to UTRMS-IRB in the "Other Attachments" section.***
- *Secondary data that will be obtained, how it is collected and used, from what source(s).*
- *Total duration of all research activities (i.e. expected time commitment of participants).*
- *If the study involves deception, include description of deception below & ensure the exempt information sheet includes disclosure to the participant that the study involves deception (see item 18).*

The study will take place over a 9-month period (September 2026 – May 2027). Participants will include Pediatric Emergency Medicine (PEM) fellows and attendings, Pediatric Intensive Care Unit (PICU) fellows and attendings, and Anesthesiology attendings at Dell Children's Medical Center (DCMC). The research study will include: 1) pre-simulation survey, 2) pre-simulation lecture on bougie usage, 3) difficult airway management simulation, 4) post-simulation survey, 5) 6-month follow-up survey.

1. Pre-Simulation Survey:
Participants will complete a brief pre-simulation survey. The survey will include questions on clinical practice experience and comfort level in using a bougie to manage a difficult airway encounter. The pre-simulation survey will take no more than 5 minutes to complete.

2. Bougie Education Lecture and Practice:
Prior to the simulation, participants will go through an educational lecture to learn about bougie use in challenging airway cases. Simulations will use a pediatric manikin that can be intubated and training on using the manikins will also be provided. The lecture will take approximately 5 minutes, followed by a practice run of 10 minutes. These will be completed prior to the simulation start. An outline of the lecture with links to instructional videos to be used is uploaded with this application.

3. Bougie Simulation:
The simulation will consist of difficult airway management cases conducted using a randomized crossover design. Participants will be randomized to the order of case presentation, and each participant will complete all cases (Cho et al., 2016; Komasawa et al., 2015). Simulations will take place either at the Ascension Seton Clinical Education Center or at one of the DCMC trauma bays. Simulations will be conducted in real-time with a facilitator providing the scenario and giving verbal details, as needed. Each simulation will be videotaped to allow for accurate analysis of timings. The participants will be able to be seen in the video recording; however, the video will only be used to help capture the measures listed in the checklist and will only be accessible to the research team members analyzing and scoring the simulation.

Completion of the simulation will be timed but we anticipate simulations will take no more than 15 minutes. Examples of the scenarios are below:

1. Post T&A bleed > bloody airway
2. Trauma C-collar: trauma with C-spine injury

The following outcomes will be measured for each scenario:
Primary measure:

1) Time to complete intubation from time of laryngoscope in the mouth and successful intubation with scope out of the mouth.

Secondary measures:

1) Comfort and confidence in using a bougie to aid in intubation post simulation.
2) Comfort and confidence in using a bougie to aid in intubation 6 months post-simulation.
3) Self-reported bougie use during the 6 months following the simulation.

4. Post-simulation survey

Following the simulations, participants will be asked to complete a survey. The post-simulation survey will ask participants for feedback on the simulations and lecture, and current comfort and confidence level with using a bougie. The post-simulation survey will take no more than 10 minutes.

5. 6-Month Follow-Up Survey

Six months following the simulation, we will send a survey to participants to assess whether bougie use has increased and current confidence level with using a bougie. The follow-up survey will take no more than 10 minutes.

Total time of study procedures is 70 minutes: 5 minutes for the pre-simulation survey, 15 minutes for the bougie education lecture and training, 30 minutes for the simulation (15 minutes each), 10 minutes for the post-simulation survey, and 10 minutes for the 6-month post-simulation survey.

Cho, T., Komasawa, N., Hattori, K., Mihara, R., & Minami, T. (2016). Gum-Elastic Bougie Efficacy for Tracheal Intubation During Continuous Chest Compression in Infants-A Crossover Simulation Trial. *The Journal of emergency medicine*, *51*(1), 19–24. https://doi.org/10.1016/j.jemermed.2016.03.003

Komasawa, N., Hyoda, A., Matsunami, S., Majima, N., & Minami, T. (2015). Utility of a gum-elastic bougie for difficult airway management in infants: a simulation-based crossover analysis. *BioMed research international*, *2015*, 617805. https://doi.org/10.1155/2015/617805

Study Types/Elements Requiring Additional Information

7. Does the study involve Category 1: Research on Education/Classroom Management? *See item 2 above.*

☐ No → *Skip to item 8*

☒ Yes

7a. State how the research activity (not the instructional material) involves "normal educational practice."

Simulations, including video recorded simulations, are a commonly used method in medical provider and emergency training. Simulation-based training is a crucial component of education, offering a safe and controlled environment for trainees to practice critical skills and decision-making. It allows for repeated practice of rare or high-risk scenarios, enhancing both technical proficiency and non-technical skills like teamwork and communication. Further, pre- and post-surveys are also commonly used both to assess the learner's competence and to provide feedback on the simulation to instructors.

7b. Explain how/why the study is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Simulation training on intubation is already part of standard medical trainee education. This study adds instruction on bougie use within a simulation setting but does not replace or limit required

educational content. Participation in the study will not reduce trainees' opportunity to learn core material. Participation is voluntary, and study activities are separate from formal evaluation processes. Study participation and performance will not be used for advancement or competency assessment. In addition, investigators will assess performance using standardized, neutral criteria solely for research purposes. Therefore, the study is not expected to adversely impact trainees' learning opportunities or the evaluation of educators.

8. Does the study involve Category 3: Benign Behavioral Intervention(s)? *See item 2 above.*

☐ No → *Skip to item 9*

☒ Yes

8a. State how the intervention activity qualifies as "harmless, painless, and not physically invasive."

Medical providers, including attendings and trainees, regularly receive simulation training on high acuity procedures, as well as pre- and post-surveys as part of their education, so the intervention mode is not out of the ordinary for the setting or event.

8b. In the investigator's opinion, is there any reason to think that the participants may find the intervention activity offensive or embarrassing? Explain why or why not.

It is unlikely that participants in this study will experience offense or embarrassment, as all elements of the study are designed to be professional, educational, and low risk.

8c. Is the intention of the study to evaluate the effect of the research intervention on *health-related* biomedical or behavioral outcomes?

☐ No → *Skip to item 9*

☒ Yes → *Federal regulations, policy, and some journal guidelines require public registration and results reporting for studies that meet the definition of a clinical trial. Note that the various definitions of "clinical trial" subject to these requirements can be quite broad and include things like behavioral interventions conducted outside of traditional healthcare settings (regardless of "exempt" status for the overall research). Complete the following questions to address requirements that may apply to this intervention.*

8ci. If yes to 8c above, go to UT Guidance on Clinical Trials Registration and Results Reporting to review requirements that may be applicable and select which of the following apply to this study:

☒ Intended to be submitted for publication in a journal subject to International Committee of Medical Journal Editors (ICMJE) requirements

☐ NIH-funded Clinical Trial *(be sure list funding on the Study Funding section of the UTRMS application)*

☐ Intended to have routine clinical trial costs covered by the Center for Medicare and Medicaid Services (CMS)

☐ CT.gov registration is required per the terms of the award/funding agency

☐ Meets none of the above requirements but will register on CT.gov voluntarily

☐ None of the above

8cii. Will the UT Austin study team register this study on ClinicalTrials.gov?

Click here for information on how to identify the "Responsible Party" for registration.

☒ Yes

☐ No – This is a multi-site study and the UT PI is not the Responsible Party for registration. The external Responsible Party is aware of their duty to register the study.

☐ No – This study meets none of the requirements in item 8ci above and the study team prefers not to register

8ciii. Attest that all relevant reporting requirements for the study will be followed as applicable (regardless of ClinicalTrials.gov registration).

Use the linked guidance in item 8ci and review the section titled "Reporting Results" for guidance. This box must be checked to confirm you have reviewed the requirements, even if you determine no reporting requirements apply to the study.

☒ Confirm

9. For this study, will the researchers obtain, use, or disclose Protected Health Information (PHI) regulated under the Health Insurance Portability and Accountability Act (HIPAA)?

This typically applies to research involving access to medical records. This does not include self-reported health information disclosed as part of research surveys/interviews. Guidance on HIPAA protected PHI is available here.

☒ No → *Skip to item 10*

☐ Yes

9a. Select all HIPAA-covered entities providing PHI:

☐ UT Health Austin
☐ Ascension Seton/other Ascension locations*
☐ UT Austin University Health Services
☐ Dell Children's Medical Center*
☐ CommUnity Care
☐ Central Health
☐ Other, specify:

***For studies obtaining data from Ascension facilities,** please submit a request to the Seton Site Approval Tool (SAT) and upload the confirmation email that states the request has been submitted in UTRMS under "Other Documents." Please note, we do NOT need the final approval letter (you will not receive SAT approval until after IRB approval is granted). If you encounter issues or have questions about SAT, please reach out to siteapproval@seton.org.*

9b. List the data points or attach a list of the data to be collected about each subject from their medical records or other HIPAA protected data source(s). *Select one of the following:*

☐ This list is uploaded to UTRMS on the Local Site Documents page under "Other Attachments"
☐ All data points listed in the text box below:

9c. Select all pathways for obtaining HIPAA authorization for accessing PHI for this research:

NOTE: If obtaining authorization from Ascension patients, use of Ascension's stand-alone HIPAA authorization form is required and should be uploaded on the Local Site Documents page in UTRMS under "Other Attachments."
Otherwise, non-Ascension HIPAA authorization may be obtained using the HIPAA template language embedded within HRP-UT926 Exempt Research Information Sheet Template (see item 18 later in this form). All UT Austin IRB templates are available in the Templates tab of the UTRMS-IRB Library.

☐ Obtaining HIPAA authorization from participants to access PHI → *Skip to item 10 if only this box is checked*
☐ Requesting *full* waiver of participant authorization
☐ Requesting *partial* waiver of authorization to access PHI for screening or recruitment only

All of the following must be checked to qualify for a partial waiver for screening or recruitment:

- ☐ Attest that PHI will be accessed ONLY to identify eligible subjects for recruitment in this research. Continued access to PHI will be limited to those who later volunteer for the study and provide written authorization.
- ☐ Attest that PHI will be accessed only by individuals who have authorization to access the records outside of the research context.
- ☐ Attest that researchers will not move or transmit identifiable PHI from the covered entity (i.e. the institution holding the records, such as the clinic).

9d. Complete the following if requesting a *full or partial* waiver of HIPAA authorization:

I. Specify the date range of records that will be accessed:

Start date (month/year):

End date (month/year):

II. Provide a justification for why the research could not practically be conducted without access to PHI and the waiver of patient authorization requested:

☐ Identification/recruitment: *– access to records is needed to identify eligible subjects (e.g., chart reviews, partial waiver for recruitment, etc.)*

☐ Large number of subjects projected *– potential subject population includes a large number of records to review and it is not feasible to attempt contact with all subjects*

☐ Outdated records *– This is a retrospective study involving subjects who may have moved or expired and researchers cannot feasibly attempt to contact required sample*

☐ Total population required - *The nature of the research is such that findings will not be valid, or will be significantly skewed, if the total eligible population is not included.*

Select all that apply above OR provide different justification below.

☐ None of the above; specify other justification:

Note that inconvenience or limited time/resources alone are not sufficient justifications for waiving a patient's right to authorize disclosure of their PHI.

III. Attest that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research where the use or disclosure of the PHI meets IRB and HIPAA requirements.

This box must be checked.

☐ Confirm

IV. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Review the linked guidance and attest below that you are obtaining only the minimum information necessary to complete the waived activities:

This box must be checked.

☐ Confirm

V. Provide any additional information you'd like the IRB to consider for why/how all the listed data points in item 9b are necessary to answer the research question and comply with the minimum necessary requirement described above *(if none, this can be left blank)*:

10. Research Activities Requiring Supplemental Forms or Additional Requirements

Select each of the items below that are relevant to your research. If none apply, this section can be left blank.	*For each item selected, complete and upload the associated Supplemental Form in UTRMS-IRB under "Other Attachments."*
☐ Research conducted outside the U.S. and/or involving international participants or subjects ☐ Research conducted in and/or involving collaborators in countries of concern.	UT Supplement 908 - International Research *The linked supplement is required for research conducted outside the US, direct remote interactions with international participants (i.e. Zoom interviews), and research that will collect identifiable data from international participants (including online surveys).*

	Be aware that any UT investigator contemplating or already working with entities or individuals in countries of concern or conducting research in those countries should reach out to the Research Security team and complete any required reviews (e.g., International Collaboration Review Committee (ICRC) review) at their direction prior to starting the research.
☐ Department of Defense (DoD) *This includes all research involving DoD funding, facilities, data, or personnel (i.e. active military personnel are targeted/discernible in the data collected). See Policies & Procedures section 25.1 for guidance on DoD applicability.*	UT Supplement 911 - Department of Defense
☐ Use of Artificial Intelligence (AI) in research	*As part of UT ISO's mission and with the growing use of AI in research, all research that involves use of AI should be in alignment with ISO's Acceptable Use of AI Policy.* *If your AI platform use is not listed or in alignment with the policy above, contact UT ISO at security@utexas.edu prior to conducting any research with that AI tool. It is strongly recommended to confirm acceptability prior to submitting to the IRB.*

Subject Population

11. Research Participant Information

Describe the general characteristics of the subject populations or groups, including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

Participants, male and female, will include:
- Pediatric Emergency Medicine (PEM) fellows and attendings
- Pediatric Intensive Care Unit (PICU) fellows and attendings
- Anesthesiology attendings

12. Age range (minimum & maximum)

Include age range below. If you have multiple research populations (e.g., teachers and students), clearly outline the age range for each group.
Individuals under age 18 can only be included in certain exempt categories. Be explicit in this response as to whether or not minors under age 18 will be included in the research.

Providers: 25 - 65

13. Inclusion/Exclusion Criteria

Describe the specific criteria that will be used to decide who will be included in or excluded from the research from interested or potential subjects. Define technical terms in lay language, as applicable.

Inclusion criteria: PEM, PICU, and Anesthesiology providers at DCMC (fellows and attendings)

Exclusion criteria: Providers not in the above specialties or not currently seeing patients at DCMC. Providers who are also simulation staff will be excluded, as well.

14. Justification for Target Population(s)

If the inclusion/exclusion criteria target or exclude a particular segment of the population(s) relevant to the research topic, provide a rationale for why this target population is appropriate to address the research questions. Specific groups should not be targeted for research based solely on convenience/availability.
For example, if only UT students are targeted for research affecting a broader population, explain why this is equitable and appropriate for this study.

Because we are interested in how providers who see patients in high acuity, emergency situations respond to bougie training, we are only conducting the research with PEM, PICU, and anesthesiology providers at this time.

15. Will the study involve recruitment of the researchers' students or personal contacts/friends/family?

☐ No → *Skip to item 16*

☒ Yes → *Complete the following:*

15a. Explain how the study procedures will be designed to mitigate potential for coercion or undue influence to participate or continue participation:

Although the fellows and faculty are healthcare professionals within the institution, participation in trainings and assessments such as this is voluntary. Participation or non-participation will not affect academic evaluation, standing, or progression within the department. Data via surveys will be kept confidential.

16. Total Sample Size

Enter the total number of individuals you hope to enroll in the research.

Up to 50 providers will participate in the study.

Recruitment & Enrollment

17. Recruitment Procedures and Materials

*Select each type of recruitment method that may be used AND **upload copies/templates for all selected materials to UTRMS-IRB in the "Recruitment Materials" section.***	*Describe the use of the selected method to recruit participants, addressing the specific points listed for it, when applicable.*	*Provide the schedule and frequency of recruitment attempts using this method, when applicable.*
☒ **E-mail/Letter** *Explain how emails/mailing addresses for potential subjects will be identified and obtained by the study team. Describe the initial invitation and any follow-up reminders, and address if there will be a way for recipients to opt-out of future emails. Uploaded email templates should include subject line(s).*	The PEM and PICU Medical Directors send a bi-weekly email with updates and information to all providers at their institutional email addresses. The Anesthesiology group has a separate email list for departmental updates that is sent out as needed, but at least monthly. Information about the study will be included in these existing email communications in the month leading up to the initial training session. It will briefly	Information via email will be distributed over approximately one month. As the email is typically sent by the PEM and PICU Medical Director bi-weekly, we anticipate providers receiving the information twice in the month leading up to the educational lecture and simulation. Anesthesiology personnel will receive the emailed information at least once in the month leading up to the simulation. Participation is voluntary. No incentives will be offered, and no

	describe the purpose of the study and information on the upcoming training session.	penalty will result from declining participation.
☐ **Flyer(s)** *Include the types of location(s) where these will be posted.*		
☐ **Social Media/Web Posts** *Address which sites and accounts will be used to post ads. Templates should include all text/images that will be included in posts. Guidance for creating templates for social media recruitment can be found on our Education & Guidance webpage.*		
☐ **Text/Direct Messaging** *Describe sites/accounts that will be used. Explain how participants' contact information is obtained, when applicable. Uploaded templates should include the initial invitation and any follow-up reminders.*		
☐ **Study-specific Website** *This refers to websites created specifically for this research study. Uploaded templates should include screenshots/mock-ups of all aspects of the website that will be created; include all text/images.*		
☒ **In-Person or Phone Scripts/Presentations** *Explain how phone numbers for potential subjects will be obtained by the study team, when applicable. If researchers will be cold-calling subjects, provide a rationale for why this method is needed to accomplish the research.*	Providers will receive information about the project and training during regularly scheduled didactic sessions. A brief PowerPoint presentation will be given to introduce the study and provide PI contact information.	Didactic sessions for PEM and PICU providers are held weekly on Wednesdays. The study will be presented once in the month leading up to the initial lecture and simulation session.
☐ **Research Recruitment pool** *Specify which pool will be used (e.g. SONA, Prolific, Amazon MTurk, etc.) and describe how offered studies are advertised to users. Upload templates of all researcher-provided advertising language that will be posted and confirm it meets the pool's standards for formatting, content, word limits, etc.*		

☐ **Newspaper ads/TV spots/Radio ads**

When applicable, upload scripts and descriptions for planned ads; final versions can be provided in a modification after IRB approval.

☐ **Medical Record Review**

If your study includes identifying potential participants using PHI (e.g., a partial HIPAA waiver for recruitment is needed), note this here and be sure you have completed the HIPAA section of this form to request a waiver.

☐ **Other recruitment material/method**

18. Exempt Research Information Sheet (RIS) and Enrollment Process

Exempt research studies do not require a full informed consent form. However, providing a Research Information Sheet (RIS) that provides some basic information about the study up front is required when there is interaction with participants (including online interactions, such as a survey).

At a minimum, the RIS must include the following required elements:

1. *A statement that the activity involves **research***
2. *A **description** of what participants will be asked to do (e.g. types of questions asked, activities they will take part in, what they can expect to see/hear/experience, etc.)*
3. *A statement that participation in the research is **voluntary***
4. *An explanation of how participants may ask **questions** (i.e. contact info for the study team)*

HRP-UT926: TEMPLATE: EXEMPT RESEARCH INFORMATION SHEET (RIS) is available in the Templates tab in UTRMS-IRB Library. Use of this template is encouraged but not required. If you plan to use one of our templates, It is strongly recommended to use the 926 rather than a full consent template.

All required elements of the RIS must be clearly presented to potential participants prior to initiating study activities, and it must be presented in a way that would allow participants to keep a copy in case they have questions in the future. It can be provided as a stand-alone document, included as a cover sheet or introduction on a survey, incorporated into recruitment materials, etc.

18a. Review the information above, then indicate below which document uploaded to UTRMS-IRB contains the required elements of a research information sheet (RIS): *Select all that apply.*
Note: Participants are generally not required to sign the RIS unless additional regulatory requirements apply (i.e. FERPA consent, HIPAA authorization, etc.); in these cases, it is recommended to use a stand-alone form.

☒ Stand-alone RIS(s) is/are uploaded to UTRMS
☐ RIS elements are embedded within other uploaded document(s), e.g. included in survey/interview documents, added to recruitment email templates, etc. → *If checked, specify in the text box below where the RIS elements can be found.*

18b. Describe the procedure(s) for ensuring participants receive the RIS prior to initiating study activities.

e.g. RIS will be displayed on the first screen prior to entering the survey, participants will have the option to print the form; RIS will be emailed to the participants prior to their interview date and we will go over the RIS before questions begin, etc.

The RIS will be given to participants at the beginning of the study (prior to the pre-simulation survey).

18c. Required Disclosures

Identify each element below that may require additional information be disclosed in the RIS. Template language for each of these items is provided in HRP-UT926: TEMPLATE: EXEMPT RESEARCH INFORMATION SHEET (RIS) available in the Templates tab in UTRMS-IRB Library.

☐ It is reasonable that researchers could discover or suspect child or elder abuse.

☐ It is reasonable that researchers could learn of an incident that could require reporting under Title IX.
See Title IX and Research Guidance for more information on this requirement.

19. Will subjects receive any compensation for their participation in the research?

See P&P section 4.8 for guidance on compensation.

☒ No → *skip to item 20*

☐ Yes

19a. Specify the type/total amount of compensation that will be provided to each participant, and include the method of payment *(e.g. course credit, gift card, cash)*:

Privacy & Confidentiality

20. Participant Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. Privacy protections apply to people, while confidentiality protections (addressed in the section below), apply to data.

In this section, describe how the study team will protect participants' privacy throughout the conduct of the study. For example, consider the locations where you will approach and question participants, the locations where data will be viewed/analyzed, how data collection procedures will limit the amount of sensitive or invasive data collected to only what is necessary to answer the research questions how participants will be described in publications/presentations, etc.

Participation in the study will be voluntary. Identifying information, such as name or date of birth, will not be collected as part of the study. The surveys will be collected via a Google Form (housed on the Ascension drive) and only designated study team members will have access to the data, and they will analyze it in secure, private locations such as locked offices or encrypted institutional computers. In any presentations or reports generated from the project, all results will be presented in aggregate form.

21. Data Confidentiality

Confidentiality refers to the way private information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, audio/video recordings, photographs, etc.) are protected from unauthorized access.

In this section, describe whether any participant identifiers (e.g. names, contact info, etc.) will be collected during the conduct of the research and if identifiers will be linked to research data for any period of time. Include the following, as applicable:

- *If identifiers will be used for contact or compensation purposes only, and will never be linked to specific responses, describe the methods used to accomplish this.*

- *If identifiers will be coded/pseudonymized to protect confidentiality, describe whether or not a code key will be created linking study IDs/pseudonyms to identifiers, who will have access to the key, and how it will be stored separately from the research data.*
- *If the study involves collection of audio/video recordings or photographs, describe any plans for protecting identifiable content (e.g., avoidance of recording identifiable information/full faces, redacting recordings or transcripts, etc.).*

No identifiable information will be conducted as part of the survey data. Each participant will be assigned an ID and data will be correlated with the ID. Consent for participation, including being video recorded will be obtained; video is only used for data analysis and will only be accessible to the research team members analyzing and scoring the simulation. Once the videos are analyzed, recordings will be deleted/destroyed. Analysis will be completed no later than May 2027. Pre- and post-simulation and follow-up surveys will be collected via Google Forms (hosted by the Ascension Google Workspace). Once the data collection is complete, it will be downloaded from the Qualtrics database for analysis in Stata and the Qualtrics project will be archived. Data will be kept in electronic form for three years after completion of the study.

22. Electronic Materials - Storage and Access

In this section, select all methods that will be used to protect the confidentiality of research data.
At least one of the following must be checked, select all that apply.

☐ Electronic data and records will be stored on a password-protected cloud service that is currently listed as approved on the UT Information Security Office (ISO) platform matrix. Access to data will be limited only to individuals who need access for purposes related directly to this research study. *(Strongly recommended)*
The matrix of current UT Austin ISO approved platforms is available here: https://security.utexas.edu/iso-policies/cloud-services/decision-matrix

☐ Electronic data and records will be stored on a third-party cloud service/platform that is not currently approved for research data storage by UT Austin's Information Security Office (ISO) and requires local ISO approval. → *If this box is checked, the study team must obtain security clearance from UT Austin ISO (or Dell Med IT, if applicable) approving use of this platform to store research data for this study. UT IRB approval cannot be granted until documentation of ISO/IT approval has been uploaded to the study in UTRMS under "Other Attachments." To avoid delaying approval, consider selecting a different option for storing data, if possible.*

☒ Other method(s) of storing and limiting access to electronic data and records, describe in the text box below:
Examples might include use of a platform hosted and approved by a collaborating institution or sponsor for this research, use of non-cloud-based electronic storage methods (e.g. hard drive), etc.:

As the study PIs are based out of Dell Children's Medical Center (an Ascension site) and research members are part of both UT Austin and Ascension, electronic data will be stored in an Ascension drive. The files will be password protected and accessible only to research staff assigned to the study.

23. Physical Materials – Storage and Access

One of the following must be checked.

☐ Physical data/records/specimens *(e.g. Signed research information sheets, paper surveys/notes, physical recordings, etc.)* will be stored in a secure location with access limited only to individuals who need access for purposes related directly to this research study.
☒ N/A – no physical materials

24. Research Records Retention Attestation

Confirm that research records will be maintained in compliance with all relevant records retention policies.

UT Austin's research record retention policy requires that data and copies of relevant study documents (e.g. consent forms, protocol, recruitment materials, etc.) be maintained for at least 3 years from completion of the research project. Note that researchers are NOT required to maintain identifiers linked to data for 3 years. To protect confidentiality, identifiers can be unlinked from study data and destroyed as soon as feasible (described in the next item). UT Austin's records retention policies are available here: https://records.utexas.edu/utrrs

Some research may be subject to other retention policies that require longer retention periods and retention of other specific data or materials (e.g. collaborating institutions, funding agencies or sponsors, FDA, HIPAA, etc.). For example, studies that involve use of protected health information (PHI) covered by HIPAA must retain all relevant records for at least 6 years.

Check the box below to acknowledge the above information and confirm the study team will comply with UT Austin's policy as well as any other records retention policies that apply to this research.

This box must be checked.

☒ Confirm

25. Destruction of Identifiable Information

One of the following must be checked. Be sure your response accounts for all data, records, audio/video recordings, etc. collected for the research.

☐ No identifiable information is recorded at any point in this research.

☒ Identifiable information will be destroyed. → *Specify at what point in the research process identifiable information collected about participants will be destroyed. At least one of the following must be checked:*

- ☒ Upon completion of procedures requiring use of identifiers *(i.e. compensation, data linkage, etc.)*
- ☐ After all data collection/cleaning/transcription is complete
- ☐ At the time of study closure/once study is complete
- ☐ Other, describe below:

☐ Identifiable information will not be destroyed.

If checked, explain the rationale for retaining identifiers indefinitely and specify if identifiers will remain linked to research data (either directly or indirectly via a code key).

Data Sharing and Future Use

26. Data Sharing and Future Use

Check the box below that best describes your plans for use and sharing of data beyond the scope of the current research. You are strongly encouraged to consider the broadest possible future plans you might have. ***One of the following must be checked.***

☒ There are no plans to use or share data/specimens for other research purposes not related to this study. → *skip to item 28*

☐ Data/specimens may be shared with other researchers or banked (by this study team or other researchers) for future research purposes *outside the scope of this study*. → *answer the following:*

26a. Select which data sharing plans/future uses apply:

"Coded" refers to data that is indirectly identifiable via a code key that links study ID#s back to participant identifiers.

☐ Anonymized data/specimens may be shared or banked for future research → *skip to item 28*

☐ Coded data/specimens may be shared or banked for future research →, *complete section 27*

☐ Identifiable data/specimens may be shared or banked for future research → *complete section 27*

27. Data Registry/Specimen Repository (Details)

Select all that apply.

☐ Contributing data/specimens to an existing registry/repository → *describe this registry below; if this registry is maintained by UT researchers, provide the IRB Study ID# and/or the registry name and Principal Investigator responsible for the registry:*

☐ Creating a new registry/repository → *complete the following:*

27a. Describe the intended purpose and target area(s) for this registry:

27b. Describe any options that will be provided to participants to stipulate future use of their data/specimens. If participants will be given the option to be contacted regarding future uses, describe the procedure(s) for this contact.

Be sure to include all options and stipulations in the RIS. If no stipulations or future contact will be offered, explain this below.

27c. Who will be allowed access to registry data/specimens?

☐ Only the PI of this study and/or other members of the current study team → *skip to item 28*

☐ Other researchers will be able to request data/specimens from the registry → *below, describe how other researchers will be able to request data/specimens from the registry, what criteria will be used to approve such requests (e.g., IRB approval, application process), and what methods will be used to release data/specimens to other researchers securely:*

Conflicts of Interest

28. Financial Conflicts of Interest

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website.

One of the following must be checked.

☒ To the best of your knowledge, the PI does NOT have a financial interest related to this study.

☐ The PI has a financial interest related to this study.

If so, please briefly describe the interest:

29. Non-financial Conflicts of Interest

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- personal beliefs/feelings impacting ability to conduct the study without bias,
- any other factors that could create bias in the study

One of the following must be checked.

☒ To the best of your knowledge, the PI does NOT have a non-financial interest related to this study.

☐ The PI has a non-financial interest related to this study.

If so, please briefly describe the interest: