JEFFERSON—Office of Human Research

SUMMARY OF NON-INTERVENTIONAL HUMAN SUBJECTS RESEARCH

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Use this form for social and behavioral research, research on education, questionnaire studies, and other prospective studies not involving drugs, devices or medical/surgical procedures. Please address all applicable points to create a complete and succinct synopsis of the protocol. If a point does not apply to your study, please state "NA." Use language, insofar as is possible, that can be understood by a layperson, and provide meanings for all acronyms used. Attach surveys, discussion/interview guides. **Form must be typewritten.**

PART A- SUMMARY OF STUDY

1. Provide a brief (2-3 sentences) lay language synopsis of the study.

The goal of this study is to teach emergency medicine resident physicians a patient-centered approach for communicating with patients at the time of emergency department discharge in the setting of diagnostic uncertainty (i.e. no definitive cause identified for the patient's symptoms). The residents will complete an online educational curriculum that has been developed by the study team, and will participate in video-based simulation deliberate practice (DP) and feedback sessions using a simulation-based mastery learning (SBML) approach. They will be assessed with the Uncertainty Communication Checklist (UCC), a tool already developed by the study team, that has a minimum passing standard (MPS) that was established through engagement of both patients and physicians. The investigators will perform a 2-arm wait-list randomized control trial with resident physicians to test the efficacy of the SBML curriculum in training residents to have a discharge discussion with patients discharged from the emergency department with diagnostic uncertainty.

2. Objectives and Significance

a. State the primary objective(s) of the study.

Investigators will measure the percentage of residents who meet or exceed the MPS on the UCC in the intervention group versus the control group.

b. State the secondary objectives(s) of the study.

Secondary analysis will look for the decay of learned skills and if residents' performance is maintained after completing a single intervention. Investigators will also evaluate: 1) the association between number of DP sessions completed and achieving the MPS and 2) the association of number of DP sessions completed with baseline characteristics, for those who pass.

c. What benefit or knowledge will be gained?

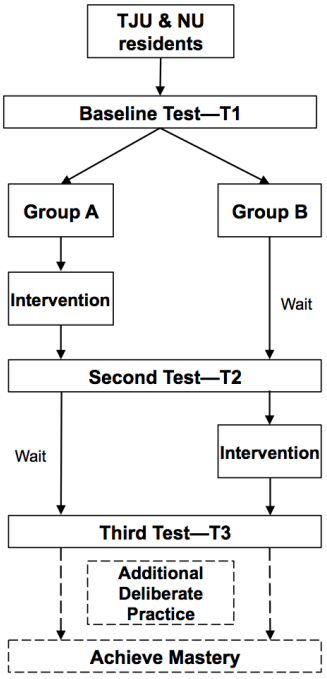
This work develops an important framework to teach and assess clinical performance competency in patient-centered communication in the setting of diagnostic uncertainty, which occurs frequently (at least 1/3 of discharges) in the emergency department. In addition, the project delivers and evaluates a technology-based educational curriculum. This project has potential to significantly impact the training and competency of providers in navigating safe and effective discharge communication for over one third of patients discharged from the emergency department.

d. State research question or hypothesis you are testing.
We hypothesize that resident physicians who receive the SBML curriculum will be significantly more likely to achieve mastery in this communication skill compared to residents who do not receive the SBML curriculum, and that all residents exposed to the curriculum will ultimately achieve mastery in this communication skill.

3. Briefly describe the background and rationale for the research/evaluative study (whichever is appropriate) in lay language. Please limit response to one paragraph. State the perceived problem and why it is being investigated. *(Do not include references and please do not cut and paste grant application or review articles.)*

At least one third of patients treated in the emergency department (ED) are discharged without a definitive diagnosis, thus leaving the encounter with diagnostic uncertainty. A recent national survey of medical trainees found that 99% of trainees had experienced challenges discharging patients with diagnostic uncertainty, and 51% wanted formal communication training regarding uncertainty. Transitions of care are high-risk periods for patient safety, and effective communication between providers and patients is essential to promote patient safety during care transitions. Approaches for educating trainees and establishing competency around effective communication during diagnostic uncertainty are needed to improve the quality of communication at ED discharge, the most common transition of care.

Figure 2: Participants flow through study



4. Briefly describe the research/evaluative study design. ***(Use charts and flow diagrams if applicable****. "See protocol" is not an acceptable response.)*

a. Subjects: State inclusion and exclusion criteria.
Eligible participants include all emergency medicine residents at TJU and NU.

b. Procedures: Explain study procedures/methods.
Members of the study team will approach all TJU and NU Emergency medicine residents for possible study enrollment prior to the Baseline Test (T1) to determine their interest in participation. Residents will have the opportunity to further discuss the study with an investigator prior to as well as on the same day as T1, prior to initiation of testing. All residents interested in participating will provide written informed consent using procedures approved by the Institutional Review Boards of TJU and NU.

Participants will be evenly assigned to Group A (intervention group) or Group B (control arm). Three study test visits (T1-T3) will be planned for all participants, with additional test visits being scheduled as needed for those who require additional practice and testing to achieve mastery. T1 will consist of the baseline test, during which participants will complete a simulated encounter with an SP to establish a baseline score on the UCC. Participants will be contacted after their T1 visit by email to be informed of the group to which they have been randomized. Participants in Group A will be given access to the intervention, an online interactive module, in this initial randomization email and will be scheduled to participate in video-based DP sessions with the SPs. The second visit will be scheduled 4-8 weeks after T1 and will consist of another

simulated test (T2) encounter with the SP for both Group A and B; following this session, participants in Group B will be introduced to the intervention. Both groups will return for a third study test visit (T3). All study test visits will involve participants completing a video-recorded simulated encounter with SPs, though the clinical scenarios will vary to maximize participants' exposure to different scenarios. Participants will all be assigned a score for their performance in each visit, with the primary endpoint being achievement of the MPS (yes/no). Participants will complete surveys at each of the study test visits (T1-T3) to collect demographic information and/or feedback on their experience with the educational curriculum.

The content of the intervention involves educational modules, DP sessions, and an interactive online game to practice skills taught within the modules. While participants will receive the intervention at different times in the study depending on their group assignment (between T1 and T2 for Group A, between T2 and T3 for Group B), once they are in the intervention period will be able to complete the online educational module at a time of their own choosing within the given study time window and to return to the module as frequently as they wish. After completing the educational module, they will be able to schedule video-based DP sessions conducted from a location of their convenience. After each practice session, participants will receive immediate and detailed feedback from the SP regarding their performance, and notice of if they achieved mastery as measured by a score that meets or exceeds the MPS. Each participant will be required to complete one DP session, with the option to complete addition DP sessions before their subsequent test visit (either T2 or T3) during which they will be officially scored. After each DP session, participants will be asked whether they would like to complete any further DP sessions. We will track the number of DP sessions that learners complete in order to accurately estimate the average time-commitment required to achieve mastery for future dissemination work. After completion of follow-up testing at T3, all participants who have not yet achieved the MPS will complete additional DP and testing until mastery is achieved.

c. Data analysis: *Provide the methods by which the study objectives/aims will be assessed or measured, i.e., statistical analysis plan, qualitative research methods such as procedures for conducting theme analysis and enhancing validity, program evaluation methods and analysis plan, or mixed methods analysis plan.*

The primary outcome of interest for Aim 3 is the percentage of residents in each arm who meet or exceed the MPS of the UCC at the T2 assessment. We will use logistic regression to compare groups with respect to the outcome at T2 adjusting for the test performance at T1 (stratification variable). Secondary analysis will consider change within groups from T2 to T3 separately using McNemar's test. In Group A, this will be a test of whether mastery is retained versus not retained. In Group B, this will be a supplemental test of the intervention's efficacy. Association between number of DP sessions completed and passing will be evaluated using logistic regression. Among those who pass, association of number of DP sessions completed with baseline characteristics will be evaluated using Poisson regression.

*For a quantitative study, include what statistical tools will be applied and **how the study is powered**, if appropriate.*

We estimate a baseline performance of 60% of residents meeting the MPS on the pre-test. We expect waitlist subjects to have only a slight improvement in meeting MPS at T2 resulting in a 65% pass rate. Randomizing 92 participants and conservatively estimating ~90% retention at the

T2 assessment (n=82, 41 per group), we will have 81% power to detect a difference of 25% between study groups at T2 (pass rate of 90%) assuming a two-sided Type I error of 5%.

5. Delineate procedures that are standard of care from those that are being performed specifically for the research.

The educational leadership of the programs at TJU and NU have committed to integrating this uncertainty communication curriculum into the simulation curriculum at both institutions as part of standard educational curriculum for this year. Therefore, all residents will be required to complete the testing visits and the educational curriculum as part of their training. We have scheduled five available dates for simulation at each testing time point to accommodate for the different scheduling needs of residents, with the goal that all resident physicians enrolled in the Emergency Medicine training programs at TJU and NU will be able to complete the educational curriculum. Though residents are required to participate in the curriculum, they will still have the choice of whether to participate in this research study. Therefore, the research components are the collection of data on resident performance to be used in analyses and randomization of residents who agree to participation into two different cohorts for timing of their educational modules.

6. How will accuracy of data be assessed?

In order to assess accuracy of passing data and demonstrate reliability of SP scoring, a research team member blinded to the participant's study arm will complete ratings for at least a 40% random sample of the videotaped encounters.

7. Identify the sources of data obtained about human subjects in the form of specimens, records, survey instruments, interviews, focus groups, observation, or other sources.

Surveys: Each participant will complete a total of 3 surveys. All participants will complete the first survey prior to T1, with items collecting basic demographic characteristics (age, gender, race/ethnicity, post-graduate-year). Additionally, participants will be asked open-ended questions including how often they encounter clinical scenarios with diagnostic uncertainty in their clinical practice, how comfortable they are in having these conversations, what strategies they have used and found successful, and if they have had prior training on this topic. All participants will additionally be asked to complete a survey following completion of study involvement. This second survey will be used to gather feedback on each participant's simulation experience with the simulation scenarios and the SBML curriculum using both open- and closed-ended questions. All participants in both groups will be contacted 3 months after completion of the RCT to ask follow-up questions regarding their use of the new communication skills in clinical practice. Questions will include topics such as: frequency of encounters with diagnostic uncertainty, comfort level in discussing this topic with patients, patients' reactions to the conversation and request for anecdotes on patient encounters that could inform future training.

Performance Scores: Residents' performance on the simulation will be rated at all study visits using the MPS. The primary outcome of interest for this trial is the participant score (pass/fail) on the UCC at T2 (post-intervention for Group A). Trained SPs will complete these ratings immediately following the simulation sessions. Additionally, a research team member, blinded to the participant's study arm, will complete ratings for at least a 20% random sample of the videotaped encounters to demonstrate reliability of scoring.

Curriculum Metrics: In order to assess the differences in participants' effort required to achieve mastery and thereby better characterize the ability to disseminate our intervention, we will track the number of DP sessions completed and relationship between the number of sessions and passing rates. We will also track the number of game sessions initiated (games are part of the educational curriculum), amount of time spent playing the online game, the number of attempts required to "pass" the game, and the number of times the participant "passed the game."

8. The following steps must be taken to ensure that identifiable data remains confidential and secure. Please check each box to confirm your understanding. There are fields below to provide explanations and to describe deviations as well as additional measures.

   a. ☒ A separate research chart must be maintained apart from the medical record/chart of the subject.
   b. ☒ There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
   c. ☒ When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
   d. ☒ Access to the data should be limited. Only the individuals who need the data should have access.
   e. ☒ If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
   f. ☒ If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
   g. ☒ If research data is stored on your work computer, encryption software must be installed on the computer. Contact IS&T if you are not sure if the encryption software is installed.
   h. ☒ PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
   i. ☒ Research data and PHI should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IS&T.
   j. ☒ External monitors will only be given access to subjects' medical records as specified in the signed consent form.
   k. ☒ Research data and PHI must be maintained per Jefferson policies.

   If you have any explanations for, or deviations to the items listed above, **please describe them: N/A**

   If applicable, **please describe any additional measures that will be taken:**
   All electronic data are password-protected on network-level-access-secured computers. All paper documents are secured in locked cabinets in a locked office accessible only to

research personnel. PHI is only collected to the extent required by our study protocol, and records are de-identified as soon as possible.

PART B- SUBJECTS AND FACILITIES

1. What is the expected number of subjects to be enrolled?

No. subjects per year	Total No. subjects	No. Subjects Nationally or Internationally (if applicable)	No. subjects at collaborating Institutions (if applicable)
Up to: 40	Up to: 62	N/A	102

2. Identify where the research will be conducted and describe the adequacy of facilities.

The study will occur at two sites. The first site is Thomas Jefferson University (TJU). TJU Hospital, the main clinical site at TJU, is an urban academic hospital located in Philadelphia, Pennsylvania that serves approximately 39,000 inpatients each year, and has approximately 100,000 emergency department visits and 500,000 outpatient visits each year. The Department of Emergency Medicine is ACGME accredited for a three year residency with a total of 39 residents (13/year). Northwestern University (NU) will serve as the second site. Northwestern Memorial Hospital, the main clinical site at Northwestern University, is an urban academic hospital, located in Chicago, Illinois with over 88,000 adult ED patient visits per year. The Department of Emergency Medicine has an ACGME accredited four-year residency training program with a total complement of 60 residents annually (15/year). Both the TJU and NU emergency medicine residency programs work closely with their institutional simulation centers and residents participate in simulation training on a regular basis as part of their educational curriculum. See more detail on the simulation centers in the resources pages.

3. Please identify any facilities to be used for research other than those assigned to Department or division.

The study will use the simulation facilities at both TJU and NU. This includes TJU's Rector Clinical Skills and Simulation Center as well as NU's Center for Simulation Technology and Immersive Learning.

4. Describe provisions to protect the privacy of subjects during the course of the study. (Privacy can be defined as the subject's desire to control the ways in which s/he is approached and/or the ways in which his/her private information is shared with others.)

The entire study constitutes minimal risk to the enrolled patients. There is no expectation of any physical risk. There is the possible risk of loss of confidentiality. All electronic data are password-protected on network-level-access-secured computers. All paper documents are secured in locked cabinets in a locked office accessible only to research personnel. PHI is only collected to the extent required by our study protocol, and records are de-identified as soon as possible.

5. How has the research staff been trained regarding study procedures/methods and their duties (in-service, investigator meeting, etc.)?

All members of the research team are HIPAA-trained and PORCITI credentialed (CITI modules). Team members who will be involved in participant enrollment have been trained to consent and enroll patients into research studies at Jefferson. The team will have regular progress meetings to ensure compliance with good clinical practices and study procedures, and will be overseen by the study PI and Research Coordinator. The Principal Investigator and Co-Investigators will ensure that all studies are run effectively and that data management, human resources and administrative tasks meet performance metrics.

Standardized Patients (SPs) will be trained on the conduct of the simulated scenarios, rating of participants (according to a rubric), and delivery of feedback. To ensure standardization between the TJU and NU sites, training sessions will be recorded and assessed by the study investigators for reliability. The SPs will be trained on scoring with the use of video-recorded pilot scenarios. These pilot encounters will demonstrate participants with variable communication skill levels and proficiency in demonstrating essential items on the UCC (resulting in some videos that demonstrate mastery and others that fail to meet the MPS). SP raters will be trained to demonstrate high inter-rater reliability with the research team Once they have completed training on the conduct and scoring of the scenarios, SPs will be trained on giving real-time feedback to the resident physicians. A key component of SBML is not simply practice, but DP with real-time feedback on performance. Their feedback practice sessions will be video-recorded and critiqued to ensure both high-quality feedback and uniformity of feedback between SPs.

6. Which of the following groups are eligible to be subjects?

	Yes	**No**
*Women of reproductive potential	X	
Pregnant women/fetuses/neonates (*if yes, and study targets pregnant women or is interventional, include OHR-27 as an addendum to the OHR-2*)	X	
Men of reproductive potential	X	
Vulnerable Populations (Please see list below)		
Individuals with impaired decision-making capacity (check yes *only if research targets and could benefit this population)* Note: If yes, please also review and complete the information in this form for decisionally –impaired subjects.		X
*Minorities	X	
Prisoners (*if yes, notify the IRB in advance of the meeting*)		X
*Economically or educationally disadvantaged persons	X	
Students/employees	X	

7. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?

Resident employees will be reminded that their participation in the research study is voluntary throughout their participation and that their participation will not impact their access to the education materials. They will also be informed that their decision to participate in the research study will not affect how they are graded on their performance.

8. If one of the populations with an (*) in the table above are excluded, provide the reason.

N/A

Note: NIH policy requires that minorities and women be adequately represented as research subjects. If this is an NIH-funded study and you will be excluding either of these populations, you must provide a scientific reason for such exclusion.

PART C - RISKS, BENEFITS, AND ALTERNATIVES

1. What are the risks of the research? Address this at the individual and/or community level as appropriate.

The entire study constitutes minimal risk to the enrolled participants. There is no expectation of any physical risk. There is the possible risk of loss of confidentiality. All electronic data are password-protected on network-level-access-secured computers. All paper documents are secured in locked cabinets in a locked office accessible only to research personnel. PHI is only collected to the extent required by our study protocol, and records are de-identified as soon as possible.

2. Discuss measures taken to minimize risks and maximize benefits associated with this research.

All electronic data are password-protected on network-level-access-secured computers. All paper documents are secured in locked cabinets in a locked office accessible only to research personnel. PHI is only collected to the extent required by our study protocol, and records are de-identified as soon as possible.

3. What are the potential benefits of participation?

Investigators hope that what we learn may be helpful to doctors and future patients. Possible benefits from being in the study may include 1) learning a new approach to conducting a more patient-centered emergency department discharge conversations for patients with diagnostic uncertainty. Patients leaving the ED with diagnostic uncertainty have been found in prior studies to have increased struggles in the transition back home, and improving the discharge conversation may reduce post-discharge struggles for this population. Participants may be better doctors as a result of this study and 2) contributing valuable information to inform the training of future physicians to communicate more effectively. There is also a chance the subjects will receive no direct benefit from participating in this study.

4. Explain how the risks of the research are justified by potential benefit to the subject or society.

Given the significant opportunity for large-scale public benefit to patients, the minimal risk of loss of confidentiality is reasonable, provided that all subjects participate in an informed consent process ensuring that they fully understand and independently consent to withstand these risks

PART D - CHILDREN

1. Will this study involve children (age 17 or under)?

___ **YES -** Submit form OHR-26, "Research Involving Children."
_X_ **NO -** Delete the REST of this Children section and skip to Part E.

PART E – RECRUITMENT, EQUITABLE SELECTION, AND CONSENT PROCESS

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g., physician referral, newspaper ad, radio, TV spot, e-mail, membership lists, flyers, social networks, etc.) *Please attach all relevant materials for IRB review and approval.*

Eligible participants include all emergency medicine residents at TJU and NU. Though residents are required to participate in the curriculum, they will still have the choice of whether to participate in this research study. An email will be sent to all residents at TJU and NU, to explain the research study prior to baseline testing. The recruitment email has been attached to this IRB submission.

Use of the University logo is dictated by University Policy. Guidelines regarding the logo's use are described on the Creative Services website. Any variation from the standards requires approval according to the policy. Misuse of the University Logo may result in disciplinary action.

2. Will all qualified subjects populations have adequate access to recruitment materials? Please explain.

Yes, eligible participants include all emergency medicine residents at TJU and NU. Every resident will have equal access to the recruitment materials.

3. Is the location and cultural setting of the research equally accessible to all qualified subject populations? If not, what can be done to make the location and setting more accessible?

Yes, the research will occur through the same mediums and at the same facilities as residents' other curricula. The research will be equally accessible to all residents.

4. Are non-English speaking participants anticipated?

Non-English speaking participants will not be included in this study. Resident physicians are necessarily English-speaking, since the residency program as well as this particular curriculum are delivered in English.

5. If you are requesting a waiver of written consent, describe the information that will be provided to subjects.

N/A

6. Who will conduct the consent interview?

A study investigator will obtain consent on the day of study enrollment, prior to initiation of any study procedures.

7. Who will provide consent or permission (e.g., subject, legally authorized representative, parent, caregiver, etc.)?

The subject will provide consent. Persons who are unable to provide consent are excluded from the study.

8. Where will the consent interview take place?

The consent interview will take place on-campus at either TJU or NU in a simulation space or another place as determined most appropriate by the research team and educational faculty on the day of enrollment.

9. Provide a step-by-step description of the consent process.

A study investigator will obtain consent on the same day as their baseline testing, prior to initiation of baseline testing. During the consent interview, a study investigator will explain that enrollment in the study will involve consenting to the research team accessing the video recordings of their simulation encounters and their individual scores, and completion of surveys to provide demographic information, feedback on their experience with the educational curriculum, and information regarding their use of the new communication skills in clinical practice. Residents will have the opportunity to further discuss the study with an investigator on the same day as their baseline testing, prior to initiation of testing. All residents interested in participating will provide written informed consent using procedures approved by the Institutional Review Boards of TJU and NU.

10. Describe your plan to assess a person's capacity to consent.

N/A – this study will only recruit emergency medicine residents; participation in an emergency residency program is in itself ensures decisional capacity to consent to a research study.

11. Will you seek assent from decisionally-impaired individuals? If so, describe your plan for obtaining assent. Note: If decisionally-impaired subjects will be included and are not capable of consenting themselves, the OHR-8 consent template must be submitted along with a simplified consent form (e.g., OHR-8C) and/or the surrogate consent form (OHR-8B).

No, persons who are unable to provide consent are excluded from the study.

12. Will the potential subject be informed of the research or be provided a copy of the consent to review prior to the actual time of consent? If so, how much time in advance? How much time will be available for the consent process?

An email explaining the research study will be sent to the residents at least one week prior to baseline testing, which will also include a copy of the consent form. Residents will have the opportunity to further discuss the study with an investigator either prior to or on the same day as their baseline testing, prior to initiation of testing. A study investigator will conduct the consent interview, and will explain that their enrollment will involve consenting to the research team accessing the video recordings of their simulation encounters and their individual scores, and completion of surveys. Residents will be given as much time as they need to go over the research study details and ask questions. All residents interested in participating will provide written informed consent using procedures approved by the Institutional Review Boards of TJU and NU. Participants will be given a copy of the written informed consent to take with them.

13. What provisions will be made if the potential subject does not wish to proceed with the consent interview?

Residents who are not interested in participating will still be required to participate in all of the educational activities, but they will not complete the additional research activities.

14. Is surrogate consent involved? YES _____ NO X

15. Will subjects be paid or receive any other inducements for participating? If yes, please explain. *Please note that payment of subjects must be on a pro-rated basis unless there are*

compelling reasons not to prorate. There cannot be a requirement to finish all study components in order for subjects to be paid, as this is considered coercive.

Participating residents will be compensated up to a total $75 for the sharing of their data and their time in completing surveys. The total amount will be pro-rated as follows: $25 for baseline survey and assessment and an additional $50 upon completion of the randomized clinical trial.

16. Describe any steps taken to minimize the possibility of coercion or undue influence.

Undue influence is minimized in this study through the exclusion of vulnerable populations, such as children and prisoners. The informed consent process explains that residents may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting the ability to access the curriculum. The possibility for coercion is further mitigated through the use of reasonable financial incentives.

17. Does the study include any of the following MCARE procedures (check all that apply)?

a. ☐ The study's initial or last continuing review was approved after March 2018 and already contains the new Investigator signature template text.
b. ☒ No MCARE procedures
c. ☐ Administration of anesthesia
d. ☐ Performance of surgical procedures
e. ☐ Administration of chemotherapy and radiation
f. ☐ Administration of blood and/or human source products
g. ☐ Insertion of a surgical device or appliance
h. ☐ Performance of any HIV-related testing
i. ☐ Administration of experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner, or removal of bone, fluids or tissue for use in research or in the manufacture of a product. (This would not include leftover tissues from clinical procedures.)
j. ☐ Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization. (Routine needle sticks, such as peripheral intravenous catheter placement, vaccination, and venipuncture are not considered invasive in the context of this policy.)

18. Select the most appropriate text to appear with the investigator signature line in the consent form (check one):

☐ **Include the text below for studies involving any MCARE procedures (See OHR policy IC 701):**

The physician investigator's signature certifies that s/he personally provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

☐ **Include the text below for studies that receive FULL IRB review but do not include any MCARE procedures (See OHR policy IC 701):**

The investigator's signature certifies that s/he personally provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

☒ **Include the text below for all other studies:**
The investigator's signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

19. If the study does not meet one of the three criteria above (e.g., the study incudes MCARE procedures, but a physician investigator will not be obtaining consent), please provide rationale.

N/A

PART F - LOCATION/COLLABORATION

1. This study involves research to be performed at/in/with *(check ALL appropriate entries)*:
   - ☐ Abington-Jefferson Health
   - ☐ East Falls (Philadelphia University)
   - ☐ Jefferson-Northeast
   - ☐ Jefferson Health-New Jersey
   - ☒ Jefferson-Center City
   - ☐ Jefferson as part of a multi-center, commercially sponsored study
   - ☐ Jefferson as part of an NCTN study
   - ☐ JKCCN sites (specify sites):
   - ☐ Rothman Institute (specify sites):
   - ☐ Methodist
   - ☒ Jefferson and Other Institution(s) *Please name institutions only for investigator-initiated and federally funded studies where data will be shared between institutions. Please provide copy of collaborating institution IRB approval letter if applicable. The OHR will effect IRB Authorization Agreements with collaborating institutions as required. Please name institutions*: **Northwestern University**
   - ☐ Collaboration with City Services *(City of Philadelphia IRB must approve study. For more information, go to http://www.phila.gov/health/irb/.) Please list collaborating city services:*
   - ☐ Unaffiliated Investigators. *Each will need to complete an unaffiliated investigator agreement available on the OHR website.* Please specify by name and role in study:

2. This question is not applicable if research is a commercially sponsored multi-center trial.

   Will research be conducted in states other than Pennsylvania? ☒ YES ☐ NO

   If YES, does research involve subjects age 17 or younger? ☐ YES ☒ NO

   If YES to either or both, in what state(s) will research be conducted? Illinois

   Below please (a) verify the age at which subjects in such state(s) have the ability to consent to participation in research, including any medical treatments or procedures, if applicable and/or (b) verify the requirements for determining who may serve as a Legally Authorized Representative, including a guardian for a child to participate in research. You must also provide information on any state specific regulations on privacy requirements and genetic research if applicable. Please contact the Office of Legal Affairs for information, as needed.

Age at which subjects have the ability to consent to participate in research: __18__

State specific requirements: ___none_____

3. If the investigator is the lead investigator or Jefferson is the lead site in a multi-site study, please address the following:

   a. Where is the repository for adverse events and unanticipated problems and how will information be disseminated to other sites?
   The PI, Dr. Kristin Rising, will be responsible for disseminating adverse events and unanticipated problems to the other study site. The study team will communicate about study related events via phone meetings.

   b. Who will tabulate and disseminate interim results?

   The PI, Dr. Kristin Rising, will be responsible for tabulating and disseminating interim results to the Co-Investigators and study sponsor. The study team will communicate about study related events via phone meetings.

   c. Who will provide information to other sites concerning methods/procedures modifications?
   The PI, Dr. Kristin Rising, will be responsible for providing information to other sites concerning methods/procedures modifications. The study team will communicate about study related events via phone meetings.

   d. Describe how information that is relevant to subject safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)
   The PI, Dr. Kristin Rising, will be responsible for providing subject safety information to other sites. The study team will communicate about study related events on a regular basis via phone meetings.

Collaborative Studies: For investigator-initiated studies that are collaborative or multi-center, or for federally funded studies where Jefferson is the lead site, please provide IRB approvals for each collaborating institution. If the institution does not have its own IRB, then the institution must first obtain a Federal-Wide Assurance (FWA) from the Office of Human Research Protection (OHRP). This registers the institution with the federal government for conducting human subjects research. The institution should then fill out an IRB Authorization Agreement (IAA) that ties the institution to the TJU IRB for this study. For more information, go to http://www.jefferson.edu/osa/irb/forms/.

Unaffiliated investigators involved with this study should fill out an Unaffiliated Investigator Agreement, also available at the above Website address.

PART G - CERTIFICATION

Federal Regulations require the following responsibilities of the Principal Investigator. Please check those items to which you have conformed, and sign.

As Principal Investigator, I certify that: *(check appropriate boxes)*

☒ I have read the IRB Policy and Procedures Manual.
☒ I understand the federally-mandated responsibilities of a research investigator in conducting research or evaluation involving human subjects.
☒ I will conduct this research in accordance with these responsibilities.
☒ I will consent all subjects with an IRB-approved consent form, if applicable to the project, and store the consent forms in a safe repository.
☒ I will provide all subjects with a copy of their signed and dated consent form.
☒ All personnel have been appropriately trained for their assigned roles in this research.

Kristin Rising 04/25/2019

Signature of Principal Investigator **Date**