Human Subjects Protocol (HSP)

Form Version: February 1, 2017

- You are applying for IRB review of the research described in this form.
- To avoid delay, respond to all items in order and include all required approvals and documents. For more tips, see the UAB IRB website.
- To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck.
- All responses should be Times New Roman, Bold, and Underlined.
- Submit all materials to AB 470, 701 20th Street South, Birmingham, AL 35294-0104.

Indicate the type of review you are applying for:

☒ Convened (Full) IRB ***-OR-***

☐ Expedited - See the Expedited Category Review Sheet, and indicate the category(ies) here:

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

1. IRB Protocol Title: **BULLET: Bladder Ultrasound Limits Length (of time), Expedites Treatment**

2. Investigator and Contact Person

a. Name of Principal Investigators: **Kathleen R. Richard**

Degree(s)/Title: **MD** BlazerID: **katricha**

Dept/Div: **Pediatric Emergency Medicine** Mailing Address: **CPP-1, Suite 110** UAB ZIP: **35233**

Phone: **205-638-7431** Fax: **205-975-4623** E-mail: **krichard@peds.uab.edu**

b. Name of Contact Person: **Nipam Shah, MBBS, MPH** Title: **Research Coordinator**

Phone: **205-638-7431**

E-mail: **nshah@peds.uab.edu** Fax: **205-975-4623**

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and all key personnel comply with reporting requirements of the UAB Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed on the protocol have completed initial IRB training and will complete continuing IRB training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator: Kathleen Renée Richard, MD **Date:** 02/28/19

3. Protocol Personnel

Including the PI, list all key personnel (each individual involved in the design and conduct of this protocol). See the Key Personnel Flowchart.

Complete the UAB (3.a.) and non-UAB (3.b) tables, as applicable. Use the checkboxes to show each individual's role, whether the individual has financial interests as defined by the UAB CIRB, and briefly describe the individual's protocol responsibilities and qualifications to perform those responsibilities. **Insert additional rows as needed.**

FDA: For studies involving investigational drugs, list all investigators who will be listed on FDA Form 1572 and include a copy of the 1572. Send the IRB a copy of Form 1572 any time you update the form with the FDA.

a. UAB Personnel (includes UAB affiliates and Children's of Alabama personnel)

Name, Degree, and Dept.	Blazer ID	Role	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: Maxwell A. Thompson Degree: MD Department: Emergency Medicine	mthomp	☒Sub-Investigator ☐Other	☒No ☐Yes	Dr. Thompson will provide administrative oversight for all aspects of th project. Emergency Medicine Physician
Name: Kathleen R. Richard Degree: MD Department: Pediatric Emergency Medicine	katricha	Principal Investigator	☒No ☐Yes	Dr. Richard will provide oversight of project creation and will provide oversight of all aspects of this program including enrollment, data collection, data analysis, and reporting and other operations and will oversee study operations in absence of PIs. Dr. Richard will also assist with data collection, data analysis, and reporting. Pediatric Emergency Medicine Attending
Name: Stephen Ruffenach Degree: MD Department: Pediatric Emergency Medicine	sruffena	☒Sub-Investigator ☐Other	☒No ☐Yes	Dr. Ruffenach will participate in study planning and operations and will oversee study operations in absence of PIs. Dr. Ruffenach will also assist with data collection, data analysis, and reporting. Fellow in Pediatric Emergency Medicine
Name: Mark Baker Degree: MD Department: Pediatric Emergency Medicine	Mdbaker	☒Sub-Investigator ☐Other	☒No ☐Yes	Dr. Baker will participate in study planning and operations and will oversee study operations in absence of PIs. Dr. Baker will also assist with data collection, data analysis, and reporting. Pediatric Emergency Medicine Attending
Name: Nipam Shah Degree: MBBS Department: Pediatric Emergency Medicine	Npshah5	☒Sub-Investigator ☐Other	☒No ☐Yes	N. Shah will assist with data collection, data analysis, and reporting. Pediatric Emergency Medicine Research Coordinator

b. Non-UAB Personnel Relying on UAB IRB - If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Financial Interest?*	Protocol Responsibilities and Qualifications (indicate if this person obtains consent)
Name: _____ Degree: _____ Institution: _____ Email: _____	☐Has own IRB but requests that UAB IRB serve as IRB of record?-***OR***- ☐Does not have own IRB and needs to rely on UAB IRB.	☐No ☐Yes	_____

***Financial Interest** – for each individual listed above, answer **Yes** or **No** as to whether the individual or an immediate family member has any of the following:

- An ownership interest, stock options, or other equity interest related to the investigator's institutional responsibilities of any value.
- Compensation greater than $5,000 in the previous two years when aggregated for the immediate family
- Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.
- Board of executive relationship, regardless of compensation.
- Any other Financial Interest as defined by the UAB CIRB.

UAB Personnel: If the individual or his/her spouse or dependent child has a Financial Interest, a disclosure has to be made to the UAB CIRB. A completed CIRB evaluation has to be available before the IRB can complete its review.

Non-UAB Personnel: If the individual has a Financial Interest, ***include a copy of the report from his/her own institution's conflict of interest review with this submission to the UAB IRB.***

c. Do the investigators listed above include any students using this research for their thesis or dissertation?

☐ No, continue with Item 3.d.
☐ Yes, complete the following

Student Name	Thesis/Dissertation Title
_____	_____

d. Is the principal investigator a student, fellow, or resident? ☒Yes ☐No

If Yes, complete items below and obtain signature of faculty advisor or supervisor:

Supervisor's Name: **Maxwell A. Thompson**
Degree(s) / Job Title: **MD, Emergency Medicine Attending**
Additional Qualifications pertinent to the protocol: Has experience in US research as well as advanced training in bedside ultrasound
Telephone: 5-7387
E-Mail: maxwellthompson@uabmc.edu
Signature: _____

e. Describe the principal investigator's activities related to this protocol and provisions made by the PI to devote sufficient time to conduct the protocol

Dr. Richard will provide oversight for all aspects of this protocol. She has experience conducting research protocols in the emergency department setting and has specialized training in ultrasonography. Dr. Richard will meet regularly with research staff to ensure compliance with UAB-IRB approved protocols.

f. Is medical supervision required for this research? ☐Yes ☒No

If Yes, who will provide the medical supervision?

☐ PI will provide ***-OR-***
☐ Other:
Name: _____ Telephone: _____
If other than PI, obtain signature of person providing medical supervision:
Signature _____

g. Describe your process for ensuring all key personnel are adequately informed about the protocol and their research-related duties and functions:

Drs. Richard, Ruffenach and Thompson will assign appropriate duties to members of the research team. The research team will meet regularly to ensure that the research protocol is being implemented and performed effectively.

4. Funding

Is this protocol funded? ☐Yes ☒No

If No, specify that costs of the protocol will be covered by funds from the UAB department or other source named: **The costs of the study will be covered by the UAB Department of Pediatric Emergency Medicine.**

If Yes, attach one copy of completed application or request for funding sent to sponsor, and complete a-d.

a. Title of Grant, Contract, or Agreement: _____

b. UAB PI of Grant, Contract, or Agreement: _____

c. Office of Sponsored Programs (OSP) Assigned Number: _____
(If not yet available, enter "Pending" and provide upon receipt from OSP.)

d. Sponsor, Funding Route:
(Check and describe all that apply)
(If subaward, list both the funding source and the institution receiving the direct award)

☐ Gov't Agency or Agencies—Agency name(s): _____
- ☐ Department of Defense (DoD): Identify DoD component: **N/A**
- ☐ Department of Energy (DOE)
- ☐ Department of Justice (DOJ)
- ☐ Department of Education

☐ NIH Cooperative Group Trial - Group name: **N/A**
☐ Private Nonprofit (e.g., Foundation) - Name: **N/A**
☐ Industry, investigator-initiated - Name: **N/A**
Describe the funding arrangement: **N/A**
NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.
☐ UAB Departmental/Division Funds—Specify: **UAB Department of Pediatric Emergency Medicine**

5. Locations Involved

a. Indicate all performance sites that will provide space, services, or facilities for the conduct of this protocol.

☐ UAB Hospital
☐ UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital
☐ The Kirklin Clinic at Acton Road
☐ UAB Callahan Eye Hospital
☐ UAB Clinical Research Unit
☒ Children's of Alabama
☐ Birmingham Veterans Affairs Medical Center
☐ Jefferson County Department of Health
☐ Other (i.e., any performance site not listed above, including those covered by subawards related to this protocol) - Describe: _____

NOTE: Documentation of IRB approvals from sites receiving subawards must be received by the UAB OIRB before funding will be released for that subaward.

b. Describe the space, service, or facilities available for the conduct of the research in the performance sites listed in Item 5.a (For research on UAB campus, include building names):

UAB Emergency Department Academic Offices, OHB 251
UAB Pediatric Emergency Medicine, CPP-1, Suite 110
Children's of Alabama Emergency Department, Ground Floor, Benjamin Russell Tower

c. Is this protocol a clinical trial requiring clinical services at one of the performance sites listed in Item 5.a above? ☒Yes ☐No

If Yes, will any of the services be billed to either participants/their insurance or to the study account through the Hospital Billing Office (PFS) or the HSF Billing Office (MSO)? ☐Yes ☒No

If Yes, submit a Full Fiscal Approval Process (FAP)-designated unit submission to s complete a FAP submission and send to fap@uab.edu. For more on the UAB FAP requirements, go to FAP - SiteMinder Processes.

d. Is this a field study? ☐Yes ☒No

If Yes, describe the community and include information about how the community will be involved in the design, implementation and analysis of the research. This would include focus groups, training local facilitators/community health advisors: _____

e. Has this protocol been rejected or disapproved by another review board (another IRB, similar review board, or departmental review committee(s)) that authorizes the use of its patient populations? ☐Yes ☒No

If Yes, provide name(s) of the review board(s) and reason(s) not approved: _____
Attach copies of the disapprovals.
NOTE: If this protocol is subsequently rejected or disapproved by another review board, promptly notify UAB IRB.

f. Will the protocol be conducted at or recruit participants from the Birmingham Veterans Affairs Medical Center (BVAMC)? ☐Yes ☒No

If Yes, describe the involvement of the BVAMC: _____
Attach the VA IRB approval and VA IRB-stamped consent form(s), if applicable.
NOTE: See the BVAMC section of the IRB Guidebook for more information.

g. Will the protocol be conducted at or recruit participants from the Jefferson County Department of Health (JCDH)? ☐Yes ☒No

If Yes, describe the involvement of the JCDH and list the JCDH clinics being used: _____
Attach the JCDH Research Review Panel approval, if applicable.
NOTE: Human subjects research conducted at certain JCDH clinics requires review by the JCDH Research Review Panel. See the JCDH section of the IRB Guidebook for more information.

6. Clinical Trial

Does this protocol meet the following definition of a clinical trial? ☒Yes ☐No
**A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial here.*

If Yes, you will need to fulfill the following requirements (regardless of funding):

a. All key personnel must complete the Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website here.

b. This protocol must be registered on ClinicalTrials.gov. Provide the National Clinical Trial (NCT) identifier number: NCT03860311

If you have any questions regarding registering a study on ClinicalTrials.gov, email the UAB Center for Clinical and Translational Science at ccts@uab.edu.

7. Multi-Site Studies

a. Is this a multi-site study with the UAB investigator as the lead investigator? ☐Yes ☒No

b. Is this a multi-site study☒ with UAB as a coordinating site? ☐Yes ☒No

c. If Yes to a or b, describe the management of information obtained in multi-site research that might be relevant to the protection of participants. Include, at a minimum, how the following items are managed:

- IRB approvals from other sites
- Unanticipated problems involving risks to participants or others. (For example, if there is an unanticipated problem involving risks to participants or others, which site is responsible for reporting it?)
- Interim results
- Protocol modifications

N/A

8. Drugs

Will any drugs or supplements be *used or studied* in this protocol? ☐Yes ☒No

If Yes, attach the completed Drug Review Sheet.

9. Devices

a. Will any devices be *studied* in this protocol? ☐Yes ☒No

b. Will any *not FDA-approved* devices be *used or studied* in this protocol? ☐Yes ☒No

If Yes to a or b, attach the completed Device Review Sheet.

10. Special Approvals

a. Does this protocol involve the use of radioisotopes? ☐Yes ☒No

If Yes, attach documentation of approval from the Radiation Safety Division.

b. Does this protocol include patients with contagious infections (e.g., mumps, measles, chickenpox, TB, meningitis)? ☐Yes ☒No

If Yes, attach documentation of approval from the Infection Control Committee of the appropriate facilities.

c. Does this protocol involve obtaining remnant biopsy or surgical material from the Department of Pathology or any other source? ☐Yes ☒No

If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Anatomic Pathology Release of Pathologic Materials).

d. Does this protocol require obtaining any remnant clinical laboratory specimens, body fluids, or microbiological isolates from the Department of Pathology or any other source? ☐Yes ☒No

If Yes, attach documentation of approval from the entity or individual providing the materials (e.g., the UAB Division of Laboratory Medicine Release of Pathologic Materials).

e. Does this protocol use stored (existing) specimens from a repository? ☐Yes ☒No

If Yes, attach documentation of approval for use of specimens, and describe how existing specimens are labeled: N/A

11. Use of Specimens

Does this protocol involve the collection of specimens? ☐Yes ☒No

If Yes, complete 11.a-11.h.
If No, skip to Item 12.

a. How will specimens be obtained, processed, distributed, and stored? **N/A**

b. How will specimens be labeled (e.g., unique identifier, medical record number, Social Security number, name, date of birth)? **N/A**

c. How will clinical data associated with the specimens be collected and stored? **N/A**

d. What participant-identifying information will be collected and linked to the specimens? **N/A**

e. What steps will be taken to maximize the confidentiality of linked identifiers? For example, procedures could include using a password-protected computer database to link identifiers, with limited personnel knowledgeable of the password, or coded identifiers released without the ability to link to clinical data (also called "stripped" or "anonymized" specimens). **N/A**

f. Is genetic testing planned as part of this protocol? ☐Yes ☒No
If Yes, describe the planned genetic testing here. **N/A**

g. Will specimens be stored for future use? ☐Yes ☒No
If Yes, indicate whether they will be used for the disease under study in this protocol or research on other diseases. **N/A**

h. Will specimens be shared with other investigators in the future? ☐Yes ☒No
If Yes, answer i. and ii.
i. What identifiers, clinical information and demographic information will be shared; or will the specimens be stripped of identifiers (i.e., anonymized)? **N/A**
ii. Outline your procedure for assuring IRB approval for release and use prior to release of specimens. **N/A**
NOTE: Investigators who receive and/or use these specimens must document approval from the appropriate IRB(s) before the specimens may be released.

12. Gene Therapy

Does this protocol involve gene therapy or administering recombinant materials to humans? ☐Yes ☒No
If Yes, submit the Gene Therapy Project Review Panel Report ***-OR-*** the Protocol Oversight Review Form For Clinical Vaccine Trials, as applicable.

13. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "protected health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? ☒Yes ☐No
If Yes, complete Items 13.a-13.f.
If No, skip to 14.

a. Will the data/information be stored or managed electronically (on a computer)? ☒Yes ☐No

b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)? ☐Yes ☒No
If Yes, attach copies of the privacy notices from each institution/entity, and provide the name of each institution/entity: **N/A**

c. Indicate which of the entities would provide health information for this protocol, maintain health information as it was collected for this protocol, and/or store health information after it has been collected for this protocol.

☐ UAB Hospital or UAB Hospital - Highlands
☐ The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
☐ UAB Callahan Eye Hospital
☒ Children's of Alabama
☐ Jefferson County Department of Health
☐ School of Dentistry
☐ School of Health Professions
☐ School of Medicine
☐ School of Nursing
☐ School of Optometry
☐ University of Alabama Health Services Foundation
☐ UAB Health Centers
☐ Viva Health
☐ Ophthalmology Services Foundation
☐ Valley Foundation
☐ Medical West - UAB Health System Affiliate
☐ None - **If None, skip to Item 14.**

d. Indicate any information systems that will be the sources of information used for the protocol.

☒ A system maintained centrally by UAB Health System (these include the following: HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

To request access to clinical systems for research purposes, visit https://www.oneuabmedicine.org/web/hsis/technical-support, click "Accounts Request" and complete the form indicating access for research purposed.

☒ Another system on a UAB server - Describe: **iConnect EMR (Children's of Alabama)**

e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.

☐ Names
☐ Geographic subdivisions smaller than a state
☒ Elements of dates (except year) related to an individual
☐ Telephone numbers
☐ Fax numbers
☐ Email addresses
☐ Social security numbers
☒ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☐ Biometric identifiers
☐ Web universal resource locators (URLs)

☐ Internet protocol address numbers
☐ Full-face photographic images
☐ Any other unique identifying number - Describe: **N/A**
NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual
☐ None - **If None, skip to Item 14.**

f. Choose one plan to describe your use of the personal health information:

☐ The data collected meet the specifications for a "limited data set" (LDS)
-If the LDS will leave the covered entity or will be received from another covered entity you will need a Data Use Agreement

☒ Research staff will obtain authorization from each participant to use the information
-Include the HIPAA Authorization form, complete except for participant name and IRB protocol number, as the final page of the consent form

☐ PI requests waiver of authorization to use the information
-Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

- The IRB will not accept grant applications and/or sponsor's protocols in lieu of the items as outlined below.
- Do not separate responses from items. Instead, insert your response to each item below the item, keeping the information in the order of this form.

14. Purpose - in nontechnical, lay language

a. Summarize the purpose and objectives of this protocol in one short paragraph.

In this study, we will enroll female pediatric emergency department (ED) patients presenting with a diagnosis of abdominal pain who may have a transabdominal pelvic ultrasound ordered by their treating physician (or nurse practitioner). In order to maximize the visualization of organs deep within the pelvis such as the ovaries and uterus, the patient's bladder must be full. The current practice at our institution, as well as numerous others, is to have a bladder catheter placed immediately when a transabdominal pelvic ultrasound is ordered, and then to fill the bladder in a retrograde manner in order to provide enhanced visualization of the pelvic structures. The process of inserting a bladder catheter into a pediatric patient is an invasive procedure which can be traumatic and painful to the patient. Additionally, if the patient's bladder is already full, this procedure may be unnecessary.

In this study, a point-of-care bladder ultrasound will be performed, upon enrollment of a patient by a study bedside sonographer (our pediatric emergency department nurse practitioners), to assess degree of bladder fullness. This measurement will then be repeated serially while the patient is receiving hydration and the ultrasound will be performed when the bladder is full. We hypothesize that this work flow will result in an equivalent time to transabdominal pelvic ultrasound completion and will reduce the number of potentially traumatic and painful, invasive urethral bladder catheterizations.

b. Describe how outcomes will be measured for this protocol. **The primary outcome variable will be time to completed pelvic ultrasound, described as time from transabdominal pelvic ultrasound order placed to time of transabdominal pelvic ultrasound image completion.**

Secondary outcomes include: proportion of urethral bladder catheterizations and patient's pain level with the process of point-of-care bladder ultrasound vs. bladder catheterization, as measured using Visual Numerical Rating Scale (VNRS) (see attached).

15. Background - in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the design of this protocol. Include any relevant past or current research by the PI. For drug and device studies, summarize the previous results (i.e., Phase I/II or III studies).

Published literature identifies that bladder volume can be accurately measured by point-of-care ultrasound, in qualitative and quantitative ways. Because accepted practice is to perform an invasive urethral catheterization into the bladder of pre- or adolescent females presenting with abdominal pain, when there is a concern for ovarian torsion or other ovarian/uterine pathology, the knowledge that non-invasive methods can predict visualization success, is an important one.

Dessie, et al. in Annals of Emergency Medicine, 2018, showed that not only could pelvic anatomy be well-visualized, but no incomplete pelvic ultrasounds occurred in patients who received their pelvic ultrasound based on point-of-care ultrasound for bladder volume, using a qualitative measure. This study also showed that the procedure could be readily taught and expertise in evaluating qualitative measurements of bladder volume could be reliably assessed after undergoing such brief training by individuals—in their case physicians or research assistants—who were not ultrasonographers.

Our study hypothesizes that similarly reliable results will be able to be obtained by CRNPs currently working in our pediatric ED, without adverse delays or detrimental outcomes in patient care. No such studies have looked at using this group of personnel to perform this goal-directed task to expedite diagnostic workup and avoid an invasive urethral bladder catheterization.

16. Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **0**
Children's of Alabama: 48

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).
Sex: **Female**
Race/Ethnicity: **All**
Age: **8-18**
Health status: **Participants will be females visiting the ED for abdominal, vaginal, or possible genitourinary-related complaints, which may include abdominal pain, vaginal discharge, pelvic bleeding, flank pain, or vomiting, and for which treating physicians/nurse practitioners have a concern for pelvic pathology, such as ovarian torsion, ovarian cysts, or other ovarian or uterine pathology.**

c. From what population(s) will the participants be derived? **Participants will consist of patients of the Department of Pediatric Emergency Medicine.**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **This will be a convenience sample, identified based on treating physician's suspicion that a transabdominal Pelvic Ultrasound/Ovarian Torsion Ultrasound (Order-set) will be placed and for whom arrival to the ED is between the hours of 0700-2300 on Mondays-Fridays, as this correlates with the times that sonographers are in-house, and hence real-time attainment, of transabdominal pelvic ultrasounds is achievable.**

d. Describe the inclusion/exclusion criteria:

Inclusion Criteria:

- Age 8yr-18yrs
- Female
- Likely to have order placed for transabdominal pelvic ultrasound/ovarian ultrasound

- No history of pelvic or bladder reconstructive surgery

Exclusion Criteria:

- Pregnancy (known)
- Critically ill patients
- Patients with known renal or genitourinary structural abnormalities or prior pelvic/GU surgery
- Chronic renal disease
- Patients presenting outside the defined treatment windows

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.

Treatment (2-Scan) Group: N = 24
The group randomized to undergo point-of-care ultrasound to assess bladder fullness, initially and at 30min increments until achieving qualitatively "full" measures by point-of-care ultrasound. When the bladder Is determined to be full, the transabdominal pelvic ultrasound will be performed.

Control Group= N= 24
The group randomized to undergo standard practice, which is to place indwelling urethral bladder catheter for purpose of retrograde bladder filling prior to transabdominal pelvic ultrasound.

f. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

☐ Pregnant Women: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Fetuses: Attach SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Neonates/Nonviable Neonates: SPRF—Pregnant Women, Fetuses, Neonates/Nonviable Neonates
☐ Prisoners: Attach SPRF—Prisoners
☒ Minors (<18 years old): Attach SPRF—Minors
☒ Employees or students at institution where research conducted
☐ Persons who are temporarily decisionally impaired
☐ Persons who are permanently decisionally impaired
☐ Non-English Speakers

For each box checked, describe why the group is included **and** the additional protections provided to protect the rights and welfare of these participants who are vulnerable to coercion:

Because Children's of Alabama routinely treats minors, and because this particular indication is often occurring in minors, we have included minors. Because employees and/or students of UAB or Children's of Alabama may seek care at Children's of Alabama, they may be included in the study population, but are not targeted by the study. Potential participants will be informed that their willingness to participate will have no effect on their employment or academic standing with the University/Hospital. Potential participants will also be informed that their willingness to participate will have no impact on the quality of care received.

g. List any persons other than those directly involved in the protocol who will be at risk. If none, enter "None": **None**

h. Describe the recruitment process (e.g., medical record review, referrals, letter of invitation, existing patients) that will be used to seek potential participants (e.g., individuals, records, specimens). Research recruitment by non-treating physicians/staff may require completion of Partial Waiver of Authorization for Recruitment/Screening.

Study staff will be notified by the bedside nurse or treating physician/nurse practitioner of any patient for whom a transabdominal pelvic ultrasound may be ordered. If the patient appears to be eligible, a member of the study staff will approach the patient to explain the study and obtain informed consent/assent. Other clinicians in the pediatric ED will be made aware of the study so that they can directly refer patients to study staff when appropriate. Study staff will utilize CoA's electronic patient tracking system to obtain information on patient's gender, age, and chief complaint, as well as PMH to determine exclusions, including prior bladder or pelvic surgical procedures, or known pregnancy.

i. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., IRB Protocol Number for approved databases) from which you will recruit participants. **Not Used**

j. Describe the screening process/procedures for potential participants. **No additional screening procedures are planned.**

17. Protocol Procedures, Methods, and Duration - in nontechnical, lay language

a. Describe the procedures for all aspects of your protocol. Tell us what you are doing.

This study enrolls patients presenting to the pediatric ED for clinical complaints including, but not limited to, abdominal or pelvic pain, and for whom the treating physician/nurse practitioner anticipates ordering a transabdominal pelvic/ovarian torsion ultrasound.

Once it has been determined that the participant is eligible, and has provided written informed consent (or legal guardian), or assent (when appropriate), the patient will be randomized into the control or the treatment group. The control group will undergo the standard care where bladder catheterization and timing of imaging is at the treatment team's discretion.

In the intervention group, a study member who has completed asynchronous didactic and hands-on training in bladder ultrasound (see attached summary of US education) will perform a point-of-care bladder ultrasound for qualitative assessment of bladder fullness, using a SonoSite Exporte or SonoSite M-Turbo ultrasound machine. The exam will be performed during a time that does not interfere with the patient's care. This ultrasound will be obtained immediately upon enrollment and serially at 30-minute intervals until the bladder is determined to be full, either by a qualitative ultrasound bladder measurement (attached) OR by patient's sensation of bladder fullness (Bladder Fullness Scale, attached). Bladder Fullness Scale is a 4-point scale which is adopted from a urology bladder sensation measurement tool and has been used in previous, similar research.

If the bladder is not full by this qualitative assessment, the patient will receive additional hydration during the interval between repeated ultrasound examinations. This hydration will be provided by either an oral or intravenous route. The decision on administration of intravenous fluids will be made by the treating physician. Repeated point-of-care ultrasounds to assess bladder fullness will be attained at 30-min increments, or when a patient has the sensation of maximal fullness.

Time to successful transabdominal pelvic ultrasound will be recorded. Bladder ultrasound images will be stored securely and reviewed by blinded ultrasound fellowship-trained or RDMS-certified attending emergency/pediatric emergency physicians to determine inter-rater reliability of the bedside ultrasound interpretation as well as for quality assurance. Such review will be conducted on a weekly or bi-weekly basis. A kappa of 0.6 to be considered excellent correlation.

At the conclusion of the intervention, the patient (or guardian, based on age), will be provided a survey regarding their satisfaction of the interventions, length of stay, and comfort level.

The following information will be recorded from the participant's medical record:

- **Volume of PO or IVF consumed**
- **Time of order of transabdominal pelvic ultrasound**
- **Time of completion of transabdominal pelvic ultrasound (as determined by time stamped on radiology report)**
- **Total ED length of stay, in minutes**
- **Door to MD/NP time, in minutes**
- **Outcome/condition at discharge**
- **MRN**
- **Visit Date**
- **Any adverse outcomes—complications with foley, severe pain, etc.**
- **Discharge diagnosis**
- **Patient weight (in kg)**
- **Patient age (in months/years)**
- **Race**

b. What is the probable length of time required for the entire protocol (i.e., recruitment through data analysis to study closure)? **2 years**

c. What is the total amount of time each participant will be involved? **Each participant's time involved will vary, but is limited to the hospital length of stay. Interaction with each participant will last the amount of time needed to perform the consent process and the exam.**

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "None." **None**

e. List the procedures, the length of time the procedure takes, the total # of times the procedure is performed, and indicate whether each is performed solely for research or would already be performed for treatment or diagnostic purposes (routine care) for the population.
-Insert additional table rows as needed.
-If procedure is sometimes research and sometimes routine care, include on separate lines with number of times as each.

Procedure	Length of Time Required of Participants	Total # of Times the Procedure is Performed	Research (Res) –OR- Routine Care
Bladder volume assessment via ultrasound	**5 minutes**	**5 (maximum)**	☒Res ☐Routine

f. Will an interview script or questionnaire be used? ☐Yes ☒No
If Yes, attach a copy.

g. Will participants incur any costs as a result of their participation? ☐Yes ☒No
If Yes, describe the reason for and amount of each foreseeable cost. **N/A**

h. Will participants be compensated? ☐Yes ☒No
If Yes, complete i-v.
i. Type: (e.g., cash, check, gift card, merchandise): **N/A**
ii. Amount or Value: **N/A**
iii. Method (e.g., mail, at visit): **N/A**
iv. Timing of Payments: (e.g., every visit, each month): **N/A**

v. Maximum Amount of Compensation per Participant: **N/A**

18. Benefits

Describe the potential benefits of the research. **We anticipate that time to successful transabdominal pelvic ultrasound will not vary by qualitatively trending bladder fullness with point-of-care ultrasound as opposed to performing urethral bladder catheterizations for retrograde bladder filling and we hypothesize that this will also decrease the number of invasive urethral bladder catheterizations placed to ensure adequate pelvic anatomy visualization.**

19. Risks - in nontechnical, lay language

a. List the known risks for participants as a result of participation in the research. This should not include the minimal risk of loss of confidentiality. However, it should include any physical, psychological, social, economic, and/or legal risks. If there is a greater than minimal risk of loss of confidentiality describe why this is so. Do not list risks associated with the standard-of-care procedures.

NOTE: Risks included here should be included in the consent form or information sheet, as applicable.

There is potential for mild discomfort experienced by the patient during the bladder ultrasound. The ultrasound gel may feel cold, and the slight pressure of the ultrasound transducer placed on the chest during the ultrasound may cause mild discomfort.

b. Estimate the frequency, severity, and reversibility of each risk listed. **The risk of discomfort during the ultrasound is rare, mild, and reversible.**

c. Is this a therapeutic study or intervention? ☒Yes ☐No

If Yes, complete i.-iii.

i. Describe the standard of care in the setting where the research will be conducted: **Standard of care is immediate placement of invasive urethral bladder catheter for retrograde bladder filling prior to attaining transabdominal pelvic ultrasound.**

ii. Describe any other alternative treatments or interventions: **Alternatives: 1) relying on patient's subjective perception of bladder fullness, or 2) attempts at transabdominal pelvic ultrasound after empiric "bladder filling" without point-of-care ultrasound visualization, such as arbitrary PO fluid consumption or IV fluid administration**

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using: **If participants in the treatment group comply with treatment protocol, urethral bladder catheterization could be avoided altogether or could be delayed, per treating physician's/nurse practitioner's discretion, and performed later if time to successful "full" bladder by point-of-care assessments and active hydration, were unsuccessful. Additionally, any participant who consents/assents, and then wishes to withdraw will immediately be converted to standard of care, which could mean routine performance of invasive urethral bladder catherization, or other measures, at treating physician's/nurse practitioner's discretion.**

d. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? ☐Yes ☒No

If Yes, describe the provisions that have been made to make these resources available. **N/A**

e. Do the benefits or knowledge to be gained outweigh the risks to participants? ☒Yes ☐No

If No, provide justification for performing the research: **N/A**

20. Precautions/Minimization of Risks

a. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks. **This study is minimal risk. The PI and study staff will monitor for cues that participants are experiencing physical discomfort or are otherwise too ill to participate.**

If the protocol involves drugs or devices skip Items 20.b. and 20.c. and go to Item 21. Instead include this information in the Drug Review Sheet or Device Review Sheet, as applicable.

b. If hazards occur to an individual participant, describe (i) the criteria that will be used to decide whether that participant should be removed from the protocol; (ii) the procedure for removing such participants when necessary to protect their rights and welfare; and (iii) any special procedures, precautions, or follow-up that will be used to ensure the safety of other currently enrolled participants. **Because this study is minimal risk, we have not established criteria that would be used to remove a participant from the protocol, or established procedures for removing participants or following other participants for safety. Any decision to remove a participant from the study would be made by the study PI, the patient/family, or the treating physician.**

c. If hazards occur that might make the risks of participation outweigh the benefits for all participants, describe (i) the criteria that will be used to stop or end the entire protocol and (ii) any special procedures, precautions, or follow-up that will be used to ensure the safety of currently enrolled participants. **Because this study is minimal risk, we have not established criteria that would be used to remove a participant from the protocol, or established procedures for removing participants or following other participants for safety. Any decision to remove a participant from the study would be made by the study PI, the patient/family, or the treating physician.**

21. Informed Consent

a. Do you plan to obtain informed consent for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent (obtain signatures) for this protocol? ☒Yes ☐No

If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained? **Study staff will be notified by the treating physician (or nurse practitioner) or bedside nurse that the patient is presenting with a complaint for which a transabdominal pelvic ultrasound may be ordered. If the patient appears to be eligible, and who matches the inclusion criteria, then a member of the study staff will approach the patient, explain the study and request written informed consent.**

d. Who will conduct the consent interview? **A member of the study staff.**

e. Who are the persons who will provide consent, permission, and/or assent? **Each participant or legal guardian (in the case of minors) will consent/assent for themselves, as applicable.**

f. What steps will be taken to minimize the possibility of coercion or undue influence? **It will be stressed to all individuals/legal guardians that participation is voluntary.**

g. What language will the prospective participant and the legally authorized representative understand? **English**

h. What language will be used to obtain consent? **English**

i. If any potential participants will be, or will have been, in a stressful, painful, or drugged condition before or during the consent process, describe the precautions proposed to overcome the effect of the condition on the consent process. If not, enter "None." **This study will enroll patients of the pediatric ED for whom a transabdominal pelvic ultrasound may be ordered for a related clinical complaint (i.e. pelvic pain, vaginal bleeding, abdominal pain, dysuria or other conditions as deemed likely to need a transabdominal pelvic ultrasound by the treating physician/nurse practitioner.) Study staff will look for cues that potential participants might be too ill to participate. Even when**

participants have been enrolled, our staff will continue to monitor for distress, and will inform participants that they can discontinue the study procedure at any time.

j. If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each. If not, enter "None."
None

k. How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll? If not 24 hours or more, describe the proposed time interval and why the 24-hour minimum is neither feasible nor practical. **Because most patients visiting the pediatric ED and for whom the treating physician/nurse practitioner thinks a transabdominal pelvic ultrasound is needed to diagnose, treat, or rule-out potentially life-threatening complaints, and for whom, such delay of 24-hours, could significantly delay emergency medical treatment, we request a waiver of the 24-hour waiting period.**

22. Procedures to Protect Privacy

Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed. **Conversations with participants will be held in private areas where individuals will not be publicly identified or embarrassed.**

23. Procedures to Maintain Confidentiality

a. Describe how you will store research data to maintain confidentiality (both paper records and electronic data), including how access is limited. If data will be stored electronically anywhere other than a server maintained centrally by UAB, identify the department and all computer systems used to store protocol-related data. **Data from this study will be collected on paper and entered into an Excel database housed at UAB Department of Pediatric Emergency Medicine on an HSIS-controlled server behind a UAB firewall. The Excel database will be password-protected, and only accessible by study staff. Participants will be entered on a pre-numbered enrollment log in sequential order, as a way of linking the participant and the study ID. Study participants will be identified only by a study ID within the database, and the paper enrollment log will be kept in a locked file cabinet within a locked office in the Department of Pediatric Emergency Medicine.**

b. Will any data from this protocol be given to any person, including the subject, or any group, including coordinating centers and sponsors? ☒Yes ☐No
If Yes, complete i-iii.
i. Who will receive the data? **The data from this study may be published.**
ii. What data will be shared? **Aggregate data or results from data analyses will be shared.**
iii. How will the data be identified, coded, etc.? **Data will be shared in aggregate form only.**

24. Genomic Data Sharing (GDS)

Researchers who collect genomic data as part of a NIH grant funded after January 25, 2008 may be required to submit those data to a NIH database for broad scientific sharing. See Genomic Data Sharing in the IRB Guidebook for more information.

a. Does this protocol involve the proposed submission of genetic data into genomic repositories created to share genetic information for research purposes? ☐Yes ☒No

b. Will UAB be uploading the final genomic data to the central repository (e.g., dbGaP)? ☐Yes ☒No
If Yes to both a and b, submit a Detailed Data Sharing Plan to the IRB for review. This plan should include any known data use limitations and indicate whether aggregate-level data are appropriate for general research use. For guidance see the NIH Genomic Data Sharing Policy.

c. Submit a copy of the NIH Institutional Certification Form.
To determine which certification form to include, answer i-ii.

i. Was this protocol funded prior to January 25, 2015? ☐Yes ☒No

- **If yes,** and consent will be obtained, submit the Extramural Institutional Certification - Before January 25 - With Consent.
- **If yes,** and consent will not be obtained, submit the Extramural Institutional Certification - Before January 25 - Without Consent.

ii. Was this protocol funded after January 25, 2015? ☐Yes ☒No

- **If yes,** submit the Extramural Institutional Certification - After January 25.

25. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None."

None