INSTRUCTIONS

- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example (**1.1**) must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: Ultrasound Imaging of Kidney Stones and Lithotripsy

1.1 Home institution. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[X] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

Our other two studies, Ultrasonic Propulsion of Kidney Stones (STUDY00002792) and Propulsion 2 (STUDY00002899), use the same investigational device. In this study, the device is used for imaging only

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[X] **No**
[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

Specific questions this research project is designed to answer:

1. How well are stones of different types seen by two standard ultrasound techniques (B-mode and Doppler)?
2. How accurate is the measurement of stone size on ultrasound?
3. How accurate is ultrasound at detecting stones?
4. Can ultrasound reliably detect stones smaller than 2 mm?
5. How much do stones and stone pieces move during lithotripsy treatment?

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

Observational study examining the accuracy of ultrasound imaging.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

Descriptor
[ ] 1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
[ ] 2. Part of an institution, organization, or program's own internal operational monitoring.

☐ 3. Improve the quality of service provided by a specific institution, organization, or program.

☒ 4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that:

- Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or
- Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

☐ 5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.

☐ 6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.

☐ 7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.

☐ 8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)

☐ 9. Expanded access use of a drug or device not yet approved for this purpose

☐ 10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

Lithotripsy (application of focused shock waves) is the most common treatment for kidney stones. It is effective more than half the time, but always is accompanied by some side effects. Fluoroscopy (x-rays) is used to align the stone and periodically confirm alignment. The goal of this study is to investigate ultrasound and acoustic techniques to provide the urologist with more information during lithotripsy treatment. The expectation is that this information would help the urologist make the treatment safer and more effective.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

N/A

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing

[X]	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
[ ]	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
[ ]	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing
[ ]	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Adult patients from the UW Urology clinic or the UW Kidney Stone Center at Northwest Hospital with at least one kidney stone and/or are being treated for nephrolithiasis (kidney and ureteral stones) with either lithotripsy or ureteroscopy (URS).

2.2 Inclusion and exclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

Inclusion criteria:

- Patients with at least one kidney stone and/or are being treated for nephrolithiasis with either lithotripsy or ureteroscopy (URS)
- Age 18 and up

Exclusion criteria:

- Inability to read the consent form
- Acute pain at the time of consent, which might impair the subject's decision-making at that time

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

[X] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☐ **No**
☐ **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

☐ **No**
☐ **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed or submitted.

Population	Worksheet
☐ Children	WORKSHEET: Children
☐ Children who are wards	WORKSHEET: Children
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates

☐ Pregnant women WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

☒ **No**
☐ **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

☒ **No**
☐ **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[X] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

We were recently approved to remove our limit on subject numbers (in DORA mod #26). We were estimating an additional 200 subjects to add to the previously approved 170.

[ ] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research ***For clinical trials: provide numbers for your site and for the study-wide total number***

3 RESEARCH SETTING

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

Dr. Bailey works with Dr. Harper to recruit his patients at the UW Urology clinic and the UW Kidney Stone Center at Northwest Hospital. Dr. Harper works primarily with kidney stones, so has a large patient population to recruit from.

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

There are no site-specific cultural issues, customs, beliefs, or values that we are aware of that may affect our research or how it is conducted.

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A Only Washington State laws are applicable.

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

N/A There are no local administrative or ethical requirements that are affecting our research currently.

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

The research team pre-screens medical records of patients at the UW Urology clinic and the UW Kidney Stone Center for Kidney Stones at Northwest Hospital for study eligibility. As the clinics have become increasingly busy and his patient load continues to grow, the ability to pre-screen the medical records allows the research staff to inform him of eligible patients, which makes his work load for the study easier. The study team may attempt to contact patients by phone before their visits to gauge interest in the study using the approved talking points. If a member of the study team is able to speak with a patient, they describe the study to them if they are interested.

Drs. Harper, Sorensen, and Sweet inquire if eligible patients at their clinic visits are interested in participating in a research study. If a patient is interested, a member of the study team will discuss the consent form with that person. However, as clinic has become increasingly busy and his patient load continues to grow, the ability to pre-screen the medical records allows the research staff to inform him of eligible patients, which makes his work load for the study easier.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

We have talking points for phone conversations for pre-screening patients.

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

☐ **No**

[X] **Yes** → If yes, describe the nature of the relationship.

Drs. Harper, Sorensen and Sweet are clinical care providers for the patients being recruited.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

N/A

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A

4.6 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[X] **No** → If no, you must still answer question **4.7** below.

[ ] **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

[ ] **No** → If no, describe the information you will provide during the consent process and for which procedures.

[ ] **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

4.7 Data and specimens for recruiting and screening. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain for recruiting and screening (prior to obtaining consent) and whether you will retain it as part of the study data.

Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time.*

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

We have a HIPAA waiver in place for pre-screen activities and we are not obtaining consent for recruiting or pre-screening. Names and EMR data are not obtained or recorded during pre-screening, other than for disclosure to UW Medicine Compliance. If a patient consents to the study, their name, EMR number and some PHI is collected as part of the study, but only after written consent is obtained for the patient to participate in the study.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB ***POLICY: Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*

Patients presenting to the UW Urology clinic or Kidney Stone Center with at least one kidney stone or who are being treated for nephrolithiasis (kidney and ureteral stones) and undergoing surgery for stones (shock wave lithotripsy, ureteroscopy, or percutaneous nephrolithotomy) to manage their stones will be screened for this study. Those who meet the study criteria and indicate initial willingness to participate to the clinical staff will be approached by research staff. The research staff will explain the study and obtain informed consent.

Group 1 – Subjects with kidney stones

- The first group consists of awake, not anaesthetized subjects with kidney stones. In this group, we want to look at how well ultrasound sees and sizes the stone, tested by comparison to CT in their medical record.
- Existing CT, x-ray, ultrasound, or fluoroscopy images of the stone will be saved from the medical record.
- The subjects will be awake during the imaging. They will be offered an examination gown during imaging and may be asked to roll to different positions for improved imaging or so that both kidneys may be imaged. These subjects may be asked to hold their breath for up to 10 seconds during imaging.
- We place a water-based gel and ultrasound probe against the subject's skin on the back, sides, and abdomen. We will image the kidney, ureter, and/or bladder with B-mode and Doppler ultrasound. Images will be saved. Audio annotation for the ultrasound images will be saved.
-

- Imaging procedure: We image the kidney(s), ureters and bladders of all subjects with the Verasonics research ultrasound device (with either C5-2 or P4-2 Philips ATL HDI commercial, clinical imaging probes – both FDA approved). These subjects who are not undergoing surgery may also have additional imaging done with the Supersonic Imagine Aixplorer, a commercial clinical ultrasound (with the system's FDA approved imaging probes). All images from the devices will be saved as de-identified images for research purposes. We save the images and the raw electrical signals received from the probe and used to make the images. We capture the images through a screen capture program that builds all the image captures into a video. There is no video camera and no images of the subject taken; there is a video composed of the ultrasound examination. The video also captures the room audio – this is used to "annotate" where we are in the kidney, what stone number we are looking at, etc. Nothing identifying the subject will be recorded, except it is possible the patient name may be recorded during this process. The ultrasound examination takes about 20-30 minutes per side.
- Images of stones taken by CT, ultrasound, or x-ray as part of clinical follow-up may be accessed in the medical record and saved. 3D images will not be placed in the medical record.
- We will use our prototype scanning device to perform a 3D imaging scan of the kidney. The prototype device uses a Verasonics research ultrasound imager with a standard clinical ultrasound imaging probe. The ultrasound imaging probe is secured in a rectangular frame that holds a motorized rotating ring, and our device performs a mechanically-operated 3D imaging scan of the kidney under computer control. The motorized rotating stage is a commercial product (RTHM-190, IntelLiDrives Inc., Philadelphia, PA). The sonographer will place the prototype 3D rotational imaging device at the same site was used for the 2D ultrasound scans. We will ask the subject to hold their breath for up to 10 seconds after inhaling while we perform the automated 3D ultrasound scan. We may repeat the procedure for quality assurance.

Group 2 – Subjects being treated by stone management surgery:

- The second group consists of anaesthetized subjects who are undergoing surgery (shock wave lithotripsy, ureteroscopy, or percutaneous nephrolithotomy) to manage their kidney stones. In this group, we will assess how well ultrasound sees and sizes the stone by comparing to the actual size of stone in surgery observation. In addition, the targeting of the treatment will be tested.
- Existing CT, x-ray, ultrasound, or fluoroscopy images of the stone will be saved from the medical record.
- The subjects will not be awake during the imaging. The imaging will occur during the procedure. We place a water-based gel and ultrasound probe against the subject's skin on the back, sides, and abdomen.
- We will image the kidney, ureter, and bladder with B-mode and Doppler ultrasound during surgery. Images will be saved. Audio annotation for the ultrasound images will be saved. Fluoroscopy images and endoscopic video images – taken normally during treatment- will be saved. When shock waves were applied and how many were applied will be recorded.
- Imaging procedure: We image the kidney(s), ureters and/or bladders of all subjects with the Verasonics research ultrasound device (with either C5-2 or P4-2 Philips ATL HDI commercial, clinical imaging probes – both FDA approved). These subjects may also be imaged with the Supersonic Imagine Aixplorer, a commercial clinical ultrasound (withthe system's FDA approved imaging probes). All images from the devices will be saved as de-identified images for research purposes. We save the images and the raw electrical signals received from the probe and used to make the images. We capture the images through a screen capture program that builds all the image captures into a video. There is no video camera and no images of the subject taken; there is

a video composed of the ultrasound examination. The video also captures the room audio – this is used to "annotate" where we are in the kidney, what stone number we are looking at, etc. Nothing identifying the subject will be recorded, except it is possible the patient name may be recorded during this process. The ultrasound examination takes about 20-30 minutes, as only 1 side is imaged.

- Images of stones taken by CT, ultrasound, or x-ray as part of clinical follow-up may be accessed in the medical record and saved. The chemistry of the stone (if determined by clinical lab analysis) will be recorded.
- We will use our prototype scanning device to perform a 3D imaging scan of the kidney. The prototype device uses a Verasonics research ultrasound imager with a standard clinical ultrasound imaging probe. The ultrasound imaging probe is secured in a rectangular frame that holds a motorized rotating ring, and our device performs a mechanically-operated 3D imaging scan of the kidney under computer control. The motorized rotating stage is a commercial product (RTHM-190, IntelLiDrives Inc., Philadelphia, PA). The sonographer will place the prototype 3D rotational imaging device at the same site was used for the 2D ultrasound scans. We will ask the subject to hold their breath for up to 10 seconds after inhaling while we perform the automated 3D ultrasound scan. We may repeat the procedure for quality assurance.

- Magnetic tracking will not be used.

5.2 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

Existing images of stones, audio annotated image videos, image raw data, size of stones, location of stones, number of stones, type of stones, treatment records, fluoroscopy images, endoscopic video images, the time shock waves were applied, number of shock waves applied, weight, height, race, age, sex and ethnicity.

5.3 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

We are obtaining some data from the subjects and some data from the subjects' EMR.

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist at the time when you submit this application)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

Retrospective data: Existing images of stones weight, treatment records, height, race, sex and ethnicity
Prospective data: audio annotated image videos, image raw data, fluoroscopy images, endoscopic video images, the time shock waves were applied and number of shock waves applied
Retrospective and Prospective data: images of stones, size of stones, location of stones, number of stones, type of stones,

5.5 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

The study team will have access to direct identifiers: subjects' names, DOB, medical record number, email address, surgery accession number.
The study team will also have access to the information that links between direct identifiers and the data.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

The study team will obtain direct identifiers: subjects' names, DOB, medical record number, email address.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

- [ ] You will store the identifiers with the data. Describe the data to which this applies:
- [X] You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

  We will keep the subjects' names, DOB, and medical record numbers separate from the rest of the data.
- [ ] You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.6 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[X] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

[ ] **No**
[ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.

[ ] **No** → If no, skip the rest of this question; go to question **5.8**
[X] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

We will access names and EMR data for identifying and screening potential subjects, and record them only for disclosure to UW Medicine Compliance.

We will access their medical records using their names, DOBs and/or medical record numbers in order to abstract data related to their kidney stone(s), such as existing stone images.

b. Is any of the PHI located in Washington State?

[ ] **No**
[X] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

We will access the PHI by referral from clinic physicians and we will obtain the PHI from Orca and Epic medical records.

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

We obtain HIPAA authorization from the subjects before we access their medical records for study data. Specific information we will obtain includes existing images of stones, size of stones, location of stones, number of stones, type of stones, treatment records, weight, height, race, sex and ethnicity.

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

[X] **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

We do not obtain HIPAA authorization from the subjects for their names, medical record numbers, phone numbers, or email addresses. We use these for pre-screening purposes.

Provide the following assurances by checking the boxes.

[X] The PHI 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 for which the use or disclosure of PHI would be permitted.

[X] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

[X] There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will you obtain or generate genomic data (as defined at *https://gds.nih.gov/13faqs_gds.html*)?

[X] **No**
[ ] **Yes** → If yes, answer the question below.

a. Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

[ ] **No**
[ ] **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.9 Data and specimen sharing/banking. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[X] **No**
[ ] **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

c. Who will oversee and/or manage the sharing?

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

e. Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

☐ **No**
☐ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 6.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

☐ **No**
☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

☐ **Confirmed**

5.10 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

There is a pre-screen talking points script used to contact patients initially about the research and explain the details of the study.

5.11 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

X	**No**
	Yes → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.12 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

X	**No**
	Yes → If yes, describe the alternatives.

5.13 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

We will upload the talking points script to Zipline. It explains the purpose of the research and the details of the study.

5.14 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

[ ] All of your research procedures → Go to question **6.2b.**

[ ] None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission	Reason why you will not obtain parental permission	Will you inform them about the research?[2] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then skip to question 7.5.
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups → Use the table below to provide your justification, then go to question 7.4.a.

☐ All of your research procedures and child groups → Go to question **7.4.a**, do not complete the table

☐ Some of your research procedures and/or child groups → Complete the table below and then to go question 7.4.a

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented	Reason why you will not document assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.5 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.6 Other regulatory requirements. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.

WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

- [X] Adult subjects
- [ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

- [X] **No**
- [ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

A member of the study team (study coordinator, resident, research fellow, physician) will approach the patient about the study in the privacy of a clinic room at UWMC or the Kidney Stone Center at NWH. The consent form will be discussed with the patient, including all risks, other options, and to explain that their standard care will not be affected by the decision whether or not to participate. The patient will be provided an opportunity to ask any questions she/he might have. Copies of the signed consent and HIPAA forms will be provided to participants, but the originals will be kept with the study files.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

During the consent process and discussion, Research Coordinator and/or research team member will have a good sense of whether the participant understands the information and will ask if the participant has any questions. If there is a doubt, the study team member will consult with the clinicians and/or PI to ensure that the participant is able to consent.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☐ **No**

☒ **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

Patients will mainly be recruited in the PI's clinics. In order to reduce any effect of the setting or relationship on their decision, the PI will not be consenting the patients for the research study. The patients will be informed that their standard care will not be affected by their decision of whether or not to participate. They will also be told that participating in this research study is completely voluntary and that they may end their participation at any time.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

N/A

8.3 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

☐ None of your research procedures	→ Use the table below to provide your justification then go to question **8.4.**
☒ All of your research procedures	→ Do not complete the table; go to question **8.4.**
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

8.4 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.5 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person; excluding individuals who cannot read and understand the consent form.

If a patient has difficulty with the standard documentation process, that person will not be enrolled into the study.

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

- [X] **No**
- [ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

- [ ] **No**
- [ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.7 Cognitively impaired adults, and other adults unable to consent.

a. Cognitively impaired adults and other adults unable to consent. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[X] **No** → If no, go to question **8.8**.

[ ] **Yes** → If yes, answer the following questions.

a.1. Rationale. Provide your rationale for including this population in your research.

a.2. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will re-assess decision-making capacity and consent during that time.

a.3. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

a.4. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

a.5. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.8 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

The PI and other physicians who refer/recruit for the study generally ask the patient first if they are interested in hearing more about a research study they may be eligible for. When screening by phone, the study staff will perform phone calls to the contact number listed in the medical record during business hours. No messages will be left if the patient is not available.

We are always willing to describe the measures we take to protect their information and answer questions from subjects about where we received their contact information. We stress the voluntary nature of the study and that they can stop participating at any time.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[X] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?
  [ ] **Yes**
  [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[X] **No**

[ ] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so: _____

9.4 Retention of identifiers and data. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf***

[ ] **Confirm**

9.5 Certificates of Confidentiality. Do you have or, are you planning to obtain, a federal Certificate of Confidentiality for your research data?

[X] **No**

[ ] **Yes**

9.6. [DETERMINATION] Data security protections. Identify the data risk level and the security protections that will be provided for all sites where data will be collected, transmitted, or stored. All data in the same system should be maintained at the highest risk level of any type of data. For example, if some of the data are level 1 (L1) and some are level 3 (L3), then the whole system should be protected at level 3 (L3).

9.6.a. Choose the level(s) of protections you will apply to the data. Refer to the WEBPAGE Data Security Requirements Guidance to answer this question.

☐ Level 1
☐ Level 2
☒ Level 3
☐ Level 4

If you checked more than one box above, use the text box to describe which level will apply to which data and in which system and/or site(s) it will be stored.

Click or tap here to enter text.

9.6.b. HSD allows researchers to request exceptions to data security requirements, if the exception is necessary and does not significantly increase risk to participants. If there are data security requirements within the selected risk level(s) listed in 9.6.a which will not be followed, list those here. Specify the data and the system or site(s) where this exception will apply. Provide a rationale for the exception and explain what (if any) alternative measures will be taken to protect the data.

Example - If you intend to store subject identifiers with study screening data (not permitted under requirement U9 for Risk Levels 3-4), then indicate this in the box below (e.g., "We will not adhere to requirement U9 for screening data because we are capturing this in REDCap via subject surveys which maintains the data together. The REDCap system has other sufficient security measures that we feel mitigates the risk of maintaining the information together").

Click or tap here to enter text.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Injury from the Hardware: The risk of injury related to the hardware equipment is minimal. The investigational device is comprised of four principle commercially available off-the-shelf components: the Verasonics data acquisition system (VDAS), ultrasound transducer, host computer, and driving software. The transducers are commercially available FDA cleared devices purchased used from a compliant source. The computer is an off the shelf commercially available PC. The VDAS unit is available through Verasonics Inc., and has previously received IRB approval within the UW for use below the FDA acoustic output intensities. Verasonics has prepared

a risk analysis for its device (uploaded to Zipline). The driving software includes Windows operating system and MATLAB computing software.
The equipment is inspected (annually) by the University of Washington Science and Instrumentation Division for electrical safety. This includes an evaluation of electrical leakage from each individual piece of equipment and the transducer, ground impedance, and line isolation. Users will conduct a visual check of the equipment, ultrasound transducer, and AC lines prior to starting the system to verify the system is in good operating order. If damage is observed, the user will replace the damaged item (if it is within their abilities), or contact someone who can.
Upon startup of the program a routine will be automatically initiated that tests for damage to the transducer elements. A log will be kept of these test results and a message placed on screen to notify the user if the study should be aborted. The output of the Push pulse will be test using a phantom to verify the output of the push pulse is within specification. The time delay allowed between Push bursts will be tested against the expected delay. The system will be tested at 50 Vp and 90 Vp. A change in color to the Push button will indicate when the program has released access to the user.

Diagnostic Mode (B-mode and Doppler): There are no additional risks associated with the diagnostic delivery (B-mode and Doppler) of ultrasound (US) than occurs with conventional US systems.

Device-related: The 3D ultrasound device under development is comprised of three commercially-available off-the-shelf components: a Verasonics ultrasound imaging system, an ultrasound transducer, and a motorized rotary stage. The Verasonics imager (Model V-1, Verasonics Inc., Kirkland, WA) is a research instrument that has previously received IRB approval within the UW for use below FDA limits for acoustic output intensities. The ultrasound transducer (P4-2, Philips Ultrasound, Bothell, WA) is an FDA-cleared device purchased from a compliant source in 'used' condition. The rotary stage (RTHM-190, IntelLiDrives Inc., Philadelphia, PA) is a commercial device designed for rotation of optical laboratory components.

The equipment is inspected (annually) by the University of Washington Scientific Instruments Division for electrical safety. This includes an evaluation of electrical leakage from each individual piece of equipment and the transducer, ground impedance, and line isolation. System operators will conduct a visual check of the equipment, ultrasound transducer, and electrical connections prior to starting the system to verify the system is in good operating order. /
Breach of Confidentiality: There is a potential risk of breach of confidentiality. See data security protections in 9.6.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3
[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[X] **No**
[ ] **Yes** → If yes, identify the procedures.

10.4 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[ ] **No**
[X] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [X] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

Bradley Spak, MD; University of Washington

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.5 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

N/A

10.6 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.7 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Subjects may also be discontinued by the study coordinator or physician because of an adverse event or other event related to the subject's health or welfare. Subjects may be discontinued from the study because their stone could not be identified on ultrasound. Subjects discontinued prior to the investigational treatment will not be counted as an enrollment and no further data will be collected.

10.8 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

None

10.9 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

☐ **No**
☒ **Yes** → If yes, explain whether and how you would share the information with the subject.

It is possible that the diagnostic ultrasound imaging will detect disease that was previously unknown. If the sonographer detects something abnormal, the images will be saved and either a dedicated genitourinary radiologist or one of the clinical urologists will review the images and inform the subject of any potential disease.

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

☒ **No**
☐ **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.10 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

If a commercial product or patent could result from this study, subjects will not receive any remuneration/compensation.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

11.2 Costs to subjects. Describe any research-related costs for which subjects may be responsible (e.g., CT scan required for research eligibility screening; co-pays; cost of a device; travel and parking expenses that will not be reimbursed).

There are no research-related costs for which the subjects may be responsible.

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

None

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The study team is adequately trained and informed about the research procedures and the device in-person. There is a dedicated regulatory specialist on the study team who informs study team members about general regulatory-related training requirements and changes (i.e., GCP training requirement for NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials).

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☐ **No**

☒ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.