FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

99th Medical Group

PARENTAL INFORMED CONSENT DOCUMENT

Title of Protocol:	**EPIC**: **E**ffect of **P**ovidone **I**odine periurethral **C**leansing on level of contamination with clean catch: A randomized control trial.
FWH #:	FWH20190009H

KEY INFORMATION ABOUT STUDY PARTICIPATION: We are asking for permission for your child to participate in this study because he/she is aged 1 month to 12 months and their Primary Care Manager (PCM) determined that your child requires a urine sample be collected. This study will compare two types of periurethral (the area around the opening that transports urine outside the body) cleansing techniques. Once your child is deemed eligible to participate, he/she will be randomized (like flipping a coin) into either the control or experiemental group. The control group will receive periurethral cleansing with normal saline (a mixture of salt and water) and the experiemental group will received periurethral cleansing with iodine swabs (antiseptic which contains iodine). We will then ask you to complete a Satisfaction Survey.

The procedures are safe and the only possible negative outcome could be skin irritation from the iodine prep group. There are risks that urine sample may show that there was growth of bacteria on culture in which event the parents will be contacted by the PI or AI and made aware of these results and will be advised to follow up with their pediatrician. There is a possibility that the child has an allergic reaction to the iodine swab. If this occurs, the child will be referred to their pediatric PCM.

INFORMATION ABOUT THIS CONSENT FORM:
Your child may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to your friends, family, or a doctor about your child's participation in this study. If you decide to have your child take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the purpose and procedures of the study, including risks and possible benefits to your child. If your child is taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION: Granting permission for your child to participate in this study is completely voluntary. If you choose not to allow your child to participate in this research study or leave before the study is completed, your decision will not affect his/her eligibility for care or any other benefits to which they are entitled as a DoD beneficiary. If significant new findings develop during the course of this study that may relate to your decision to allow your child to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your child's rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Travis Callahan, EMPA-C	Capt	USAF	Emergency Department/99MDG

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STUDY SPONSOR: There are no sponsors of this study.

PURPOSE OF THIS STUDY (Why is this study being done?)**:**
You are being asked to grant permission for your child to participate in a research study to determine if the use of an antiseptic iodine preparation prior to the Quick-Wee method of urine collection in pediatric patients will decrease rates of urine contamination. We are asking for permission for your child to participate in this study because he/she is aged 1 month to 12 months and their Primary Care Manager (PCM) has determined that your child requires a urine sample be collected as a standard of care course of treatment.

The Quick-Wee method of urine collection is when we use cold water soaked gauze to stimulate urination for urine collection in pediatric patients will decrease rates of urine contamination.

This study will compare two types of periurethral (the area around the opening that transports urine outside the body) cleansing techniques. The control group will receive periurethral cleansing with normal saline (a mixture of salt and water) and the experiemental group will received periurethral cleansing with iodine swabs (antiseptic which contains iodine).

This study will enroll approximately 60 subjects overall.

PROCEDURES: If you decide to grant permission for your child to take part in this research study, you will be asked to sign this consent form. During your child's participation in this study, you will be asked to make approximately 1 outpatient visit with Capt Travis Callahan, the Principal Investigator (PI), or study staff. This will be in conjunction with standard of care visit for the urine collection as ordered by your child's pediatric PCM.

Study-Related Screening Visit: [Research-Related]

- Obtain your signed Informed Consent Document and Parental HIPAA Authorization.
- Review your child's past medical history.
- You will be asked if your child has had an allergic reaction to iodine in the past (i.e. skin irritation, rash, etc.).

Assignment to Research-Related Study Groups:[Research-Related] When it is determined that your child is eligible for the study, he/she will be assigned by chance (like flipping a coin to 1 of 2 study groups:

- **Group 1:** Periurethral cleaning with normal saline
- **Group 2:** Periurethral cleaning with an iodine swab

Study Procedures: As a participant, your child will undergo the following research-related procedures:

Visit 1-Day 1 (may be the same day as screening visit):

- The research staff will complete the Participant Data Sheet for your child's urine collection [Research-Related]
- Your child's urine sample will be collected. [Standard of Care]
- Investigators will utilize the periurethral cleansing method, based on your child's assigned study group. [Research-Related]

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- You will be asked to complete the Satisfaction Survey [Research-Related]

RISKS OR DISCOMFORTS: The investigators have designed this study to learn how well the Quick-Wee method of urine collection (with the use of iodine swabs) compares with the Quick-Wee method of urine collection (with the use of saline) . There are risks to taking part in this research study. One risk is that your child may have side effects to iodine while on the study. Everyone taking part in this study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that your child has while taking part in the study. For more information about risks and side effects, ask one of the researchers or study staff.

Likely and not serious:

- Crying from the cold saline water
- Allergy to iodine

There may be a risk of inadvertent breach of confidentiality.

WITHDRAWAL FROM THE STUDY: If you first agree to allow your child to participate and then you change your mind, you are free to withdraw your consent and discontinue your child's participation at any time. Your decision will not affect your child's ability to receive medical care and your child will not be penalized or lose any benefits to which he/she would otherwise be entitled.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY? If you decide to withdraw your child from this study early, please discuss your decision with the principal investigator.

COULD YOUR PARTICIPATION END EARLY?The researcher may withdraw your child from the study prior to the study's end, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.
- The researcher decides that continuing your child's participation is not in his/her best interests.
- Your child becomes ineligible to participate (i.e. your child is unable to urinate in a period of 5 minutes following stimulation).
- Your child needs treatment not allowed in the study.
- The study is cancelled.
- Unanticipated circumstances.

Should your child be withdrawn from the study, he/she will still be able to get their urine collection without participating in the study. If your child loses his/her status as a military health care beneficiary, he/she can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

BENEFITS: The possible benefit of your child's participating in this study is that there may be decreased levels of urine contamination in either the saline or the iodine prep group's urine sample. If so, this will give the child's treatment team more reliable test results and decrease the need for more invasive testing. Additionally the normal saline preparation may be effective at decreasing level of contatmination as the iodine. However, there is no guarantee or promise that your child

will receive any personal benefit from this study. We hope the information learned from this study may help future patients.

COSTS: Will taking part in this study cost anything? The investigators have designed this study so that there is no cost to you for allowing your child to participate in this study other than what it will cost you to travel to the research appointments, beyond any scheduled standard of care appointments.

The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your child's entitlement to medical and dental care is governed by Federal laws and regulations.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for allowing your child to participate in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS: Choosing not to allow your child to participate in this study is the only alternateive. Your child can still receive standard of care treatment through their Primary Care Provider, without participating in this study.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION: Records of your childs participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give permission for information gained from your child's participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. Your child will not be personally identified; all information will be presented as anonymous data.

Your child's records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your child's research record. All research data will be kept separately from your child's identifiable information in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between your child's identity and the research information will be destroyed, which means research information about your child will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about your child for this study will not be used for any additional research activity beyond what you have approved by signing this consent. The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

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Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE: In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your child's entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your child's rights as a research subject or if you believe your child has received a research-related injury, you may contact the the 99MDG Human Subject Research Protections Point of Contact, (702) 653-3298.

If you sign this form, you do not give up your right to seek additional compensation if your child is harmed as a result of being in this study.

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DE-IDENTIFIED RESEARCH DATA: All de-identified research data obtained from this study will be kept at the Mike O'Callaghan Military Medical Center, Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of the 99MDG will have access to this database without permission of the "Mike O'Callaghan Military Medical Center General Research Data Repository (FWH20180064H"), Manager Col Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for your permission to store your child's de-identified research data in the above database repository for future use in research studies. The specifics of these research studies are unknown at this time. Your child's stored de-identified research data will be information such as gender, age, medical history, and laboratory tests. This data is considered de-identified information and cannot be traced back to your child when added to a database. The Principle Investigator and Database Repository Manager will take every precaution possible to safeguard your child's information to eliminate the possibility of any breach of confidentiality. This is explained above in the section, "Confidentiality".

The Database Repository Manager, Col Paul Crawford, is responsible for all de-identified research data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the 59th MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Generally, you will not be provided with the results of these research studies using your child's de-identified data from the repository. Any results would be of unclear value and unknown clinical meaning, since your child's de-identified data will be combined with other de-identified data from numerous patients used for the study. You will not be able to request that your child's de-identified research data be withdrawn from the database repository, since we will have no way of identifying your child's specific data. If you have any questions, you can contact: Col Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

Choose one:

☐ NO: I do not authorize the storage of my child's de-identified research data in this repository.

☐ YES: I authorize the storage of my child's identifying de-identified research data in this repository.

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Parent's Signature

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CONTACT INFORMATION:

****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI): The principal investigators or research staff will be available to answer any questions concerning procedures throughout this study. Please contact the investigator:

Principal Investigator: Capt Travis Callahan Duty Phone: (702) 653-3619 After-Hours Phone: (702) 349-0452

Associate Investigator: Maj Danny Villalobos Duty Phone: (702) 653-2344 After-Hours Phone: (702) 349-0452

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. If you have any questions about your child's rights as a research subject, research-related injuries or any other concerns that can not be addressed by the PI, you can also contact the Mike O'Callaghan Military Medical Center Human Subject Research Protections Point of Contact, (702) 653-3298. All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to allow your child to participate in this research study, please sign this section. You do not waive any of your child's legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to allow your child to participate in this study is given on a voluntary basis.

A signed copy of this form will be given to you for your records.

_____ _____

Parent's Signature **Date**

_____

Parent's Printed Name

_____ _____

Study Staff Signature **Date**

_____

Study Staff Printed Name

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