Boston Children's Hospital

RESEARCH CONSENT FORM

MRN#:

DOB:

Subject's Name:

Study ID#:

Pilot Study: Safety of Chlorhexidine (CHG) Baths in Patients Less Than 2 Months of Age

Principal Investigator: Celeste Chandonnet

Why is this research study being conducted? What is its purpose?

The purpose of this research study is to evaluate the safety of twice weekly Chlorhexidine gluconate (CHG) baths in hospitalized infants less than 2 months of age (equal to 48 weeks' postmenstrual age) with central venous catheters (CVC) in place.

The current standard of care at Boston Children's Hospital (BCH) for infants greater than 36 weeks postmenstrual age and less than 2 months of age is twice weekly baths with comfort clothes (Fragrance free, hygienic bath cloths with purified water, Vitamin E and Aloe), manufactured by Sage Products Inc.

Having a CVC places hospitalized infants at increased risk for infection. These infections can be severe, and can make an infant very ill.

Topically applied CHG antiseptic has been shown to reduce bacteria that can potentially cause skin infections in hospitalized adults and older children, but safety concerns have resulted in the limited use of CHG on infants less than 2 months of age. At present time, CHG is only applied to the skin of infants less than 2 months of age when CVCs are inserted, during CVC dressing changes and prior to cardiac surgery. CHG is not routinely used to reduce skin bacteria during infant baths.

This study involves the use of a CHG soaked antiseptic bathing cloths. The Food and Drug Administration (FDA) approves CHG for use with caution in premature infants and infants less than 2 months of age. This is because CHG has been associated with a number of problems including mild skin irritation, allergic contact dermatitis (skin rash) and more serious life threatening conditions. However the more serious side effects were seen when there has been simultaneous exposure to multiple products containing CHG, or with direct contact between the CHG product and the mucous membranes.

Who is conducting this research study, and where is it being conducted?

This study is being conducted in the Neonatal Intensive Care Unit (NICU) and the pediatric Cardiac Intensive Care Unit (CICU) at Boston Children's Hospital. The primary investigators are Celeste Chandonnet BSN, RN, CCRN, CIC and Cheryl Toole MS, RN, CCRN, NEA-BC in collaboration with medical doctors, doctors of laboratory medicine and nurses from both the NICU and pediatric CICU.

How long will my infant be a study participant?

Our goal is to enroll 50 infants total from the NICU and pediatric CICU. Infants will remain in the study up to a maximum 12 weeks' time, until hospital discharge/transfer, or at the time the CVC is removed. (Example: infant enrolled in the study at 36 weeks postmenstrual age has their CVC removed at 42 weeks postmenstrual age, will have remained in the study for 6 weeks).

How are individuals selected for this research study? How many will participate?

Your infant has been chosen to participate in the study because he/she is:

- A patient in the NICU or pediatric CICU
- Greater than or equal to 36 weeks postmenstrual age (gestational age + age in days)
- Less than or equal to 2 months of age (48 weeks postmenstrual age)
- Has an existing or soon to be placed, peripheral or surgical CVC

What do I have to do if I am in this research study?

Participation in this study is voluntary. If you decide to have your infant participate in this study, your infant will receive a bath every Monday and Thursday and a blood draw for a CHG level (and possibly additional blood work) every Friday.

The bath: Study nurses will use pre-warmed 2% CHG soaked cloths from Sage Products Inc. Baths will involve cleaning your infant beginning at the neck, working down the body toward the feet. The study nurses will not clean your infant's face, scalp, feet, body openings and wounds with the CHG cloths.

Skin evaluation: Study nurses will perform a full body skin assessment for skin irritation, or open areas on your infant prior to receiving each bath. Following each bath, bedside nurses will conduct a full body assessment every 12 hours for the duration for the study. Any findings that are unfavorable (such as a rash) will be documented and reported to the primary investigator.

The blood sample: CHG levels will be obtained before the first bath and on Fridays. Also every Friday additional labs may be obtained to monitor your infant's liver function, renal function and red blood cell count, if these labs are not part of your infant's routine lab work. All blood levels will be drawn with other scheduled lab work using your infant's CVC whenever possible. When no other lab work is to be obtained or if your infant's CVC is too small to draw blood, your infant will need 1-2 extra heel sticks per week. Heel sticks are safely performed on patient care units using the side of your infants' pre-warmed heel. Heel sticks may also be performed to limit accessing your infant's CVC, minimizing the risk of infection, in some situations.

The maximum volume of blood for these lab tests equals approximately 1/3 of a teaspoon per week. If your infant's participation in the study is for the maximum length of time of 12 weeks, the total amount of blood that will be obtained for this study is approximately 31/2 teaspoons.

What are the risks of this research study? What could go wrong?

Participation in this study involves some risk to your infant. While chlorhexidine has become a widely used antiseptic, it is not used without risk. Side effects associated with CHG have included mild to severe skin reactions and possible absorption of CHG into the blood that could result in changes to liver and renal function, reduced red blood cell count and more serious problems such as respiratory problems or anaphylaxis (a generalized allergic reaction). However the most common documented side effect with the 2% CHG baths cloths has been mild, local skin redness with no serious problems reported. If a severe skin reaction does occur such as blisters or burns, we will discontinue the CHG baths and treatment will be provided from your infant's medical provider. Due to the limited use of CHG bathing cloths in infants less than 2 months of age there may be risks, which are currently unforeseeable.

Another cause of discomfort to your infant may occur when the CHG level and other blood work is obtained, and needs to be drawn by heel stick. Risks associated with a blood draw from a heel stick are minor discomfort and bruising. Heel sticks are safely and routinely performed using the side of your infants' pre-warmed heel. A single stick is usually enough for the small sample of blood needed, however more than one heel stick may be needed if your infant's blood clots quickly, preventing collection of the sample.

Our study team has elected to investigate the safety of twice-weekly 2% CHG baths. There is some evidence to indicate that twice weekly baths may prevent infection; however that has not been proven in patients less than 2 months of age. Since the safety profile for using CHG in infants less than 2 months of age is not known this study is considered greater than minimal risk with a potential for direct benefit to your infant.

To maintain your infant's privacy and anonymity all records associated with your infant's participation in this study will be confidential. However, because the use of this product is regulated by the Food and Drug Administration (FDA), the FDA may have access to these records during the course of their duties.

What are the benefits of this research study?

Research in other patient populations supports the use of CHG, a topical antiseptic for reducing healthcare-associated infections (HAIs) in adult and pediatric patients. It is proven to decrease bacteria on the skin, which may help to decrease infections in these patients. Preventing an infection could shorten the length of time your infant is hospitalized and could shorten the length of stay for future patients in the NICU and pediatric CICU.

This study will help to establish the safety of twice weekly CHG baths and help determine the need for a larger study that will examine infection control.

Are there costs associated with this research study? Will I receive any payments?

There is no cost for participating in this study. However, you and your insurance company will be charged for routine medical and or nursing care that is considered standard treatment for your infant's medical condition. In addition, neither you nor your infant will be paid to participate in the study.

In the event of an injury resulting directly from your participation in this research study, medical treatment will be provided if the injury is reported in a timely manner. Provision of such medical care does not imply any negligence or other wrongdoing on the part of the Hospital or any of the physicians or other personnel involved in the study. Where applicable, the Hospital reserves the right to seek payment from third-party payers for any medical care or services rendered. The Hospital has no program to provide you with any additional compensation as a result of any such injuries.

What will happen with the information obtained as part of this research study? What about confidentiality?

The researchers will make every effort to protect your infant's identity. To protect your infant, a study ID number will be assigned to him/her upon enrollment in the study. This study ID will be used on all study documentation including the data collection tool and the special laboratory request form. All data will be entered into a computerized password protected logbook. The data collection tool will be stored by study staff in the primary investigators work room in a locked cabinet behind a locked door and special laboratory request forms will be stored by study staff in the laboratory in a locked file behind a locked door and entered into the computerized password protected logbook.

Only the members of the researcher team will have access to the information from this study. However Federal and state agencies (for example the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Office of Human Research Protections, the Department of Social Services or other governmental offices as required by law) have authority over the research and can request to see your infant's research records.

Clinical staff not involved in the study, but who are caring for your infant will have knowledge of your infant's participation, but will not have access to your infant's research records or lab results. The research records and CHG lab results will not appear in your infant's medical record.

A copy of this consent form will be placed in your infant's medical record. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in their course of carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in you/your infant's medical record may not be given to anyone unaffiliated with Children's Hospital in a way that could identify you/your infant without

written consent, except as required or permitted by law. Information collected during the study that does not become part of your infant's medical record will be stored in separate research files maintained by the investigator. These research records will not be made available to any individuals who are not part of the research team unless you so request or as required by law. If you withdraw your infant from the research study, information that has already been collected will become part of the research data; however, you/your infant will not be identified.

The results of the study intervention will not be placed in your infant's medical record. In this manner it will be unlikely that others within the hospital, an insurance company or employer would ever learn of such results.

If I do not want to take part in this research study, what are the other choices?

Participation in this study is voluntary. The treatment being offered is experimental, and there are no alternative topical antiseptic treatments being offered. If you choose not to participate in this study or if you decide to withdraw your infant from the study, your decision will not interfere with current or future care received at Boston Children's Hospital. The current standard of care for infants at BCH is to provide routine bathing with Comfort Cloth by Sage Products Inc. CHG is only applied to the skin of infants less than 2 months of age when CVCs are inserted, during CVC dressing changes and prior to cardiac surgery. Currently, CHG is not routinely used to reduce skin bacteria during routine infant baths.

What are my rights as a research participant?

This study is voluntary. If you choose to participate, you have the right to withdraw from the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor, nurses or with the hospital. There will be no unfavorable consequences for withdrawing your infant from this study. If you decide to withdraw your infant from this study, you can do so at any time by notifying your infant's nurse. Your infant's nurse can notify the primary investigators.

In the event of injury (such as blisters or burns, or evidence of renal/liver problems), we will discontinue the CHG baths and treatment will be provided from your infant's medical provider. Due to the limited use of CHG bathing cloths in infants less than 2 months of age there may be risks, which are currently unforeseeable.

Why would I be taken off the study early?

Sometimes there are circumstances under which the investigator, without regard to your consent, will stop the participant's involvement. In this study your infant's participation may be terminated by the investigator without regard to the participant's consent if after receiving a CHG bath, the participant experiences:

- Mild redness after 2 consecutive baths
- Persistent redness leading up to 2nd bath

- Moderate redness
- Raised rash
- Blister(s)
- Open area(s) that develop after bath
- Evidence of a serious reaction. Examples of serious reactions include inflammation, elevated temperature, seizures, and total body rash.
- A rapidly progressing, life-threatening allergic reaction such as wheezing, nausea and vomiting, hives and altered heart rhythms.

OR:

- Due to the following lab results, as it would be dangerous for your infant to continue in the study:
  - Elevated Liver function test
  - Elevated Kidney function test
  - Decreased red blood cell count
- The Principal Investigator feels it is in the best interest of your infant to be taken off this study.

What information do I need to know about the Health Insurance Portability and Accountability Act (HIPAA)?

You/your infant's health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study.
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it.
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital.
- People at Boston Children's Hospital who oversee, advise and evaluate research and care. This includes the ethics board and quality improvement program.
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities.
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories, and others.
- Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your infant's health information might not have to follow the same privacy rules. Once your infant's information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Boston Children's Hospital Privacy Office at 857-218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

We will also create a code for the research information we collect about your infant so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your infant's name or identifying information will not be used without your specific permission.

Your privacy rights

If you do not want your infant to participate in this study, you do not have to. If you do want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care or your infant's care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw your infant from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your infant's health information, you will need to do so in writing.

Your infant may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 857-218-4680.

Other information that may help you

Boston Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or

concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30and 5:00.

A description of this clinical trial will be available on HTTP://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. **Contact Information**

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study.

I can call…	At	If I have questions or concerns about
Study Contacts		
Primary Investigator: Celeste Chandonnet	**Cell Phone:** (603)320-9218 (first call) **Beeper:** #4508 **In hospital: (617) 355**-1920 **Email:** Celeste.chandonnet@childrens.harvard.edu	☐ **General questions about the study** ☐ **Research-related injuries or emergencies** ☐ **Any research-related concerns or complaints**
Co-Investigator: Cheryl Toole	**Cell Phone:** (617)33-7765 **In hospital: (617) 355**-7555 **Email:** Cheryl.Toole@childrens.harvard.edu	☐ **General questions about the study** ☐ **Research-related injuries or emergencies** ☐ **Any research-related concerns or complaints**
CICU Study Team: Deb Morrow	**Cell Phone:** **In hospital:** 617-355-9859 **Email:** Debra.Morrow@cardio.chboston.org	☐ **General questions about the study** ☐ **Research-related injuries or emergencies** ☐ **Any research-related concerns or complaints**
Office of Clinical Investigations	**Phone: 617-355-7052**	☐ **Rights of a research subject** ☐ **Use of protected health information.** ☐ **Compensation in event of research-related injury** ☐ **Any research-related concerns or complaints.** ☐ **If investigator/study contact cannot be reached.** ☐ **If I want to speak with someone other than the Investigator, Study Contact or research staff.**

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this study.
- This research study has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research study is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.

- I give permission for my/my child's participation in this research study and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research study is a foster child *or a* ward of the state *please notify the researcher or their staff who is obtaining your consent.*

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent or Guardian** Relationship to child

Investigator or Associate's Statement & Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.
- I have provided a copy of the consent form sign by the subject/ parent / guardian and a copy of the hospital's privacy notification (if requested)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

Required ONLY IF (check which one applies):

☐ Consent document needs to be read to subject or legal representative, **or**

☐ Communication impairments limit the subject's ability to clearly express consent, **or**

☐ Other reason: please specify _____

I confirm that the information in this consent form was accurately explained to, and understood by the subject, parent and/or legally authorized representative as required, and that informed consent was given freely.

■ _____ _____

Date (MM/DD/YEAR) Signature of **Witness**