Research Consent Form

Title of Research: [redacted]

Principal Investigator: [redacted]

Collaborating Investigators: [redacted]

Collaborating Research Institutions: Cook Children's Healthcare System
Harris Methodist Hospital
University of North Texas Health Science Center

Research Team: [redacted]

Why is this study being done?

This is an invitation to participate in a research study regarding the effectiveness of current decontamination (decon) procedures used for victims of biological or chemical exposures. The Researchers wish to learn about how to more effectively decontaminate these victims prior to entering the emergency room where hospital staff could become contaminated. The purpose of this research study is to determine if the current process is adequately protecting hospital workers and to provide visual confirmation of the efficiency of the current process.

The research involves the following: the volunteers will participate in a decontamination exercise where they will be "contaminated" with either theatrical body paint, "Glow Germs" (a training product used by infection control to train on the effectiveness of hand washing), Ben-Gay (an over-the counter product used for mild arthritis pain which contains 2.5% menthol), or a combination of these products. All of these products are non-toxic and are detectable by means of black light photography and/or a CAM, which is a hand-held chemical detection device that detects concentrations of certain chemicals in air. The CAM specifically detects menthol vapors released by the Ben-Gay. These measures may help the decon team evaluate the effectiveness of the decontamination regimen. The researchers wish to enroll at least 20 adult volunteers and no children in this research study, and about 10 will be from this location.

Subject Initials _____
Date _____

What will happen in this study?

As a research subject, the procedures associated with this research include the following:

- You will be "contaminated" with one of the agents (theatrical body paint, Glow Germs, Ben-Gay, or a combination of these products as described above)
- You will be processed through the decontamination protocol, which includes removing all outer clothing and being "cleaned" in outdoor showers by a member(s) of the hospital decon team.
- We will measure residual amounts of the agents, either by photography, CAM detection, or both after the decontamination process is completed.

How long will I be in this study?

Your participation will last approximately 6-8 hours in a one day time span.

Are there any risks associated with taking part in this study?

The risks that can be identified specifically with this research are:

- Mild hypothermia. This depends partially on the weather on the day of the study and all precautions will be taken to minimize or avoid hypothermia (e.g. minimizing shower time, using warmed blankets after the procedure is over, warm beverages available after the procedure). The shower water will be approximately 110°.
- Photography during the procedure and after the procedure will be performed and will only be used for training purposes; however, it is possible that you can still be "identified" even with appropriate measures put into place to maintain your anonymity.
- There is always a risk of loss of confidentiality associated with participating in a research study. All information pertaining to your participation in this research will be kept in a locked file cabinet in [redacted]'s office within the [redacted] Department of Cook Children's. The risk of loss of confidentiality is considered to be minimal. However, the researchers involved in this study will take every precaution necessary to ensure that your privacy is protected. No protected health information (PHI) will be collected.
- Very low risk of allergic reaction to the "contamination" agents listed above (Glow Germs, BenGay, theatrical paint, etc.)

It is unlikely that you will be injured as a result of taking part in this study. However, if you are, there are no funds set aside to compensate (pay) you in case you are injured as a result of taking part in the study. Further, you or your insurance company will continue to be responsible for any standard (regular) medical care needed to treat any health condition that may arise from participating in this research study.

Subject Initials _____
Date _____

Are there any benefits?

The benefits of participating in this study include the following:

- Participants in the study will not likely receive any direct benefit from participating in this study unless although it may be educational, even enjoyable.
- It is possible that the information learned from this research study could help hospital-based decon team learn about how to more effectively clean victims of chemical or biological exposure and could possibly help others in the future who have been true victims of unintentional exposures or intentional (terrorism or war) exposures to these agents.

What are the alternatives to taking part in this study?

You can choose not to participate in this research. You can withdraw from the study at any time. Refusing to participate or withdrawing from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

Are there any costs associated with taking part in this study?

There are no costs associated with this study.

Is there any Payment, Compensation, or Incentive to participate in this study?

All participants will receive a $10 Starbucks gift card. Industrial hygienists, nurses, and other professionals may receive education credit for participating.

Who do I call if I have questions about this study?

[redacted] XXX-XXX-XXXX
XXX-XXX-XXXX
XXX-XXX-XXXX

Who do I call if I have questions about my rights as a research participant?

If you have questions regarding rights as a research participant, you can contact the following Institutional Review Board representatives: Dr. Brian Gladue at the University of North Texas Health Science Center (phone: (817) 735-0409), [redacted] at Cook Children's Health Care System (phone: [redacted]), and/or [redacted] at Harris Methodist Hospital ([redacted]).

You will be given a copy of this consent form to keep.

Subject Initials _____
Date _____

Signatures

Printed Name of research Subject _____

Signature _____ Date _____

Name of Person Obtaining Consent _____

Signature _____ Date _____

Name of Witness * _____

Signature of Witness _____ Date_____

***Please note that the signature of the witness indicates that this person is an impartial third party and observed the consent process (which included the discussion between the Investigator(s) and the participant) as well as the signature of the participant.**

NOTE: Informed consent must be obtained in language understandable to the subject. This requires use of either (i) a full, translated informed consent document approved by the IRB, or (ii) a translated, IRB-approved "short form" and a translator for the consent process.