

## **POLICIES AND PROCEDURES**

SECTION: Research and Compliance			NUMBER: CLN-25.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/27/2010	REV. C:
TITLE: Study Participant Safety and Comfort			Page 1 of 3	

### **1. PURPOSE**

To provide a safe, friendly, accommodating, pleasant, and family-focused environment for all Study Participants (SPs) and their parents/legal guardians or representatives if required.

### **2. SCOPE**

Applies to all personnel involved in the review and implementation of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

### **3. RESPONSIBILITIES**

The PI is responsible for all aspects of all clinical research studies, including the safety of all SPs under her/his care. The study staff assists the PI in many of these activities, guaranteeing and maintaining the safety and comfort of all SPs.

### **4. BACKGROUND**

A private, friendly, and comfortable environment is meant to give the SP a pleasant experience. SP amenities include an environment that is comfortable that provides them the possibility of utilizing their time between study activities in a manner of their choice.

### **5. PROCEDURE**

#### **5.1. General**

- 5.1.1. SP privacy and safety have priority over any other interests.
- 5.1.2. Staff are trained to understand both the problems of SP confinement for protracted periods of time and, in addition, the unique growth and development needs of children so confined.

#### **5.2. Guardian Presence in Studies Involving Children**

- 5.2.1. Parent(s)/legal guardian(s) are encouraged to stay with their child during the study visit.
- 5.2.2. Parent(s)/legal guardian(s) accompanying a young SP may temporarily leave the clinic as per protocol, provided that prior permission of the PI has been secured and the absence is documented in the source documents progress notes.
- 5.2.3. Child SPs may stay in the study unit without a parent/legal guardian, with another caretaker or the clinic research staff, only if the parent/legal guardian as well as the PI/Investigator and clinic research staff all agree this will not cause the child undue distress.

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TITLE: Study Participant Safety and Comfort			Page 2 of 3	

5.2.4. The PI/Investigator will provide additional privacy as requested by the SP (e.g., an older child who requests that his/her parent or legal guardian not be present for part of a study visit).

### 5.3. Anxiety/Minor Pain Management

- 5.3.1. Diversions such as games, videos, toys, and books are available in the research unit.
- 5.3.2. For venipuncture in children, a topical anesthetic (i.e., EMLA cream or ethyl chloride solution) should be available for anesthesia. EMLA is placed on up to two venipuncture sites at least one-half to one hour prior to the scheduled blood draw.
- 5.3.3. No more than three insertion attempts will be performed for all blood specimen collections.
- 5.3.4. Child SPs are permitted to leave the unit with their parent(s)/guardian(s) if the protocol permits and the PI/Investigators agree. Adult SPs are not permitted to leave a clinical research unit during the course of a study.

### 5.4. Privacy and Confidentiality

- 5.4.1. The PI and/or research team are responsible for ensuring that SPs will be provided an environment that ensures that the SP's participation and any communication between the Investigator/research staff and the SP remains private.
- 5.4.2. The PI and/or research team are responsible for maintaining confidentiality as described in the Informed Consent Form and HIPAA Authorization.

### 5.5. Emergency Procedures for Patient Safety

- 5.5.1. All SP visits associated with new medication administration will have a licensed RN or an MD available on site.
- 5.5.2. In the event of an emergency, the research staff will call the appropriate number to activate the Creighton University Medical Center emergency response team.
  - 5.5.2.1. Code Blue/Medical Emergency/Cardiac Arrest Dial 449-4199
  - 5.5.2.2. Fire Emergency Dial 449-4711
  - 5.5.2.3. Security Emergency Dial 449-4534
- 5.5.3. If the research unit is not located within Creighton University Medical Center, in case of emergency, dial 911, or follow standard clinic emergency procedures.
- 5.5.4. Documentation surrounding the events of the emergency are recorded by the staff in attendance and maintained in the source documents.
- 5.5.5. The sponsor is notified as per the protocol.

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### **5.6. Study Participant Compensation**

- 5.6.1. SPs may be compensated for their time and travel-related expenses by an Institutional Review Board (IRB)-approved study schedule.
- 5.6.2. If compensation is allowed, it will be fair and comply with the overriding principle of not offering an amount that could be taken as a coercive (excessively large).
- 5.6.3. All methods and amounts of compensation must be approved by the IRB of record.

## **6. TERMS & ABBREVIATIONS**

<b>AE</b>	Adverse Event
<b>CFR</b>	Code of Federal Regulations
<b>FDA</b>	Food and Drug Administration
<b>GCP</b>	Good Clinical Practice
<b>ICH</b>	International Conference on Harmonisation
<b>IRB</b>	Institutional Review Board
<b>PI</b>	Principal Investigator
<b>SP</b>	Study Participants

## **7. REFERENCES**

- 7.1. ICH GCP Consolidated Guideline - Parts 4.2.3, 4.3.1, and 4.3.2

## **8. ATTACHMENTS**

None