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| TITLE: Emergency Contact | | | Page 1 of 2 | |

## 1. PURPOSE

To provide a mechanism by which every Study Participant (SP) has a means of communicating with study site personnel after usual hours of operation and/or in case of a medical emergency.

## 2. SCOPE

Applies to all Principal Investigators (PIs) and, when delegated by the PI, additional Investigator(s), Study Coordinators (SCs), and designated site personnel.

## 3. RESPONSIBILITIES

The PI is responsible for ensuring that a system is in place to knowledgably respond to SPs' medical emergency needs on a 24-hour basis seven days per week.

## 4. BACKGROUND

A 24-hour emergency contact is important to ensure the safety and welfare of the SP. The SP may need to contact the PI to report potential adverse events (AEs) or changes to his/her health status. Healthcare providers may need to inquire about the study drug during the delivery of routine or emergency care for the SP as a patient.

## 5. PROCEDURE

5.1. Person(s) responsible for emergency coverage will have study-specific information available and will have the knowledge and training to respond appropriately to the reported medical emergency.

5.2. SPs will be given a telephone number for 24-hour contact with study staff so that, in the event of a medical emergency, the participant is able to get immediate assistance. This information is provided on the Informed Consent Form (ICF). The study site may also give a study-related card with essential emergency-related information on it.

5.3. Site personnel with appropriate knowledge and training will assess the SP's emergency and, depending on the nature of the situation, will respond accordingly.

5.4. Research staff receiving emergency calls must have knowledge of all ongoing studies within their research area. This information should include: PI's emergency contact number, sponsor's medical monitor emergency number, schema or possible treatment groups of study, protocol-specific risks, disease-specific risks, medication-specific side effects, procedure for unblinding, and emergency number for pharmacy involved, if applicable.

5.5. In the event the emergency warrants possible unblinding, study personnel should refer to SOP CLN 32.00, "Breaking Study Blind," on the unblinding of the Investigational Product (IP).

5.6. In the event the emergency meets the criteria for a serious adverse event (SAE), study personnel should refer to SOP CLN 37.00, "Serious Adverse Event Reporting."

5.7. Follow-up with the SP after the initial medical emergency contact will be performed as needed.

## 6. TERMS & ABBREVIATIONS

**AE** Adverse Event
**ICF** Informed Consent Form
**IP** Investigational Product
**PI** Principal Investigator
**SAE** Serious Adverse Event
**SP** Study Participant

## 7. REFERENCES

7.1. ICH GCP Consolidated Guideline - Part 4.7 Randomization Procedures and Unblinding

## 8. ATTACHMENTS

None