SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1220
Date Last Revised: 5/10
Date Last Reviewed: 5/10

SUBJECT: **CONSENT UNDER EMERGENT CONDITIONS**

1. PURPOSE

   Define the processes for waiver of consent under emergent conditions.

2. SCOPE

   This applies to research studies for investigational drugs or medical devices to be used in patients with life-threatening situations and who are unable to give informed consent as defined in 21 CFR Part 56 will be considered.

3. POLICY

   Applications to the Board for studies whereby it is recognized that the potential subjects will be in a life-threatening situation, whereby consent is impossible to obtain at the time that the study would be initiated, will require a request for 'Consent Under Emergent Conditions.'

4. PROCEDURE

   4.1. To meet the requirements of this category, the Investigator must submit to the Board as part of his/her application documentation of the following:

      4.1.1. Principal Investigator and IRB agree the clinical study addresses a life-threatening situation;

      4.1.2. An individual is in a life threatening situation and in need of emergency therapy;

      4.1.3. A legally authorized representative is not available;

      4.1.4. Available treatments are unproven or unsatisfactory;

4.1.5. Collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions;

4.1.6. Intervention of research must be administered due to time before consent is possible from subject's legally authorized representative;

4.1.7. The risk(s) and benefit(s) of the research intervention are reasonable compared to the risk(s) and benefit(s) of the patient's medical condition and standard therapy.

4.1.8. Demonstrate adequate disclosure and consent by the representative community-at-large in a manner that can be documented and quantified.

4.1.9. Submission of two different consents: 1) 'Consent to Participate', and 2) 'Consent to Continue.'

4.2. When 'Consent Under Emergent Conditions is initiated the Investigator will include the following:

4.2.1. Use of two approved consents: 1) 'Consent to Participate', and 2) 'Consent to Continue.'

4.2.2. Copy of informed consent(s) placed in patient's chart [even though consent to participate form may not be signed by the patient].

4.2.3. Documentation by the Principal Investigator enrolling the patient of the following:

4.2.3.1. Patient enrolled

4.2.3.2. Pt received device/drug

4.2.3.3. Mechanism of injury

4.2.3.4. Document attempt to contact family member BEFORE enrolling

4.2.3.5. Family was / was not spoken to BEFORE enrolling

4.2.3.6. At first opportunity that patient can participate, the Principal Investigator consents patient with 'Consent to Continue.' OR

4.2.3.7. At first opportunity that a family member arrives, Principal Investigator explains study to family and asks family to sign 'Consent to Continue.'

4.2.3.8. Investigator must document informed consent process as defined in Section R-1217.

4.2.3.9. The Investigator will place a signed and dated copy of the Informed consent in the medical record.

REGULATORY REFERENCES

21 CFR 50, 812, 814	Informed Consent of Human Subjects
ICH E6	Good Clinical Practice: Consolidated Guidance (April 1996)
OIP – 10	SAMC SOP: OIP Education