SAINT AGNES MEDICAL CENTER

CLINICAL RESEARCH CENTER

Fresno, California

STANDARD OPERATING PROCEDURES

Institutional Review Board

Date Effective: April 26, 2001 Index No. R – 1219
Date Last Revised: 09/11
Date Last Reviewed: 09/11

SUBJECT: **EMERGENCY USE OF A RESEARCH INTERVENTION**

1. PURPOSE

   Define the process for the emergency use of a research intervention, including drugs and devices.

2. SCOPE

   - FDA exempts from IRB review the emergency use of a research intervention so long as the emergency use is reported to the IRB within five (5) working days of its occurrence.
   - Any subsequent use of the research intervention is subject to IRB review.
   - Subsequent use means any use of the research intervention that occurs after its initial emergency use.

3. POLICY

   3.1. Emergency use is defined as the use of a research intervention, including drugs and devices, on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use.

   3.2. Emergencies qualifying for exemption are defined as:

   3.2.1. Life threatening situations necessitating use of the research intervention:

   3.2.1.1. Where the subject is unable to provide effective consent;

3.2.1.2. There is insufficient time in which to obtain consent from the subject's legal representative; and

3.2.1.3. There is no available method of approved or generally recognized therapy of equal or greater likelihood of saving the subject's life.

3.2.2. The Investigator is still required to obtain informed consent under these circumstances.

4. PROCEDURE

4.1. When a research intervention is used during an emergency the Investigator and another physician must certify in writing the existence of all four conditions before use of the research intervention.

4.2. If there is insufficient time to obtain the independent determination required before using the research intervention, the Investigator is to make his/her own written determinations, then obtain the written review and independent evaluation of a physician who is not participating in the clinical investigation within five (5) working days after the use of the research intervention and submitted to the IRB within the five (5) workings days after the use of the research intervention.

4.3. When the IRB receives a report by an Investigator of an emergency use, the IRB will examine each case to ensure that the emergency use was justified.

4.4. The intent is to permit only a single emergency use of a research intervention for the treatment of one patient by one physician within an institution, the regulation is not intended to limit the authority of a physician to provide emergency care in a life-threatening situation.

4.5. If it appears probable that similar emergencies will require subsequent use of the research intervention, every effort should be made either to sign on to the sponsor's protocol or to develop a protocol for future emergency use of the article. Such a protocol would be prospectively reviewed and approved for future use of the research intervention.

REGULATORY REFERENCES

45 CFR 46	Protection of Human Subjects ("The Common Rule")
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