SAINT AGNES MEDICAL CENTER
CLINICAL RESEARCH CENTER
Fresno, California

STANDARD OPERATING PROCEDURES
Institutional Review Board

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SUBJECT: **TREATMENT OR INDIVIDUAL PATIENT USE OF AN INVESTIGATIONAL DRUG OR DEVICE**

1. PURPOSE

Outline the process for submitting an IRB application for either *treatment use* or *individual patient* use of an investigational drug or device under FDA's "Expanded Access" regulations.

2. SCOPE

This applies to treatment of patients within Saint Agnes Medical Center facilities when those patients have a serious or immediately life-threatening condition that may benefit from the drug or device when there is no satisfactory alternative, and they do not have access to, or are not eligible for enrollment in, a controlled clinical trial.

3. POLICY

- The IRB will review a "treatment protocol" submitted by a physician under a manufacturer's approved IND for an investigational drug as well as review a "treatment plan" submitted by a physician under an Individual-Patient IND wherein the physician is designated the "Investigator–Sponsor".

- The IRB will review a "treatment protocol" submitted by a physician under a manufacturer's approved IDE.

4. PROCEDURE

4.1 **INVESTIGATIONAL DRUGS**

A. *CRITERIA FOR TREATMENT USE UNDER A MANUFACTURER'S PROTOCOL*:

The FDA will permit *treatment use* of an investigational drug under its Expanded Access regulations [21 CFR 312.305, 312.315] if:

- the drug is intended to treat a serious or immediately life-threatening disease;

- there is no comparable or satisfactory alternative drug or other therapy;
- the drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed;
- the commercial Sponsor of the controlled clinical trial has an existing IND and is actively pursuing marketing approval of the investigational drug with due diligence.

B. *CRITERIA FOR A PHYSICIAN REQUESTED INDIVIDUAL PATIENT IND:*

The criteria outlined in Section 4.1 above apply to an Individual Patient IND, with the exception of the last bulleted point (pursuit of marketing approval). To be eligible for IRB approval under the FDA's Expanded Access regulations for an Individual Patient IND [21 CFR 312.310], the physician must first have:

- contacted the manufacturer to obtain their willingness to provide the unapproved drug for an individual patient and have provided them the information they need to base their decision;
- obtained from the manufacturer a letter of cross reference to their IND to be submitted to the FDA;
- submitted an Individual Patient IND to the FDA with the information they require to provide approval [21 CFR 312.10].

C. *IRB SUBMISSION:*

Because most treatment use requests are for non-emergency cases, protocol applications for treatment use will be submitted to the IRB using the 'Protocol Application for Treatment or Use' (obtained from the IRB Office) by the monthly due date published by the IRB Administrator. **Emergency Use requests should follow the procedures outlined in IRB SOP 1219.**

To be considered for review, the signed 'Protocol Application for Treatment Use' (whether for an individual patient or several patients) must be accompanied by the following documents:

- the current version of the commercial Sponsor's treatment protocol (if applicable), or the Investigator-Sponsor's "treatment plan"
- the Investigator's Brochure
- the patient informed consent document drafted using the SAMC IRB Informed Consent template
- an Investigator signed FDA 1572 ('Statement of the Investigator')
- a copy of the Sponsor-Investigator (i.e., the physician) signed FDA 1571 ('Investigational New Drug Application')
- the 'California Experimental Subject's Bill of Rights'
- a valid HIPAA Authorization
- a signed 'Financial Disclosure By Clinical Investigator'
- Investigator(s) curriculum vitae and medical license.

D. ***INVESTIGATOR RECORDS AND REPORTS***

An Investigator treating patients under any of the Expanded Access mechanisms is required to keep records and submit reports to the Sponsor, IRB and FDA in accordance with the requirements set forth in 21 CFR 312.62 and 312.64.

4.2 INVESTIGATIONAL DEVICES

A. *CRITERIA FOR TREATMENT USE UNDER A MANUFACTURER'S TREATMENT PROTOCOL*:

The FDA will permit *treatment use* of an investigational device under its Expanded Access regulations [21 CFR 812.36] if:

- the device is intended to treat or diagnose a serious or immediately life-threatening disease
- there is no comparable or satisfactory alternative device or other therapy
- the device is under investigation in a controlled clinical trial under an IDE in effect for the trial, or all clinical trials have been completed
- the commercial Sponsor of the controlled clinical trial has an existing IDE and is actively pursuing marketing approval of the investigational device with due diligence

B. *CRITERIA FOR INDIVIDUAL/SMALL GROUP ACCESS:*

To be eligible for IRB approval under the FDA's Expanded Access regulations for devices [21 CFR 812.35 and 812.36], the physician must first have:

- contacted the IDE Sponsor to obtain their willingness to provide the unapproved device for an individual patient (small group) and have provided them the information they need to base their decision
- have received notice from the Sponsor that they have submitted an IDE Supplement [21 CFR 812.35] to the FDA requesting approval, and that 30 days have elapsed since the submission before the device may be used.

C. *IRB SUBMISSION:*

Because most treatment use requests are for non-emergency cases, protocol applications for treatment use will be submitted to the IRB using the 'Protocol Application for Treatment or Use' (obtained from the IRB Office) by the monthly due date published by the IRB Administrator. **Emergency Use requests should follow the procedures outlined in IRB SOP 1219.**

To be considered for review, the signed 'Protocol Application for Treatment Use' (whether for an individual patient or several patients) must be accompanied by the following documents:

- the current version of the commercial Sponsor's Treatment IDE protocol

- the Investigator's Brochure or equivalent
- the patient informed consent document drafted using the SAMC IRB Informed Consent template
- the 'California Experimental Subject's Bill of Rights'
- a valid HIPAA Authorization
- a signed 'Financial Disclosure By Clinical Investigator'
- Investigator(s) curriculum vitae and medical license.

D. ***INVESTIGATOR RECORDS AND REPORTS***

An Investigator treating patients under any of the Expanded Access mechanisms is required to keep records and submit reports to the Sponsor, IRB and FDA in accordance with the requirements set forth in 21 CFR 812.100 to 110 and 812.140 to 812.150.

REGULATORY REFERENCES

45 CFR 46	Protection of Human Subjects ("The Common Rule")
21 CFR 50	Protection of Human Subjects
21 CFR 54	Financial Disclosure By Investigators
21 CFR 312.300 to 312.320	Expanded Access to Investigational Drugs for Treatment Use
21 CFR 312.60 to 312.69	Responsibilities of Investigators
21 CFR 812.36	Treatment Use of an Investigational Device
21 CFR 812.100 to 110, 812.140 to 812.150	Responsibilities of Investigators
ICH E6	Good Clinical Practice: Consolidated Guidance (April 1996)
CAMH RI.2.180	Protection of Research Subjects
CAMH MM 7.4	Investigational Medications
IRB SOP 1207	Clinical Research Proposal Submissions