D. All IRB members are required to undergo formal training at the time of their initial appointment. Training that satisfies this requirement is the on-line tutorial offered by a third-party company, CITI (or equivalent). The IRB chair maintains a log of training completion dates. Continuing education of IRB members is accomplished through annual sessions to refresh knowledge, and upon expiration of CITI certification. IRB members must complete:

1. Review and sign the Common Rule
2. Complete CITI training for IRB Members
3. Complete CITI training Biomedical Research

If needed, for a certain area of subject matter expertise, the IRB chair retains the right to assign education, for the greater protection of the college.

F. Liability coverage for IRB college members is provided through Saddleback College's liability insurance coverage.

G. Consultants with competence in special areas may be used when deemed appropriate.

H. Conflict of interest policy and procedure

1. Investigators shall not be involved in the selection of IRB members.

2. Investigators will be asked in Saddleback College's IRB Conflict of Interest form, "IRB Conflict of Interest Policy and Statement" whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

3. Investigators and IRB members who are Saddleback employees and who apply for federal grants and contracts are subject to the Saddleback College Conflict of Interest Policy.

4. The IRB chair will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.

5. Other conflict of interest guidelines specifically for IRB members are found in section XIV of this Charter and Standard Operating Procedures.

VIII. PROCEDURES OF THE IRB.

A. Initial Review.

1. No or Minimal Risk:
Under the auspices of the IRB, the chair will review Petitions eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the Petition to the IRB for full board review.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101]. Exempt types of research may include:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use

found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The IRB chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must Petition with an exemption request citing the specific exemption category and providing justification for the exemption. The IRB chairs' determination must be submitted to the president for concurrence.

Under federal regulations certain types of research qualify for an 'expedited' review [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm]. These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

> (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases th
>
> e acceptability of the risks associated with the use of the product is not eligible for expedited review.)
>
> (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

> (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) un cannulated saliva collected either in an un stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt

from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit one (1) original and the required number of copies of the "Exempt Protocol Summary Form" to the IRB Chair at least eight (8) days prior to any proposal deadline in order to provide time for review and processing. Copies of the form are available via **http://www.saddleback.edu/opra/institutional-review-board-irb/.**

The IRB chair may recommend a protocol to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full board. The IRB chair cannot "disapprove" of a protocol but may table action pending further information/clarifications. The IRB chair will inform the PI and, if applicable, the Faculty Advisor of its actions. Any disagreement between the PI and

the IRB chair must be resolved by the fully convened IRB. The PI will be notified of the IRB decision by the chair.

If it is determined that one of these protocols require IRB review, it will be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the material from the PI, the IRB chair will distribute copies to each IRB member.

2. More Than Minimal Risk

Protocols for **full-board (IRB) review** must be submitted twenty (**20**) working days before the end of the Spring and/or Fall semester (no IRB review occurs during the Summer semesters). The prospective PI will submit to the IRB Chair one (1) original and the required number of copies of the "Full IRB Review Form." Copies of the form are available via **http://www.saddleback.edu/opra/institutional-review-board-irb/**. In the Petition, the investigator assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy. The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

3. Actions of the IRB:

The IRB may take one of the following four actions in regard to the proposed protocol and consent form: *Approved, Approved Subject to Restrictions, Tabled,* or *Disapproved.*

Approved

When a protocol has been approved, the Chair completes the "Action of the IRB" letter, signs and dates it, and distributes one copy of the form to the principal investigator, the IRB files, and, if appropriate, the performance site.

Approval of the protocol will be based on the following:

a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.

b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.

c. Assurances of acceptable debriefing, if appropriate.