Stockton University
INTRODUCTION TO THE APPLICATION TO UNDERTAKE RESEARCH INVOLVING HUMAN SUBJECTS

Institutional Review Board

All active human studies at Stockton University must be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk but not less than annually. All Human Subjects Research conducted by **Stockton Faculty, Administrators, Staff, and Students** or on its campus must be in accordance with Federal Regulations and the Multiple Project Assurance filed with the Office for the Protection for Research Risks (OPRR). Subpart A-D of the PHS Act, implemented by 45 CFR Part 46, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html requires basic protection for human subjects involved in research covered under the Multiple Project Assurance. All researchers submitting IRB applications are required to demonstrate proficiency in knowledge about how to protect human subjects by completing the online training and submitting certificates of that training. See www.citiprogram.org the website for Collaborative Institutional Training Initiative (CITI) training modules.

A ***human subject*** is defined in the regulation as "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information." The regulation extends to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The regulation also specifies additional protections for certain classes of human research involving fetuses, pregnant women, human in vitro fertilization, and prisoners.

Research is defined as "systematic investigation designed to develop or contribute to generalizable knowledge." The federal government requires research to be reviewed by an institution's IRB based on the level of risk involved for human participants. There are three review categories: exempt, expedited, and full.

Applications marked "exempt" are reviewed by the IRB chair only; they are exempt from review by the full committee. If they are exempt they are electronically signed, stamped and filed within the online IRB application system. IRB approval is valid for one year. If the research described is not exempt, the applicant will be notified and the application must be processed as expedited or full.

Applications marked "expedited" are reviewed by the IRB chair or by one or more experienced members of the full IRB committee. If they are expedited and no additional information is needed, they are electronically signed, stamped and filed. IRB approval is valid for one year. If the research described is not exempt, the applicant will be notified and the application must be processed as exempt or full.

Applications marked "full" are reviewed by the full IRB committee. Applications are due by the 15th of the month and will be reviewed by the committee and then discussed at the next full committee meeting. The committee meets the first Thursday of every month. The meetings are closed to the public. However, the committee is happy to meet with individuals if advance notice is given.

CODE OF FEDERAL REGULATIONS
TITLE 45: PUBLIC WELFARE
PART 46: PROTECTION OF HUMAN SUBJECTS

EXEMPT ACTIVITIES

Paragraph 46.10 1

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal education 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, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (please see a and b above)

(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 (b)(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 the 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.

Source: *63FR 60364-60367, June 23, 2005. Department of Health and Human Services.*

See FAQ for examples of exempt activities.

EXPEDITED ACTIVITIES

While your study must still be reviewed, it may be exempt from full review by every IRB member and/or receive an expedited review if any of the following criteria are met. Note, however, that a study must still meet standard requirements for informed consent, regardless of the type of review-expedited, exempt or full- utilized by the IRB.

The *expedited review* may not be used where information is recorded in such a way that human participants can be identified and that disclosure of the information could create criminal or civil liability for them or damage their financial standing, employability, insurability, reputation or be stigmatizing.

Research categories that may apply for expedited review include, but are not limited to:
1. Research conducted in an established educational setting and involves normal educational practices, such as research on instructional strategies or comparison among instructional techniques, curricula, or classroom management methods.

2. Research that involves educational tests or surveys, interviews, oral history, focus groups, program evaluation, quality assurance methodologies or observation of public behavior. If the participants are children, this exemption applies only to research involving educational tests or to observations of public behavior where the investigators do not participate in the observed activities.

3. Research involving the use of educational tests, survey procedures, interviews, or observations of public behavior will be exempt if the subjects are elected or appointed public officials or candidates for public office. However, confidentiality of personally identifiable information is to be maintained.

4. Research involving existing data, voice, digital or image recordings, documents, records, pathological specimens, or diagnostic specimens made for research purposes or if these sources are publicly available or recorded so that individual identification is not possible.

5. Research and demonstration projects whose purpose is to study public benefit or service programs.

6. Continuing review of research previously approved by the convened IRB as follows: research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants; or no participants have been enrolled and no additional risks have been identified; or the remaining research activities are limited to data analysis.

*An expedited review procedure consists of a review of research involving human participants by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

Source: 63FR 60364-60367, June 23, 2005. Department of Health and Human Services.

See FAQ for examples of expedited activities.

Statement of Principles - §46.103(b)(1)

Stockton University is committed to the pursuit of excellence in teaching, research, and service. In an effort to maintain these pursuits, the Institutional Review Board for the Protection of Human Subjects (IRB) is primarily concerned with the welfare and consideration of the best interests of all subjects participating in research. Stockton gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46) better known as the "Common Rule." In doing so, all active human subject studies at Stockton University will be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk but not less than annually. University faculty, staff, and students are required to be certified using the Collaborative Institutional Training Initiative (CITI) subscription service before conducting research on human subjects. There are several general modules which all investigators must pass. There are also specific modules geared toward those investigators who study vulnerable populations. Investigators are required to submit paper copies of their certification records upon completion of the modules. These records can be accessed through the CITI database housed at Stockton University and will be verified prior to the approval of the IRB application. The IRB may also mandate that investigators who place human subjects at risk become certified in specific modules of the CITI software. These modules include specific training about how to protect vulnerable populations (e.g., prisoners, mentally challenged persons, children, and others) who will be targeted in research projects.

A human subject is defined in the regulation as "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information." The regulation extends to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The regulation also specifies additional protections for certain classes or human research involving fetuses, pregnant women, human in vitro fertilization, and prisoners. Subsequent to the publishing of these regulations, the term "subjects" has been replaced with the more accurate "participants" and will be used in the remainder of this document. Research is defined as "systematic investigation designed to develop or contribute to generalize knowledge."

Meeting Space and Staff - §46.103(b)(2)

The IRB office is located inside the Office of Research & Sponsored Programs, MCE-226. This office is maintained by five full-time staff members. The equivalent of one full-time staff person is dedicated to IRB duties including record-keeping. All official IRB records are kept electronically on a secure, password protected University intra-web system accessed through the Office of Research & Sponsored Programs web page. Only the IRB committee chair has full access to the intra-web system. Designated committee members and administrator have limited access based on responsibility level of review. The IRB meeting space is located in MCE-116.

Stockton University IRB Members - §46.103(b)(3)

Member Name (LAST, First MI)	Gender M / F	Earned Degree	Primary Scientific or Nonscientific Specialty	Affiliation with Institution(s) Y/ N	IRB Role
1. IRB Chair: Marissa P. Levy	F	Ph.D.	Criminal Justice	Yes	Faculty
2. Mark Mallet	M	Ph.D.	Theatre Arts	Yes	Faculty
3. Mary Lou Galantino	F	Ph.D.	Physical Therapy, Healthcare	Yes	Faculty
4.Adam Miyashiro	M	Ph.D	Literature	Yes	Faculty
5. M. Alysia Mastrangelo	F	Ph.D.	Physical Therapy, Healthcare	Yes	Faculty
6. Betsy McShea	F	Ph.D.	Education, Mathematics	Yes	Faculty
7. Amanda Leese	F	MA	Criminal Justice	No	Community
8. Deeana Button	F	Ph.D.	Criminal Justice	Yes	Faculty
9. Melissa Zwick	F	Ph.D.	Biology	Yes	Faculty

IRB Procedures

***§46.103(b)(4)(i)* for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;**

All students, faculty and staff at Stockton University who are actively engaged in research are required to conduct Collaborative Institutional Training Initiatives (CITI) training and certification. Investigators are required to submit paper copies of their certification records upon completion of the modules. These records can be accessed through the CITI database housed at Stockton University and will be verified prior to the approval of the IRB application. The IRB may also mandate that investigators who place human participants at risk become certified in specific modules of the CITI software. These modules will include specific training about how to protect vulnerable populations (such as prisoners, mentally challenged persons, children, etc.). If you are an investigator and you are not sure about which modules you must complete prior to IRB certification, please contact the IRB Chair, Marissa Levy at Marissa.Levy@Stockton.edu or 609-626-6825.

for conducting its initial review of research

The applicant should submit the online IRB application through this link http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=53&action=IRB. When the IRB application is received it will be distributed to the designated reviewer(s) via electronic email notice. All electronic applications are viewed by the committee chair. The applicant should be sure that the anticipated level of review, Exempt, Expedited or Full, is correctly selected, but the final decision about the level of review will be made by the IRB Chair. Please use the guidelines

and examples at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49 to determine the level of review.

Exempt Review applications –

Exempt applications will be reviewed by the Chair (or another experienced member of the IRB in the Chair's absence) within two weeks of the submission. Since exempt applications *do not* involve any risk or harm to human subjects, they do not need to be reviewed by the full IRB committee. The Chair will receive the application and review the application using the review sheet template which can be found at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49 . The review sheet will be submitted electronically as part of the application file. After reviewing the application, the Chair may:

- Return the application if it is not complete.
- Ask for clarification or changes on the application. Correspondence will be initiated from the IRB online application system via email to the applicant. The applicant will have 30 days to submit changes or clarifications to the applications. When the changes or clarifications have been received, the Chair will again review the application in its entirety before granting approval. If the changes are not received within 30 days, the application will be withdrawn from the approval process.
- Approve the application.

Once the application is approved, the Chair will generate an electronic approval via the IRB online application system to the applicant. The approval will expire one year from the date in which the approval was granted. If the research is not complete after one year, the applicant can apply for a "Renewal" to extend the project.

Expedited Review applications –

Expedited applications will be reviewed by the Chair (or another experienced member of the IRB in the Chair's absence) within two weeks of the submission. Since exempt applications involve *little to no* risk or harm to human subjects, they do not need to be reviewed by the full IRB committee. The Chair will receive the application and review the application using the review sheet template which can be found at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49 . The review sheet will be submitted electronically as part of the application file. After reviewing the application, the Chair may:

- Return the application if it is not complete.
- Ask for clarification or changes on the application. Correspondence will be initiated from the IRB online application system via email to the applicant. The applicant will have 30 days to submit changes or clarifications to the applications. When the changes or clarifications have been received, the Chair will again review the application in its entirety before granting approval. If the changes are not received within 30 days, the application will be withdrawn from the approval process.
- Approve the application.

Once the application is approved, you will be sent an email and the stamped Informed Consent Form (ICF), Assent Form (AF) or other pertinent documents will be uploaded through the IRB portal to your project. The applicant must use the informed consent form and assent forms that are stamped by the chair when collecting informed consent from the research participants in the study. Researchers may print as many copies of those stamped forms as needed for the research project. The IRB approval will expire one year from the date in which the approval was granted. If the research is not complete after one year, the applicant can apply for a "Renewal" to continue the project.

Please find examples of ICF, checklists for contents to be included on the ICF, and the review sheet template used by the IRB Chair and committee when reviewing applications at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49

Full Review applications –

Applications requiring full review expose human subjects to *some* risk so they must be reviewed by the full IRB committee. Applications requiring a review by the full IRB committee will be reviewed the first Thursday of each month assuming they have been submitted two weeks prior to that meeting*. The Committee receives the application electronically through the IRB online application system and reviews the application using the review sheet template which can be found at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49 . Each committee member will submit the review sheet electronically which will attach to the application file. The Committee may:

- Return the application if it is not complete.
- "Request Modifications" to the application. Notification about this outcome will be delivered via email to the Primary Investigator/Faculty Sponsor. The email will include a summary of the decision by the IRB including a list of modifications that are required before the application will be reviewed again. If the modifications are submitted within 30 days, the application does not need to go back to the full IRB committee. Instead, the Chair will review the modifications to determine if approval can be given.
- "Approve" the application.

Once the application is approved, the Chair will notify the Primary Investigator/Faculty Sponsor vie email and upload the stamped Informed Consent Form (ICF), Assent Form (AF) or other pertinent documents to the project within the IRB portal. The applicant must use the informed consent form and assent forms that are stamped by the chair when collecting informed consent from the research participants in the study. Researchers may print as many copies of those stamped forms as needed for the research project. The IRB approval will expire one year from the date in which the approval was granted. If the research is not complete after one year, the applicant can apply for a "Renewal" to continue the project.

Please find examples of ICF, checklists for contents to be included on the ICF, and the review sheet template used by the IRB Chair and committee when reviewing applications at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49

*The full IRB committee meets the first Thursday of each month, September-June. Applications are due 2 weeks prior to the full IRB committee meeting. Applications received after this deadline will be reviewed at the next monthly meeting. Please see IRB website at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=16 for the full meeting schedule and application due dates.

Closing IRB approval for a research study

Within one month of the anniversary date which signifies the expiration of the project, the Primary Investigator will receive an email asking for assurance that the study has finished or, if not, reminding the Primary Investigator to apply for a renewal. The Primary Investigator should respond by the anniversary date to certify that the project has ended or his/her intention to apply for a renewal. If no correspondence is received by the anniversary date of the approval, the IRB will assume that the data collection phase of the research project is complete.

for conducting its continuing review of research

If the applicant is continuing a research project past the expiration date, the applicant must apply to the IRB for "Renewal." The applicant should log on to the IRB portal and request a renewal. Renewal applications, for which "Expedited" or "Full" review status was granted during the initial review, will be reviewed by the Chair within two weeks. If there is an informed consent form and/or assent form, they will be stamped with a new expiration date and a copy will be uploaded to the IRB portal. If substantial changes have occurred, the renewal application will be treated as a new application and follow the procedures outlined above.

***§46.103(b)(4)(ii)* the procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;**

All projects that have been approved by the IRB will be reviewed on a continuing basis at intervals appropriate to the degree of risk as determined by the IRB, but not less than once per year. The IRB will determine the frequency of continuing review when it grants final approval to a proposed study. A standard approval letter via electronic email will be used to notify the investigator of the approval and length of approval for each proposal.

The IRB will determine whether a project requires more than annual review and may require an additional monitoring procedure that could include monitoring the consent process, observation of the research procedures, verification from a third party that there have been no material changes in the research since the previous review, and/or review of research-related records. Projects requiring increased levels of monitoring may be: randomly selected projects, complex projects involving unusual levels or types of risk to participants, projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB, and/or projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

The IRB requires complete transparency in the research process. IRB members must have access to all stages of the research process unless presence of the IRB member could compromise the confidentiality or anonymity of research participants and thus, increase risk to human participants.

The IRB may be called into an interim review session by the Chairperson at the request of an IRB member or investigator to consider any matter concerned with the rights and welfare of any subject. The length of the approval will be documented in the Minutes of the meeting, on the review form completed by each IRB member, and communicated to the applicant in the email correspondence.

§46.103(b)(4)(iii) **the procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.**

In the event that there are changes to your project or protocol after it has been approved, you must notify the IRB immediately submitting a Change in Research form which is available at: http://intraweb.stockton.edu/eyos/grantsoffice/content/docs/Change%20in%20Research%20Form%2009.pdf . You may not continue your research study until the new protocol or changes have been approved by the IRB. If the changes are immediately necessary for the safety of a participant who is currently involved in the project, you must create an interim management plan to insure the safety of your participant and notify the IRB within 24 hours of the event. This may require the Primary Investigator to submit an Adverse Event form detailing the event or issue. The interim management plan should be submitted to the IRB and should explain what steps you took to eliminate the immediate hazard to the participant. Once the IRB receives your Change in Research form or Adverse Event form, the IRB may approve the change in research or request modifications in order to better protect human participants. The applicant will be notified via electronic email about the outcome of the event.

If an unanticipated problem or event has occurred, the investigator must fill out the Unanticipated Problem Safety Form which is available at: http://intraweb.stockton.edu/eyos/grantsoffice/content/docs/Change%20in%20Research%20Form%2009.pdf and submit it through the IRB portal. This form will be discussed further, below.

§46.103(b)(5)the procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

If an unanticipated problem or event has occurred, the researcher must complete and submit the Unanticipated Problem Safety Form which is available at: http://intraweb.stockton.edu/eyos/grantsoffice/content/docs/Change%20in%20Research%20For

m%2009.pdf. Federal regulations and Stockton University IRB require the prompt reporting of research problems, incidents, or new information that involves risk or harm to subjects or others.

Unanticipated Problem involving Risk/Harm to Subjects or Others (UP) - includes all 3 of the following conditions: (a) not anticipated or foreseen (eg. not described in the consent form); *AND* (b) involves risk or harm to a research participant or others; *AND* (c) probably, or definitely related to, or caused by, the research. UP is an umbrella term which includes *unanticipated* 'Adverse Events' and also includes other unanticipated events, such as 'breaches in confidentiality'. An unanticipated event may be the availability of new information about risk from the sponsor or safety monitoring board. Risks of the research or side effects that are addressed in the protocol and informed consent document are generally not unanticipated problems **unless** they occur with greater frequency or severity than anticipated.

If the investigator suspects an UP, she or he should review the definition of an unanticipated problem, specify urgency and identify the type of unanticipated problem, using the form located on the web:
http://intraweb.stockton.edu/eyos/grantsoffice/content/docs/Unanticipated%20Problems%20Reporting%20Form09.pdf . Complete the Investigator's Assessment Section and (with any supporting materials) to Stockton University IRB submit through the IRB online application system within 24 hours of occurrence or notification of a problem from an external site. The IRB will be provided with the original IRB application as well the UP form and materials through the IRB online application system. The IRB will evaluate the nature and extent of the UP and report findings using the IRB section of the UP form. Findings will be forwarded to the appropriate parties (see below).

Unanticipated problems involving risks to subjects or others or any serious and/or continuing noncompliance may lead to suspension or termination of IRB approval. If Unanticipated Problems, any serious and/or continuing noncompliance, suspension or termination occurs, the IRB's actions will be reported to the appropriate institutional official(s) and to the appropriate federal department(s) or agency head(s) as follows:

- The IRB Chair and experienced IRB committee members will prepare and forward correspondence. Unless unavailable, the correspondence will go out over the signature of the Provost. If the Provost is not available, then the correspondence will go out over the signature of the Executive Director of ORSP.

- The correspondence will be prepared and forwarded within ten working days of the IRB's final determination.

- A copy of the correspondence will be forwarded to the following parties in all cases:
  a. Principal Investigator,
  b. Dean or Assistant Dean,
  c. Program Coordinator or Program Director
  d. Office of Research & Sponsored Programs

- If the study is externally funded, the Office of Research & Sponsored Programs is responsible for notifying:
    a. The study sponsor, including any federal funding sponsors or agency;
    b. Office for Protection of Human Research if the study is federally funded;
    c. Other Common Rule agencies if the research project is conducted under the oversight of these agencies, e.g., the Department of Energy, Department of Defense, Department of Homeland Security, and others.

- Written correspondence will include but is not limited to the following:
    a. Name of the institution;
    b. Title of the research project;
    c. Name of the principal investigator;
    d. The type of determination made by the IRB (i.e., unanticipated problem, serious and/or continuing noncompliance, suspension or termination);
    e. Detailed description of the findings and the reason for the determination;
    f. Change of Protocol or Unanticipated Events forms;
    g. Actions undertaken to address the problem; and
    h. Plans for continued investigation or action, if any.

In order to minimize UP and to maintain the integrity of all research that is conducted at Stockton University or by Stockton University members, all investigators are required to conduct Collaborative Institutional Training Initiatives (CITI) training and certification. Investigators are required to submit paper copies of their certification records upon completion of the modules. These records can be accessed through the CITI database housed at Stockton University and will be verified prior to the approval of the IRB application. The IRB may also mandate that investigators who place human participants at risk become certified in specific modules of the CITI software. These modules will include specific training about how to protect vulnerable populations (such as prisoners, mentally challenged persons, children, and others)

IRB Guidelines for Convened Meetings

In accordance with HHS regulations contained in article 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas and one member whose primary concerns are in scientific areas, except where expedited review is appropriate. Stockton University IRB meets the first Thursday of every month, September – June. Materials are due to the IRB portal no later than two weeks prior to the review date, in order to be considered at that month's convened meeting. The materials are then distributed to the IRB Committee at least one week prior to the convened meeting.

Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

The IRB will review materials, complete the review form (found at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49), and determine if protection for human participants has been provided. In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under HHS regulations contained in article 45 CFR 46.111. Materials should include:

- the full protocol method,
- a proposed informed consent document (on letterhead),
- any relevant grant application(s),
- any recruitment materials, including advertisements intended to be seen or heard by potential subjects.

Furthermore, for any federal granting agency (for example, HHS-supported multicenter clinical trials or the like), along with the IRB application, the IRB should receive and review a copy of the agency-approved sample informed consent document and the complete agency-approved protocol, if they exist. These materials should be received by the IRB office two weeks in advance of the meeting date to allow review of the materials.

The minutes of IRB meetings will document separate deliberations, actions, and votes for each protocol undergoing full or continuing review by the convened IRB.

Continuing Review Materials. Continuing review of research must be substantive and meaningful. The IRB must ensure that the criteria set forth by HHS regulations contained in article 45 CFR 46.111 are satisfied at the time of continuing review.

In conducting continuing review of research not eligible for expedited review, all IRB members should at least receive and review a protocol summary and a status report on the progress of the research that includes:

- the number of subjects accrued;
- a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document);
- a summary of any withdrawal of subjects from the research since the last IRB review;
- a summary of any complaints about the research since the last IRB review;
- a summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last IRB review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document and any newly proposed consent document (on letterhead).

IRB Review in Emergency Situations. HHS and Stockton University regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review

and approval (see 45 CFR 46.103(b) and 46.116(f) and OHRP guidance at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. When emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject under 45 CFR Part 46. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied.

Contingent Approval of Research. The applicant may not make changes to the protocol in non-emergency situations unless those changes have been reviewed by the convened IRB.

Conflicting Interest. HHS regulations contained in article 45 CFR 46.107(e) and Stockton University IRB stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP recommends that except when requested by the IRB to be present to provide information, IRB members absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such removal should be noted in the IRB meeting minutes.

Minutes of IRB Meetings. The minutes of IRB meetings include, among other things, separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The comments from the IRB are recorded and are only visible to the IRB members and the researchers who are given access to the portal by the Primary Investigator.

Documentation of Consent Procedure. HHS regulations contained in article 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure:

- approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
- approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207);
- approving research involving prisoners (see 45 CFR 46.305-306);or
- approving research involving children (see 45 CFR 46.404-407).

Retention of IRB Records. HHS regulations contained in article 45 CFR 46.115(b) require that IRB records be retained for at least three years after completion of a research project. All applications and review files are kept on a server and are accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.

Selection of the IRB Members and Chairperson. The IRB committee must include at least five (5) members who are actively engaged in research. The committee must consist of at least one male and one female member, at least one science and one non-science member, and at least one person from outside the University. Stockton University IRB will actively seek to recruit members to the IRB. Once potential IRB members are identified, approached, and are willing to join the IRB committee, a letter directed to the Chair of the IRB from the individual's Dean or Director is required to formally recommend the member. The IRB member must become

certified in all appropriate modules of the Collaborative Institutional Training Initiative (CITI). Because the IRB member must commit to substantial training, time, and effort, the member will hold his or her position until resignation. The IRB Chairperson, however, should be elected by the IRB members from the IRB committee membership (if possible) to serve for a period of two years. If a complaint, problem or other issue arises regarding a member of the IRB, it should be directed to the Chair. If a complaint, problem or other issue arises regarding the Chair of the IRB, it should be directed to the Provost.

Training. Each member of the IRB is responsible for knowing and following all rules and regulations regarding the IRB approval process. IRB members are also required to complete Collaborative Institutional Training Initiative (CITI) training. IRB members and staff are also responsible for educating the University community regarding the purpose, intentions and federal requirements of the IRB.