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 passing an exam. Individual human subject regulations define an investigator (whether professional or student) conducting research obtains data through intervention or interaction wcnet 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 federrtt -4.6(ol1.7(i)-d.7( ) 2)the level of risk involved for human participants. There are three review c 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 15

th 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

EXPEDITED ACTIVITIES

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
[redacted]					
8. Deeana Button	F	Ph.D.	Criminal Justice	Yes	Faculty
9. Melissa Zwick	F	Ph.D.	Biolog75.-0 0 12 l		

[redacted]

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

*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

The IRB requires r r1me 704 Tna10(rr)-n4 Tncy esI10(rr)-1me15(ea10(r(c0(I)1 04 14510(r)o4 Tnc)- 72-1me 71

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

- 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.

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

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 vtct(e)4(nds) inf0 0 Tc m-3(F)(E)-2t1(e)4

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