Stockton University
Institutional Review Board
Guidelines and Regulations

All active human studies at Stockton University must be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk. All research involving human participants conducted by **Stockton Faculty, Administrators, Staff, and Students,** or on its campus, must be conducted 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, and updated on January 18, 2018, requires basic protection for human participants involved in research covered under the Multiple Project Assurance. All researchers submitting IRB applications requiring expedited and full review are required to demonstrate proficiency in knowledge about how to protect human participants by completing the online training and submitting certificates of that training. To fulfill this requirement, see www.citiprogram.org, the website for Collaborative Institutional Training Initiative (CITI) training modules.

A ***human participant*** 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 participants as well as to graphic, written, or recorded information derived from individually identifiable human participants. The regulation also specifies additional protections for certain classes of human research involving prisoners, children, individuals with impaired decision-making, and economically or educationally disadvantaged persons.

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. The following are not considered research: oral history, journalism, literary criticism, historical scholarship, legal research, public health surveillance, collection/analysis of biospecimens by criminal justice agencies, national security measures, program improvement activities, and quality assurance or quality improvement. There are three review categories for research: exempt, expedited, and full. 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.

An application marked "exempt" is reviewed by the IRB chair only; it is exempt from review by the full committee. If it is exempt it is electronically signed, stamped, and filed within the online IRB application system. If the applicant selects "exempt" review but the chair determines the level of review required is expedited or full, the applicant will be notified and the application will be processed as expedited or full. See FAQs for examples of exempt research.

An application marked "expedited" is reviewed by the IRB chair or by one or more experienced members of the full IRB committee. If it is expedited and no additional information is needed, the application will be electronically signed, stamped, and filed. If the research described is not expedited, the applicant will be notified and the application will be processed as exempt or full. See FAQs for examples of expedited research.

An application marked "full" is reviewed by the full IRB committee. Applications are due two weeks prior to the full committee meeting (see schedule online) to 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. See FAQs for examples of research requiring full review.

Statement of Principles

Stockton University is committed to the pursuit of excellence in teaching, scholarship, and service. In an effort to maintain these pursuits, the Institutional Review Board for the Protection of Human Participants (IRB) is primarily concerned with the welfare and consideration of the best interest of all participants 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 Participants (45 CFR 46) better known as the "Common Rule" most recently updated on January 18, 2018. In doing so, all active human participant studies at Stockton University will be reviewed by the Institutional Review Board (IRB) at intervals appropriate to the degree of risk. University faculty, staff, and students are required to be certified using the Collaborative Institutional Training Initiative (CITI) subscription service before conducting research requiring expedited for full board review.

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 upload their certification records to the IRB portal along with the other application materials. 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 training. 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.

Meeting Space and Staff

The IRB office is located inside the Office of Research & Sponsored Programs, MC E-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 an administrator have limited access based on the responsible level of review. The IRB meeting space is located in MC E-116.

IRB Procedures for New Projects

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.

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 participants, they do not need to be reviewed by the full IRB committee. 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. When the changes or clarifications have been received, the Chair will again review the application in its entirety before granting approval.
- 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 be given an expiration date. If the research is not complete after the expiration date, 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 participants, they do not need to be reviewed by the full IRB committee. The Chair will receive the application and review the application. After reviewing the application, the Chair 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. Correspondence will be initiated from the IRB online application system via email to the applicant. When the changes or clarifications have been received, the Chair will again review the application in its entirety before granting approval.
- 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 include an expiration date. The applicant can apply for a "renewal" to continue the project.

Please find examples of Informed Consent Form (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 on the website.

Full Review applications –

Applications requiring full review expose human participants 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, 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 via 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 be given an expiration date. If the research is not complete by the expiration date, 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

* Please see IRB website at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49 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 request a renewal by the anniversary date. If no renewal is requested by the anniversary date of the approval, the IRB will assume that the data collection phase of the research project is complete.

IRB Procedures for Existing Projects

If the applicant is continuing a research project past the expiration date, the applicant must apply to the IRB for "Renewal" and upload the original application as well as any informed consent or assent forms to be stamped with a new expiration date. 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.

IRB Procedures for Documenting Change in Research Projects or Adverse Events

In the event that there are changes to a project or protocol after it has been approved, the primary investigator must notify the IRB immediately by submitting a Change in Research form which is available at: http://intraweb.stockton.edu/eyos/page.cfm?siteID=92&pageID=49. The research project may not continue 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, create an interim management plan to insure the safety of the 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 were taken to eliminate the immediate hazard to the participant. Once the IRB receives the 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.

Unanticipated Problem involving Risk/Harm to Participants 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 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/page.cfm?siteID=92&pageID=49. Federal regulations and Stockton University IRB require the prompt reporting of research problems, incidents, or new information that involves risk or harm to participants or others. If an UP has occurred, 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 participants or others or any serious and/or continuing noncompliance may lead to suspension or termination of IRB approval. If 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.

IRB Review in Emergency Situations

HHS and Stockton University regulations do not permit human participant 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 participant 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.

Transparency in Research

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 participant. The results of that meeting 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.

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 exempt or 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 10 days 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, 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 participants.

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 two weeks in advance of

the meeting date to allow review of the materials.

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.

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 for IRB members. IRB members and staff are also responsible for educating the University community regarding the purpose, intentions and federal requirements of the IRB.