Institutional Review Board Guidelines for the Protection of Human Participants in Research

Internal Policies and Procedures

Developed May 2023[1]

[1] The information in this manual is adapted from a variety of institutions. Permission was sought and obtained from several institutions to adapt large sections of information. Permission was not sought in instances where information from multiple sources was combined or limited text from one institution was modified. Instead, we list sources of information here and extend our ongoing appreciation for the common practice of information sharing among IRBs. In particular, we are grateful to HRP Consulting, Solutions IRB, Rowan University, Montclair University, The College of New Jersey, William Paterson University, WCG IRB, University of Texas at Austin, University of Virginia, University of Oklahoma, Nova Southeastern University, University of Santa Cruz, Yale University, California State University at San Marcos, University College of Dublin, University of Oregon, University of Pittsburgh, University of Nevada at Reno, Iowa State University, University of Maryland at Baltimore County, University of Mississippi, and Pennsylvania State University for the direct and indirect use of their IRB policies, procedures, and practices.

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1. Statement of Principles and Purpose

Stockton University is committed to the pursuit of excellence in teaching, research, and service. In an effort to maintain these pursuits and permit the advancement of research, Stockton has established an Institutional Review Board (IRB) to ensure the welfare, safety, and rights of every person who may be involved in research with human participants. 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). Stockton's IRB will review all research involving human participants to ensure that human subjects research is competent, ethical, and sound, regardless of the source of funding.

The ethical principles of respect for persons, beneficence, and justice outlined in the Belmont Report guide Stockton's IRB review to ensure that (1) all participants in research are respected as autonomous persons and that special care is taken not to exploit those with diminished autonomy, (2) the benefits of the research are reasonable and outweigh any risk, and (3) no group or category of people is given undue opportunity or undue burden through participation in research.

2. Engagement in Research

Stockton is responsible for ensuring appropriate oversight of the human subjects research it engages in human subjects research. The Office of Human Research Protections (OHRP) states:

> *An institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents, for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.*

When Stockton University is an awardee institution of an award through a grant, contract, or cooperative agreement directly from the Department of Health and Human Services (DHHS) for non-exempt human subjects research, it is considered engaged in research, even if all activities involving human subjects are carried out by employees or agents of another institution.

When Stockton University is engaged in research, the Institutional Official[2] may choose to enter into an agreement to cede review to an external IRB. See Section 27 for additional information on agreements.

3. Required Training For Researchers

Stockton University is committed to providing training and on-going education for investigators and research staff members on human subjects protections and other relevant topics.

A. Initial Training

All researchers at Stockton University must complete Collaborative Institutional Training Initiative (CITI) tutorials on Conflict of Interest (COI) and Responsible Conduct of Research (RCR) training. Investigators and research staff who interact or intervene with subjects or use a subject's identifiable information for the purposes of research must complete Human Subjects Research (HSR) courses relevant to the type of research being conducted and/or to the investigator or staff member's responsibilities.

Students who wish to participate in faculty or staff-led research projects must complete the CITI's Student Researcher module. Students who are completing theses, dissertations, or distinction projects should complete the Human Subjects Research (HSR) courses relevant to the type of research being conducted. The Student Learner module is recommended for students who are enrolled in research courses.

The CITI website is available here and an information sheet detailing Stockton's CITI training requirements may be found here or through Stockton's Office of Research and Sponsored Programs (ORSP) IRB webpage here. Training certifications are valid for three years and must be valid for at least three remaining months at the time of initial IRB approval. Evidence of current COI, RCR, and HSR training for each member of the research team must be included with every new study application and applications to add study personnel. New study applications and additions of study personnel will not be moved forward for IRB review without evidence of training.

Research team members unaffiliated with Stockton may provide documentation of equivalent training through another institution in lieu of Stockton's CITI courses. Stockton's IRB Chair or Administrator will review the documentation and determine if it satisfies organizational standards. However, if previous training has not been

[2] Attachment A: Initial Considerations for Single IRB Review: Points to Consider

completed, external investigators should complete Stockton's CITI training requirements specified here.

B. Continuing Education

Initial training is considered current for a period of three years. Upon expiration, investigators and research staff must recomplete basic or refresher CITI training or provide evidence of equivalent training. There is no exception to this requirement.

Training will be verified at the time of either continuing or administrative review and when applications request to add study personnel. If training has not been completed, is set to expire less than three months after application approval or has lapsed and is not completed in a timely manner, the investigator or staff member may be removed from the study or otherwise restricted from participating in all research-related activities until there is evidence of training completion.

In addition to the basic requirements described above, Stockon will periodically provide training on topics relevant to human subject protections, regulations, policies and standards, and IRB submission processes and requirements. Training may be provided via in-service, workshops, webinars, e-Learning, or through the distribution of articles, presentations, and other materials. Investigators and staff may request training or offer training suggestions by contacting the IRB Chair and/or Administrator.

The OHRP maintains an education website here with links to training material such as webinars, YouTube videos, and PDF documents for investigators who are interested in learning more.[3]

4. Applicability

All research involving the collection of information, data, or specimens/samples from or about human subjects or information, data, specimens/samples gathered from humans at some prior time either by the researchers themselves or someone else, must be reviewed and approved by the IRB prior to such studies being undertaken.

The information presented here applies to any research whether it is new, ongoing, or proposed, regardless of funding status and source, whether conducted at Stockton University or elsewhere, even if approved by an institutional review board of another

[3] Researchers applying for federal funding through NIH must complete the NIH On-line Educational Module prior to beginning the research study. The NIH On-line Educational Module can be accessed here. The certification of completion from this module must be forwarded to Stockton's ORSP and/or IRB.

institution of higher education or other entity, by anyone affiliated with Stockton University (i.e., faculty, adjuncts, staff, students).

5. Enactment

Enactment of the Institutional Review Board Guidelines for the Protection of Human Participants in Research is subject to currently approved procedures at Stockton University. See Procedure 1060 for more information.

Amendments will be required to reflect changes in Federal, State, and/or Local legislation. In the event of legislative changes impacting research and compliance the IRB Chair, Administrator, and Compliance Officer must consult to determine the appropriate amendment proposal to maintain legal compliance. The IRB Chair will inform the IRB of these changes on an annual basis at a convened IRB meeting.

6. Institutional Official

The Institutional Official (IO) is the individual who is legally authorized to act for the institution and on behalf of the institution and obligates the institution to the Terms of the Federalwide Assurance (FWA). The IO is responsible for ensuring that the larger Human Research Protections (HRPP) program functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. At Stockton, the IO holds the rank and authority to ensure that all obligations of the HRPP and FWA are carried out effectively and efficiently. The IO is appointed by the University President without specific term limits.

Stockton's IO, in conjunction with the IRB and other entities of the HRPP, will promote and support an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is maintained at all levels of the organization. In particular, the IO is responsible for:

- Completing the Conflict of Interest (COI), Essentials of Research Administration, Responsible Conduct of Research (RCR) for Research Administrators, and Institutional/Signatory Official: Human Subject Research (HSR) CITI Training modules;
- Assuming the signatory authority of the FWA;
- Ensuring that the IRB functions independently and that its chair and members have direct access to the IO for appeal, if they experience undue influence or if they have concerns about the function of the IRB;

- Ensuring that sufficient resources, space, and staff are available to support the operation of the IRB;
- Ensuring that sufficient resources, training, and educational opportunities are available for the IRB and investigators;
- Ensuring that effective mechanisms for institution-wide communication and guidance on human subjects research are available;
- Authorizing necessary administrative or legal action, if required, related to HRPP.

The IO may delegate the performance of certain oversight and operational duties to one or more individuals. Any delegation of duty must be in writing. As with any institution, the IO does not have the authority to approve research that has been disapproved or not yet approved by the IRB, but may disapprove research approved by the IRB. Any disapproval of research by the IO needs written justification, provided to the investigator and IRB, that indicates what University Policy or Procedure prevents the research from institutional approval.

7. Executive Director of ORSP

The Executive Director (ED) is the individual responsible for overseeing the ORSP. As the ED, they are responsible for the University's research integrity, regulatory compliance and the overall guidance, management, and execution of Stockton University's sponsored research activities. Responsibilities of the ED includes but is not limited to:

- Ensuring that adequate personnel, space, and other resources are allocated to the IRB;
- Connecting researchers to appropriate regulatory departments and personnel regarding their proposal, (e.g., Tax Department, Legal Department, Compliance Officer, IRB Administrator, etc.);
- Performing periodic evaluations of ORSP administrative staff;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities; and
- Serving as a knowledgeable point of contact for OHRP and other federal agencies or delegating this responsibility to another appropriate individual.

8. Compliance Officer

The Compliance Officer (CO) is the individual responsible for ensuring university-affiliated activities are compliant with applicable federal, state, local, sponsor, and university policies in the areas of human subjects, animal care and use, biosafety,

research misconduct, and responsible conduct of research. Key responsibilities of the CO include:

- Overseeing policies and procedures relating to human subjects research and the ORSP;
- Serving as liaison for, university faculty, staff, administrators, and/or legal counsel to interpret and resolve research compliance issues;
- Providing guidance and assistance to campus community with regard to the interpretation and application of regulations and requirement involving research activities;
- Preparing correspondence with the OHRP, and/or other agencies as applicable, including reports to federal agencies, on matters related to human subjects research;
- Engaging in quality assurance and improvement activities;
- Determining on an annual basis if the membership and composition of the IRB continues to meet regulatory and organizational requirements;
- Participating, where necessary, in "for cause" and "not for cause" compliance reviews; and
- Serving as the university's research integrity officer (RIO) with oversight of the university research misconduct policy, procedures, and investigations.

9. Institutional Review Board (IRB)

A. Federal Wide Assurance and IRB Registration

DHHS regulations require that institutions engaged in non-exempt human subjects research that is conducted or supported by any HHS agency file must maintain a Federalwide Assurance with the OHRP. A FWA is an organization's assurance to the U.S. government that human subject research is conducted in compliance with federal regulations pertaining to the protection of human subjects. Stockton University maintains a FWA on file with OHRP and ensures that it remains current. Stockton University has opted to voluntarily apply the Common Rule (i.e., Subpart A) and Subparts B, C, and D to all of its non-exempt human subject research regardless of the source of support.

Stockton University maintains its FWA and IRB registration(s) in accordance with applicable regulations and guidance provided by OHRP. The HHS registration system database can be used to verify the status of Stockton University's FWA, IORG, and IRB registration.

Stockton University's Federal Registration Numbers

FWA	FWA00014746
IORG	IORG0005882
IRB Registration	IRB00010183

All members, the Chair, and the IO are included in the OHRP IRB registration. Per federal requirements, each IRB must renew its registration every three years. An IRB registration also must be updated within 90 calendar days after changes occur.

B. Authority of the IRB

Under §46.109, IRBs have the authority:

- To approve, require modifications to secure approval, or disapprove human subjects research activities, including exempt research activities;
- To require that informed consent is obtained and documented in accordance with regulatory and policy requirements, unless the IRB determines that the criteria for the waiver or alteration of such requirements have been satisfied and approves the waiver or alteration. The IRB may require that information, beyond what is required, be given to the subjects when it would meaningfully add to the protection of the rights and welfare of subjects;
- To conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk of the research, but not less than once per year,
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
- To observe, or have a third party observe, the consent process; and
- To observe, or have a third party observe, the conduct of the research.

In order to verify compliance with IRB regulations, the IRB has the authority to physically inspect any research premises or review non-confidential research documents relating to the protocol and procedures used in human subject research. Failure to comply with an IRB request for information may result in suspension or termination of IRB approval of research.

C. Responsibilities of the IRB

The IRB is housed in Stockton's Office of Research and Sponsored Programs (ORSP) and reviews research involving human subjects conducted at or sponsored by the University to ensure that all Human Subject Research complies with applicable regulations, meets commonly accepted ethical standards, follows institutional policies,

and adequately protects research participants. Specifically, the IRB is responsible for ensuring that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2) selection of subjects is equitable, (3) informed consent is obtained by adequate and appropriate means, and (4) ongoing research is reviewed at least every 12 months.

i. Risk to Benefit Ratio and the IRB's Responsibility

One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care or social understanding. Stockton's IRB considers study design and the overall quality of a study in order to effectively evaluate the risk-benefit ratio and to ensure that risks to subjects are reasonable in relation to the knowledge that may reasonably be expected to result. In order to assess the risks and benefits of the proposed research, the IRB must determine that:

- The research uses procedures consistent with sound research design;
- The research design is sound enough to reasonably expect the research to answer its proposed question; and
- The knowledge expected to result from this research is sufficiently important to justify the risk.

If there are no direct benefits for research participation and the proposed research study is methodologically flawed to the point that no meaningful or reliable information will result, it may be considered unethical to expose subjects to any level of risk or inconvenience by including them in the research study. At the same time, the IRB recognizes that certain circumstances warrant approval of research even if study design is not preeminent, but where the risks to participants are virtually non-existent (e.g. social science research submitted by students).

As such, Stockton's IRB uses the individual and collective judgment of its members when considering whether or not to approve a study based on the risk to benefit ratio. Researchers can assist in this process by carefully considering whether the design of their study will adequately answer the research question. If not, the researcher must consider whether there is undue risk present for participation.

D. Confidentiality of IRB Proceedings

The IRB seeks to maintain the fundamental principle of openness in research. However, the value of openness is limited by considerations of the (1) privacy of human participants in research, (2) confidentiality of proprietary data, (3) need to encourage

free discussion at IRB meetings, and (4) desire to promote cooperation in carrying out the responsibilities of the IRB.

To promote a balance between openness and privacy concerns, the IRB adheres to the following guidelines:

- Consider a research protocol and all associated application materials to be confidential documents. IRB members and staff will maintain confidentiality of any IRB proceedings and ensure that all IRB-related materials are properly stored or disposed of. IRB members and staff will not discuss protocols or share discussions of protocols with others outside the IRB, other than the research team of the proposal.
- Attendance at regular IRB Meetings will be limited to IRB members and staff, unless a consultant or investigator has been invited by the IRB Chair.
- Minutes of IRB meetings will not be made available to others outside the IRB, unless otherwise required by law or external regulations. Individual IRB members will not be identified in the minutes in relation to discussions of research protocols. Meeting minutes are maintained by the IRB Administrator in the electronic IRB system, as well as saved to the IRB shared drive.

10. Composition of the IRB

The structure and composition of Stockton's IRB is based upon regulatory requirements and characteristics of the research it reviews. Stockton's IRB is sufficiently qualified through the experience and expertise of its members and includes those who are knowledgeable about and experienced in working with subjects vulnerable to coercion or undue influence. To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, Stockton's IRB includes persons diverse in race, gender, cultural backgrounds, and those who are sensitive to community attitudes. In particular, Stockton's IRB includes:

- At least five members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted at Stockton. The IRB aims to include at least one faculty member from SOBL, EDUC, HLTH, NAMS, ARHU, GENS, and BUSN to ensure sufficient knowledge of the specific discipline(s) relevant to the research reviewed at Stockton.
- At least one member whose primary concern is in a scientific area. A *scientific member* is an individual who has formal education and training as a physician or other medical professional, a Master's, or Doctoral level physical, biological, or social-behavioral scientist, or significant post-baccalaureate work experience in a physical, biological, or social-behavioral sciences.

- At least one member whose primary concern is in a nonscientific area. A *non-scientific member* is an individual who may have formal education and training in a discipline generally considered to be non-scientific (e.g. humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be nonscientific (e.g. law enforcement, management, minister, lawyer, clergy, ethicists, accountants) even if the individual did have some formal training in a scientific field unrelated to his/her current occupation and career.
- At least one member who is unaffiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization. *Unaffiliated members* may not be a current or previous employee or student and/or may not have an immediate family member who is a current or recent employee or student of Stockton University. *Recent employees* are defined as individuals who have been employed by Stockton any time during the previous three years.

A member of the IRB may fill multiple membership position requirements (e.g., nonscientific and unaffiliated). On an annual basis, the IRB Chair and the Compliance Officer will review the membership and composition of the IRB to determine if it continues to meet regulatory and organizational requirements. A current list of the IRB members is posted on the IRB website here.

Any change in appointment, including reappointment or removal before the end of a member's term, requires written notification. Members may resign by written notification to the IRB Chair, Administrator, and/or Compliance Officer. The Compliance Officer and Institutional Official will ensure that changes in IRB membership are reported via the federal IRB registration in accordance with the instructions provided on OHRP's website. All members, the Chair, and the IO are included in the OHRP IRB registration. Per federal requirements, each IRB must renew its registration every three years. An IRB registration also must be updated within 90 days after changes occur.

A. IRB Chairperson

The IRB Chair should be a highly respected individual who is fully capable of managing the IRB and the matters brought before it with fairness and impartiality. Ensuring that the IRB is a respected part of the institutional community is a primary responsibility of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

The IRB Chair must hold at least a rank of a tenured Associate Professor and have significant human subjects research experience and training, as well as significant IRB experience.

The Chair of the IRB will be appointed by the Provost upon recommendation of a selection committee. The selection committee shall consist of the current Chair of the IRB, the Executive Director of the ORSP (or designee), a designee chosen by the Provost, and three (3) faculty members selected through consultation with the President of the Faculty Senate, and Executive Director of the ORSP.

The IRB chair must read and familiarize themselves with the following institutional policies and procedures:

- IRB Guidelines for the Protection of Human Participants in Research: Internal Policies and Procedures,
- Procedure 1035 General Assurances Statement: Protection of Human Rights in Experiments,
- Policy I-52.5 Committee on the Protection of Humans Subjects,
- Procedure 6350 Managing Conflicts of Interest,
- Procedure 1097 Research Participant Payment Process, and the
- Memorandum of Agreement for the IRB Chair.

The IRB Chair will:

- Complete the required human subjects protection training and ensure that all IRB members are also in compliance with ethics training;
- Ensure that the criteria for IRB approvals according to 45 CFR 46.111 are met for all review assignments, including expedited and full protocols;
- Ensure that all IRB actions are in accordance with University policies and applicable federal, state, and local laws;
- Maintain confidentiality for all matters related to IRB review and those provided to the Chair for IRB consultation;
- Serve as the signatory for all correspondence generated by the IRB;
- Determine the appropriate level of review (Exempted, Expedited or Full IRB) for all human subjects research or determine if the research is excluded from review by the IRB;
- Review and approve protocols requiring exempt and expedited review on a weekly basis and communicate findings to Primary Investigator;
- Facilitate at least nine (9) full IRB meetings annually;
- Review Full Board protocols, as necessary, and communicate findings from the Full Board to Primary Investigator;

- Ensure that any member of the IRB who is conflicted is not involved in reviewing a protocol, that current IRB members are up-to-date with required training, and that all members complete required activities for satisfactory service;
- Participate in recruitment and training of new IRB members;
- Work with the IRB Administrator to ensure regular maintenance of the IRB's website, application system, and supporting documents on at least an annual basis; and
- Support outreach efforts to Stockton students, staff, and faculty to increase community knowledge about the IRB and its process.

The IRB Chair is authorized to take immediate action to suspend a study if subjects may be at risk of harm, when serious noncompliance may have occurred, or for any other reason where such action would be deemed appropriate. Such action requires subsequent notice to and review by the convened IRB.

The IRB Chair may designate other IRB members or staff to perform duties, as appropriate, for review, signature authority, and other IRB functions.

The performance of the IRB Chair will be reviewed on an annual basis by the Compliance Officer with feedback from the full IRB and Administrator. Feedback from this evaluation will be provided to the Chair. In the exceptional circumstance when either the full IRB, the Compliance Officer, and/or ED of ORSP believes the Chair is not acting in accordance with the IRB's mission, following policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, s/he may be removed if, after an opportunity to demonstrate improvement over a reasonable amount of time, the Chair has not met their responsibilities.

B. IRB Members

IRB members are trained to adhere to the principles of Belmont Report to ensure the safeguarding of the rights and welfare of human subjects when reviewing specific activities proposed in a study. IRB members ensure that human research activities comply with federal regulations, state and local laws, and organizational policies and procedures.

Aside from the unaffiliated member, Stockton faculty members of any rank are eligible to serve as an IRB member. To ensure sufficient qualifications and the adequate review of all HSR, all IRB members must complete, prior to their first full IRB meeting, and maintain currency of CITI training credentials. CITI training requirements can be found on the IRB homepage.

Additionally, IRB members must also be familiar the following institutional policies and procedures:

- IRB Guidelines for the Protection of Human Participants in Research: Internal Policies and Procedures,
- Procedure 1035 General Assurances Statement: Protection of Human Rights in Experiments,
- Policy I-52.5 Committee on the Protection of Humans Subjects,
- Procedure 6350 Managing Conflicts of Interest, and
- Procedure 1097 Research Participant Payment Process.

When the need for a new IRB member or alternate is identified, the IRB Administrator will seek out affiliated candidates by contacting various deans for IRB nominations. See Policy I-52.5 Committee on the Protection of Human Subjects for more information.

IRB members are responsible for:

- Completing the required human subjects protection training;
- Maintaining the confidentiality of IRB deliberations and research reviewed by the IRB;
- Attending IRB meetings as scheduled; IRB members must attend at least 80% of all meetings;
- Active participation during IRB meetings for Full Board proposals and/or any other IRB business;
- Conducting and documenting reviews of Full Board protocols in a timely fashion; IRB members must complete and document their review of at least 80% of all Full Board protocols;
- Assisting the Chair in review of expedited protocol reviews when additional collaboration is necessary or the when the Chair has a conflicted interest;
- Recusing self from reviewing or voting on research when there is a conflict of interest;
- Supporting outreach efforts to Stockton students, staff, and faculty to increase community knowledge about the IRB and its process: IRB members should expect to participate in at least one outreach education event per academic year;
- Participating, when necessary, in quality assurance and improvement activities and compliance reviews; and
- Conducting themselves in a collegial manner consistent with the policies and ethical and professional responsibilities of the IRB.

If a member is unable to attend a scheduled meeting, they should inform the IRB Administrator or Chair as soon as possible. If a member's availability changes and they are no longer able to regularly attend IRB meetings or will be absent for an extended

period of time, they should inform the IRB Administrator. The Administrator will assess the situation, including the availability of the alternate when applicable, and make recommendations to the IRB Chair to ensure the IRB is able to meet quorum requirements and has the necessary expertise to review the research which regularly comes before it.

In the unlikely event that a member of the IRB is unable to fulfill the above listed responsibilities, they will receive written notification. If, after an opportunity to demonstrate improvement over a reasonable amount of time, the member is still unable to meet their responsibilities, the IRB member will be removed from the Board.

C. Alternate Members

Alternate IRB members replace regular IRB members with either a member conflict of interest or when they are unable to attend convened meetings, in part or in full. The IRB will consist of at least one alternate affiliated IRB member to represent a scientist and one alternate affiliated IRB member to represent non-scientists. Alternate IRB members who are unaffiliated with the institution may serve as an alternate for either a fellow scientist or non-scientist member. Unaffiliated scientist members cannot serve as the alternate for a non-scientist, and vice versa.
Aside from the unaffiliated member, Stockton faculty members of any rank are eligible to serve as an alternate IRB member. Alternate members should have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member(s) and may be alternates for more than one member.

When the need for a new alternate IRB member is identified, qualified candidates will be recruited and appointed in the same manner as regular IRB members. Alternate members are also appointed for a term of three (3) years and they may be reappointed for additional terms.

Alternate members are subject to the same training requirements as regular IRB members. IRB alternate members are not expected to attend all meetings but may be required to attend in an IRB member's absence. An alternate member may be present in a convened meeting when the primary member is also present. However, the alternate member will only register a vote when a regular voting member is absent for the entire or part of the meeting. The minutes of the IRB meeting will document the attendance of all primary and alternate IRB members who attended any part of the IRB meeting. IRB minutes will clearly indicate when and why an alternate IRB member has replaced a designated primary IRB member and clearly indicate when the alternate assumes voting responsibilities for the primary member.

IRB alternate members may also be called upon to complete initial reviews of exempt, expedited protocols, or Full Board protocols, annual continuing reviews, and other responsibilities of IRB members on an as needed basis, particularly responsibilities related to IRB outreach efforts.

D. Student IRB Members

Annually, Stockton University accepts applications from Stockton graduate students to serve a one-year term on the Stockton University IRB. Announcements for new recruitment are sent at the end of each academic year for service the following year

To apply, graduate students must submit a letter of interest and resume to the IRB Administrator and IRB Chair. A maximum of 2 students will be selected annually for this volunteer position. One student will serve as a primary IRB member, the other will serve as an alternate.

Student IRB Members are subject to the same training qualifications and responsibilities as all other IRB members.

E. IRB Administrator and Support Staff

IRB Administrator and support staff are members of the ORSP designated to support the IRB, manage the IRB system and operations, including working in collaboration with the Board to develop and maintain appropriate policy, procedures, processes, and records.

To ensure sufficient qualifications and the adequate pre-review of all HSR, all IRB administrative support staff must complete and maintain currency of CITI training credentials. CITI training requirements can be found on the IRB homepage.
The IRB Administrator is responsible for:

- Ensuring that all IRB actions are in accordance with University policies and applicable federal, state, and local laws;
- Assisting investigators with the application submission process through providing advice on applicable policies, procedures, guidelines, federal regulations, and other compliance related requirements;
- Screening initial research study applications to suggest level of review and initial, revised, and resubmitted applications to assess completeness and accuracy;
- Providing administrative assistance by (1) ensuring that all IRB members' training is up-to-date; (2) drafting correspondence on behalf of the IRB Chair; (3) stamping study documents, and (4) following up with investigators to ensure they

are aware of time limits and deadlines and instructions for corrections based on deliberations at the meeting;
- Coordinating, attending, and supporting the management of meetings for the IRB by (1) creating and disseminating agendas and minutes, (2) ensuring that federal regulations for quorum are met, that no conflicted IRB members are involved, and that proper meeting procedures are followed; and (3) ensuring that all IRB members have completed and documented their reviews prior to the Full Board meeting;
- Supporting the IRB, IO, and CO in the development and maintenance of appropriate policy, procedure, processes, and records;
- Ensuring regular maintenance of the IRB's website, application system, and supporting documents on at least an annual basis; and
- Provide outreach and education to Stockton students, staff, and faculty to increase community knowledge about the IRB and its process.

The IRB Administrator and ORSP support staff will maintain confidentiality for all matters related to IRB review and those provided to the Chair for IRB consultation. All records and minutes related to the IRB's activity and meetings, protocols submitted to the IRB and related support materials, and other materials related to the operation and support of the IRB are maintained by the IRB Administrator. Records are destroyed after three (3) fiscal years after a protocol is closed.

The performance of the IRB Administrator will be reviewed by the Associate Director of ORSP on an annual basis, with feedback from the IRB Chair. In the unlikely event that the IRB Administrator is not performing duties in a satisfactory manner, written notification with an action plan will be provided by the Associate Director of ORSP with feedback from the IRB Chair. If, after an opportunity to demonstrate improvement over a reasonable amount of time, the IRB Administrator is still unable to meet responsibilities, another IRB Administrator will be appointed.

F. Consultants

A *consultant* is an individual with competence in a special area whom the IRB has invited to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. Reasons for seeking additional or special competence from outside experts may include, but are not limited to the:
- Need for additional scientific, clinical, or scholarly expertise;
- Need for particular knowledge and understanding about potentially vulnerable populations of subjects; and/or the
- Desire to ensure appropriate consideration of race, gender, language, cultural background, and sensitivity to other issues such as community attitudes.

The IRB Administrator will ensure that all relevant materials are provided to the consultant prior to the convened meeting or expedited review. The consultant's findings may be presented to the IRB for consideration either verbally or in writing. Written statements from consultants will be kept in the IRB records. Information provided verbally by consultants at IRB meetings will be documented in the minutes. Consultants will be required to sign confidentiality agreements and may assist in the IRB's deliberations, but may not participate in the vote per federal regulations.

11. IRB Meetings

Full Board meetings are held on the first Thursday every month from September to December and February to June. Protocols that require full review are due two weeks prior to the full committee meeting. Additional meetings may be convened by the IRB Chair as necessary. The current schedule for convened meetings is on the IRB website and viewable here.

A. Quorum

A *quorum* of the IRB consists of a majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

The IRB Chair, with the assistance of the IRB Administrator, will confirm that quorum is present before calling the meeting to order. The IRB Chair, with the assistance of the IRB Administrator, is responsible for ensuring that meetings remain appropriately convened. If a quorum is not maintained, either by losing a majority of the members, all non-scientific members, or another required member, the IRB may not vote on any matters until quorum is restored.

In addition to the required attendance of at least one non-scientist member, it is generally expected that at least one scientific member, one unaffiliated member, and one member who represents the general perspective of participants will be present at all IRB meetings. Member(s) who represent the general perspective of participants are the IRB's community member and/or student member depending on the participants being recruited for a given study.

IRB members are considered present and participating at a duly convened IRB meeting when either physically present or participating through electronic means that permit the ability to listen to and speak during IRB deliberations and voting. Opinions of absent

members may be considered by the attending IRB members, but may not be counted as votes or to satisfy quorum requirements for convened meetings. IRB members on sabbatical, medical, or other extended leave from IRB duties will not be counted towards quorum, however, must notify the IRB Chair or IRB Administrator as soon as possible.

B. Agendas

Members are notified, by email, at least one week prior to the meeting of the agenda. The email will include the agenda, which includes all IRB members with their representative capacity, the minutes from the previous meeting, and a link to the IRB electronic system with the studies to be reviewed. The IRB administrator prepares the agenda with input from the IRB Chair. The Chair will facilitate the meeting, based on the following agenda items:

- Call the meeting to order,
- Approval of minutes from previous meeting,
- Adverse Events,
- Protocol Deviations,
- Notification of Expedited or Exempt Protocol Approvals,
- Review of Protocols,
- Educational Items,
- General Business
- Announcements,
- Notification of Next Convened Meeting, and
- Adjournment.

On occasion, a time-sensitive item may be added to the agenda with less than one week before the meeting. This may only occur when circumstances warrant and the IRB Administrator has confirmed with IRB members that there is sufficient time for review.

C. Minutes

The minutes shall serve as IRB records of full review proceedings. All individual and identifying remarks, commentaries, and opinions of board memories will be omitted from the meeting minutes. Individual votes of board members will not be recorded, but reported in the aggregate. The minutes of IRB meetings will be in sufficient detail to show:

- Attendance at meetings;
- A written summary of the discussion of issues related to each research protocol being considered as an initial review or for renewal;
- The basis for requiring changes in research for each protocol, as relevant;

- Actions taken by the IRB on each protocol considered;
- The vote on these actions, including the number of members voting for, against, and abstaining;
- The date at which continuing review of the research project is required and, if less than one year, the reasons for such;
- The basis for disapproving any research, as relevant;
- A written summary of announcements made, education items reviewed, and business conducted that was unrelated to the protocols considered.

D. Member Conflicts of Interest

In each IRB meeting, the Chair will determine whether any members have a conflict in reviewing protocols. A *member conflict of interest* (MCOI) is a situation in which financial or other personal or professional circumstances may compromise, or have the appearance of compromising, an IRB member's professional judgment or objectivity in reviewing or evaluating a research study. A MCOI in reviewing research is indicated by:

- Involvement in the design, conduct, and reporting of the research;
- An immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research;
- *Significant financial interests*, which include any remuneration received in the preceding twelve (12) months from the entity, when aggregated, that exceeds $5,000) related to the research being reviewed; and/or
- Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

No member of the IRB may participate in any way in the initial or continuing review of any project where a COI has been determined under governmental or institutional policies, except to provide information requested by the IRB. In the event that the Chair has a conflict, the designated alternate IRB member will preside over the meeting.

12. Investigators

A. Principal Investigators

Principal investigators (PI) are ultimately responsible for assuring compliance with applicable University IRB policies and procedures, federal policy regulations, and for the oversight of the research study and the informed consent process. Although PIs may delegate tasks to members of the research team, they retain the ultimate responsibility for the conduct of the study. PIs may be any category of faculty and/or staff who have appropriate qualifications to conduct the research.

As a general condition for the approval of a research study, the IRB holds the PI responsible for ensuring that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2) selection of subjects is equitable, (3) informed consent is obtained by adequate and appropriate means. The PI has the following specific responsibilities:

- Abstaining from enrolling any individual in a research study until such study is approved in writing, by the IRB;
- Conducting the study in strict accordance with the current IRB-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject;
- Obtaining prospectively and documenting informed consent in accordance with the current IRB-approved informed consent documents (i.e., unless the IRB has granted a waiver of the consent process)
- Maintaining adequate, current, and accurate records of research data, outcomes, and reportable new information to (1) reflect adherence to protocol specific requirements and (2) permit an ongoing assessment of the risk/benefit ratio of study participation;
- Promptly responding to all requests for information or materials solicited by the IRB, including the timely submission of the research study for IRB renewal;
- Requesting IRB approval of any proposed modification to the research protocol or informed consent documents prior to implementing such modifications;
- Ensuring that adequate resources and facilities are available to carry out the proposed research study;
- Ensuring that all associates, colleagues, and other personnel assisting in the conduct of the research study are appropriately informed of (1) the study procedures; (2) informed consent requirements; (3) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (4) reportable new information requirements; and (5) data collection and record-keeping criteria;
- Maintaining research records and training records for **all** research team members for 3 years following study closeout
- Notifying the IRB promptly, and, if applicable, external agencies or sponsors, of any internal or external reportable events;
- Complying with additional requirements for federal agencies.

PIs leaving the institution are responsible for notifying the IRB well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI.

B. Co-Investigators

Co-investigators (Co-I) are individuals working in partnership with the PI in the management, development and/or execution of the project. Appropriately qualified Co-Is and research staff may perform tasks as delegated by the PI, but they do not accept primary responsibility for the research study. In general, Co-I's are responsible for:

- Completing required institutional and protocol specific training;
- Adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants;

C. Student Researchers

Undergraduate and graduate students may be designated as PIs. In the IRB submission platform, once a researcher self-identifies as a student, they will be required to register a Stockton faculty member as a Co-I. When the student PI makes a submission, modification, or any change for a given study, the faculty will be notified to certify and sign off on the changes made. Upon the faculty member's certification, the submission will be routed to the IRB for final determinations.

D. Investigator Conflict of Interests

Investigator conflicts of interest (ICOI) are situations in which an investigator's professional judgment regarding his or her research could be negatively influenced by a secondary interest, like potential financial gain or professional advancement. Allowing conflicts to dictate professional actions can have negative consequences for the outcomes of research and for research participants. Such actions can also erode public trust in the research enterprise. ICOI may include:

- *Non-financial COI* which are influences other than financial reward; for example, not recusing oneself from the review of a proposal from an organization where the investigator serves as an unpaid advisor, or
- *Financial COI* which may include a prospect of financial gain from the research; for example, owning stock in a company that could directly benefit from the outcome of a research project.

Investigators are required to complete CITI tutorials on Conflict of Interest (COI) (see Section 3.A) so they are better able to identify and disclose any potential ICOIs. In particular, investigators should identify and disclose (1) any possible activities and relationships that could present a conflict of interest with their research or (2) significant financial interests to IRB through the IRB electronic system. *Significant financial interests* exist when the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

Once identified, ICOI must be managed. Investigators are required to document COI management strategies in the IRB protocol. Managing ICOI does not require that investigators discontinue relationships or divestiture financial interests. Rather, ICOI may be managed through disclosure to potential research participants during informed consent or can be mitigated procedurally. Note, though, that failure to disclose, develop, or follow ICOI management plans may be considered noncompliance (see Section 21.C) and may lead funding agencies to take actions such as delaying or suspending funding.

13. Human Subjects Research Determination

The purpose of a research determination is for the IRB Chair to determine if an activity involving human participants is research. To determine whether an activity is human subjects research (HSR), federal definitions provided by §46.102 and listed below will be used.

Investigators are responsible for the initial assessment as to whether an activity constitutes HSR. The investigator should make this assessment based on the definitions listed below and may also use Human Subject Regulations Decision Charts: 2018 from the ORHP, found here. Investigators are encouraged to complete an Initial Submission in the IRB platform and utilize the HSR determination feature. All requests for a determination of HSR must include sufficient documentation of the activity to support the determination. Inaccurate HSR determinations made by researchers without the consultation of the IRB through a HSR determination requestion, may lead to incidence of noncompliance.

Determinations regarding activities that are either clearly, or clearly not human subject research may be made by the IRB Administrator. Determinations regarding less clear-cut activities will be referred to the IRB Chair, who may make the determination or refer the matter to the IRB. Investigators will be notified of the determination through the IRB electronic system where all documentation and determinations will be recorded and maintained. If it is determined that the project meets the definition of HSR and requires IRB review, the investigator will be directed to submit a modification for their initial protocol submission to accurately reflect the determination made. Upon updating the type of research being conducted, the PI will be prompted to respond to a series of questions and provide additional documentation to meet the appropriate regulatory requirements. If the project does not meet the definition of HSR, the determination notification is retained in the IRB electronic system.

A. Research

The OHRP defines *research* as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes.

OHRP specifies that a *systematic investigation* generally refers to a methodical approach to the activity and often involves a hypothesis, research question, and/or plan to systematically collect and analyze data. *Contributing to generalizable knowledge* is indicated when the systematic investigation adds information and contributes to generalizable knowledge that can be applied to the field, a discipline, or a population.

Whether or how an investigator shares results of an activity should not determine if the activity develops or contributes to generalizable knowledge. For example, plenty of information is published that comes from activities that do not meet the federal definition of research. Conversely, many times results from research that meets the federal definition never get published.

Pedagogical exercises typically do not require IRB approval. However, if data collected contains personally identifiable information (PII), the project will be subject to IRB review and approval. See Section 14. A for more information on what is considered PII.)

B. Human Subjects

OHRP defines a *human subject* as a living individual about whom an investigator, whether professional or student, conducting research

- obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; *or*
- obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

More simply, research likely involves human subjects if an investigator:

- interacts with a living individual,
- asks them to take part in an intervention,
- manipulates their environment,
- collects identifiable materials, biospecimens, or private information about living individuals through active intervention or archival data.

Interaction includes communication or interpersonal contact between an investigator and human subject.

Intervention includes both physical procedures where information or biospecimens are gathered and/or manipulations of the subject or the subject's environment that are performed for research purposes.

Private information includes information (1) about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or (2) that has been provided for specific purposes by an individual where the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An *identifiable biospecimen* is a biospecimen where the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Biospecimens include sample material such as urine, blood, tissue, cells, DNA, RNA, or protein from humans.

C. Specific Activities Not Considered Research

Although the IRB is the final determiner for whether activity is considered human subjects research, the following activities are typically excluded from IRB review and approval because they either do not meet the federal definition of research and/or human subjects.

However, if an investigator may want to use any of the following activities as a contribution to generalized knowledge in a discipline, field, and/or population and/or if an investigator may want to present or publish findings from these activities, it is likely that IRB review and approval is required. The investigator should err on the side of caution and consult IRB staff to clarify whether a study is considered human subjects research or not.

i. Case Studies

A case study is a detailed report about a single participant or a small group, and frequently includes personal accounts from the subjects themselves. In qualitative descriptive research, a case study's conclusions may be based about a single participant or group in a very specific context.

Case studies generally are considered non-HSR, however a HSR determination request must be sent to the Stockton University IRB regarding case studies. Typically, case studies are categorized as non-HSR or as exempt, provided that the study does not contain sensitive topics, adequately protects participant's identities, and does not involve at-risk or special populations.

ii. Scholarly and Journalistic Activities

Oral history, journalism, biography, literary criticism, legal research, and historical scholarship, including the collection and use of information from or about a specific individual, is not generalizable beyond that individual and therefore does not meet the federal definition of research. As such, these activities do not require IRB review and approval.

iii. Institutional Research and Assessment

The purpose of institutional research is typically to gather data about Stockton University for in-house use to assess, improve, or develop University services/programs for students, employees, or alumni. In cases where there is no intention to use the data to contribute to generalizable knowledge, IRB review and approval is not necessary if the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. However, if investigators believe the data may help inform or develop other initiatives on campus or at other institutions, IRB review and approval would be required as this information would be used to produce generalizable knowledge.

iv. External Program Evaluations

External program evaluations involve the systematic collection and analysis of information about the effectiveness of a program to make judgments about the program, improve its effectiveness, and/or inform decisions about future program development. Evaluations are not considered research when (1) they do not involve experimental or non-standard interventions; (2) their intent is only to provide information for and about the setting in which they are conducted; and (3) they are conducted as part of the standard operating procedures of the setting.

Although these evaluations may involve various methods of human interaction such as surveys, interviews, and the analysis of documents and background information, if the intent is to inform the particular program about that program's effectiveness and needs, rather than to contribute to generalizable knowledge, the activity does not meet the federal definition of research and therefore is excluded from IRB review and approval.

As such, faculty or staff members of Stockton who are hired as a consultant by an unaffiliated third party to conduct program evaluations not related to the University typically do not require IRB review and approval. Likewise, when an external third party consultant is hired by the University to evaluate Stockton programs, IRB review and approval is typically not required. Nonetheless, there may still be ethical issues associated with program evaluations such as risks to participants and privacy and confidentiality concerns that should be considered by the investigator.

v. Marketing Research

Marketing research is the process of evaluating the viability of a new service or product through research conducted directly with potential customers. Market research allows a company to define its target market and get feedback from consumers about their interest in a product or service. Gathering data and information for purposes of organizational assessment, quality assurance, or quality improvement does not generally require IRB review or approval because such activities usually serve to assess and document matters specific to the organization, rather than contribute to generalizable knowledge. Likewise, gathering data information about a customer's satisfaction or experience with a product would not likely meet the regulatory definition of research requiring IRB review when those activities are intended to guide a customers' decision about purchasing a product rather than to add or contribute to generalizable knowledge. However, if marketing research may be applied, used to draw broader conclusions, or contribute knowledge to a field, discipline, or population of study, it would require IRB review and approval.

vi. Course Assignments and Class Activities

Research method courses may require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants as a way to help train students and provide opportunities to practice various research methods. If these projects are conducted *solely* for the purpose of learning about and getting practice with research techniques, rather than to produce generalizable knowledge, *and* if the data from those projects are not used outside the class for which they were collected *and* if the data are not *identifiable*, *private*, or *sensitive*, they are not considered research and do not require IRB review. See Section 14.A for more information on identifiable, private, and/or sensitive data.

Note that student projects that are intended to produce a presentation, poster session, master's thesis, doctoral dissertation, an article or result in any other publication or presentation are beyond the scope of what is considered a course assignment or class activity.

Regardless of whether IRB review and approval is necessary, students participating in these instructional activities should receive adequate training in how to work with participants ethically. All assignments and activities should also be consistent with the ethical standards and applicable rules of their profession. It is recommended that students in these courses either complete the Basics of Research for Student Learners or Student Research tutorial available through Stockton's CITI Training. The IRB can also provide additional appropriate training resources as needed.

vii. Additional Determinations of Non-Human Subjects Research by OHRP

In addition to the more common activities listed above, §46.102 indicates that the following activities, while not typical to the work done at Stockton, are not deemed to be research.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

14. Levels of IRB Review

All research involving human subjects is determined to be under one of the following categories:

- Exempt Review;
- Expedited Review; or
- Full Committee Review

A. Considerations in Determining Level of Review

Level of review is determined by multiple factors such as (1) level of risk to subjects, (2) involvement of vulnerable populations, (3) type of research methodology, and (4) sensitivity of the research topic. When the determination that an increased level of review is required, it is to ensure that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2) selection of subjects is equitable, and (3) informed consent is obtained by adequate and appropriate means.

i. Risk of Harm

Harm is defined as any injury to the rights, safety or welfare of a research participant that may include physical, psychological, social, financial or economic, and/or legal factors.

- *Physical risks* include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the involvement of physical stimuli such as noise, electric shock, or engaging a subject in a social situation which could involve violence.
- *Psychological risks* include the production of negative affective states such as anxiety, depression, guilt, shock, loss of self-esteem, etc.. Sensory deprivation, sleep deprivation, use of hypnosis, deception, or mental stresses related to sensitive topics may increase psychological risks.
- *Social risks* include the detailed use of information that may be hazardous to the social position of an individual or may be detrimental to groups of people in the participant's community. Social risks include alterations to relationships that disadvantage the subject, including embarrassment, loss of respect of others, negative labeling with consequences, or diminish the opportunities and power a person has by virtue of relationships with others.
- *Financial or economic risks* involve the loss of benefits, insurance, wages or other income, or employment for the participant.
- *Legal risks* exist when the subject or others may be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which the subject or others may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.

Minimal risk of harm means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. HSR activities that are classified as having no greater than minimal risk of harm may qualify for exempt review. Studies that involve minimal risk are typically reviewed through expedited procedures, whereas studies that involve greater than minimal risk require full review by the convened board. Exempt and expedited

reviews are typically carried out by the IRB Chair alone. See Section 17.B for more information.

ii. Vulnerable Populations

Certain groups or individuals are recognized as potentially *vulnerable populations* because they are (1) unable to independently make informed decisions, (2) easily manipulated and/or likely to experience coercion or undue influence, and/or (3) a convenient and readily available study population, which may lead to exploitation and unfair treatment to the benefit of others.

Undue influence refers to the use of persuasion, authority figures, or the offer of an excessive or inappropriate reward or other overture in order to obtain research participation or compliance.

Coercion occurs when an overt or implicit threat of harm, such as loss of services or access to programs otherwise entitled, is intentionally presented by one person to another in order to obtain compliance or research participation

Federal regulations identify the following as *vulnerable populations that require additional considerations and/or protections* in research and must be processed through Full Board review:

- Pregnant women, human fetuses, and neonates,
- Prisoners,
- Minors,
- Individuals with impaired decision-making capacity, and
- Economically or educationally disadvantaged persons

Individuals with impaired decision-making capacity are persons with characteristics or in situations that affect cognitive or emotional functions in a manner that judgment and reason is significantly diminished. Other persons, including those under the influence of or dependent on alcohol or drugs, those affected by degenerative brain diseases, those who are terminally ill, and those who have severe physically disabling handicaps, may be compromised in their ability to make decisions in their best interests.

Economically disadvantaged persons include those who struggle to provide basic necessities for themselves and their families or communities. *Educationally disadvantaged persons* may have educational deficits, learning disabilities, or cultural backgrounds that limit communication with a researcher.

Some additional populations may raise concerns of potential coercion and undue influence. The IRB Chair may recommend Full Board review when the following populations are involved:

- Students, colleagues, employees, or subordinates,
- Individuals with physical impairments, including terminally ill or very sick individuals,
- Racial and ethnic minorities,
- Individuals with sexual or gender minority status,
- Institutionalized persons, including those in nursing homes or mental health facilities,
- Undocumented persons,
- Non-English speaking persons,
- Veterans, and/or
- Elderly or aged persons.

See Section 17.B for more information.

iii. Research Methodology Type

Research methodologies listed under §46.104 that do not involve risk or vulnerable populations may qualify for an exempt determination. Research methodologies, described here, may be determined appropriate for an expedited review per federal regulations in §46.110. Exempt and expedited reviews are typically carried out by the IRB Chair alone. See Section 17.B for more information.

iv. Private, Identifiable, Protected, and/or Sensitive Information

Private information includes information (1) about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or (2) that has been provided for specific purposes by an individual where the individual can reasonably expect will not be made public (e.g., a medical record). *Personally identifiable information* (PII) is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. PII can be (1) sensitive, such as medical, financial, or legal information; (2) neutral, such as name, facial photos, or work address; or (3) contextual, such as a file for a specific health condition that contains a list of treated patients. Some PII is subject to additional protections (e.g., HIPAA), such as *protected health information* (PHI). PHI is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. PHI is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an

individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Sensitive data includes identifying information that could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. Sensitive data may include, but is not limited to, topics related to:

- Sexual behavior or practices,
- Illegal activities or ethically questionable behaviors,
- Racism, ageism, classism, discrimination, and sexism,
- Experiences of grief and loss, trauma, or violence,
- The experience of being part of any potentially vulnerable population,
- Job performance or competency, and/or
- International settings.

In all research involving human subjects, *confidentiality*–the state of keeping or being kept private–of private, identifiable, protected, or sensitive information is presumed and must be maintained. Studies that include collection of private, identifiable, protected, and/or sensitive information will require either expedited or Full Board review (see Section 17.B for more information).

Note that only private, identifiable, protected, and/or sensitive information that is absolutely essential to the research activity will be approved for collection by the IRB. If these data must be collected, investigators will be required to link data and identifiers with a code as early in the activity as possible and securely store data and identifiers separately in a manner that ensures only investigator and authorized staff access.

B. Studies Eligible for Exempt Review

§46.104 indicates that some types of HSR (1) with no or less than minimal risk and (2) that does not target vulnerable subject populations may be eligible for an IRB exemption. An exempt determination indicates that the research may be released from some federal regulations governing human subjects' research, although state laws, institutional policies, or the requirements for ethical research are still applicable. Exempt protocols are reviewed by the IRB Chair alone rather than by the full IRB. See Section 17.B for more information on IRB review procedures.

Stockton's IRB may apply the exempt determination to the following types of research activities:

- Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices;

- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is (1) obtained and recorded in a manner that the identity of the human subjects cannot readily be ascertained or (2) would not reasonably place the subjects at risk;
- Research involving benign behavioral interventions with adults where information is (1) obtained and recorded in a manner that the identity of the human subjects cannot readily be ascertained or (2) would not reasonably place the subjects at risk;
- Secondary research with identifiable private information or biospecimens that is (1) publicly available or (2) recorded in a manner that the identity of the human subjects cannot readily be ascertained;
- Research and demonstration projects that are conducted or supported by a Federal department or agency that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs;
- Taste and food quality evaluation and consumer acceptance studies where (1) wholesome foods without additives are consumed or (2) food with an ingredient or 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.

Although federal regulations indicate that exempt research does not require informed consent, Stockton's IRB requires that investigators obtain and document informed consent unless the protocol qualifies for a waiver. See Section 16.D and 16.E for more information on consent waivers.

Investigators who believe their HSR falls under one of these categories should review the full specifications under §46.104 and submit the protocol, along with any study related materials, to the IRB electronic system for review. Final determination of exempt status is made by the IRB Chair to ensure accuracy and that compliance with state laws, institutional policies, and ethical research guidelines is met.

C. Studies Eligible for Expedited Review

Research activities that (1) present no more than minimal risk to human subjects, (2) do not target vulnerable subjects, and (3) involve only procedures listed in one or more of federally designated categories may be reviewed by the IRB through the expedited review procedure authorized by §46.110. Expedited research protocols are reviewed and approved by the IRB Chair alone without convening a meeting of the full IRB. See Section 17.B for more information on IRB review procedures.

Stockton's IRB may includes the following categories of research as eligible for expedited review:

- Clinical studies of (1) drugs when new drug applications are not required or (2) medical devices when (a) an investigational device exemption application is not required or (b) the medical device is approved for marketing and used for approved purposes;
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (a) from healthy, nonpregnant adults who weigh at least 110 pounds or (b) from other adults when 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 has been considered safe;
- Prospective collection of biological specimens for research purposes by noninvasive means;
- Collection of data through noninvasive procedures routinely employed in clinical practice, not involving general anesthesia or sedation, x-rays, or microwaves;
- Research involving materials that have been collected for nonresearch purposes[4];
- Collection of data from voice, video, digital, or image recordings made for research purposes;
- Research on individual or group characteristics or behavior employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;
- Continuing review of research previously approved by the convened IRB where (a)(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) no subjects have been enrolled and no additional risks have been identified; or (c) the remaining research activities are limited to data analysis.

Please note that the above research methodologies cannot be assumed to pose minimal risk simply because they are listed here. Indeed, the expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

[4] if informed consent has been obtained to use information for research purposes

Investigators who believe their HSR may be eligible for an expedited review process should review the full specifications of §46.110 and submit an initial protocol, along with any study related materials, to the IRB electronic system for review. Final determination of expedited status is made by the IRB Chair to ensure accuracy.

i. Informing the IRB of Expedited Research Protocols

Federal regulation §46.110 requires that expedited approvals be reported to the IRB. Members of the IRB will be informed of expedited review approvals, including limited IRB reviews conducted using expedited review procedures, via a list in the agenda for the next scheduled meeting. Any IRB member can request to review the materials for any study by contacting the IRB Administrator.

D. Studies Requiring Full Board Review

IRB Full Board review is required for research protocols that (1) involve more than minimal risk to human subjects, (2) target vulnerable populations, and/or (3) have been referred to the committee by an expedited reviewer or the Chair. Stockton's IRB may require Full Board review when the research either involves sensitive topics or studies complex in nature or beyond the scope of specialty of IRB members to ensure adequate assessment and adherence to federal policies.

When Full Board Review is necessary, the research proposal is discussed and voted upon at a meeting at which a quorum of IRB members is present (see Section 17.B for more information on IRB review procedures). Applications requiring Full Board review are accepted by the submission deadlines and reviewed by the Full Board on the scheduled IRB meeting dates (see Section 11 for more information about IRB meetings). Investigators are welcome to attend the meeting to answer questions from the board.

Investigators who believe their HSR requires Full Board review should submit the protocol, along with any study related materials, to the IRB electronic system two weeks prior to the full committee meeting. Final determination of full review status is made by the IRB Chair[4] to ensure accuracy.

15. Criteria for IRB Approval for Research

In order for the IRB to approve HSR, either through expedited review or by the convened IRB, it must determine that criteria in §46.111 are satisfied. The criteria listed below apply to initial reviews, continuing reviews, and modifications of previously approved research. When criteria for approval are met, Stockton's IRB approves all

initial research protocols for a period of one year. After the initial approval period, investigators may initiate the process to renew IRB approval through the IRB electronic system.

A. Risks to Subjects are Minimized and Reasonable

Risks to subjects must be minimized through (1) procedures consistent with sound research design that do not unnecessarily expose subjects to risk and/or (2) through procedures already performed for diagnosis/treatment, when appropriate. Risks to participants must also be reasonable in relation to (1) anticipated benefits, if any, to participants and (2) the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB will focus on the risks and benefits that may result from the research, rather than risks and benefits of therapies or interventions subjects would receive if not participating in the research. As such, the IRB will judge whether risks have been minimized and whether the anticipated benefit, either of new knowledge or of direct benefit for the research subjects, justifies asking any person to undertake the risks. The IRB does not consider possible long-range effects, like the potential long-term impact to public policy, of knowledge gained in the research as among risk or benefit that falls within the purview of its responsibility.

i. Scientific Merit

In order to assess the risks and benefits of the proposed research, the IRB must determine that:

- The research uses procedures consistent with sound research design;
- The research design is sound enough to reasonably expect the research to answer its proposed question; and
- The knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, most commonly through a summary of the research literature by the investigator. When scientific review is conducted by an individual or entity external to the IRB, documentation that the above questions were considered must be provided to the IRB for review and consideration. Researchers can assist in this process by justifying, through the literature, that the design of their study adequately answers the research question.

B. Selection of Participants is Equitable

Selection of subjects must be equitable with respect to gender, age, class, etc. and scientific and ethical justification for (1) including vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons or (2) excluding classes of persons who may benefit from the research is required.

The IRB evaluates whether the selection of subjects is equitable by reviewing the IRB application, protocol, and other materials and information. Studies that do not adequately provide the equitable selection of subjects or do provide an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research cannot be approved. In making this determination, the IRB evaluates:

- The purposes of the research;
- The setting in which the research occurs;
- Scientific and ethical justification for including vulnerable populations or subjects vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons;
- The scientific and ethical justification for excluding classes of persons who might benefit from the research; and
- The inclusion/exclusion criteria, and the procedures/materials intended for use for the identification and recruitment of potential subjects.

i. Recruitment of Subjects

The IRB requires that the investigator submit a plan for recruitment of potential subjects. All inclusion and exclusion criteria, along with the procedures and materials intended to identify and recruit potential subjects must be submitted through the IRB electronic system. This includes advertisements, flyers, scripts, letters, information sheets, social media posts, emails, and brochures.

ii. Letters of Support

Investigators must have appropriate authorization to access the subjects and/or the subjects' information. When contact information is not publicly available, a letter of support from an individual authorized to speak on behalf of the institution indicating that access to private information will be provided in a manner that does not violate any internal or external policies is required.

C. Informed Consent is Sought and Documented

Informed consent must be sought and appropriately documented from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the federal regulations.

Informed consent is the process of providing potential research participants with information about the key elements of a research study and what participation will involve. The consent process typically includes providing a written consent document containing the required elements of informed consent and the presentation of that information to prospective participants. In most cases, investigators are expected to obtain a signature from the participant on a written informed consent document, unless the IRB has waived the consent requirement or documentation requirement. See Section 16 for more information on informed consent.

D. Adequate Data and Safety Monitoring Plans

Investigators must have a plan for monitoring the reactions of subjects and the collection of data to ensure the safety of subjects and address problems that may arise over the course of the study. Given that most studies at Stockton are low risk studies, continuous, close monitoring by the investigator is typically an adequate and appropriate format for monitoring, with prompt reporting of problems to the IRB, sponsor, and/or regulatory bodies as appropriate.

However, when risk is beyond minimal, data and safety monitoring plans should ensure that monitoring is commensurate with the nature, complexity, size and risk involved and that the frequency of monitoring is commensurate with risk. When necessary, data and safety monitoring plans should indicate:

- Who reviews the safety data;
- What safety data is collected,
- How often safety data is compiled;
- What conditions trigger a suspension or termination of the research; and
- The procedures for reporting to the IRB, including a summary description of what information will be provided.

E. Protections to Privacy and Confidentiality

When appropriate, there must be adequate provisions to (1) protect the privacy of subjects and (2) maintain the confidentiality of data.

Privacy is having control over the extent, timing, and circumstances of sharing oneself–either physically, behaviorally, or intellectually–with others. It is freedom from unauthorized intrusion, being observed, or disturbed by other people. Investigators must have appropriate authorization to access the subjects and/or the subjects' information. Information obtained in the research process is considered *private information*, as it has been provided for specific purposes with the reasonable expectation that it will not be made public (for example, a medical record). Information where the identity of the subject is or may readily be ascertained by the investigator is considered *identifiable information* and must be kept confidential.

Confidentiality is the state of keeping or being kept private. Investigators must ensure that information obtained about subjects is not improperly divulged, particularly if it is identifiable and/or sensitive. *Sensitive data* is information that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. Sensitive data requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, unauthorized access, misuse, alteration, or loss or destruction of the information.

The IRB must determine if the research plan appropriately protects the privacy of potential and actual subject by considering:

- The methods used to identify and contact potential participants;
- The setting of interaction and the appropriateness of all personnel present for research activities;
- The methods used to obtain information about participants and the nature of requested information, with the intent of obtaining only the minimal amount of information needed to achieve the aims of the research;
- Information obtained about other individuals and whether they meet the regulatory definition of "human subject".

The IRB must also determine if appropriate protections are in place to ensure confidentiality and minimize the likelihood that information will be inappropriately divulged. Safeguards designed to protect confidentiality should be commensurate with the potential of harm from unauthorized, inappropriate or unintentional disclosure. The IRB will evaluate the methods used to obtain, record, share, and store information about individuals who may be recruited to participate in studies and about subjects. Investigators should provide details regarding:

- Information security procedures; all data should be stored under two sets of lock and key;
- Plans to address the protection of paper documents, other physical media (e.g., audio or videotapes), and electronic data; and

- Use, maintenance, storage, and transmission of information.

Where possible, data should be de-identified. When identifiers must be stored, the IRB prefers the use of coding systems that allow researchers to store data separately from identifiers.

F. Additional Safeguards for Vulnerable Populations

Certain individuals, by nature of their age or mental, physical, economic, educational, or other situation, may be more vulnerable to coercion or undue influence than others. When some or all subjects are likely to be vulnerable to coercion or undue influence, additional safeguards must be included in the study to protect their rights and welfare. Children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons are identified by regulations recognized as vulnerable and require additional safeguards. Additional populations may also be considered vulnerable. See Section 14.A for more information on vulnerable subjects.

When working with vulnerable populations, investigators must demonstrate to the IRB that:

- Subjects' disadvantages will be accommodated–including language barriers–during recruitment, informed consent, and throughout research procedures;
- Additional risks subjects may face as a result of the population being studied and/or the local research context have been communicated to participants;
- Sufficient opportunity is provided on an ongoing basis for subjects to consider whether to participate in the research;
- The possibility of coercion or undue influence has been limited during the informed consent process and research procedures; and
- Procedures utilized to protect and respect subjects' rights are in place.

Studies that demonstrate sensitivity to the participants' needs, minimize unnecessary risks, and provide participants with an appropriate consent procedure will be approved.

16. Informed Consent

Informed consent is the process of providing potential research participants with information about the key elements of a research study and what participation will involve. The consent process typically includes providing a written consent document containing the required elements of informed consent (see §46.116) and the presentation of that information to prospective participants. In most cases, investigators are expected to obtain a signature from the participant on a written informed consent

document (see §46.117), unless the IRB has waived the consent requirement or documentation requirement.

A. General Requirements of Informed Consent

According to §46.116, the informed consent process should entail an organized account of the research to facilitate the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. There must be an opportunity for potential participants to discuss and consider whether to participate in a manner free of coercion or undue influence.

Information in the informed consent must be in language understandable to participants or representatives and the reading level of the informed consent document should be no higher than an 8th grade level.

Exculpatory language should not be used. Participants cannot be required to (1) waive or appear to waive any legal rights or (2) release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence;

B. Basic Required Elements of Informed Consent

Federal regulations in §46.116 specify that when seeking informed consent, the following information must be provided to each subject or legally authorized representative:

- Statement that the **study involves research**, explanation of the **purpose(s) of the research**, and the **expected duration** of the participant's participation,
- Description of the **procedures to be followed**, including the identification of any procedures which are experimental;
- Description of any reasonably **foreseeable risks** or discomforts to the participant;
- Description of any **direct benefits** to the participant or **indirect benefits** to others that may reasonably be expected from the research, including the advancement of scientific knowledge;
- A detailed account of the terms of payment or **incentives**, if applicable, including a description of the conditions under which a subject may receive partial or no payment if withdrawal or removal from the study occurs;
- Disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the participant;
- Statement describing the extent, if any, to which **confidentiality** of records identifying the participant will be maintained;

- **Contact information** for the research team for questions, concerns, or complaints and an explanation of whom to contact in the event of a research-related injury to the participant;
- Statement about **future use of data** to indicate that either (1) information may be used for future research studies or shared with another investigator for future research studies without additional informed consent from the subject; indicate whether identifiable information will or will not be shared OR (2) that the subject's information, even if identifiers are removed, will not be used or distributed for future research studies;
- Statement that participation is **voluntary** that participant may refuse or discontinue participation at any time with no penalty or loss of benefits to which the participant is otherwise entitled.

Additional guidance on the basic elements of informed consent, including a checklist, can be found here.

C. Additional Elements of Informed Consent

When appropriate, the following information must also be provided to each subject or legally authorized representative per §46.116:

- The approximate number of participants involved in the study;
- Statement that the treatment or procedure may involve unforeseeable risks to the participant or to the embryo or fetus, if the participant is or may become pregnant;
- Statement that significant findings that may relate to participant's willingness to continue participating will be provided;
- Anticipated circumstances under participation may be terminated without participant's consent;
- Consequences of a participant's decision to withdraw from the study;
- Procedures for orderly termination of participation by the participant;
- Compensation or reimbursement for the participant;
- Any additional costs to the participant that may result from research participation;
- The amount and schedule of payments to the participants.

D. Waiver or Alteration of Informed Consent

In limited circumstances, such as secondary analysis of existing data or projects involving deception, investigators conducting research that is no more than minimal risk may apply to waive or alter some or all of the required elements of informed consent. Approval is contingent upon the following five (5) requirements specified in §46.116:

- The research involves no more than minimal risk;
- The research could not practicably be carried out without the waiver or alteration
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

E. Waiver of Documentation of Informed Consent

For some research projects, the IRB may approve a request to waive the documentation of informed consent. Although the investigator must provide the required consent information, typically through a written statement, the requirement to document the subject's signature on the informed consent document can be waived, per §46.117, when:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality (e.g., research on sensitive topics, such as domestic violence or illegal activities), or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context (e.g., minimal risk research that involves surveys/interviews conducted via telephone or online), or
- Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

17. IRB Procedures for Protocol Review

Exempt and expedited reviews will be as thorough as a full IRB review. All protocols must meet criteria for approval found in §46.111, including the criteria for seeking (§46.116) and documenting (§46.117) informed consent, unless the protocol qualifies for exemption (§46.104) from these requirements. Investigators submitting a protocol for the first time or who are not well-versed in submission procedures can arrange for a consultation with the IRB Administrator and/or Chair.

A. Pre-Review

To ensure timely, appropriate, and ethical reviews of all IRB protocols, the IRB must be provided with all the required documentation necessary for its review. The IRB Administrator will perform a preliminary review of all submissions to determine completeness and accuracy, including a checklist review of all elements of consent, when applicable. If necessary, the investigator will be informed via the IRB electronic system of missing materials and any recommended changes prior to review by the IRB.

B. Initial Protocol Review

Complete protocols will be forwarded to the IRB for review by the IRB Administrator. An in-depth review of submission materials will be performed to obtain a thorough understanding of the protocol. Protocols will be evaluated to ensure that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2) selection of subjects is equitable, and (3) informed consent is obtained and documented through an appropriate process.

Using the appropriate reviewer checklists, the review will be documented through the electronic IRB system. Review documentation will include (1) justification for the category under which the protocol is reviewed, (2) request for changes or additional information, and (3) actions taken (see Section 18).

Any requests for revisions or additional information after initial review should be submitted to the IRB electronic system as soon as possible to ensure timely processing of the protocol.

i. Materials Required for Initial Review

The following materials are required for initial review and must be submitted through the IRB electronic system:

- Completed IRB Initial Submission;
- Proposed recruitment materials, including advertisements or verbal scripts intended to be seen or heard by potential study participants;
- Informed consent documents;
- Measurement tools such as questionnaires, interview guides, tracking sheets, etc.;
- Letters of support from external agencies involved;
- Grant application(s), and
- Any other relevant materials.

IRB reviewers will have access to these materials through the IRB electronic system. If additional information is needed to complete the initial review, the request will be made by the IRB Administrator.

ii. Full Board Reviews

Full board applications will be reviewed at a convened meeting monthly. In convened meetings, the protocol will be discussed until all concerns and questions have been addressed. After discussion, the IRB action will be determined by vote of the Full Board using the Criteria for IRB Approval of Research, as articulated in the Federal Regulation §46.111. For the research to be approved, it must be approved by most voting members present. The investigator will be notified of the outcome via the IRB electronic system.

iii. Exempt and Expedited Reviews

Exempt and expedited reviews are carried out by the IRB Chair who may exercise all authorities of the IRB, except disapproval of the research.[5] The Chair will have access to and review the same materials that are required for convened IRB review, unless the protocol qualifies for any exemptions to these requirements. The criteria for approval are the same as those for review by a convened IRB. The investigator will be notified of the IRB action via the IRB electronic system.

iv. Possible IRB Actions for Initial Review

The convened IRB, or the IRB Chair when conducting exempt or expedited review, may take any of the actions described in Section 18 when conducting an initial review.

C. Modifications to Approved Research

Investigators may wish to modify or amend approved research. Investigators should consider whether the proposed changes to the research alter the original scope, purpose, or intent of the research. When the research itself is fundamentally changed, the IRB will typically require a new study protocol rather than allow such changes to be made through a modification to the existing research plan. If a modification to approved research is appropriate, investigators must obtain IRB approval before implementing any changes, no matter how minor, in approved research unless the change is necessary to eliminate an apparent immediate hazard to the subject. Changes made prior to IRB approval to eliminate an apparent immediate hazard to the subject must be reported to the IRB immediately (see Section 21).

Modifications to an approved protocol may be major, minor, or administrative. *Major*

[5] Research may be disapproved only after review and vote by the Full IRB.

modifications are any alterations to an approved protocol that (1) increases risk to participants beyond what is considered minimal, (2) include activities or procedures that would not be eligible for expedited review if submitted as part of new research, or (3) was initially required full-review reviewed that significantly alters the already approved study design. *Minor modifications* are any alterations to an approved protocol that (1) increases risk to participants, but risk still remains no more than minimal (2) include activities or procedures that are eligible for expedited review if submitted as part of new research, or (3) initially involved minimal risk and the changes do not significantly alter the study design. *Administrative modifications* are alterations to an approved protocol that include (1) addition or removal of study personnel or research sites or (2) correcting typographical, grammatical, or spelling errors. Common modifications to approved research typically include:

- Addition or removal of study personnel,
- Addition or removal of research sites,
- Changes to recruitment materials, including advertisements or verbal scripts
- Informed consent documents,
- Changes to measurement tools such as questionnaires, interview guides, tracking sheets.

The IRB Administrator will review the submission and determine if the proposed changes are major, minor, or administrative. The IRB Administrator will escalate major protocol changes to the full IRB at the next convened IRB meeting to vote upon.

i. Materials Required for a Review of Modification Requests

To modify an approved research protocol, the investigator must submit a Modification Submission via the IRB electronic system, along with all supporting documents that require modification. These documents may include, but are not limited to:

- Proposed recruitment materials, including advertisements or verbal scripts,
- Informed consent documents,
- Measurement tools such as questionnaires, interview guides, tracking sheets,
- Letters of support from external agencies.

ii. Review of Modifications

Major modifications to either exempt, expedited, or Full Board studies will be reviewed by the full committee at a convened meeting and follow procedures delineated in Section 17.B. For the modifications to be approved, approval of a majority of voting members must be obtained. Minor modifications[6] to either exempt, expedited, or Full

[6] Definition of a Minor Change in Research

Board studies may be reviewed and approved by the IRB Chair using expedited review procedures in Section 17.B. Administrative modifications to any study, regardless of level of review, may be reviewed and approved by the IRB Administrator.

iii. Possible IRB Actions for Modifications

The IRB may take any of the actions described in Section 18. If proposed changes to an expedited or exempt study render it no longer eligible for expedited review or exemption, the level of review will be modified accordingly.

D. Approval/Expiration Dates and Study Renewal

The *approval date* represents the date that study activities involving human subjects may start and/or the research activities (or change of activities) may begin. For full review protocols, the approval date would be the date of the convened IRB meeting at which the protocol was voted and approved.

The *expiration date* indicates the date at which IRB approval is no longer effective. For initial reviews and continuing reviews, the expiration date will be one (1) year, minus one (1) day from the approval date for research subject to continuing review. Approval and expiration dates are clearly noted on the IRB Approval Notification, available in the IRB electronic system, and must be strictly adhered to.

Investigators may renew their IRB approval prior to the expiration date through the IRB electronic system. Study renewals will either undergo continuing review or administrative review, depending on the protocol's initial level of review. Renewal of an IRB-approved study is necessary when current or future research activities involve any of the following:

- Obtaining data through intervention or interaction with human subjects;
- Obtaining identifiable private information about living individuals; or
- Analyzing identifiable private information about living individuals.

Information is identifiable if subjects can be identified directly or through identifiers linked to subjects. This includes any lists of participants that have not yet been destroyed.

Federal regulations permit no grace period or approval extension after expiration of approval. As a courtesy to investigators, the IRB electronic system will send out Reminder Notifications to investigators three months, two months, and again one month in advance of the expiration date. It is the investigator's responsibility to ensure that the renewal of ongoing research is approved prior to the expiration date. Investigators must

submit their renewal materials enough before expiration to allow sufficient time for IRB review before the expiration date.

If re-approval does not occur within the time set by the IRB, all research activities must stop, including recruitment (advertisements must be withdrawn), enrollment, consent, interventions, interactions, and data collection. All research activities must stop *even if* the investigator has submitted renewal materials *before* the expiration date,*but* has not yet received a response from the IRB. Research that continues after the approval period has expired and is considered noncompliance.

Investigators who lapse in IRB approval due to a failure to complete the renewal procedures necessary to obtain re-approval before the expiration date will receive notification from the IRB electronic system that the protocol has expired and that all research activities must stop. If the investigator fails to respond to the notification and does not submit a closure report within seven (7) business days, the IRB Administrator will close the study and refer the matter to the IRB Chair to evaluate as possible noncompliance (see Sections 21-24). Investigators who wish to continue research will need to complete a new IRB protocol which is subject to all procedures indicated for initial review (see Section 17.B).

If the IRB notes a pattern of noncompliance with the requirements for renewal where either an investigator repeatedly or deliberately neglects to submit materials for renewal in a timely fashion or the IRB itself is not meeting the renewal dates, the IRB will determine the reasons for the non-compliance and take appropriate corrective actions, which may include suspension or revocation of the investigator's privileges to conduct HSR (see Section 23.B). When research is subject to federal reporting mandates, the IRB must report any instance of serious or continuing noncompliance to OHRP (see Section 24.C).

E. Continuing Review of Ongoing Research

Continuing review, required by §46.109*,* is the process by which minimal risk and greater than minimal risk non-exempt human subjects research studies are reviewed by the IRB to ensure that the research continues to meet the criteria for IRB approval under §46.111. Most protocols that require Full Board review will undergo an annual review by the IRB prior to receiving renewed approval to continue the research. However, at the IRB's discretion, continuing review may be required for full-review protocols more often than annually, particularly in studies where the degree of risk is uncertain or unknown, the subject population is vulnerable, and/or when the investigator is inexperienced or has a history of prior noncompliance.

Any research involving human subjects, regardless of level of review, that involves reports of injury or unanticipated problems because of participation in the research will require a review interval shorter than one-year (e.g., semi-annually, quarterly, or after accrual of a specific number of participants).

Federal regulation §46.109 indicates that exempt and expedited protocols do not require continuing review unless the IRB determines otherwise. In these cases, the IRB will document the rationale for continued review at the time of initial review in the IRB Approval Notice, which is available via the IRB electronic system.

i. Materials Required for Continuing Review

To re-approve research at the time of continuing review, the IRB must determine that the regulatory criteria for approval continue to be satisfied. Because the research was previously found to satisfy the criteria for approval, continuing review focuses on new information that may affect the IRB's prior determination that the criteria for approval are satisfied. In particular, the IRB focuses on information related to (1) research progress, (2) adequacy of the informed consent process; (3) risk assessment and monitoring; and (4) any local investigator and organizational issues. The investigator must provide the following information through a Renewal Submission via the IRB electronic system:

- The number of subjects who have participated,
- The number of subjects planned for enrollment in the coming year,
- A summary of modifications to the research since the previous review,
- A summary of any relevant interim findings,
- The currently approved informed consent form,
- Any withdrawal of subjects from the research and reasoning,
- A summary of adverse events and unanticipated problems involving risks to subjects,
- Any complaints about the research since the previous IRB review,
- Any other relevant information, especially about risks associated with the research,
- Any new funding documentation, including funding applications and proposals.

The IRB Administrator will conduct a completeness evaluation and, when appropriate, forward the materials to the Full Board or IRB Chair for evaluation and determination of an IRB action.

ii. Full Board Continuing Review

When continuing review is necessary for protocols that initially received Full Board review, the IRB will follow the same procedures as noted in Section 17.B.ii. The IRB action will be determined by vote of the full board.

iii. Expedited Continuing Review

Under §46.109, studies that initially require Full Board review may be eligible for an expedited continuing review process when the research has progressed to the point where it only involves (1) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (2) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, if either or both were part of the initially IRB-approved study. The IRB Chair will follow all procedures listed in Section 17.B.iii to determine an IRB action.

iv. Possible IRB Actions for Continuing Review

As with initial review, at the time of continuing review, the convened IRB, or IRB Chair, when conducting expedited review, may take any of the actions described in Section 18.

If a renewal protocol receives requests for *minor revisions*, research activities involving currently enrolled subjects may continue, but no new subjects may be enrolled until a revised protocol has been reviewed and approved by the IRB Chair. If a renewal protocol receives a request for *major revisions*, all research activities must stop until the request for revisions has been satisfied and approval has been granted by either the convened IRB or the IRB Chair, depending on the initial level of review.

In cases where concern for subject safety and/or risk is significant, the IRB may vote to suspend or terminate the research (see Section 23.B). If the IRB Chair conducting expedited review believes that continuation of the research should be disapproved, the protocol will be referred to the convened board for review.

F. Administrative Review of Ongoing Research

Administrative review is the process by which minimal risk exempt and non-exempt human subjects research studies are reviewed by the IRB Administrator to keep the ORSP updated on the status of active studies for which it has an oversight responsibility and to ensure that the research continues to meet exemption criteria under §46.104 or criteria for IRB approval under §46.111.

i. Materials Required for Administrative Review

The IRB requires less information for administrative reviews than continuing reviews. To ensure that the research continues to meet exemption or expedited criteria, investigators will provide:

- The number of subjects who have participated,
- The planned for enrollment goal of subjects in the coming year,
- The currently approved informed consent form, if required,

- A summary of modifications to the research since the previous review,
- Confirmation that study risk has not changed,
- Confirmation that no adverse events, unanticipated problems involving risks to subjects, or complaints about the research have occurred since the previous IRB review,
- Information on any new funding documentation, including funding applications and proposals, and an
- Anticipated completion date.

G. Study Closure

All IRB protocols must be closed at the end of their study, including exempt protocols. A study should be closed when all the following apply:

- The study was not and will not be initiated,
- The study was discontinued prior to its completion,
- All subject recruitment and enrollment are complete and subject recruitment or enrollment has ended;
- All subject specimens, records, data have been obtained and no further collection of data/information from or about living individuals will be obtained;
- No further contact with subjects is necessary and all interactions or interventions are complete; and
- Analysis of subject identifiable data, records, specimens is complete and use or access to subject identifiable data is no longer necessary. Identifiable private information about the subjects and any identifiers and code keys linking the data to the participants have been stripped and destroyed.

After study closure, investigators may continue to:

- Perform data analysis, manuscript preparation, and publication activities with deidentified data;
- Follow data security measures and assure confidentiality of records and data;
- Report any adverse events or unanticipated problems if they occur;
- Maintain all research-related records for a minimum of three years after study closure. Documentation of IRB approval documents, the approved research plan, and informed consent of subjects are records that are typically held records.

Once a study is closed or expired, it cannot be reopened. Investigators who wish to resume research activity on closed protocol will need to submit a new protocol subject to all procedures indicated for initial review.

i. Materials Required for Study Closure

To close a research protocol, the investigator must provide the following information via the Study Closure Submission, available in the IRB electronic system:

- Date project closed,
- Reason for closing the project,
- Number of participants,
- Summary of research activity,
- Project outcomes,
- Summary of any adverse events, unanticipated problems involving risks to subjects, or complaints about the research, and
- Data storage plans.

ii. Review of Study Closure Forms

When a Study Closure Submission is submitted, an evaluation for completeness will be conducted by the IRB Administrator. If additional information is needed, it will be requested through the IRB electronic system. After the evaluation is considered satisfactory, the submission will be forwarded to the IRB Chair for review.

iii. Possible IRB Actions for Study Closure

The IRB Chair will review the Study Closure Submission, typically by expedited review, and either approve the closure of the study or request additional information or confirmation of facts from the investigator. Pending satisfactory completion of the Study Closure Submission, the IRB Chair will report closure of the study to the IRB at the next convened meeting. Any reports of new adverse events, unanticipated problems involving risks to subjects, or complaints about the research that have not been previously reported to the IRB will be addressed at the next convened meeting. A study may not be closed until all outstanding adverse events, unanticipated problems, or complaints about the research have been resolved. Note that the IRB will not accept new or renewal submissions from investigators who have any other outstanding submissions.

iv. Data and IRB-Related Document Retention after Study Closure

All research data and IRB-related documents must be maintained for at least three years after the project is closed per §46.115, although investigators may be required to keep the data for a longer time if mandated by a funding agency or publisher. *Data* includes but is not limited to, completed surveys, electronic data files, notebooks, printouts, photographs, slides, negatives, films, scans, images, videotapes, audiotapes,

flash memory and electrophysiological recordings. Other *IRB-related documents* may include consent and assent forms, receipts for payments to participants, etc.

Investigators may maintain the data that they collected, including identifiable private data, if this is consistent with the IRB-approved research plan. The best practice is to maintain research data without identifiers to eliminate the risk of loss of confidentiality. However, if investigators opt to maintain data with identifiers, they may not conduct any additional analysis of identified data without applying for IRB approval or exemption. Investigators must continue to protect the confidentiality of the data as described to the IRB and honor any other commitments that were agreed to as part of the approved research including, for example, future use of data or specimens, provision of research results to subjects, and provision of any outstanding payments or compensation.

v. Study Closure for Multisite Research

For multi-center research, the study may be closed once all research activities are complete at Stockton *and* any sites for which the IRB is serving as the reviewing IRB-of-record. If the investigator is serving as the lead investigator or the site is the coordinating center, the study must remain open as long as the lead investigator or coordinating center is still receiving, studying, using, or analyzing identifiable private information from other sites, even if local interventions, interactions, observations, and data gathering is complete.

18. IRB Actions for Protocol Review

Under §46.109, IRBs have the authority to approve, require modifications to secure approval, or disapprove human subjects research activities, including exempt research activities under §46.104 of the revised Common Rule. One or more of the following actions will be determined by the IRB. For full reviews, the convened IRB will determine the action by vote. For exempt and expedited reviews, the same decisions, aside from disapproval, are made by the IRB Chair.[7]

A. Approval

An action decision of *Approval* indicates that the protocol meets all criteria required for approval and, when necessary, includes all required elements of informed consent. For full reviews, approval must receive a majority vote of those present. The investigator(s) may begin the proposed research project after receiving the notification of approval. After the initial approval period, investigators may initiate the process to renew IRB approval through the IRB electronic system.

[7] A research protocol may be disapproved only after a review and vote by the full IRB.

B. Request for Minor Revisions

An action decision of *Request for Minor Revisions* indicates a need for a limited number of changes or a limited need for additional information to either (1) fully understand the protocol and/or document that (2) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (3) selection of subjects is equitable, and (4) informed consent is obtained and documented through an appropriate process. The investigator will be notified that the protocol requires minor revisions and the reasons why via the IRB electronic system.

For all levels of review, the investigator will be asked to resubmit the proposal with the requested changes for review by the IRB Chair alone. Until the investigator convincingly demonstrates, in writing through the IRB electronic system, that all required changes have been made to the IRB's satisfaction, the project may not begin. The IRB Chair will determine that the investigator has responded to the requested changes and that criteria for approval have been met. Approval notification will be sent to the investigator and the project can begin. Minor revision requests must be fully addressed and approved prior to initiating any research activities.

C. Request for Major Revisions

An action decision of *Request for Major Revisions* indicates a need for major changes to the protocol and that (1) risks to subjects have not been minimized and/or are not reasonable in relation to potential benefits of the investigation, (2) selection of subjects is not equitable, and/or (3) informed consent is not obtained and documented through an appropriate process. The investigator will be notified that the protocol requires major revisions and the reasons why via the IRB electronic system. The revisions made to the protocol will be reviewed at the next convened IRB meeting to affirm that the changes made were sufficient, and determine whether the proposed protocol meets the criteria for approval.

i. Exempt and Expedited Protocols

For exempt and expedited levels of review, the investigator will be asked to resubmit the proposal for review by the IRB Chair alone. The investigator will need to convincingly demonstrate, in writing and through the IRB electronic system, that previously noted concerns have been addressed. The IRB Chair will also ensure that no additional concerns are raised. If the investigator is unable to satisfactorily address concerns and/or meet criteria for approval, additional rounds of revisions may be necessary. Until the investigator convincingly demonstrates, in writing and through the IRB electronic system, that all required changes have been made, the project may not begin. Once the IRB Chair determines that the investigator has responded fully to all concerns and the

requested changes, an approval notification will be sent to the PI, and the project can begin.

ii. Full Board Protocols

For Full Board protocols, major revisions are re-reviewed by the Full Board at the next regularly scheduled meeting. The Board will again engage in a thorough protocol review to determine whether previously noted concerns have been addressed and to ensure that no additional concerns are raised. After deliberation, a vote for a decision action will be called. Approval must receive a majority vote of those present.

If the investigator is unable to satisfactorily address concerns and/or meet criteria for approval, additional rounds of either minor or major revisions may be necessary. Until the investigator convincingly demonstrates, in writing and through the IRB electronic system, that all required changes have been made to the IRB's satisfaction, the project may not begin. Once it has been determined that the investigator has fully responded to all concerns and the requested changes, a notification of approval will be sent, and the project can begin.

D. Disapproval

An action of *Disapprova*l indicates that a protocol places subjects at unacceptable risk relative to benefits or knowledge gained and that the research project as designed and described is not suitable for involvement of human subjects. A research protocol, at any level of review, may be disapproved only after a review and a majority vote by the full IRB. Projects disapproved by the IRB may not be carried out and cannot be resubmitted with revisions as the protocol's risks are too significant.

19. Notification of IRB Actions for Protocol Review

After a review, the IRB Chair or Administrator will notify investigator(s) of the findings and actions regarding their protocol. Findings are processed through the IRB electronic system and sent via email to the researchers. Records of IRB Approval Letters are available within the electronic IRB system for both the study personnel and IRB access.

It is the goal of the IRB to review all exempt and expedited applications and render an action decision within three weeks of submission. Full review submission are due to the IRB two weeks prior to the full committee meeting. A current meeting schedule along with due dates for submission can be found here. Investigators may expect notification of Full Board findings and action within five (5) business days after the convened meeting.

20. Appeal of IRB Actions for Protocol Review

Per federal regulation §46.112 and University policy, research may only be disapproved by the IRB at a convened meeting and no external body, institutional official, or other individual may approve human subjects research that has not received approval of the IRB or has been disapproved by the IRB. Although investigators are permitted by the University to submit a request for appeal, the IRB retains the final authority for approval of proposed research with human subjects.

A. Exempt and Expedited Protocols

Applications that are reviewed on an exempt or expedited basis by the Chair may not be disapproved without review by the convened IRB per §46.110. If an investigator objects to specific revision requests, they may contact the IRB Chair and/or Administrator to further discuss the protocol.

If, however, resolution is not possible through the typical revision process, an investigator may request that the protocol be reviewed by the full board. In these cases, the investigator must submit a written request within ten (10) business days stating that an appeal is being made with the rationale for the appeal to the IRB Administrator. Upon receipt of appeal notification, the protocol will be added to the agenda of the next available IRB meeting. All IRB members will receive a copy of the appeal and the investigator may attend the IRB meeting to further discuss the appeal. The IRB will carefully review the appeal and reach a final decision by a formal vote. Final votes are not subject to additional appeals and may not be overridden by any individual, committee, or entity internal or external to Stockton.

B. Full Review Protocols

Investigators who object to specific revision requests by the Full Board should reach out to the IRB Chair and/or Administrator to further discuss the protocol. As noted above, these concerns can typically be addressed through the normal revision process.

If however, resolution is not possible or if the investigator wishes to appeal the IRB's decision of disapproval, the investigator must submit a written request within ten (10) business days stating that an appeal is being made with the rationale for the appeal to the IRB Administrator. Upon receipt of appeal notification, the protocol will be added to the agenda of the next available IRB meeting. All IRB members will receive a copy of the appeal and the investigator may attend the IRB meeting to further discuss the appeal. The IRB will carefully review the appeal and reach a final decision by a formal vote.

21. Reportable Events

Investigators must report any adverse events, unanticipated problems related to the research, instances of possible noncompliance and/or protocol deviation, or subject complaints immediately to the IRB or Compliance Officer to provide information on the event, ensure subject safety, and initiate University response as needed.

Investigators should use their best judgment regarding the nature and degree of an adverse event, unanticipated problem, or protocol deviation. In general, whether anticipated or not, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints of subjects in which they proclaim that participation presents substantial discomfort, risk, and/or endangerment beyond that explained to them, or as otherwise stated in the consent form.

The IRB approaches the management of reportable events as a collaborative process with investigators and the institution. The IRB operates from the purview that investigators generally operate in good faith and, as such, no assumption of ill intent will be made, even in cases of noncompliance, when a reportable event is made. Any resulting mandate of the IRB will be corrective and preventative in nature, unless and until investigator maleficent intent, misconduct, and/or uncooperativeness has been established. In these cases, in addition to corrective action, investigators may also be subject to disciplinary action as determined by the Provost.

Corrective actions are action(s) required by the IRB on behalf of present or future human participants in research. Corrective actions must adequately address the problem and should ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Examples of corrective actions are available in Section 23.

Disciplinary actions are penalties imposed by University administrators on an investigator for non-compliance with human subjects or related research regulations. In the event that any form of sanction or disciplinary action is applied, the appropriate Union will be notified. Disciplinary actions may include, but are not limited to:

- Limiting the investigator’s human subject research privileges,
- Letters of censure in the personnel file,
- Revoking internal funding privileges,
- Revoking options to apply for external funding.

A. Adverse Events

An *adverse event* (AE) is any undesirable and unintended, although not necessarily unexpected, negative consequence for the subject from participation in the study–either through (1) the interventions and interactions used in the research or (2) the collection of identifiable private information for research purposes. Adverse events include all types of harm such as negative physical, psychological, social, legal, or economic consequences. A *serious adverse event* is a detrimental physical or psychological occurrence in a subject. An *unexpected adverse event* is any AE that is not described in the protocol or an event whose severity exceeds that described in the current approved protocol. Adverse events occur most commonly in the context of biomedical research, although they can occur in the context of social and behavioral research. Examples of AEs include:

- A physical (e.g., rash, soreness), psychological event (e.g., altered cognition, anxiety), or laboratory event (e.g., elevated creatinine);
- Worsening in severity of pre-existing condition (uncontrolled blood glucose levels for subject with diabetes, suicide attempt for subject with depression);
- Results that differ significantly from what was expected (e.g., subjects score higher on a depression scale);
- Subject participation that results in a threat to wellbeing, livelihood or social standing (hospitalization, incarceration, etc.).

Where possible, all potential serious AEs should be identified in an investigator's research protocol in conjunction with a risk mitigation plan.

B. Unanticipated Problems Involving Risk to Subjects or Others

Unanticipated problems involving risks to subjects or others (UAPs) refer to any incident, experience, outcome, or new information that:

- Is unexpected; *and*
- Is at least possibly related to participation in the research; *and*
- Indicates that subjects or others are at a greater risk of harm–including physical, psychological, economic, legal or social harm–than was previously known or recognized.

Unexpected indicates that the incident, experience, or outcome was not anticipated in terms of nature, severity, or frequency, given the (1) research procedures that were described in the study-related documents, including the IRB-approved research protocol and informed consent documents; and/ or the (2) characteristics of the subject population being studied. *Related* means that there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in

the research. Examples of reportable UAP, which may or may not be AEs, include, but are not limited to:

- A breach in confidentiality resulting from disclosure of confidential information or from lost or stolen confidential information (e.g., lost or stolen laptop or thumb drive);
- Complaint of a participant or family member that indicates an unanticipated risk or outcome;
- Harm or risk of harm to research staff, students, and/or the public;
- Errors that may involve potential risk to a participant or others;
- Accidental deviation from the IRB-approved protocol that involves risk or has the potential to recur;
- Deviation from the IRB-approved protocol without prior IRB review to eliminate apparent immediate hazard to a research participant;
- Any deviation from the IRB-approved protocol that increases risk or affects the participants' rights, safety, or welfare; or
- Newly discovered information that indicates a change in the risk/benefit ratio of the research.

i. Relationship between Adverse Events and Unanticipated Problems

An UAP is by definition, unexpected, whereas an AE may be either expected or unexpected. Unanticipated problems may or may not be AE. Adverse events relate to harm to participants; UAP may involve an increased risk of harm even if no actual harm occurred. Determining whether a particular AE is a UAP depends on whether the AE meets the three criteria for being defined as an UAP. Is the AE (1) unexpected, (2) related or possibly related to participation in research, and (3) does it place subjects or others at a greater risk of harm than was previously known or recognized? If so, the AE is considered an UAP.

C. Noncompliance

Noncompliance is defined as any failure to follow:

- Applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or
- The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).

Noncompliance can result from performing an act that violates these requirements or failing to act when required. Noncompliance may be minor or sporadic or it may be serious or continuing.

Minor noncompliance is noncompliance that does not increase the risk to research participants or others, nor does the noncompliance compromise the participants' rights or welfare, or affect the integrity of the research/data or the human research protection program or the University. Examples of minor noncompliance may include, but are not limited to:

- Lapses in continuing IRB approval,
- Failure to obtain exempt determination before exempt research involving human subjects is conducted,
- Minor changes in or deviations from an approved protocol, or administrative errors.

Serious noncompliance is defined as noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data or the research. Examples of serious noncompliance may include, but are not limited to:

- Conducting or continuing non-exempt human subjects research without IRB approval;
- Lack of legally effective informed consent from research participants;
- Failure to report or review serious adverse events, unanticipated problems, or substantive changes in research; or
- Inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

Continuing noncompliance is defined as a pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe. Examples of continuing noncompliance may include, but are not limited to:

- Repeated failures to provide or review progress reports resulting in lapses of IRB approval,
- Inadequate oversight of ongoing research, or
- Failure to respond to or resolve previous allegations or findings of noncompliance.

Apparent noncompliance describes an event that appears to constitute noncompliance, but the IRB has not yet made a formal assessment of the event.

In conducting its review of unanticipated problems, subject complaints, and other reportable events, the IRB will also consider whether the event or issue was caused by, contributed to, or otherwise related to noncompliance.

i. Protocol Deviations and Violations

A *protocol deviation* is any departure, intentionally or unintentionally from the study procedures or treatment plans as specified in the IRB-approved protocol that does not significantly impact a subject's rights, safety, wellbeing, or study outcomes.

Protocol violations occur when a protocol deviation has the potential to significantly impact the completeness, accuracy, and/or reliability of the study data or may significantly impact a subject's rights, safety or well-being. A protocol violation exposes subjects to increased risk and impacts scientific integrity.

Protocol deviations *may* be determined to be serious or continuing non-compliance. Investigators must report protocol deviations/violations to the IRB as soon as they are discovered to ensure risk is minimized in a timely manner.

D. Procedures to Notify the IRB of Reportable Events

Investigators are responsible for detecting and documenting AE, UAP, noncompliance and/or protocol deviation/violation, as well as reporting this information to the IRB and, in some cases, to the study sponsor. In addition to immediately reporting the event to the IRB by phone, email, or in-person, investigators must submit, as soon as possible and within seven (7) business days, an Incident Submission through the IRB electronic system so the IRB has adequate information for its response and to ensure the safety of participants and others involved in the research.

Additionally, anyone else may report concerns of possible noncompliance to the IRB or staff of ORSP verbally, by email, or other means. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and, unless reporting anonymously, cooperating with any subsequent fact-finding in relation to the report. In cases of allegations of noncompliance, the investigator(s) will be informed in writing of the allegation, and any possible investigations within seven (7) business days of receipt.

If an individual, whether investigator, study staff, or other is uncertain whether there is cause to report any of the above events, they may contact the IRB Chair directly to discuss the situation informally.

22. IRB Procedures for Reportable Events

The IRB will fully investigate and review reports of UAP, AE, and/or allegations, complaints, or concerns of noncompliance. To make a report, investigators must make an Incident Submission on the IRB electronic system. Information requested includes, but is not limited to the following:

- Date of discovery,
- Date of occurrence,
- Event summary,
- Risk/benefit assessment,
- Response to event, and
- Corrective and preventive action plan.

A. Completeness Evaluation

Upon receipt of the Incident Submission, the IRB Administrator will conduct an evaluation of completeness to ensure all requested information has been provided. If necessary, the IRB Administrator may contact the investigator for corrections or additional information. If the investigator(s) is contacted for a response during the initial inquiry, a written response will be requested within three (3) business days.

B. Initial Determination

The Incident Submission will be forwarded to the IRB Chair for an initial determination as to whether the event represents an AE, UAP, and/or noncompliance. If needed, the IRB Chair may request additional information from the investigator, sponsor, or others. In the event that interviews, or other investigative strategies are required to obtain necessary information, the IRB Chair and Administrator will coordinate subsequent fact-finding efforts and document any additional information. Any investigative process will be completed within 14 business days, if possible.

The IRB Chair will make an initial determination, as to whether the event represents:

- Not noncompliance, an unanticipated, or adverse event,
- An adverse event,
- An unanticipated event involving risk to subjects or others,
- Minor noncompliance, or
- Serious and/or continuing noncompliance.

Once made, the investigator will be informed of the initial determination, in writing and through the IRB electronic system, within three business days. The investigator and any

co-investigator(s), as applicable, may respond to the initial determination, in writing, within seven (7) business days of receipt of the report. When circumstances warrant, the IRB Chair or Administrator may bypass the initial determination step and report the event immediately to the convened board for review.

C. IRB Determinations for Reportable Events

IRB actions for initial determinations of events that do not meet regulatory definitions of an AE, UAP, and/or serious or continuing noncompliance may be determined by the IRB Chair. However, any initial determination that identifies an event as a possible AE, UAP, and/or noncompliance that is serious or continuing will be referred to the full board for review and final determination. Any actions by the IRB will be determined by majority vote.

The investigator(s) may be invited to respond in person to the IRB at the convened meeting.

i. Not AE, UAP, or Noncompliance

If the IRB Chair determines that the problem does *not* meet the definition of an AE, UAP, or serious and/or continuing noncompliance, the IRB Chair will determine whether any additional actions are necessary to ensure the protection of human subjects (see Section 23). The results of the review will be recorded in the IRB electronic system and communicated to the investigator.

Cases where the (1) investigator deviated from the protocol in order to eliminate immediate and apparent risks of harm or hazards to the subjects, or (2) continued participation of enrolled subjects post approval was necessary to protect the best interest of the currently enrolled subjects will *not* be considered noncompliance but may be considered an AE or UAP.

ii. Not Noncompliance with Other Potential Concerns

If the IRB Chair's initial determination indicates that the event is not noncompliance, but research concerns unrelated to human subjects exist, the IRB Chair may refer the instance to the Compliance Officer for further investigation of research misconduct or risk of harm to non-participants in research. In these cases, the Compliance Officer becomes responsible for reviewing, investigating, responding to, and reporting the concern to the appropriate institutional officials and regulatory agencies. The Compliance Officer is responsible for maintaining records of incidences of research misconduct and risk of harm to non-participants in research. Any information and/or documentation obtained by the IRB, as well as any determined actions, may be

provided to the Compliance Officer for use in any other internal investigative procedures.

iii. Minor Noncompliance

If the IRB Chair determines that the event or issue is noncompliance, but not serious or continuing, the IRB Chair will review any proposed corrective and preventive action plans from the investigator to determine if the plan is acceptable as proposed, or if modifications are required (see Section 23).

If minor noncompliance is found to have occurred, additional actions may be required (see Section 23). The results and mandate of any corrective action will be recorded in the IRB electronic system and communicated to the investigator. Whenever appropriate, the investigator will be assisted so they can achieve compliance. However, if the investigator fails to cooperate with IRB requests to correct instances of minor noncompliance, the inaction may be considered continuing noncompliance.

iv. AE, UAP, and/or Serious or Continuing Noncompliance

If the IRB Chair determines that the event or issue *may* be an AE, UAP, or serious or continuing noncompliance during the initial determination phase, the event will be referred to the convened IRB, Compliance Officer, and Provost.

The convened IRB will review all available information and decide as to whether the event is considered an AE, UAP, and/or serious or continuing noncompliance by majority vote. If needed, the IRB may request additional information from the investigator or others. The convened IRB will also review any available proposed corrective and preventive action plans submitted by the investigator to determine if the plan is acceptable as proposed, or if modifications are necessary to ensure the protection of human subjects (see Section 23). The results and mandate of any corrective action will be recorded in the IRB minutes and the IRB electronic system and communicated to the investigator.

The Compliance Officer will maintain documentation of events of potential AEs, UAPs, and serious and continuing non-compliance and determine if research misconduct has occurred. The Compliance Officer and Provost will determine with input from the IRB if disciplinary action is required for the investigator(s) involved.

Events of non-compliance must also be referred to procedures under the Research Misconduct Policy.

23. IRB Actions for Reportable Events

A. Any Reportable Event

Based upon the circumstances of *any reportable event*, the IRB may mandate any of the following actions, or others, to ensure compliance with federal regulations and the protection of human subjects:

- Additional training of the investigator and/or study staff;
- Submission of an updated plan for corrective and preventative actions by the investigator;
- Modification to the research protocol or procedures;
- Revision to the continuing review timetable;
- Modification to the consent process;
- Modification to the consent document;
- Provision of additional information to current participants regarding the subject's rights, welfare, or willingness to continue participation;
- Provision of additional information to past participants;
- Reconsent of current subjects;
- Monitoring of the research;
- Monitoring of consent.

B. AE, UAP, and/or Serious or Continuing Noncompliance

For an *AE, UAP, and/or serious or continuing noncompliance*, the IRB and/or IO may also (1) suspend or (2) terminate IRB approval to ensure compliance with federal regulations and the protection of human subjects. Per §46.113, the IRB and IO's authority to suspend or terminate research applies to all research subject to IRB approval, including exempt research and research for which continuing review is no longer required. Written Notices of Suspensions or Terminations will include a statement of the reason(s) for the IRB or IO's action and any requirements or conditions associated with the suspension or termination (e.g., notification of subjects). The investigator will be provided with an opportunity to respond in person or in writing. Suspensions or terminations of IRB approval by the IRB must be reported promptly to the IO, sponsors, including federal department or agency heads, and federal oversight agencies as applicable (see Section 24).

i. Suspension of IRB Approval

Suspension of IRB approval is a directive of the convened IRB, IRB Chair, or IO to temporarily stop some or all previously approved research activities. The IRB Chair or IO may temporarily suspend IRB approval, in part or in full, when the available information suggests that actions must be taken to protect human subjects or the integrity of the research, prior to the next convened meeting of the IRB. Temporary

suspensions by the Chair or IO will be reported to the convened IRB at the next scheduled meeting. The convened IRB will determine by majority vote if the suspension should continue, be lifted, or be modified. If the IRB opts to lift or modify the suspension of IRB Approval, the IO must be notified prior to implementation of the agreed upon course of action.

Suspended research studies require continuing review, as the study is considered open despite research activities coming to a halt. All items that need to be reported–to both the IRB and sponsors–during the study need to continue to be reported during the suspension period. When approval of some or all research activities is suspended by the IRB, the convened IRB will consider whether subjects should be notified and determine any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected.

ii. Termination of IRB Approval

Termination of IRB approval is a directive of the convened IRB or IO to permanently stop all activities in a previously approved research study. Terminations of IRB approval of research studies must be made by the convened IRB by majority vote or by the IO as the delegated representative of the IRB. Terminated research studies are closed and no longer require continuing review. When study approval is terminated by the IRB, in addition to stopping all research activities, the convened IRB will consider notification of subjects and determine any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected.

iii. Serious or Continuing Noncompliance

For *serious or continuing noncompliance*, the IRB may additionally mandate any of the following actions:

- Audits of other active protocols;
- Prohibit publication of data collected during non-compliance;
- Require that data collected during non-compliance be destroyed;
- Require that a statement be included with all publications or research reports indicating that the research was not approved by the IRB;
- Disqualify the investigator from conducting research involving human participants at the university;
- Letter of censure in the personnel file; and/or
- Other actions as appropriate given the specific circumstances.

IRB actions mandated in response to a reportable event must be completed in a timely manner, based on the circumstances or seriousness of the potential noncompliance, and as specified by the IRB. The investigator must submit a written report detailing

progress or completion of corrective actions by the specified IRB date. The Chair and Compliance Officer will review the investigator(s)' written response to determine if all mandates have been satisfactorily met or if additional action is required. If the investigator(s) do not comply with the required corrective action(s) within the time specified in the corrective action plan, additional action may be required, including suspension or termination of IRB approval. Incidents of serious or continuing noncompliance must be reported to the IO and Provost for disciplinary action.

24. Notification of Reportable Events

IRB determinations of AE, UAP, serious or continuing noncompliance, and suspensions or terminations of IRB approval are reported to organizational officials at the University and may be reported to external entities as determined by the IRB and Compliance Officer per the following procedures.

Any individual outside of the research team who originates a report or concern of an AE, UAP, and/or noncompliance will be notified of the IRB's determination within 30 calendar days. No information beyond the IRB's determination, including confidential information regarding human subjects or corrective and/or disciplinary action, will be shared.

A. Investigator(s)

The IRB will notify the investigator, in writing, of any reports or concerns of AE, UAP, noncompliance, and/or subject complaints made by others within three (3) business days. Once made, the investigator will be informed of the initial determination, in writing and through the IRB electronic system, within three (3) business days. The investigator will be notified of any final determinations, in writing and through the IRB electronic system made either by the IRB Chair or full board, within seven (7) business days.

B. Organizational Officials

When the IRB determines that an AE, UAP, and/or serious or continuing noncompliance has occurred, written notifications of the IRB's final determination, and required corrective or preventative actions will be forwarded to the following organizational officials within seven (7) business days:

- Full IRB,
- Compliance Officer,
- Executive Director of ORSP,
- Dean(s) of investigator(s),
- Institutional Official, and

- Provost.

The Provost will exclusively make executive decisions related to disciplinary actions for research investigators.

The above officials will be notified of any written reports submitted by the investigator(s) detailing the progress or completion of any IRB mandated corrective actions. If the investigator(s) does not comply with the required corrective action(s) within the time specified in the corrective action plan, the above entities will be notified of any additional action required by the IRB, including suspension or termination of IRB approval..

The following events will only be reported to the full IRB and Compliance Director at the next convened meeting:

- Not AE, UAP, and noncompliance,
- Minor noncompliance,
- Resolvable subject complaints that do *not* involve AE, UAP, and/or serious and/or continuing noncompliance, and/or
- Unresolvable subject complaints that do *not* (1) involve AE, UAP, and/or serious and/or continuing noncompliance or (2) require institutional support beyond the IRB.

The full IRB and Compliance Officer will be notified of any written reports submitted by the investigator(s) detailing the progress or completion of any IRB mandated corrective actions at regularly scheduled meetings. Failure of the investigator to comply with the required corrective action(s) within the time specified will be reported to the full IRB and Compliance Officer within three (3) business days. Procedures listed in Section 22 will be followed.

C. External Entities

HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5) require prompt reporting to appropriate institutional officials and, as applicable, the federal department or agency (e.g., OHRP) of (1) any unanticipated problems involving risks to subjects or others; (2) any serious or continuing noncompliance with the applicable federal regulations or the requirements or determinations of the IRB; and (3) any suspension or termination of IRB approval. Stockton's IRB complies with this requirement as follows. When research is under the oversight of an external IRB, the terms of the agreement with that IRB will guide reporting.

The Compliance Officer will initiate the external notification process as soon as the IRB takes any of the following actions:

- Determines that an event may be considered an unanticipated problem involving risks to participants or others,
- Determines that noncompliance was serious or continuing, and/or
- Suspends or terminates approval of research.

The Compliance Officer may be instructed by Federal departments or agencies to prepare reports on instances of UAPs, noncompliance, and suspensions or termination of approval of research. The Compliance Officer will send a copy of the report to the:

- Investigator,
- IRB Chair and Administrator,
- Executive Director of ORSP,
- Dean(s) of the investigator(s),
- IO,
- Provost,
- Sponsor, if applicable,
- Federal departments or agencies, as applicable.[8]

The Compliance Officer will ensure that all necessary external parties are notified within 30 business days of the determination. For more serious actions, the Compliance Director will expedite reporting. If additional time is needed to gather facts, or determine corrective actions, a preliminary report will be submitted within 30 business days, to be followed by a final report as described above.

25. Appeal of IRB Actions for Reportable Events

Any action of the IRB with respect to research involving human subjects is final. An IRB ruling cannot be overturned by another group or person(s) (see §46.112). Only the IRB can alter its previous determination. The convened IRB may review an investigator's request for reconsideration or appeal to a determination regarding noncompliance and/or corrective actions as warranted only through the presentation of new information or unusual circumstances. The investigator may submit an appeal request and other supportive materials to the IRB Chair and IO within ten (10) days of notification of the IRB's finding. The investigator may attend the IRB meeting to discuss the request and provide information but will be asked to leave prior to the IRB's final deliberations and

[8] Reports should be submitted to the OHRP, if the research is conducted or supported by DHHS. If the research is conducted or supported by a Common Rule Department or Agency other than DHHS, the report is sent to the party identified. If the study is conducted or supported by a federal department or agency that has not adopted the Common Rule, and reporting is required, the report is sent to the party identified. Reports are not submitted to federal departments or agencies such as OHRP unless the research is subject to federal regulations or another mandate that necessitates such reporting

vote. The investigator will be notified in writing of the IRB's decision within three (3) business days of the review through the IRB electronic system.

Alternatively, IRB approval for research that has been suspended or terminated can be reinstated with a demonstration that the project meets criteria for approval via a new protocol submission and initial review. Similarly, a disapproved project can be altered so that it can secure approval.

26. Subject Complaints

Stockton's IRB is concerned about the safety, rights, and welfare of all individuals participating in research projects at Stockton and its affiliated sites and reviews complaints submitted in a variety of ways and from a number of different sources, including research participants, the public, faculty, staff and government agencies. Although most reported concerns and complaints are minor and routine, like a subject complaint about late study payment, all research concerns or complaints are taken seriously to ensure that suitable resolutions can be identified to protect the rights and welfare of research participants.

A. Complaints Received by the Investigator(s)

If a participant complaint is received by the investigator or study team, the investigator must ensure that the complaint is addressed and resolved in a method that protects the rights and welfare of the participant and is consistent with the IRB-approved study. In all cases in which a participant writes to the researcher with a complaint, it is imperative the researcher reply to the participant as soon as possible. The initial response can be short and simply confirm the complaint was received. A prompt response from the investigator acknowledging that the complaint was received *is* required and the investigator is obligated to make a good faith effort to try to resolve any study-related concerns or complaints that they receive or are made aware of.

All complaints received by the investigator or study team must be reported to the IRB per procedures below. If the complaint is significant or cannot be resolved, investigator(s) must submit an Incident Submission through the IRB electronic system. If an investigator is unsure if a complaint is significant or unresolvable, the investigator must contact the IRB Chair or IRB Administrator to confirm whether or not an IRB submission is required.

i. Resolvable Complaints that are Not AE, UAP, or Noncompliance

If the complaint does *not* meet the definition of an AE, UAP, or does *not* involve possible noncompliance or research misconduct *and* the investigator is *able* to resolve the complaint satisfactorily with the participant, the complaint should be reported to the IRB through the IRB electronic system either at study renewal or closure. The investigator must provide a short summary of the complaint, how it was resolved, and why it did not meet criteria for prompt reporting as a UAP or possible noncompliance or research misconduct.

ii. Unresolvable Complaints that are Not AE, UAP, or Noncompliance

If the complaint does *not* meet the definition of an UAP or does *not* involve possible noncompliance or research misconduct *and* the investigator is *unable* to resolve the complaint satisfactorily with the participant, the complaint should be reported to the IRB through the IRB electronic system's Incident Submission so that the problem can be resolved with additional help from the IRB and/or institution. The IRB will process Incident Submissions according to Section 22.

iii. AE, UAP, or Noncompliance Complaints

If the complaint meets the definition of an AE, UAP, or involves possible noncompliance or research misconduct, the investigator must report the complaint immediately to the IRB using the IRB electronic system's Incident Submission feature. In the Incident Submission, the investigator must describe the current status of the complaint, as well as a plan for future action toward resolution. An Incident Submission should still be submitted *even if* the investigator is able to satisfactorily resolve the issue. The IRB will process Incident Submissions according to Section 22.

B. Complaints Received by the IRB

If a participant complaint is received by the IRB, the IRB will take necessary steps to address the complaint. If the complaint identifies a specific study of concern, the investigator of the study will be contacted to assist in addressing the complaint. The investigator must then complete an Incident Submission through the IRB electronic system. The IRB will process Incident Submissions according to Section 22.

C. Complaints Received by Other Institutional Officials

Any participant complaints received by any other member of the institution must be reported to the IRB immediately by contacting either the IRB Chair or Administrator via email, phone, or in-person. Procedures for Complaints Received by the IRB in Section 26.B above will be followed.

D. Complaints Received by ORSP Staff

Any participant complaints received by ORSP staff must be reported immediately by contacting either the IRB Chair or Administrator via email, phone, or in-person. The investigator of the associated study will be contacted to assist in addressing the complaint and filing an incident report.

27. Cooperative Research Projects

Cooperative research projects are projects that involve two or more U.S. research sites where each site is conducting a different part of a research protocol under the direction/control of the lead investigator. Per §46.114, any institution located in the United States engaged in cooperative research must rely upon approval by a single IRB for that portion of the research conducted in the United States, although each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR §46.

When relying upon another IRB or when serving as the reviewing IRB for an outside organization or as an external investigator, a formal relationship must be established between Stockton University and the outside organization or investigator through an *Institutional Authorization Agreement*\ (IAA). An IAA, also known as a *Reliance Agreement*, is used to enable an IRB at one institution to be the IRB-of-record or lead institution for a collaborative research protocol. These agreements establish the authorities, roles, and responsibilities of the reviewing IRB-of-record and the relying organization. IAAs are useful in a number of situations including when:

- An investigator at one institution will be working on research entirely at another institution or location without involving their home institution. Little to no involvement of the secondary institution may be needed beyond identifying the investigator's involvement;
- The study is a large, multi-institutional project with a high expectation for consistency or coordination across research sites, and the strict requirements of the research methodology must be carefully followed by each research location; or when
- All research partners are involved in substantive ways that may require sharing resources and collaboration agreements.

To support compliance, Stockton University will make every effort to ensure as much consistency as possible across IAAs/reliance agreements.

A. Identification of Opportunity and Institutions

The *Reviewing IRB* is the IRB that assumes IRB reviewing responsibilities for another institution for a specific study, group of studies, or for all research conducted by the other institution/investigator. The reviewing IRB is also known as the *IRB-ofrecord,* or the *lead institution* and this relationship must be documented in advance by a written IAA. The Reviewing IRB is typically responsible for the following regarding the research protocol or activities:

- Provide initial and continuing review in accordance with §45 CFR 46 and its FWA;
- Arrange for prompt reporting to the Relying Institution's IRB of any of the following, as defined and determined by the Reviewing Institution's IRB:
    - Any unanticipated events or problems involving risks to subjects or others,
    - Any serious or continuing non-compliance,
    - Any suspension or termination of IRB approval,
- Comply will all applicable Federal, State and Local laws, and regulations;
- Provide IRB meeting minutes to the Relying Institution's IRB upon request; and
- Copy the Relying Institution on all correspondence to regulatory agencies if reporting of an event is required.

The *Relying Institution* is an institution or site that has entered into an IRB reliance agreement with a reviewing IRB to carry out the cooperative study's IRB review. A relying institution or participating site may or may not have its own IRB and is also known as the secondary institution. The relying institution cedes review. When an institution cedes review, it agrees to rely on another IRB to serve as the reviewing institution/IRB-of-record for the cooperative research study. The Relying Institution is typically responsible for the following:

- Ensuring research activities at its site are in compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance;
- Adhering to its institutional conflict of interest policies and procedures, which includes providing the Reviewing Institution with any applicable COI management plan related to the study;
- Ensuring investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including, but are not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.
- Maintaining, implementing or having access to a human subject research post approval monitoring process, function, program, or service not directly involved with the research that can conduct and report the results of for-cause and not-for-

cause audits of the research study to ensure compliance with human subject's protections regulations and other relevant requirements. The post approval monitoring process, function, program, or service should have the ability to monitor the conduct of research under this Agreement and ensure any relevant findings are reported to the Reviewing Institution upon request.

Requests for Stockton University to either rely upon an external IRB or to serve as the reviewing IRB-of-record for an external organization or investigator must be documented through the IRB electronic systemin either the Initial Submission or a subsequent Modification Submission, if the investigator must identify the IRB oversight arrangements for cooperative research. A Reliance Agreement (also called an Institutional Authorization Agreement, or IAA) identifies which entity will serve as IRB-of-record. Contact the IRB Chair and Administrator to determine if Stockton's IRB should be serving as the reviewing or relying institution and to determine the steps in obtaining an IAA.

B. Stockton's IRB as the Reviewing IRB

Stockton's IRB may serve as the lead institution and reviewing IRB-of-record by establishing an IAA when:

- Stockton is the prime awardee for any grant funded awards;
- The majority of the research activities, excluding recruitment, will be conducted on Stockton campuses or sites;
- The research is conducted exclusively with Stockton students, faculty, and/or staff as participants;
- The primary investigator is a Stockton student; and/or
- When the expertise of Stockton's IRB is more suited to the review of the research.

When Stockton's IRB serves as the reviewing IRB-of-record for another organization, the requirements and procedures outlined throughout this manual apply unless an alternative procedure has been agreed to in the reliance agreement or outlined in a companion document. Where it is appropriate for Stockton's IRB serve as the reviewing IRB-of-record, the following procedures will be followed:

- Stockton's IRB Administrator will ensure that all investigators–internal and external to Stockton–have completed required trainings for researchers (see Section 3). Research team members unaffiliated with Stockton may provide documentation of equivalent training. Stockton's IRB Chair or Administrator will review the documentation and determine if it satisfies organizational standards. If previous training has not been completed, external investigators should complete Stockton's CITI training requirements specified in Section 3 and here.

- Once Stockton's IRB has noted the protocol meets the criteria for approval, the IRB Administrator will prepare an IAA form to send to the relying institution/IRB for review, completion, and signature.
- When the IAA is returned, the IRB Administrator will submit it to the IO for review and signature.
- The IRB Administrator will upload the signed IAA to the IRB electronic system and provide a copy via email to the investigator and external contact associated with the IAA agreement.
- The IRB Chair will use the IRB electronic system to submit the IRB Approval Notice that includes instructions to follow all applicable Stockton policies, procedures, and requirements.

When continuing reviews are completed, a copy of the signed IRB Approval Notice will be forwarded to the relying institution's IRB to document oversight. Outcomes of any annual continuing or administrative review should be forwarded to the relying institution/IRB by the investigator. Any AE, UAP, concerns related to noncompliance, or unresolvable subject complaints must be reported to the relying institution's IRB per their specified procedures. Investigators should also follow any procedures required by the relying institution's IRB when the study is completed.

C. Stockton's IRB as the Relying IRB

Stockton's IRB may cede IRB review, establish an IAA, and rely on an external IRB for review of HSR when:

- The external IRB has Federalwide Assurance from the OHRP;
- The funding is *not* primarily allocated to a Stockton investigator;
- The majority of the research will be conducted off Stockton campuses or sites;
- When the expertise of the collaborating IRB is more suited to the review of the research (e.g., a medical or inpatient study at a medical facility).

Research reviewed by an external IRB remains subject to oversight by Stockton's IRB and must adhere to all applicable Stockton policies, procedures, and requirements. Where it is appropriate for Stockton's IRB to cede review and rely on another institution's IRB, the following procedures will be followed:

- The IRB Administrator will ensure that all Stockton investigators have completed required trainings for researchers (see Section 3).
- The reviewing institution will provide their IAA template, a copy of all applicable award notices, and a copy of the approved protocol to Stockton's investigator. Stockton's investigator will provide this documentation in their Initial or Modification Submission.

- The IRB Administrator will review the submission and determine if sufficient information is included. Once all required information is obtained, the IRB Administrator will complete the IAA form and submit it to the IO for review and signature.
- The IRB Administrator will return the signed form to the reviewing institution and request that a fully signed copy be returned.
- The IRB Administrator will upload the completed IAA to Stockton's IRB electronic system with an IRB Approval Notice that includes instructions to follow the requirements of the lead institution's IRB.

An annual administrative review should occur per Stockton's procedures in Section 17.F and any AE, UAP, concerns related to noncompliance, or unresolvable subject complaints must be reported to Stockton's IRB per procedures in Section 22. When the project is complete, the investigator should submit a Study Closure Submission through Stockton's IRB electronic system.

28. Research Previously Approved by Another IRB

When an investigator transfers human subjects research to Stockton University that was previously approved by another IRB, the investigator must (1) submit the research protocol for initial review and determination by Stockton's IRB, or (2) request for Stockton's IRB to rely upon the existing IRB-of-Record, which must be approved by both organizations.

Research submitted for review by Stockton's IRB will follow procedures in Section 17.B. Research activities under the auspices of Stockton cannot commence until all necessary approvals are in place, including approval by the Stockton's IRB or an IRB IAA is executed (see Section 27).

For research transfers where stopping research interventions or procedures might harm subjects, the investigator can request permission from both organizations to continue the research under the oversight of the prior organization's IRB until final Stockton IRB approval is obtained.

29. Payment for Participation in Research

Payments to research subjects are commonly proposed as a monetary incentive for participation in recognition of the time, effort, inconveniences, and discomforts that participation in the proposed research may entail. The IRB does not consider payment as a benefit when weighing the risks and benefits of the research; payment is an incentive, not a benefit, of the research. In contrast to payments, *reimbursement* is

provided to cover actual costs incurred by subjects as a result of participation (e.g., travel, parking, lodging, etc.). Reimbursement offsets costs and may decrease financial risks associated with participation and, in doing so, may facilitate equitable selection of subjects. Payment arrangements should be managed separately from reimbursement whenever possible because the ethical considerations differ (as well as the potential tax implications).

Undue influence occurs when an offer of an excessive or inappropriate reward or other overture is used to obtain compliance. It interferes with truly voluntary informed consent because participants accept discomforts or risks that they otherwise would find unacceptable. Payment arrangements may also create issues with equitable selection of subjects, including the societal distribution of research risks and benefits and the generalizability of the research results. As such, the amount, timing, and nature of payments must be carefully considered by the IRB. To evaluate the acceptability of a proposed payment plan, the IRB must consider the:

- Proposed amount of payment,
- Method and timing of disbursement,
- Subject population,
- Recruitment methods and materials, and
- Information provided within the proposed consent form.

Investigators who wish to pay research subjects must include in their IRB protocol the (1) amount and schedule of all payments and (2) the justification or basis for payment. A justification should substantiate that proposed payments are reasonable and commensurate with the time and inconveniences associated with study participation and do not constitute–or appear to constitute–undue influence. Plans to reimburse subjects for incurred expenses must also be outlined in the IRB protocol.

When research involves multiple visits or interactions, payment should be prorated and not be contingent upon the participant completing the entire study. Further, any amount paid as a bonus for completion of the entire study should not be so excessive that it could unduly influence subjects to remain in the study when they otherwise would have withdrawn.

The consent form must describe the terms of payment and/or reimbursement including the amount, form, schedule of payments, and any conditions under which subjects would receive partial payment (e.g., if they withdraw from the study before their participation is completed) or no payment.

Stockton University has policies in place to address how and what information is collected and reported for subjects who receive the amount of compensation required to be reported to the Internal Revenue Service (IRS). Please see Policy 1097 for additional information. When applicable, the consent form must disclose the information that will be collected, who will be provided or have access to the information, and the circumstances that necessitate IRS reporting.

30. Students and Employees as Research Participants

Students and employees recruited as research subjects are more vulnerable to coercion because they may perceive grades, employment, or other benefits as dependent upon their participation in research. Challenges related to maintaining confidentiality are also greater when subjects are affiliated with Stockton or known to the researchers. Additional safeguards may be required to protect the rights and welfare of these individuals. One such safeguard is that absent sound justification, researchers may not enroll students currently enrolled in a class taught by the researcher or employees who report to them directly in studies determined to involve greater than minimal risk to subjects. Additional safeguards may be required at the IRB's discretion.

A. Recruitment

Students and/or employees should not be recruited or selected solely for convenience. IRB approval for the recruitment of these populations in a research study will not be granted when they would not be appropriate for inclusion.

Recruitment of students or employees as research participants must be designed to minimize the possibility of undue influence. In general, potential participants should be solicited from a broad base of individuals meeting the conditions for study, rather than by personal solicitation of specific individuals. Strategies to minimize the potential influence of an investigator when recruiting his/her own students or employees may include recruitment by general announcements, postings or sign-up sheets, or other methods that require an interested participant to initiate contact with the investigator(s).

i. Letters of Support

When access to student or educational records or employee data is needed for recruitment and/or research activities, a letter of support from an individual authorized to speak on behalf of the institution is required. Authorized individuals should address FERPA and/or PPRA regulations noted in Section 30.D, if applicable.

ii. University Mass Email Guidelines

Although investigators may receive approval to recruit Stockton students and/or employees, University guidelines regarding mass emails must be followed. Moderators of University wide mass email lists may or may not grant requests for distribution, regardless of IRB approval. See here for more information.

B. Voluntary Participation

Student and employee participation must remain voluntary. Students and employees may not be required to participate in research as part of a course or employment requirements. Investigators are required to document strategies in the IRB protocol that ensure voluntary participation and must ensure, via the informed consent form, that (1) participants may choose not to participate in the research and (2) decisions about research participation may not affect–either favorably or unfavorably–grades or performance evaluations, class or employment standing, potential letters of recommendation, relationships with, or other opportunities or decisions made by investigators. Researchers should not use student or employee data for research purposes without the prior written consent from participants and letters of support from appropriate authorized officials.

C. Safeguards for Privacy

In situations where conditions make it difficult to keep an individual's participation confidential, consideration should be given to conducting the research anonymously, off-site, and/or outside of regular class or business hours. Participants should be notified via the informed consent and/or assent process of any circumstance where personal information and/or research data may be accessible to parents, teachers, colleagues, or others not directly involved in the research.

D. Additional Considerations for Students as Research Participants

Investigators who wish to use students–at Stockton or elsewhere–as research participants should also consider the following:

i. Research Involving Regular Classroom Activities and Education Records

In cases where regular classroom activities are the topic of research, investigators must distinguish between research activities that are optional and distinct from required classroom activities that would take place outside of research purposes. Investigators who wish to use required classroom activities (e.g., assignments, grades, journals, term

papers, etc.) for research purposes must obtain prior written informed consent from students to use these materials for research purposes.

ii. Course Credit or Extra Credit

Course or extra credit for research participation may not be offered without a comparable non-research alternative offered. Alternative assignments must be equivalent in time and effort and should be made available for those who cannot or choose not to participate in a study. The alternative assignment must be articulated in the research protocol and referenced in the informed consent form document.

iii. Use of Class Time

Protocols proposing the use of class time for research should include an explanation of the benefit of the research to the students. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class. An alternative activity should be provided for students who choose not to participate. Protocols proposing the use of class time for research should include an explanation of the benefit of the research to the students. Specifically, the investigator should explain how participation in the research would be a learning experience for the students and how the research is relevant to the course of study being taught in that class. An alternative activity should be provided for students who choose not to participate.

iv. Potential Coercion

Instructors cannot require or encourage participation in research among their students as this may be considered coercive in nature. Due to the power dynamic between instructor and student, students may feel undue pressure to participate as is. Participation cannot be a requirement and students have full autonomy to determine whether they would like to participate.

v. Family Educational and Rights Privacy Act (FERPA)

The proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). *FERPA* is a federal law that protects the privacy of student education records and applies to all schools that receive funds under an applicable program of the U.S. Department of Education. An *education record* is any record directly related to a student which contains personally identifiable information (e.g. class assignments, grades, audio/visual recordings, and/or non-directory level information) and is maintained by the university or a party (i.e., instructor) acting on behalf of the university.

Stockton articulates Student Privacy Rights that are applicable to researchers who are conducting research on students at this institution. For researchers conducting research at other institutions, please note that FERPA restricts researchers' access to student records without written permission from parents of minor children, or permission of students over the age of 18. Investigators must contact each institution in which they will be conducting research and follow that institution's FERPA policy, in addition to the requirements of the IRB. A letter of support from the Office of the Registrar indicating that the proposed protocol complies with FERPA regulations is required.

vi. Protection of Pupil Rights Amendment (PPRA)

Human subject research with students must also comply with the Protection of Pupil Rights Amendment (PPRA). *PPRA* is a federal law intended to protect the rights of students and their parents in educational settings and applies to all children younger than age 21 who are in elementary or secondary programs that receive funding from the U.S. Department of Education. PPRA requires prior consent of the student or prior written permission of the parent or guardian and student assent before participation in any research involving seven specifically designated topics listed in the link above. PPRA also indicates that researchers must have provisions to allow parents to review surveys and instructional materials (e.g., teachers' manuals, films, tapes, or other supplementary materials) to be used in connection with any research study.

Researchers conducting research at institutions with PPRA requirements must contact each institution in which they will be conducting research and follow that institution's PPRA policy, in addition to the requirements of the IRB. A letter of support indicating that the proposed protocol complies with PPRA regulations is required.

31. Studies with Protected Health Information

Protected health information (PHI) is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. PHI includes individually identifiable health information, including genetic information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. PHI is one or more of the following 18 identifiers:

- Patient/Participant names

- Geographic subdivisions smaller than a State (with exceptions for initial 3 digits of zip code)
- Age information for those over 89
- All elements of dates (except year) that are directly related to an individual
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security Numbers
- Medical record numbers
- Account numbers
- Health Plan Beneficiary numbers
- Certificate/License numbers
- Device identifiers and serial numbers
- Vehicle identifiers and serial numbers (including license plate numbers)
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers (including finger and voice prints)
- Full face photographic images and any comparable identifying images
- Results of a genetic test
- Any other unique identifying number, characteristic, or code

Individuals using PHI for research purposes must abide by HIPAA Privacy Rule, which was implemented to protect the privacy of individually identifiable health information, while also ensuring that researchers continue to have access to medical information necessary to conduct vital research. The Privacy Rule requires an individual to provide signed permission, known as an *Authorization*, before a covered entity can use or disclose the individual's PHI for research purposes. *Covered entities* are (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which Health and Human Services has adopted standards.

Under certain circumstances, a covered entity can use or disclose PHI for research without an individual's Authorization by obtaining proper documentation of a waiver of the Authorization requirement by the IRB. The following three (3) criteria must be satisfied for the IRB to approve a waiver of authorization under the Privacy Rule:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - An adequate plan to protect identifiers from improper use and disclosure;

    - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research[9]; and
    - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart; and
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practically be conducted without access to and use of the PHI.

32. Computer and Internet-Based Research

Computer- and internet-based research protocols must provide the same level of protection as any other type of research involving human participants. All studies using computer and internet technologies must ensure that (1) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (2) selection of subjects is equitable, (3) informed consent is obtained by adequate and appropriate means.

The following information may help researchers plan, propose, and implement computer- and internet-based research protocols in a manner that provides the same level of protection of human participants as more traditional research methodologies. The information below is consistent with the basic IRB principles applied to all research involving human participants.

A. Recruitment

Online and internet-based procedures for advertising and recruiting study participants (e.g., Internet advertising, e-mail solicitation, social media posting) must follow the IRB guidelines for recruitment that apply to any traditional media, such as flyers, letters, information sheets, etc.

Methods for identification and qualification of subjects may be a challenge in Internet-based research, particularly in relation to legal age of consent and/or if the study presents more than minimal risk to subjects or asks particularly sensitive questions. Minors may be screened out by checking for Internet monitoring software such as

[9] Unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law

SafeSurf and RSACi rating or using Adult Check systems. In most studies involving no greater than minimal risk, it is sufficient for the informed consent document to simply ask participants to confirm that they are the appropriate age of majority.

B. Informed Consent

Investigators must include all required elements of informed consent under §46.116, unless exemptions apply, when generating consent documents for computer and internet-based research. In general, investigators conducting internet-based research with minors must obtain both child assent and parent permission. Researchers may request a waiver of parent permission provided the study fits the appropriate criteria (see §46.116(f)).

For less than minimal risk studies with no direct identifiers, investigators may use a binary yes/no response to the statement “I agree to participate” rather than a signature to document informed consent. If documented consent is required, the consent form may be mailed or emailed to the participant who can then print and sign the form and return it to investigators via email, postal mail, or fax. Alternatively, a verifiable electronic signature may be obtained. The informed consent document should also instruct subjects to close their browser window after participation and suggest that they clear their cache to protect their confidentiality, especially if using a shared computer.

Collecting data over the Internet can increase potential risks to confidentiality because of the frequent involvement of third party sites and the risk of third party interception when transmitting data across a network. When using a third party website to administer surveys, the website might store collected data on backups or server logs beyond the timeframe of the research project. In addition, third party sites may have their own security measures that do not match those of the investigators’. Participants should be informed of these potential risks in the informed consent document. Example language for the informed consent may include:

- Although every reasonable effort has been taken, confidentiality during actual Internet communication procedures cannot be guaranteed.
- Your confidentiality will be kept to the degree permitted by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties.
- Data may exist on backups or server logs beyond the timeframe of this research project.

C. Data Collection and Storage

It is strongly recommended that any data collected from human participants over computer networks be transmitted securely using data encrypting software. This helps ensure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent. The level of security should be appropriate to the risk. For most research, standard security measures like data encryption, password protected files, and multi-factor authentication will suffice. However, with sensitive topics, additional protections include certified digital signatures for informed consent, encryption of data transmission, and separation of identifiers from study data.

It is recommended that a professionally administered survey server be used for online data collection (e.g., Qualtrics, Google, Microsoft). If researchers choose to run a separate server for data collection and/or storage, the IRB recommends that:

- Data is stored on a server or service that is beholden to a non-disclosure agreement and HIPAA compliant, if appropriate;
- Servers or services storing data are managed by trained professionals or approved Stockton University service providers;
- Access to the server is limited to key project personnel;
- There are frequent, regularly scheduled security audits of the server; and
- The server is subject to the periodic security scan of servers.

If a server is used for data storage, personal identifying information should be kept separate from the data, and data should be stored in encrypted format. When a physical device is used to store downloaded data, it should support hardware encryption, such as use of a code or pin to access the device computer. Use of Social Security Numbers is not permitted and researchers are advised to use pseudonyms when reporting results.

It is recommended that data backups be stored in a safe location with at least two forms of modern security protocols and controls (i.e., two sets of lock and key) with limited access. It is recommended that data destruction services be used to ensure that no data can be recovered from obsolete electronic media and that investigators destroy physical media devices (e.g., USB drives, external hard drives, etc.) after use.

D. Online Surveys

It is recommended that investigators use Qualtrics, Microsoft, and/or Google to collect survey data. Stockton has non-disclosure agreements with these companies, and they are HIPAA compliant. However, other online survey tools are generally permitted for

most minimal risk studies employing online survey procedures. Investigators should indicate within the IRB protocol where the survey will be hosted (i.e., on the survey platform or if there will be a link to an external survey site) and provide a live link and PDF version of the survey. Investigators must review confidentiality measures and data security policies for the given online survey tool and make sure that they are described in the IRB protocol and informed consent.

For less than minimal risk studies with no direct identifiers, investigators may use a binary yes/no response to the statement “I agree to participate” rather than a signature to document informed consent. The informed consent document should also instruct subjects to close their browser window after participation and suggest that they clear their cache to protect their confidentiality, especially if using a shared computer.

Internet-based survey instruments must be formatted in a way that will allow participants to skip questions or provide a response such as “I choose not to answer.” Online surveys should also include mechanisms for withdrawal. In addition to informed consent at the beginning of a survey, investigators are encouraged to have a binary-response question at the end of the survey to confirm whether participants want to (1) include their study in the data or (2) discard the data. In cases of anonymous data, participants should be informed that once responses are submitted, withdrawal from the study is not an option.

Some online survey research may require a debriefing after completion. Debriefing forms should be similar to the debriefing process done in-person. A debriefing page, with more information about the purpose of the study, should be provided immediately after the last question on the survey. If necessary, researchers should include contact information and information about other resources (e.g., help numbers, Stockton resources, etc.).

E. Online Interviews and Focus Groups

Interviews or focus groups may be conducted over the Internet using cross-platform communication technology such as Zoom, Google Chat, WhatsApp, Skype, etc. When using such an application, researchers should state in the IRB protocol which method of communication they will use.

Investigators must indicate in the informed consent form if audio and/or video recording is a condition of participation and/or if alternatives to recording are available; informed consent forms must have separate indicators for participants to consent to audio and/or video recording. When conducting online focus groups, participants should be

encouraged, in writing via the informed consent, to display pseudonyms rather than real names or other identifying information.

F. Online Observations

When online observation research procedures are employed, investigators must be sensitive to expectations of public and private behavior. *Public behavio*r refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy. *Private behavior* refers to behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

Despite navigating in a public space online, an individual may have an expectation of privacy, and investigators need to be sensitive to that expectation. Investigators should be familiar with the online space in which they intend to conduct research. As with other types of participant observation, investigators generally must disclose their role as researchers to the group participants and the IRB protocol should indicate how participants may let the researcher know if they are not comfortable with the researcher's presence.

Investigators need to indicate how informed consent will be obtained from subjects' when conducting online observations. The informed consent should clearly indicate what information will be gathered, including, but not limited to tracking participants' use of the Internet (e.g., using cookies to track websites visited) or recording user information or comments (e.g., participant observation of an on-line discussion group) and how it will be used (e.g, no identifiers, use of avatar names, etc.).

G. Children's Online Privacy Protection Act (COPPA)

The goal of COPPA is to protect children's privacy and safety online, in recognition of the easy access that children often have to the web. COPPA requires website operators to post a privacy policy on their website and create a mechanism by which parents can control what information is collected from their children and how such information may be used. It is the responsibility of the researcher to ensure full compliance with the COPPA regulation. For more information about COPPA, visit here.

33. Compliance Monitoring

ORSP will conduct research compliance audits that are internal to the University. The goal of internal auditing human subjects research is to review, inspect and verify the ethical conduct of research, adherence to the approved study protocol and institutional,

state, and federal guidelines. Audits are categorized as either for-cause or not-for-cause.

For-cause audits may be requested by the Compliance Officer, IRB, IRB Chair, or the IRB Administrator. For-cause audits are prompted if information is obtained that indicates there is a risk to subject safety, violation of subject rights, or non-compliance with institutional, state, or federal guidelines. For-cause audits are intended to evaluate the specific issue that triggered the need for the audit, as well as overall compliance.

Not-for-cause audits are regularly scheduled audits by the Compliance Officer that can occur on an annual or semi-annual basis depending on the risk level associated with the study.

34. Glossary of Terms and Definitions

Administrative modifications	Alterations to an approved protocol that include (1) addition or removal of study personnel or research sites or (2) correcting typographical, grammatical, or spelling errors.
Administrative review	Process by which minimal risk exempt and non-exempt human subjects research studies are reviewed annually by the IRB administrator to keep the ORSP updated on the status of active studies for which it has an oversight responsibility and to ensure that the research continues to meet exemption criteria or criteria for IRB approval under the Common Rule.
Adverse event (AE)	Any undesirable and unintended, although not necessarily unexpected, negative consequence for the subject from participation in the study–either through (1) the interventions and interactions used in the research or (2) the collection of identifiable private information for research purposes.
Apparent noncompliance	Apparent noncompliance describes an event that appears to constitute noncompliance, but the IRB has not yet made a formal assessment of the event.
Approval	The protocol meets all criteria required for approval and, when necessary, includes all required elements of informed consent.
Approval date	Date that study activities involving human subjects may start and/or the research activities (or change of activities) may begin. For full review protocols, the approval date would be the date of the convened IRB meeting at which the protocol was voted and approved.
Authorization	Signed permission by an individual for a covered entity to use or disclose the individual's protected health information for research purposes.
Biospecimens	Sample material such as urine, blood, tissue, cells, DNA, RNA, or protein from humans.
Cede review	Where one institution/IRB relies on another IRB to serve as the reviewing institution/IRB-of-record for the cooperative research study.

Co-Investigator (Co-I)	Individual working in partnership with the Principal Investigator in the management, development and/or execution of the project.
Confidentiality	The state of keeping or being kept private.
Consultant	Individual with competence in a special area whom the IRB has invited to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
Continuing noncompliance	Pattern of repeated noncompliance which continues after it has been determined that noncompliance occurred, including inadequate effort to take corrective actions or comply with IRB requirements within a reasonable timeframe.
Continuing review	Process by which minimal risk and greater than minimal risk non-exempt human subjects research studies are reviewed by the IRB to ensure that the research continues to meet the criteria for IRB approval under the Common Rule.
Contributing to generalizable knowledge	When the systematic investigation adds information with the intended use of the research findings can be applied to populations or situations beyond that studied. In the event there are no direct benefits to participants in a research study, contributing to generalizable knowledge may be documented in protocols and informed consent as a benefit of participation.
Cooperative research projects	A project involves two or more U.S. research sites where each site is conducting a different part of a research protocol under the direction/control of the lead investigator.
Corrective actions	Action(s) required by the IRB on behalf of present or future human participants in research that adequately address the problem and ensure that the incident will not happen again with the investigator or protocol in question, with any other investigator or protocol, or with the IRB.
Covered entities	Health plans, health care clearinghouses, and health care providers who electronically transmit any health information in connection with transactions for which Health and Human Services has adopted standards.
Data	Completed surveys, electronic data files, notebooks, printouts, photographs, slides, negatives, films, scans, images, videotapes, audiotapes, flash memory, electrophysiological recordings, etc.
Disapproval	The protocol places subjects at unacceptable risk relative to benefits or knowledge gained and the research project, as designed and described, is not suitable for involvement of human subjects.
Disciplinary actions	Penalties imposed by University administrators on an investigator for non-compliance with human subjects or related research regulations.
Economically disadvantaged persons	Individuals who struggle to provide basic necessities for themselves and their families or communities.
Education record	Any record directly related to a student which contains personally identifiable information (e.g. class assignments, grades, audio/visual recordings, and/or non-directory level information) and is maintained by the university or a party (i.e, instructor) acting on behalf of the university.

Educationally disadvantaged persons	Individuals who have educational deficits, learning disabilities, or cultural backgrounds that limit communication with a researcher.
Expiration date	Indicates the date at which IRB approval is no longer effective. For initial reviews and continuing reviews, the expiration date will be one (1) year, minus one (1) day from the approval date for research subject to continuing review
Family Educational Rights and Privacy Act (FERPA)	Federal law that protects the privacy of student education records and applies to all schools that receive funds under an applicable program of the U.S. Department of Education.
Financial Conflict of Interest (FCOI)	The prospect of financial gain from the research.
Financial or economic risks	The loss of benefits, insurance, wages or other income, or employment for the participant.
For-cause audit	Investigation of a research protocol performed when other information, such as subject complaints, adverse events, or reports of noncompliance indicate a potential problem with safety of research participants and/or the ethical conduct of research activities that warrants an investigation.
Harm	Any injury to the rights, safety or welfare of a research participant that may include physical, psychological, social, financial or economic factors.
Human source research	Researcher interaction with another individual to gain knowledge about something, but not identifiable or personal information about that person; research with a focus on things, products, or policies, rather than people or their thoughts regarding themselves or others.
Human subject	A living individual about whom an investigator, whether professional or student, conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Identifiable biospecimen	Biospecimen where the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
Identifiable private information	Private information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
Individuals with impaired decision-making capacity	Persons with characteristics or in situations that affect cognitive or emotional functions in a manner that judgment and reason is significantly diminished.
Institutional Authorization Agreements (IAA)	Used to enable an IRB at one institution to be the IRB-of-record or lead institution for a collaborative research protocol; also known as reliance agreements.
Interaction	Communication or interpersonal contact between an investigator and human subject.

Intervention	Physical procedures where information or biospecimens are gathered and/or manipulations of the subject or the subject's environment that are performed for research purposes.
Investigator Conflict of Interest (ICOI)	Situations in which an investigator's professional judgment regarding his or her research could be negatively influenced by a secondary interest, like potential financial gain or professional advancement.
IRB-of-record	An IRB that assumes IRB responsibilities for another institution or independent investigator for a specific study, group of studies, or for all research conducted by another external institution or investigator. For an IRB-of-record to exist, a relationship between entities must be documented in advance by an Institutional Authorization Agreement (IAA).
Lead institution	The institution that assumes the majority of the workload in terms of writing the proposal and/or managing the largest portion of funds, should the proposal be rewarded for collaborative research projects. The lead institution oftentimes directs and coordinates the activities or participating or collaborative sites. Also known as Reviewing Institution/IRB or IRB-of-record.
Legal risks	When the subject or others may be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which the subject or others may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.
Major modifications	Any alterations to an approved protocol that (1) increases risk to participants beyond what is considered minimal, (2) includes activities or procedures that would not be eligible for expedited review if submitted as part of new research, or (3) was initially required full-review reviewed that significantly alters the already approved study design.
Member Conflict of Interest (MCOI)	(1) IRB member involvement in the design, conduct, and reporting of the research, (2) an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research; or (3) significant financial interests related to the research being reviewed; and/or (4) any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.
Minimal risk of harm	When the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Minor modifications	Any alterations to an approved protocol that (1) increases risk to participants, but risk still remains no more than minimal (2) include activities or procedures that are eligible for expedited review if submitted as part of new research, or (3) initially involved minimal risk and the changes do not significantly alter the study design.
Minor noncompliance	Noncompliance that does not increase the risk to research participants or others, nor does the noncompliance compromise the participants' rights or welfare, or affect the integrity of the research/data or the human research protection program or the University.

Non-Financial Conflict of Interest (NFCOI)	Influences other than financial reward.
Non-scientific member	An individual who may have formal education and training in a discipline generally considered to be non-scientific (e.g. humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be nonscientific (e.g. law enforcement, management, minister, lawyer, clergy, ethicists, accountants), even if the individual did have some formal training in a scientific field unrelated to his/her current occupation and career.
Noncompliance	Any failure to follow (1) applicable federal regulations, state or local laws, or institutional policies governing human subject protections, or (2) the requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations).
Not-for-cause audit	Regularly scheduled inspection of research record keeping, informed consent, and data collection practices to identify areas of concern and ensure records are consistent with institutional, state, and federal requirements.
Payments	A monetary incentive for participation in recognition of the time, effort, inconveniences, and discomforts that participation in the proposed research may entail.
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. PII can be (1) sensitive, such as medical, financial, or legal information; (2) neutral, such as name, facial photos, or work address; or (3) contextual, such as a file for a specific health condition that contains a list of treated patients.
Physical risks	Physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.
Principal Investigator (PI)	The individual responsible for the preparation, conduct, and administration of a research grant, contract, or other sponsored project.
Privacy	Having control over the extent, timing, and circumstances of sharing oneself–either physically, behaviorally, or intellectually–with others. It is freedom from unauthorized intrusion, being observed, or disturbed by other people.
Private behavior	Behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
Private information	Information (1) about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or (2) that has been provided for specific purposes by an individual where the individual can reasonably expect will not be made public (e.g., a medical record).
Protected Health Information (PHI)	Any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.
Protection of Pupil Rights Amendment (PPRA)	A federal law intended to protect the rights of students and their parents in educational settings and applies to all children younger than age 21 who are in elementary or secondary programs that receive funding from the U.S. Department of Education.

Protocol deviation	Any departure from the study procedures or treatment plans as specified in the IRB-approved protocol. Protocol deviations occur when an investigator does not implement or follow some aspect of a research study as approved by the IRB.
Psychological risks	The production of negative affective states such as anxiety, depression, guilt, shock, loss of self-esteem, etc.
Public behavior	Behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy.
Quorum	A majority (more than half) of the voting membership, including at least one member whose primary concern is in a non-scientific area.
Recent employee	Individuals who have been employed by Stockton any time during the previous three years.
Reimbursement	Payment to cover actual costs incurred by subjects as a result of participation (e.g., travel, parking, lodging, etc.).
Related	A reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
Reliance Agreement	Used to enable an IRB at one institution to be the IRB-of-record or lead institution for a collaborative research protocol; also known as reliance agreements.
Relying Institution/IRB	An institution or site that has entered into an IRB reliance agreement with a reviewing IRB to carry out the cooperative study's IRB review; also known as a secondary institution.
Request for Major Revisions	Request for Major Revisions indicates a need for major changes to the protocol and that (1) risks to subjects have not been minimized and/or are not reasonable in relation to potential benefits of the investigation, (2) selection of subjects is not equitable, and/or (3) informed consent is not obtained and documented through an appropriate process.
Request for Minor Revisions	Request for Minor Revisions indicates a need for a limited number of changes or a limited need for additional information to either (1) fully understand the protocol and/or document that (2) risks to subjects are minimized and are reasonable in relation to potential benefits of the investigation, (3) selection of subjects is equitable, and (4) informed consent is obtained and documented through an appropriate process.
Research	Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
Reviewing Institution/IRB	An institution or site that has entered into an IRB reliance agreement with a relying IRB and has agreed to carry out the cooperative study's IRB review; also known as the IRB-of record or the lead institution.
Scientific member	An individual who has formal education and training as a physician or other medical professional, a Master’s or Doctoral level physical, biological, or social-behavioral scientist, or significant post-baccalaureate work experience in a physical, biological, or social-behavioral sciences.
Sensitive data	Information that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, or reputation

Serious Adverse Event (SAE)	A detrimental physical or psychological occurrence in a subject.
Serious noncompliance	Noncompliance that (1) increases risk of harm to subjects, (2) adversely affects the rights, safety, or welfare of subjects, or (3) adversely affects the integrity of the data or the research.
Significant financial interest	When the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
Social risks	Detailed use of information that (1) be hazardous to the social position of an individual or (2) may be detrimental to groups of people in the participant's community.
Suspension of IRB approval	A directive of the convened IRB or IRB Chair to temporarily stop some or all previously approved research activities.
Systematic investigation	A methodical approach to the activity and often involves a hypothesis, research question, and/or plan to systematically collect and analyze data.
Termination of IRB approval	A directive of the convened IRB to permanently stop all activities in a previously approved research study.
Unaffiliated member	May not be a current or recent employee or student and/or may not have an immediate family member who is a current or recent employee or student of Stockton University.
Unanticipated Problem (UAP)	Any incident, experience, outcome, or new information that (1) is unexpected, and (2) is at least possibly related to participation in the research; and (3) indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal or social harm) than was previously known or recognized.
Undue influence	When an offer of an excessive or inappropriate reward or other overture is used to obtain compliance.
Unexpected	The incident, experience or outcome was not anticipated in terms of nature, severity, or frequency, given the (1) research procedures that were described in the study-related documents, including the IRB-approved research protocol and informed consent documents; and/ or the (2) characteristics of the subject population being studied.
Unexpected adverse event	Any adverse event that is not described in the protocol or an event whose severity exceeds that described in the current approved protocol.
Vulnerable populations	Individuals who are (1) unable to independently make informed decisions, (2) easily manipulated and/or likely to experience coercion or undue influence, and/or (3) a convenient and readily available study population, which may lead to exploitation and unfair treatment to the benefit of others.

35. Timelines

Task	**IRB Timeline**

Exempt and Expedited review	Reviewed within three weeks of submission; It is the goal of the IRB to review all exempt and expedited applications and render a decision within three weeks of submission.
Reminder Notices to investigators	Reminder notices will be sent to investigators three months, two months, and again one month in advance of the expiration date.
Administrative closure	If the investigator fails to respond to the notifications of renewal, revisions, or other necessary submissions within 90 days, the IRB Administrator will administratively close the study.
Full Reviews	Full reviews are due to the IRB two weeks prior to the full committee meeting. Investigators may expect notification of Full Board findings and action within five (5) business days after the convened meeting.
Appeal of Exempt or Expedited Review Actions	In these cases, the investigator must submit a written request within ten (10) business days stating that an appeal is being made with the rationale for the appeal to the IRB Administrator and/or IRB Chair.
Appeal of Full Board Review Actions	The investigator must submit a written request within ten (10) business days stating that an appeal is being made with the rationale for the appeal to the IRB Administrator and/or IRB Chair.
Reportable Event	Investigators must submit, as soon as possible and within three (3) days, an event report form through the IRB electronic system so the IRB has adequate information for its response and to ensure the safety of participants and others involved in the research.
Allegations of Noncompliance	In these cases, the investigator(s) will be informed in writing of the allegation, and any possible investigations within seven (7) days of receipt.
Response to Completeness Evaluation for Reportable Events	If the investigator(s) is contacted for a response during the initial inquiry, a written response will be requested within three (3) business days.
Investigation of Reportable Events	Any investigative process will be completed within 14 days, if possible.
Initial Determination of Reportable Event	Once made, the investigator will be informed of the initial determination, in writing and through the IRB electronic system, within three (3) days.
Response to Initial Determination for Reportable Events	The investigator and any co-investigator(s), as applicable, may respond to the initial determination, in writing, within seven (7) days of receipt of the report.
Notification of Reportable Event to External Reporters	Any individual outside of the research team who originates a report or concern of an AE, UAP, and/or noncompliance will be notified of the IRB's determination within 30 days.
Notification of Reportable Event to Investigator	The IRB will notify the investigator, in writing, of any reports or concerns of AE, UAP, noncompliance, and/or subject complaints made by others within three (3) business days. Once made, the investigator will be informed of the initial determination, in writing and through the IRB electronic system, within three (3) business days. The investigator will be notified of any final determinations, in writing and through the IRB electronic system made either by the IRB Chair or Full Board, within seven (7) business days or three (3) business days following the convened IRB meeting.
Notification of Reportable Event to Organizational Officials	Written notifications of the IRB's final determination, required corrective or preventative actions will be forwarded to the Provost, IO, and Compliance Officer within three (3) business days:
Notification of Reportable Event to External Entities	The Compliance Officer will ensure that all necessary external parties are notified within 30 business days of the determination. If additional time is needed to gather facts, or determine corrective actions, a preliminary report will be submitted within 30 days, to be followed by a final report as described above.

Failure to Comply with Corrective Action Plan (CAP)	Failure of the investigator to comply with the required corrective action(s) within the time specified will be reported to the full IRB and Compliance Officer within three (3) business days.
Appeal of IRB Actions of Reportable Events	The investigator may submit an appeal memo and other supportive materials via the IRB electronic system within ten (10) days of notification of the IRB's finding
IRB Decision for Appeal for Reportable Action	The investigator will be notified in writing of the IRB's decision within three (3) business days of the review through the IRB electronic system.