General Policies and Procedures

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The purpose and responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects. The IRB reviews and oversees research activities involving human subjects and requires that the research complies, as applicable, with Federal regulations at 45 CFR 46, Subparts A, B, C, and D, (or equivalent policies and procedures), the FDA 21 CFR Parts 50, 56, 312, and 812, California law, and all other pertinent regulations and guidelines.

Institutional Review Board
Purpose
Safeguarding the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the University. In order to provide for the adequate discharge of the institutional responsibility, no non-exempt research activity involving human subjects may be undertaken by any faculty, staff, employee, or student unless an IRB has reviewed and approved the research prior to commencing the research activity.

Designation and Authority
The University has designated the Chapman IRB responsible for conducting initial and continuing reviews and providing oversight for all research activities involving the use of human subjects performed by agents or employees of the University. The scope of research reviewed by the IRB is not limited and the IRB reviews all types of research submitted.

The Institutional Official (IO) formally grants the IRB the following authority relative to the protection of human subjects:
1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the agents of the organization and involving human subjects, based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;
2. To require reports for protocol continuing review;
3. To continuously monitor the conduct of research with human subjects;
4. To suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious risk to subjects;
5. To place restrictions on a study, if necessary to protect human research subjects;
6. To observe, or have a third party observe, the consent process;
7. To observe, or have a third party observe, the conduct of the research.

No official within the organization may approve a protocol or human subjects research activity that has not been approved by the IRB. However, the IO or any other University executive administrative official may disapprove a protocol or research activity that has been approved by the IRB.

**Composition and Appointment of the IRB**

The IRB is composed of full board members, alternate members, and a community member, who represent Chapman University and the community. With backgrounds in the physical, medical, and social sciences, IRB board members are guided by regulations and standards of practice formulated and enforced by various government departments, including the Department of Health and Human Services.

The IRB is formally appointed by the IO, with input and membership nominations coming from the IRB Chair(s) and IRB members, University department chairs, directors, and deans, and is composed of a sufficient number of members to assure complete and adequate review of activities commonly conducted at the University.

Scientific members of the IRB generally will have experience in research involving human subjects, and will be recruited from among active research members of the University.

Non scientific members will be recruited from the faculty at large and will reflect professional expertise in a non-scientific area, such as law, ethics, human or patient rights, etc. The appointment of non-affiliated (community) members will also be done by the IO but the IRB Chair(s), Director of Research Integrity, and IRB Administrator are responsible for determining whether or not the nominees are truly unaffiliated and/or have appropriate expertise. Chapman IRB shall not review research involving prisoners unless there is an experienced Prisoner
Representative appointed to the IRB. As such, research involving prisoners will require review by an external IRB.

Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may call upon ad hoc consultants for assistance in review of scientific merit or to perform an in-depth review of the study. The ad hoc consultants are not considered to be members of the IRB, are utilized only for expert scientific review, have no voting rights, and must disclose whether or not they have any conflicts of interest with the protocol. The consultants will submit a written report and copies of the report will be distributed to all IRB members. The report and recommendations will be documented in the IRB minutes for the meeting. It is expected that because of the wide diversity of IRB members, the use of ad hoc consultants will be a rare occurrence.

The IO may appoint administrative staff and/or faculty (e.g., legal counsel) at the University to serve as non-voting members of the IRB should the IO, the IRB Chair, or the Director of Research Integrity decide that such persons would be of assistance to the IRB in conducting its duties. Individuals involved in the business function or in research development do not serve in any capacity on the IRB and have no involvement in the day-to-day operations of the review process. A non-voting member cannot be counted in the quorum and cannot vote, but can participate in discussions. In addition, funding agencies may have additional IRB membership requirements.

The Director of Research Integrity or designee will report changes in IRB membership to Office for Human Research Protections (OHRP) as required.

**Term of Appointment**

IRB members are appointed to 3-year, renewable terms. The IRB Chair(s) are expected to hold the position for several years. Upon appointment and again at time of reappointment, each IRB member is queried to determine roster information such as
affiliation status, relationship of the member to the University, indications of experience and other relevant information.

**IRB Chair(s)**

The IRB has Co-Chairs chosen from IRB members who will typically be members of the faculty of the University, knowledgeable in human subjects research, including the federal and state regulations, University policies, and ethics relevant to such research. The IRB Chairs shall preside over and be authorized to speak for the IRB.

**Meetings**

In order to conduct IRB business, there must be a quorum of members present at a convened meeting. If quorum is lost, votes are not taken until it is restored. To be approved, a protocol must receive a majority of votes of members present at the meeting. The IRB shall hold regular meetings at a time and place to be determined by the IRB and posted electronically. Researchers may be invited to attend the meetings to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. Other members of the University community are permitted to attend meetings but must request attendance through the IRB Administrator, the Director of Research Integrity, or IRB Chair. Guests will be asked to sign a confidentiality agreement.

Prior to each full board meeting the IRB Administrator or other designee will assign primary reviewer(s) knowledgeable about or experienced in working with these types of studies. The IRB Administrator ensures that either the Primary or Secondary Reviewer is present at the meeting or available by teleconference during the convened meeting.

**IRB Meeting Minutes**

IRB meeting minutes are recorded in writing in sufficient detail to allow an outside observer to reconstruct protocol specific discussions and determinations. The IRB Administrator monitors quorum at each meeting and records IRB discussion points for the minutes. Meeting minutes are distributed each month to those IRB members who attended the given meeting. The IRB Administrator will provide a draft of the minutes for the Director of Research Integrity and the IRB Chairs to review for comments and/or suggested changes regarding the document's accuracy. After all comments are reviewed and addressed, a pending version of the minutes are available for review by the IRB members who attended the given meeting, prior to and for discussion at the next IRB meeting. A vote for approval of the final version of the minutes occurs at the next convened meeting. Once approved, a copy of the approved minutes will be posted in the Cayuse IRB system in order to document all actions taken by the IRB.

Minutes shall include:

1. A protocol summary and the deliberations for each protocol and the resulting IRB
action.
2. The approval period for each initial review, continuing review, and amendment.
3. A record of attendance for each protocol including the names of members who left the meeting due to a conflict of interest and a notation of such.
4. The voting record for each protocol and the previous meeting’s minutes reflecting the number of members for, against or abstaining from the vote and when alternate members replaced a primary member.
5. The basis for requiring changes to a protocol, tabling, or disapproving research.
6. A written summary of the discussion and resolution of controverted issues.
7. Justification of deletions or substantive modifications of information concerning risks or alternative procedures contained in a consent form.
8. If applicable, summaries of deliberations of protocols for inclusion of vulnerable populations.
9. If applicable, the rationale for significant risk/non-significant risk device determinations.
10. If applicable, protocol specific justifications for waivers of consent and research involving vulnerable populations.
11. A list of all actions that were taken administratively during the previous month.

Confidentiality of the Review Process
During the process of initial, continuing review, or amendment of research activity, material provided to the IRB shall be considered privileged information and the IRB shall assure the confidentiality of the data contained therein.

Conflict of Interest (COI)

IRB Members - Convened Meeting
Prior to discussion of protocols at a convened meeting, the IRB Chair will ask if any member has a COI with any protocol being discussed at that meeting. Should an IRB member declare any level of involvement in a research protocol under review by the IRB, or state a COI with the research protocol the following is required:

1. IRB member is excluded from discussion and voting except to provide information requested by the IRB.
2. IRB member leaves the meeting room during discussion and voting.
3. IRB member is not counted towards quorum.

Designated Reviewers for Expedited Review
IRB members (including experienced IRB staff members) who have been designated by the IRB Chair as reviewers for initial or continuing review of research protocols, reports of noncompliance, protocol deviations, unanticipated problems, and amendment requests that qualify for expedited review will self-identify any COI that they may have with the research or principal investigator (PI). In such cases, the review responsibility will be reassigned to another experienced
IRB member.

**Examples of IRB Member COI**
IRB members are considered to have a conflict of interest if they:

1. Are involved in the design, conduct, or reporting of the research study.
2. Have direct administrative powers over the investigators or the study.
3. Are reviewing a proposal from a position who may determine promotion or merit (e.g., reviewing a protocol by the chair of your department or dean of your school).
4. Have a financial and/or ownership interest of any amount in or related to the research and the value can be readily determined.
5. Have a financial and/or ownership interest in or related to the research but the value cannot be readily determined.
6. Received or will receive compensation and/or have ownership interest of any amount with value that may be affected by the outcome of the study.
7. Have received in the past year, currently are receiving, or will receive from the sponsor of the study honoraria, payments, or compensation of any amount.
8. Have a proprietary interest in the research, including but not limited to a patent, trademark, copyright, or licensing agreement.
9. Serve as directors, board members, scientific advisors, or hold other decision-making positions in the entity sponsoring the research.
10. Are not an investigator, co-investigator, or consultant on a study, but are closely associated with the investigators on the study being reviewed, or other studies.
11. Have personal, familial, or intimate relationships with the principal investigator.
12. For any reason, believe they cannot be objective concerning a study.

**Principal Investigator**
All PIs and their research staff are required to disclose any financial COI according to the University COI policy. Disclosed COIs that might affect the protection of subjects must have a management plan in place. Management plans may include: partial or complete divestment, limiting involvement of the conflicted individual, additional oversight, or disclosure. Disclosure alone cannot be used to manage conflicts of interests that might affect the protection of subjects.

When made aware of a possible researcher conflict, the IRB formally refers cases to the Conflict of Interest Officer (Director of Research Integrity), which in turn determines if formal COI management strategies are required. If required, a draft COI Management Plan will be prepared by the Director of Research Integrity in consultation with the COI Committee. The COI Committee Chair and
Director of Research Integrity will work with the researcher to develop and finalize a COI Management Plan. When finalized, the COI Management Plan will be submitted to the IRB for review and final approval. Under no circumstances will research be approved until the IRB has reviewed and approved the COI Management Plan.

Institutional COIs are handled through the Office Institutional Compliance according to the Institutional Conflict of Interest policy.

**Interaction with Other University Components and Commencement of Research Activities**
The University is comprised of multiple types of research review and some reviews are accomplished by standing committees, e.g., Institutional Biosafety Committee (IBC). The successful fulfillment of the University’s intent to protect human research subjects is dependent upon open communication among these various institutional components. Committees and offices exchange information, when necessary, to assure that, in addition to IRB review, human subjects research receives all appropriate review prior to implementation of the research activities. Human subjects research is not allowed to commence until all applicable reviews are complete and notification of approval is received by the IRB.

**Types of Research Conducted at the University**
The majority of research at the University is social-behavioral in nature. The University does not participate in planned emergency research described in and covered under 21 CFR 50.54 and OHRP Guidance 97-01.

**Categories of Research Subjects**
Human subjects research at the University generally includes normal healthy individuals; adults, and/or children. The IRB reviews and approves research proposing inclusion of vulnerable populations. The vulnerable populations most commonly included in research activities are children, prisoners, pregnant women, cognitively impaired adults, and economically or educationally disadvantaged individuals.

**Determining if IRB Review is Required**

**Determination of Human Subjects Research**
The federal regulations include a very specific definition for what constitutes “research” (see 45 CFR 46.102(d)) and for what is meant by a “human subject” (see 45 CFR 46.102(f)). A formal determination from the IRB can be made if a project either is not research and/or does not involve human subjects (e.g., as may be required by a student’s doctoral dissertation committee, a funding agency, or a journal editor). The IRB will not provide a formal written determination after the project has been initiated.

If a researcher is unsure whether a project meets this criteria, they should
contact the IRB staff before submitting their application for review.

The federal research regulations (45 CFR 46) do not require the IRB to make a formal determination that projects are not research, or do not involve human subjects. Thus, a Non-Research Determination Form should be used only if a formal determination is required by a university entity (e.g., dissertation committee) or by an external agency.

According to HHS regulations, the University becomes engaged in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes, or (ii) obtain individually identifiable private information about those individuals for research purposes. Under FDA regulations, the institution becomes engaged in human subjects research when it undertakes a clinical investigation on individuals who are or become subjects in the investigation, either as recipients of a test article or as controls and may be either patients or healthy non-patients.

PIs are automatically considered to be "engaged" in human subjects research whenever they apply for or receive a direct award to support research that includes human subjects, even if all the activities involving human subjects will be carried out by a subcontractor or collaborator. In all cases the institution to which the grant has been awarded bears the responsibility for protecting human subjects under the award.

**Classroom-Based Projects**
Classroom-based research projects typically do not meet the definition of human subjects research. As such, IRB review may not be required. For guidance regarding institutional policy for the review of classroom-based projects see additional guidance information on the IRB website: Chapman University IRB Guidelines for Student Classroom Projects and Research Involving Human Subjects

**Use of De-Identified Secondary Data**
By federal regulation, existing (or secondary) data are defined as data that existed "before the research is proposed" to an institutional official or the IRB. This provision is frequently interpreted as data that were "on the shelf" at the time the protocol was written. Existing data include both those provided to the investigator from any source; and those already in the possession of the investigator.

**Secondary data analysis that does not require review by the IRB**
Using the following types of public data does not constitute federally-regulated human subjects research and requires no further action with the IRB.

1. Data that is not about living individuals (e.g., historical records of
deceased individuals, death records, historical archives)

2. Publicly available data; i.e. data with identifiable but not private information. (e.g., individual public records such as address, phone number, property value; data found on an unrestricted website, in publications, phone books, political campaign contributions, or obtained through a Freedom of Information Act request).

3. A project that merges public datasets with other datasets containing private information may enable the identification of individuals and requires IRB review.

**Secondary data analysis that may require IRB review**

1. Non-public, de-identified, or anonymous data

2. Use of the following types of non-publicly available datasets does not constitute federally regulated human subjects research, if the provider of the data is NOT involved in the design, conduct or reporting of the research, including sharing any authorship rights:
   a) Datasets that are anonymized or
   b) Datasets that include coded private information, such that the investigator has no access to identifiable information. In such cases, no further action with the IRB is required.

Investigators are advised to have on file a confidentiality statement from the data provider stating that identifiers were not included in the dataset that they received (e.g., de-identified data given by a colleague or provided by a data provider where no collaboration is expected).

3. Non-public, identifiable data, but where research does not record, retain, or use identifiers.

4. Use of datasets that contain private, identifiable data, but from which no identifiable information will be recorded, retained or used by any member of the research team in a manner that allows the direct or indirect identification of individuals, may be eligible for exemption from IRB review. Investigators are required to submit an Exemption application to the IRB.

Investigators should include a data security plan that clearly describes measures to ensure that individuals cannot be identified, including the process for de-identifying information.

5. Non-public, identifiable data where research has access to and records private identifiable information.

6. Use of non-publicly available data when members of the research team or their collaborators have access to and plan to use private
identifiable information about living individuals, is considered human subjects research and requires review by the IRB. Investigations using such data are required to submit an application to the IRB.

**Written Agreement for Restricted Access or Licensed Data**

An investigator planning to obtain data under contractual terms, such as a restricted access data agreement or licensed data agreement, must contact the Office of Research Sponsored Projects Services (SPS). SPS will negotiate the terms of that agreement with the data provider on behalf of the University. Chapman investigators are not authorized to sign data use agreements themselves.

**Coded Private Information as Relates to Human Subjects Research**

The OHRP does not consider an institution or PI to be engaged in human subjects research if the PI consults or collaborates on human subjects research by obtaining coded private information or human biological specimens from another institution, engaged in the research, which retains the code. However, one of the following four conditions must be met:

1. The key to decipher the code is destroyed before the investigator receives the coded information.
2. The consulting or collaborating PI and the holder of the key enter into an agreement prohibiting release of the key under any circumstances.
3. The releasing institution has Internal Revenue Service-approved written policies and procedures applicable to the research project that prohibit release of the key to consultants or collaborators under any circumstances.
4. There are other legal requirements prohibiting release of the key to consultants or collaborators.

OHRP also does not necessarily consider authorship as a factor in determining whether or not an institution is engaged in human subjects research. It is possible that the authors of a paper or presentation were not involved in obtaining "data about subjects of the research through intervention or interaction with them" or "identifiable private information about the subjects of the research." If a PI simply receives unidentifiable or coded information about human subjects, OHRP has determined that analysis of the information and/or publication of conclusions based on analysis of the information does not constitute being engaged in human subjects research.

**Cooperative Activities**

The IRB shall have special responsibilities in the review and approval of proposals involving cooperative activities. Cooperative activities are those in which the University faculty, students, or staff obtain access to human subjects involved through one or more cooperating institutions, or when PIs from cooperating institutions obtain access to
human subjects at the University.

When a PI plans to conduct research at a site external to the University, the PI must respond to questions in a protocol application that informs the IRB of:

1. The contact information of the site(s);
2. Whether the site(s) has an IRB;
3. Whether the site(s) has granted permission for the research to be conducted and;
4. If the site has an IRB, has the IRB approved the research or does the site plan to defer to Chapman’s IRB.

For research that will be conducted off-site, the IRB requires a letter from an appropriate official from that site (e.g., schools, prisons, non-profit service organizations) when they are partners in a research project. If the research will be conducted outside the U.S., it is required that the PI obtain appropriate authorization and observe any local laws and regulations established in the foreign country. Depending on the location, identifying a local partner when conducting international research may also be required.

**Reliance Agreements**

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research. A reliance agreement can take many different forms, but Chapman primarily uses the Institutional Authorization Agreements (IAA) template.

Investigators working at multiple institutions, each having an IRB, may choose to have one IRB become the IRB of record over some or all participating sites (commonly referred to as ceded review, reliance agreements, or deferral of IRB oversight.) This means that the Chapman IRB is either the reviewing IRB (IRB of Record) or is ceding (Relying) oversight of the research activity to another equally-qualified IRB.

The Office of Research Integrity, in coordination with the Institutional Official, determines whether ceding IRB review is appropriate on a case-by-case basis.

For PIs performing research in which Chapman is the lead or coordinating institution, the PI should note in the initial IRB application that the University is the lead or coordinating institution of a multi-site study. The PI should also provide the following information:

1. The name(s) of each participating institution that will be engaged in human subjects research.
2. Confirmation that each participating institution has an FWA.
3. The contact name and information for the PI at each institution.
4. The contact name and information for the IRB of record at each institution.
5. The method of multilateral communication between institutions/IRBs of any
unanticipated problems involving risks to subjects or others and other study related information.

When Chapman cedes review to another IRB, the Chapman PI is responsible for obtaining all regulatory protocol information (e.g., approved protocol, approved consent documents) from the ‘overall PI’ at the collaborating institution. Any questions or required reporting will need to go through the PI at the reviewing IRB site. PI’s will no longer interact with the Chapman IRB for protocol issues related to that research, but PI’s are responsible for providing information of any unanticipated problems or adverse events.

The final IAA will dictate any additional responsibilities the Chapman PI will have.

**Undue Influence of the IRB or Research Integrity Staff**

It is the policy of the University that the human subjects research review process and implementation of IRB policies and procedures are conducted objectively and without undue influence over deliberations or processes. Individual members of the IRB, whether employed by the institution or community members, have the right and obligation to report any undue pressure upon them to make decisions that would favor an individual PI over subject protections, during the initial and continuing review processes or when conducting or participating in other IRB-related business. IRB members or staff are asked to document the issues related to the case in writing to both the Director of Research Integrity and the IO in order to open a formal report. The IO will formally review the information and may convene a meeting and/or otherwise obtain additional information as necessary. The Director of Research Integrity will subsequently inform the IRB of the findings. The IO has the authority to take corrective action in consultation with the IRB.

Upon resolution, the IRB will determine if the attempted, inappropriate influence represents an unanticipated problem involving risks to subjects or others and will determine if reporting to OHRP is appropriate.

**Training Requirements**

**Researchers and Research Staff**

The University requires training for all faculty, faculty mentors, researchers, and students, including researchers from other institutions who wish to conduct human subjects research at the University. All key personnel (PI, Co-PI, faculty sponsor), originally listed or later added to a study through an amendment, must complete the required human subjects training. In order to comply with the policy, researchers are required to complete the University’s training through the **Collaborative Institutional Training Initiative (CITI)**. CITI is comprised of modules
relating to ethics, regulations, risk assessment, informed consent, and privacy and confidentiality. Based on the type of research conducted, additional training modules may be required. Completion of this training must be accomplished every three years. Protocol submissions (initial, continuing, amendments) are checked to assure all researchers and research staff have completed training.

Student investigators and their faculty sponsor/advisor must both complete and maintain valid training per the IRB policy. Protocol actions are not approved until training is completed by all listed on the protocol.

**IRB Members and Chairs**
IRB members and their alternates and the IRB chair(s) must complete the required human subjects training upon being appointed to the IRB and every three years for the duration of their membership. Initial training consists of completion of the identical CITI modules required for IRB members. At the time of initial appointment, IRB staff will also provide IRB orientation information (meeting schedules, locations, etc.)

As a part of annual evaluation of members, the IRB staff provides the Chair with the training status for all members. Members in need of completing their training are reminded by the IRB Administrator of this requirement. Failure to complete the training may result in removal from the IRB. Continuing educational materials are distributed at IRB meetings in the form of relevant periodicals or articles. Webinars and local conferences are made available to the members to attend.

**Research Integrity Staff**
IRB staff must document that they have completed the CITI training. Attendance at regional and national meetings, (e.g., PRIM&R) is encouraged and supported for IRB staff. Research Integrity staff are encouraged to attend any additional training, such as webinars, that are offered.

**Roles and Responsibilities**
Chapman’s Human Subjects Protection Program Policy outlines the general responsibilities for researchers and staff involved in the Human Research Protection Program (HRPP). Below are additional considerations.

**Principal Investigators**
Chapman has a separate Principal Investigator (PI) Eligibility Policy. The following are the PI responsibilities and are not all inclusive:

1. Assure that all faculty and staff personnel listed on the research protocol have completed the human subjects research training and submitted an annual Financial Conflicts of Interest Disclosure.
2. Submit protocols for IRB review and approval of proposed
research activities prior to commencing research activities.
3. Employ sound study design in accordance with standards of the PI's discipline.
4. Assure that adequate time and resources are present before conducting a research study to assure participant protections.
5. Maintain appropriate oversight of each research study, as well as research staff, and appropriately delegate research responsibilities and functions.
6. Ensure that the research is conducted according to the protocol, any signed agreements, and in compliance with all applicable laws, regulations, and organizational policies and procedures with the highest of ethical standards.
7. Submit for review and approval all proposed protocol and consent form changes prior to implementing the changes in the protocol except where necessary to eliminate immediate hazards to human subjects.
8. Obtain legally effective informed consent from subjects prior to commencement of research activities, unless the requirement is waived by the IRB.
9. Ensure the rights, safety, and welfare of the research subjects are upheld; honor all commitments that were agreed to as part of the approved research (e.g., providing information about the study results to research subjects or honoring commitments for reimbursements to subjects).
10. Upon completion of a study, submit a Closure Report on Cayuse IRB.
11. Disclose all COIs.
12. Retain records as required by the regulations, the sponsoring entity, and local policy for the appropriate time period.
13. When a PI is the lead researcher for a multi-site study, applications must include information about the management of information that is relevant to the protection of research participants (e.g., interim results, protocol modifications, how unanticipated problems involving risks to participants or other unanticipated problems will be managed, how communication of unanticipated problems to all sites will occur, how protocol modifications will be managed, formal agreements delineating each site's roles and responsibilities).
14. If the PI holds an investigational new drug (IND)/investigational device exemption (IDE), adhere to sponsor responsibilities in addition to investigator responsibilities as per 21 CFR Parts 312/812.
15. If appropriate, assure that applicable clinical trials (including some National Institutes of Health [NIH] funded trials) are registered on the governmental database at http://www.ClinicalTrials.gov.
16. Address research participant's concerns, complaints, or requests for information.
17. Follow reporting requirements for problems that require prompt reporting.
18. Submit requested data at specified times for continuing review of ongoing research activities.

**Institutional Official (IO)**
The IO is designated by the President to have responsibility for the IRB with the authority to delegate activities as may be necessary to fulfill the following responsibilities:

1. Assures compliance with institutional policies and all applicable regulations for the protection of human research subjects.
2. Is legally authorized to represent the institution in matters regarding human subjects research and is the signatory authority for all the FWA to the OHRP.
3. Is responsible for review and evaluation of reports on HRPP performance and Quality Improvement activities.
4. Is responsible for further institutional review and approval or disapproval of research approved by the University IRB (neither the IO nor any other University official can approve research that was disapproved by the IRB).
5. Reviews copies of all IRB meeting minutes containing the results of Quality Improvement audits, and noncompliance findings and other issues as needed.
6. Signs all correspondence and reports sent to federal regulatory agencies regarding PI or institutional noncompliance.

**Institutional Review Board**
The IRB’s main responsibilities in safeguarding the rights and welfare of subjects are as follows and are not all inclusive:

1. Conduct review of initial protocol submissions, continuing reviews, and all revisions to protocols of human subjects research conducted by the University researchers.
2. Approve, require modifications to secure approval, defer (table), or disapprove research activities overseen and conducted under the auspices of the University, regardless of location of the research activities.
3. Systematically analyze protocols for benefits to subjects and importance of knowledge to be expected and assess the potential
benefits in relation to the potential risks involved in the research.
4. Report in writing the findings and actions of the IRB to the PIs, IO, and, when applicable, to federal regulatory agencies or departments.
5. Determine the interval at which ongoing studies need to be reviewed by the IRB.
6. Determine which studies need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.
7. Observe, or have a third party observe, consent processes and/or the conduct of research.
8. Ensure prompt reporting of any changes in research activities to the IRB by researchers.
9. Ensure prompt reporting, by PIs, to the IRB and/or federal agencies or departments (where applicable) of:
   a. Unanticipated problems involving risks to subjects or others.
   b. Serious or continuing noncompliance with regulations.
   c. Suspension or termination of IRB approval.
10. Determine if studies involving drugs need an investigational new drug (IND) number designated by the FDA.
11. Determine if studies involving investigational devices pose significant or non-significant risk and whether an IDE is required.
12. Suspend or terminate approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

IRB Chair(s)

IRB Chair(s) main responsibilities are as follows and are not all inclusive:
1. Serve as public spokesperson for the IRB.
2. Lead convened meetings of the IRB.
3. Ensure adequate expertise for review and determinations.
4. Review protocols, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB.
5. Obtain an individual vote on all IRB actions (For, Against, Abstain).
6. Vote on each IRB action.
7. Delegate review responsibilities as necessary and applicable.
8. Maintain up-to-date knowledge of human subjects regulations and pertinent events.
9. Consult with investigators as necessary.
10. Suspend the conduct of research when individuals are placed at an unacceptable level of risk.
11. Collaborate with the Director of Research Integrity and the IRB Administrator to provide continuing education for IRB members.
12. Collaborate with the Director of Research Integrity to resolve IRB-related
issues with researchers or subjects.
13. Recognize and support partnership with the office of Research Integrity to assure IRB efficiency and effectiveness.

**IRB Members**

IRB members responsibilities are as follows and are not all inclusive:

1. Be familiar with IRB policies and procedure, as well as federal, state, and local regulations, policies, or guidelines relating to human subjects research.
2. Review submitted proposals as assigned in a timely manner.
3. Review documents in advance of IRB meetings and be prepared for discussion of submitted protocols.
4. Act as a primary or secondary reviewer of protocols when assigned.
5. Maintain confidentiality of IRB proceedings.
6. Disclose conflicts of interest, if applicable.

**Monitoring/Verification of Compliance from Sources Other than the PI**

In accordance with 21 CFR 56.108(a)(2) (FDA) and 45 CFR 46.103(b)(4)(ii) (OHRP), it is incumbent upon the IRB to assure itself, by whatever method it deems appropriate, that the rights and welfare of human subjects are being protected. This applies to international research and research taking place in other states and in California. In doing so, the IRB may determine that it is appropriate to use sources other than reports from the investigator to verify that no material changes in the protocols have occurred since their most recent review, and that investigators are conducting the research in compliance with all regulations, laws (domestic and international), policies, and guidelines. Also, the IRB may determine that the consent process for some higher risk protocols should be observed.

To assess whether there have been no material changes in the protocols as stated above, the IRB may request that members of the IRB and/or IRB staff conduct an observational visit for a specific protocol. This review will help ensure that investigators are not implementing protocol changes prior to IRB review and approval, except when necessary to eliminate immediate hazards to subjects.

**Contacts for Questions, Concerns, Complaints or Input**

Faculty, research staff, students, and research subjects or any other person who has a question, concern, complaint, suggestion, or input regarding the HRPP or feels that they have been subjected to coercion or undue influence regarding aspects of human subjects research, or feels that they have observed issues of concern regarding human subjects research, may contact:

Office of Research Integrity
Phone: (714) 628-2805
E-mail: IRB@chapman.edu
Any and all concerns, complaints, input or suggestions regarding the HRPP and all allegations of coercion, undue influence or noncompliance are thoroughly investigated and, if applicable, corrective actions taken to rectify the situation. Ultimately, the Director of Research Integrity is responsible to assure that all concerns, complaints, and allegations have been addressed appropriately and that input and suggestions related to the HRPP are considered when reviewing the program.

**IRB Record Retention (See University’s Policy on Record Retention)**

In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of protocols, the IRB records include copies of:

1. Protocol applications, research protocols, consent documents and all other documents submitted for review of proposed human subject research
2. Scientific evaluations, when provided by an entity other than the IRB
3. Progress reports submitted by researchers
4. Reports of injuries to participants
5. Data and safety monitoring reports, if any
6. Modifications to previously approved research
7. Unanticipated problems involving risks to subjects or others
8. Documentation of noncompliance
9. Significant new findings

Records related to IRB operations (as well as research related records) are retained in accordance with institutional records retention policies as required by state and federal regulations. Acceptable storage for research records must be maintained as outlined in the study protocol describing data security (i.e., on a password-protected computer or in a secured, locked cabinet).