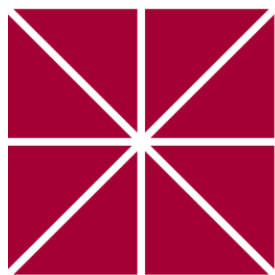


# General Procedures Manual

Office of Research: Human Research Protection Program

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UNIVERSITY

# Table of Contents

<b>Acronyms</b>	<b>3</b>
<b>Definitions</b>	<b>4</b>
<b>General Procedures Manual</b>	<b>7</b>
Chapman University's Human Research Protection Program	7
POLICY STATEMENT	7
REASON FOR THE POLICY	7
POLICY	7
Scope of Human Research Protection Program	10
<b>Activities Subject to the HRPP</b>	<b>11</b>
Activities That Do Not Require IRB Review	11
Determining Whether Research Involves Human Participants	12
Determining Whether the University Is Engaged in Human Participants Research	12
Determining When Research Involving Human Participants Begins and Ends	13
Authority to Make Regulated/Not-Regulated Determinations	13
<b>Human Research Protection Program Roles and Responsibilities</b>	<b>13</b>
Institutional Official/Organizational Official (IO/OO)	14
The Director for Research Integrity & Compliance	14
IRB Administrators	14
IRB Chair(s)	15
IRB Members	16
Researchers and Research Staff	16
Sponsored Projects Services	16
<b>IRBs</b>	<b>16</b>
Composition and Appointment of IRB Members and Chairs	17
Terms of Appointment, Evaluation, and Reappointment	18
IRB Functions and Operations	18
IRB Minutes	19
Conflicts of Interest of IRB Members, Consultants, and Staff	19
Liability Coverage	20
Confidentiality of the Review Process	20
IRB Record Retention (See University's Policy on Record Retention)	20
<b>Education and Training</b>	<b>21</b>
Researchers and Research Staff	21
<b>Questions or Additional Information in the Manual</b>	<b>21</b>
Reporting and Management of Concerns regarding the HRPP	21
Approval and Revisions to the manual	21

## Acronyms

AAHRPP	Association for the Accreditation for Human Research Protection Programs
AE	Adverse Event
DHHS	Department of Health and Human Services
COI	Conflict of Interest
DUA	Data Use Agreement
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HHS	Health and Human Services
HPA	Human Protections Administrator
HRPP	Human Research Protection Program
HUD	Humanitarian Use Device
IBC	Institutional Biosafety Committee
IDE	Investigational Device Exemption
IRB	Institutional Review Board
IO	Institutional Official
IRB	Institutional Review Board
LAR	Legally Authorized Representative
MP	Management Plan
NHSR	Non-Human Subjects Research
NSR	Non-Significant Risk
OHRP	Office for Human Research Protections
PI	Principal Investigator
SPS	Sponsored Projects Services
SR	Significant Risk
UAP	Unanticipated Problems Involving Risks to Subjects and Others

## Definitions

<b>ASSENT</b>	<ul style="list-style-type: none"> <li>• <b>Assent</b> means when a child affirmatively agrees, either orally or in writing, to participate in research. Acquiescence is not evidence of assent.</li> </ul>
<b>AUTHORIZED ORGANIZATIONAL OFFICIALS</b>	<ul style="list-style-type: none"> <li>• <b>Authorized organizational officials</b> are those individuals authorized by the institution to suspend IRB approved research. Those individuals include the Institutional Official or the IRB Chair.</li> </ul>
<b>CHILDREN</b>	<ul style="list-style-type: none"> <li>• <b>Children</b> are persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction where the research will be conducted (in California, individuals younger than 18 years old are considered children).</li> </ul>
<b>COERCION</b>	<ul style="list-style-type: none"> <li>• <b>Coercion</b> is when someone uses a credible threat of harm or force to control another person.</li> </ul>
<b>COGNITIVELY IMPAIRED</b>	<ul style="list-style-type: none"> <li>• <b>Cognitively impaired</b> means having a psychiatric disorder (e.g., psychosis, neurosis, personality, or behavior disorders), an organic impairment (e.g., stroke, dementia, delirium), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that an individual's capacity to make judgements through reasoning is significantly diminished.</li> </ul>
<b>CONTINUING NONCOMPLIANCE</b>	<ul style="list-style-type: none"> <li>• <b>Continuing noncompliance</b> is a pattern of repeated actions or omissions taken by research investigators or study personnel that indicates a lack of ability or willingness to comply with federal regulations, IRB policies and procedures, or the determinations of the IRB.</li> </ul>
<b>DECEPTION</b>	<ul style="list-style-type: none"> <li>• <b>Deception</b> occurs when researchers give false information to subjects or intentionally mislead them about some key aspect of the research.</li> <li>• Authorized deception occurs when individuals agree to be ignorant or misled about the true purpose of the study. Also see Incomplete Disclosure.</li> </ul>
<b>DECISIONAL IMPAIRMENT</b>	<ul style="list-style-type: none"> <li>• <b>Decisional impairment</b> means that individuals have a diminished capacity to understand information, reason through it, and then make decisions because of a disorder that affects either cognitive or emotional functions.</li> <li>• Other individuals may have decisional impairment because they suffer from a degenerative disease that affects their processing of information and decision-making capacity.</li> <li>• Readers should be advised that the terms decisional impairment and diminished decisional capacity are frequently used interchangeably.</li> </ul>
<b>DEVICE</b>	<ul style="list-style-type: none"> <li>• <b>Device</b> is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, software application (e.g., for a phone or tablet), or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.</li> </ul>
<b>ECONOMICALLY OR EDUCATIONALLY</b>	<ul style="list-style-type: none"> <li>• <b>Economically or educationally disadvantaged individuals</b> who, by virtue of their socioeconomic and/or educational background, are disadvantaged, and therefore have a</li> </ul>

<b>DISADVANTAGED INDIVIDUALS</b>	special risk. When these individuals participate in research, they may be more susceptible to coercion or undue influence.
<b>EXPEDITED REVIEW</b>	<ul style="list-style-type: none"> <li>An <b>expedited review</b> procedure consists of a review of research involving human participants by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in <a href="#">45 CFR 46.110</a>.</li> </ul>
<b>GUARDIAN</b>	<ul style="list-style-type: none"> <li><b>Guardian</b> means an individual who is authorized under applicable state or local law to consent on behalf of a child.</li> </ul>
<b>HUMAN SUBJECT / HUMAN PARTICIPANT</b>	<ul style="list-style-type: none"> <li><b>Human subject</b> means a living individual about whom an investigator (whether professional or student) conducting research (<a href="#">45 CFR 46.102(e)(1)</a>): <ul style="list-style-type: none"> <li>Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens (<a href="#">45 CFR 46.102(e)(1)(i)</a>); or</li> <li>Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (<a href="#">45 CFR 46.102(e)(1)(ii)</a>).</li> </ul> </li> <li>Readers should be advised that when the term <b>participant</b> is used in this policy document it refers to individuals who voluntarily participate as human subjects in research. This choice to use <b>participant</b> instead of “subjects” has been determined solely by stylistic preference and does not override how the federal regulations have defined human subject.</li> </ul>
<b>INCOMPETENCE</b>	<ul style="list-style-type: none"> <li><b>Incompetence</b> is a legal term meaning inability to manage one's own affairs. It is often used as a synonym for incapacity.</li> </ul>
<b>INCOMPLETE DISCLOSURE</b>	<ul style="list-style-type: none"> <li><b>Incomplete disclosure</b> occurs when researchers withhold information about the specific purpose, nature, or other aspects of the research. Withholding information may or may not be considered deception. Also see Deception.</li> </ul>
<b>INVESTIGATIONAL DEVICE EXEMPTION</b>	<ul style="list-style-type: none"> <li><b>Investigational device exemption (IDE)</b> is an allowance from the Food and Drug Administration (FDA) for the use of an investigational device in a clinical study in order to collect safety and effectiveness data</li> </ul>
<b>INSTITUTIONAL REVIEW BOARD</b>	<ul style="list-style-type: none"> <li><b>IRB</b> means an institutional review board established in accordance with and for the purposes outlined in the federal regulations at 45 CFR 46 and 21 CFR 56.</li> </ul>
<b>INSTITUTIONAL REVIEW BOARD CHAIR(S)</b>	<ul style="list-style-type: none"> <li><b>Individuals 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.</b></li> </ul>
<b>LEGALLY AUTHORIZED REPRESENTATIVE (LAR)</b>	<ul style="list-style-type: none"> <li><b>Legally authorized representative (LAR)</b>, in relation to research involving human participants, means “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research” (<a href="#">45 CFR 46.102(i)</a>, <a href="#">21 CFR 50.3(1)</a>).</li> </ul>
<b>MINIMAL RISK</b>	<ul style="list-style-type: none"> <li><b>Minimal risk</b> 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 (<a href="#">45 CFR 46.102(j)</a>).</li> </ul>

<b>MONITORING</b>	<ul style="list-style-type: none"> <li>• <b>Monitoring</b> is an ongoing process usually directed by management to ensure processes are working as intended.</li> </ul>
<b>NONCOMPLIANCE</b>	<ul style="list-style-type: none"> <li>• <b>Noncompliance</b> is a failure to comply with applicable federal regulations, IRB policies and procedures, Chapman University policies or procedures, or the determination of the IRB.</li> </ul>
<b>NONSIGNIFICANT RISK DEVICE</b>	<ul style="list-style-type: none"> <li>• <b>Nonsignificant risk device</b> does not meet the definition of a significant risk device. It only requires IRB approval prior to initiation of a clinical study.</li> </ul>
<b>OFFICE OF RESEARCH (OOR)</b>	<ul style="list-style-type: none"> <li>• <b>Includes the Director of Research Integrity and the IRB Administrator and is responsible for the oversight of the HRPP. The Office of Research is lead by the Vice Provost for Research/Institutional Official.</b></li> </ul>
<b>PARENT</b>	<ul style="list-style-type: none"> <li>• <b>Parent</b> means a child's biological or adoptive parent.</li> </ul>
<b>PARENTAL PERMISSION</b>	<ul style="list-style-type: none"> <li>• <b>Parental permission</b> means that parent(s) or guardian(s) have agreed to allow their child or ward to participate in research.</li> </ul>
<b>RESEARCH</b>	<ul style="list-style-type: none"> <li>• <b>Research</b> means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (<a href="#">45 CFR 46.102(l)</a>).</li> <li>• <b>Research (clinical investigation per FDA)</b> means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms <i>research</i>, <i>clinical research</i>, <i>clinical study</i>, <i>study</i>, and <i>clinical investigation</i> are deemed to be synonymous (<a href="#">21 CFR 56.102(c)</a>).</li> <li>• <b>Research (clinical trial per NIH)</b> is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.</li> </ul>
<b>SERIOUS NONCOMPLIANCE</b>	<ul style="list-style-type: none"> <li>• <b>Serious noncompliance</b> is an action or omission taken by research investigators or study personnel that any other reasonable investigator would have foreseen as compromising the rights, safety, and/or welfare of the participant; the integrity of the data and study outcomes; or the regulatory standing of the research.</li> </ul>

<p><b>SIGNIFICANT RISK DEVICE</b></p>	<ul style="list-style-type: none"> <li>• <b>Significant risk device</b> means an investigational device that: <ul style="list-style-type: none"> <li>○ Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant;</li> <li>○ Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant;</li> <li>○ Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant; or</li> <li>○ Otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.</li> </ul> </li> </ul>
<p><b>SUSPENSION</b></p>	<ul style="list-style-type: none"> <li>• <b>Suspension</b> is an action where all or some of the research activities must stop until issues have been satisfactorily resolved. Suspended projects still have IRB approval. Note that suspensions issued by the IRB are reportable to federal agencies.</li> </ul>
<p><b>TERMINATION</b></p>	<ul style="list-style-type: none"> <li>• <b>Termination</b> is an action issued by the convened IRB that all or some of the research must stop permanently except for the continuation of follow-up activities necessary to protect the participants' safety.</li> </ul>
<p><b>UNANTICIPATED PROBLEM</b></p>	<ul style="list-style-type: none"> <li>• An <b>unanticipated problem</b> is any event or information that was unforeseen (in terms of nature, severity, or frequency) and indicates that the research procedures caused harm (including physical, psychological, economic, or social harm) to participants or others, or indicates that participants or others are at increased risk of harm than was previously known or recognized.</li> </ul>
<p><b>UNDUE INFLUENCE</b></p>	<ul style="list-style-type: none"> <li>• <b>Undue influence</b> is when someone misuses a position of power, of confidence, or of trust to exercise influence over others so they make decisions they would not otherwise make.</li> </ul>
<p><b>VULNERABLE POPULATIONS</b></p>	<ul style="list-style-type: none"> <li>• <b>Vulnerable populations</b> are certain groups of participants who enroll in research that may be more vulnerable to undue influence or coercion. These participants may require additional protections and safeguards when they participate in research. Examples of vulnerable populations include children, prisoners, individuals with impaired decision-making capacity, or participants in circumstances that would make them vulnerable (e.g., students, employees, or economically or educationally disadvantaged persons).</li> </ul>
<p><b>WARDS</b></p>	<ul style="list-style-type: none"> <li>• <b>Wards</b> are children in the care or custody of the state, courts, or any other agency, institution, or entity.</li> </ul>

# General Procedures Manual

## Chapman University's Human Research Protection Program

### POLICY STATEMENT

Chapman University fosters a research environment that promotes respect for the rights, safety, and welfare of individuals recruited for or participating in research conducted by members of the University.

### REASON FOR THE POLICY

This policy exists to responsibly govern human subjects research at Chapman University.

### POLICY

All employees and students of the University who are conducting human subject research are required to comply with Chapman requirements, procedures, and protocols of the Human Research Protection Program (HRPP). The HRPP includes mechanisms to establish, monitor, evaluate and continually improve the protection of human research participants, educate investigators and research staff about their ethical responsibility to protect research participants, and, when appropriate, intervene in research and respond to concerns of research participants.

The University's HRPP is established under and in accordance with the laws, regulations, and principles listed below regarding the protection of human subjects. The University and its employees and students will adhere to these laws, regulations, and principles concerning human subject research:

The Department of Health and Human Services (HHS) policy and regulations at 45 CFR part 46, also known as the [Federal Policy for the Protection of Human Subjects](#) or the "*Common Rule*";

Food and Drug Administration (FDA) regulations related to clinical trials and human subject protections at [21 CFR Parts 51 and 56](#) (collectively referred to in this document as the "*FDA Regulations*");

The principles (i.e., respect for persons, beneficence, and justice) set forth in the [Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#) (collectively referred to in this document as the "*Belmont Report*");

Other federal regulations implementing the Common Rule that apply when carrying out studies sponsored by those agencies; and

All state and local laws and regulations governing human subject research, including California's requirements for the protection of human subjects as provided in the Protection of Human Subjects in Medical Experimentation Act, [CA Health and Safety Code, Section 24170- 24179.5](#).

Federal and state regulations governing the administration of controlled substances or regulated devices.

### The Institutional Official

The President of Chapman University has the power and authority to designate an individual within the University to serve as the Institutional Official (IO), who is legally authorized to act for the University, obligates Chapman to the terms of the Federal Wide Assurance, and is responsible for carrying out the HRPP. The person designated as the IO must meet qualifications including being an employee of the University, being authorized to act and speak for the University as a whole, and ensuring that the Institutional Review Board (IRB) will effectively fulfill its research oversight function. The



President has designated the Vice President for Research as the IO, and the Chapman IRB as the body within the University that has jurisdiction over all human subject research conducted at or in connection with the University.

The HRPP operates under the guidance and direction of the IO and the IRB and is administered through and by the Office of Research.

### **IRB Authority**

The IRB is 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 and students of the University, regardless of the funding source for the study. No researcher may conduct human subject research without the approval of the Chapman IRB or an outside IRB that Chapman agrees to rely upon.

The IRB has authority to grant approval for studies involving human subjects, to require modifications to secure approval, to disapprove research, to suspend or terminate approval pursuant to these policies, to observe or have a third party observe consent processes or the conduct of research, or to grant an exemption pursuant to this policy. Studies involving human subjects that have been approved by an IRB may be subject to further review by the University (e.g., when data safety plans are needed, controlled substances or regulated devices are used, or where there is a potential conflict of interest). The President or the IO may disapprove a protocol that the IRB has approved; however, neither may approve the research if it has not been approved by an IRB.

### **Setting IRB Policy**

The IRB Chair and IRB committee share authority over IRB policy in collaboration with the IO. Any member of the IRB may at any time suggest revisions to the IRB policy through the IRB Chair. It is also expected that the IRB policies will be amended when changes in federal regulations occur. The IRB Chair may revise IRB policy in consultation with the IO as needed.

This HRPP policy may only be revised upon recommendation by the IO and with the approval of the President, in accordance with Chapman's Policy Development and Publication Policy.

### **Evaluation of Risk by the IRB**

The IRB is responsible for evaluating the potential risks of a study and weighing the probability of the risk occurring and the magnitude of harm that may result. The IRB will not approve research where the risks are judged unreasonable in relation to the anticipated benefits.

The IRB is also responsible for evaluating Chapman's ability to protect the human subject's safety, rights, and welfare for studies that involve elevated or significant risk. At this time, because Chapman does not have the appropriate medical or hospital facilities, in vivo human testing of drugs and biologics cannot be conducted at the Orange or Rinker campuses. Similarly, studies using FDA-regulated devices deemed by the FDA or the Chapman IRB to be of significant risk will not be undertaken at Chapman. Such studies may only be conducted off-site with a collaborator at a medical institution with adequate facilities, significant clinical trial experience, and appropriate medical expertise, or by contracting the services of a professional clinical research organization. Chapman must enter into a formal agreement with the IRB of the clinical research organization or collaborating medical institution, agreeing to rely on the external organization's or institution's IRB review of the protocol. This policy will be reviewed from time to time and revised accordingly based on Chapman's ability to support these studies on campus.

## Oversight by the IRB

Human subject research that is subject to the authority of the Chapman IRB includes:

- Human subjects research conducted by or under the direction of any employee or agent for Chapman in connection with their institutional responsibilities;
- Human subject research conducted by Chapman students;
- Human subject research conducted by or under the direction of any employee or agent of Chapman using any property or facility of the University or using any University's name or resources to contact or identify human subjects; and
- Human subject research conducted at the Orange or Rinker campuses by a non-Chapman employee or agent.

Institutions and individuals who are not employees or students of Chapman may not rely upon the Chapman IRB unless there is a written agreement including compliance with the Chapman IRB policies and procedures, signed by an authorized official of Chapman.

## Scope of Human Research Protection Program

- 1) The Chapman HRPP oversees all research involving human participants being conducted by Chapman, faculty employees, students, and other agents of the institution, as well as research being conducted by non-Chapman employees or agents for which the Chapman IRB has been asked to be the IRB of record. However, the Chapman IRB does not review or approve the following:
  - a) Research involving fetuses
  - b) Research involving non-viable neonates
  - c) Research involving neonates of uncertain viability
  - d) Research involving in vitro fertilization
  - e) Research involving drugs that are regulated by the FDA
  - f) Research involving significant risk devices that require an Investigational Device Exemption (IDE) in accordance with FDA regulations
  - g) Activities involving humanitarian use devices (HUD)
  - h) Research that plans to or is likely to involve prisoners as participants
  - i) Emergency use of a test article in a life-threatening situation
  - j) Classified research (e.g., secret research to which access is restricted by law to a particular hierarchical class of people or that with which a security clearance is required)

## Activities Subject to the HRPP

### Activities That Do Not Require IRB Review

- 1) The following activities are not considered research as defined by HHS, and therefore do not fall under the Chapman HRPP and thus do not require IRB review and approval:
  - a) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
  - b) Public health surveillance activities conducted by a public health authority, 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.
    - i) Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority
    - ii) Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products
    - iii) Including 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)
  - c) 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.
  - d) Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

### Determining Whether Research Involves Human Participants

- 1) The fact that an activity is research does not mean that it is research that involves human participants under the Common Rule.
- 2) The Common Rule defines a *human subject* as a living individual about whom an investigator (whether professional or student) conducting research:
  - a) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens (e.g., an investigator obtains information from a participant via a survey and then analyzes survey responses); or
  - b) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (e.g., an investigator analyzes previously collected individually identifiable information in order to answer a research question).
- 3) Private information must be individually identifiable (e.g., the identity of the participant is or may readily be ascertained by the investigator or associated with the information being collected) in order for obtaining or using the information to constitute research involving human participants.

- 4) Research using specimens derived from living individuals may be considered human participants research under the Common Rule. Guidance on whether a project involving human specimens may be considered regulated research is available on the following federal websites:
  - a) [Office for Human Research Protections Decision Charts](#)
  - b) [NIH Office for Extramural Research Human Participants Research Homepage](#)
  - c) 2006 FDA guidance, [Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable](#)

## **Determining Whether the University Is Engaged in Human Participants Research**

- 1) Chapman is considered engaged in research involving human participants when Chapman's faculty, employees, students, or agents (individuals who act on behalf of the institution) exercise institutional authority, or perform one or more of the following institutionally designed activities:
  - a) Apply for or receive a direct federal award to support research that includes human participants, even if all the activities involving human participants 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 participants under the award.
  - b) Obtain data about the participants of the research through intervention or interaction with them.
  - c) Obtain identifiable private information about or identifiable biospecimens from the participants of the research.
  - d) Obtain the informed consent of human participants for the research. This institution follows OHRP guidance on [Engagement of Institutions in Human Subjects Research](#) when determining whether Chapman is engaged in human participants research.
- 2) Under FDA regulations, Chapman becomes engaged in human participants research when a Chapman faculty, employee, or student undertakes a clinical investigation on individuals who are or become participants in the investigation, either as recipients of a test article or as controls.

## **Determining When Research Involving Human Participants Begins and Ends**

- 1) Research begins when a researcher first "obtains data through intervention or interaction," or otherwise obtains "private information," as described above.
  - a) Screening activities and pilot testing are part of the research process and must be reviewed and approved (or an exemption issued) before those activities can begin.
- 2) Research ends when the study has been closed by the PI or terminated by the IRB. Research remains subject to Chapman IRB oversight until such time as the research has ended or been closed by the PI.
- 3) Chapman investigators are encouraged to de-identify research data (i.e., remove all personal identifiers including name, email address, phone number, etc.) at the earliest opportunity. Once all personal identifiers and links to identifiers are destroyed, the research is no longer regulated under federal regulations or the University's HRPP.
- 4) Secondary analysis of data collected as part of a previous study that retains identifiers must be submitted to the IRB for approval or exemption. The submission must include information regarding the primary data collection, including the original informed consent document. The language of the original consent is a factor in the IRB's determination of whether secondary data analysis may be conducted and should therefore be included in the initial submission to the IRB.

## Authority to Make Regulated/Not-Regulated Determinations

- 1) The IO has delegated the authority to make human research/not human research determinations to the IRB.
- 2) Expedited, and full board review studies must be reviewed by the IRB. Only the IRB or those individuals designated by the IRB Chairs are authorized to determine whether a study meets exemption criteria. Researchers can make non human subjects determination themselves on their own if they feel to be qualified to do so.
- 3) If a PI is unsure whether their project meets the criteria for Human Subject Research, or in instances when a formal determination is required (e.g., for funding agencies or publication purposes), principal investigators should submit “Non-Research Determination Form” to the IRB. This submission will prompt an IRB review to confirm the status of the project that may then be used for funding or publication purposes.
- 4) The IRB will not provide retroactive review and approval for projects deemed human subject research. However, if needed, the IRB can provide documentation of non-human subject determination after the project has been initiated.

## Human Research Protection Program Roles and Responsibilities

### Institutional Official/Organizational Official (IO/OO)

- 1) As per the [HRPP Policy](#), the IO is designated by the President to have responsibility for the HRPP with the authority to delegate activities as may be necessary to fulfill the following responsibilities:
  - a) The IO assures compliance with institutional policies and all applicable regulations for the protection of human participants involved in research. To that end, the IO formally grants the IRB the following authority relative to the protection of human subjects:
    - i) To approve, require modifications to secure approval, or disapprove all research activities subject to Chapman HRPP oversight based on its consideration of the risks and potential benefits of the research, and whether the rights and welfare of the participants are adequately protected
    - ii) To require reports for renewal of research
    - iii) To continuously monitor the conduct of research with human participants
    - iv) 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 participants
    - v) To place restrictions on research, if necessary, to protect human research participants
    - vi) To observe, or have a third party observe, the consent process
    - vii) To observe, or have a third party observe, the conduct of the research
  - b) The IO is legally authorized to represent the institution in matters regarding human participants research and is the signatory authority for the FWA to OHRP.
  - c) The IO is responsible for review and evaluation of reports on HRPP performance.
  - d) The IO is responsible for further review, approval, or disapproval of research approved by the IRB (neither the IO nor any other University official can approve research that was disapproved by the IRB).

- e) The IO is provided with copies of all IRB meeting minutes, noncompliance findings, and other issues as needed.
  - f) The IO signs all correspondence and reports sent to federal regulatory agencies regarding investigator or institutional noncompliance.
- 2) Delegation of any of these activities will be in the form of a memorandum and will remain on file with the HRPP.

## **The Director for Research Integrity & Compliance**

- 1) The Director for Research Integrity & Compliance is responsible for the continued development, refinement, administration, and execution of a comprehensive HRPP. This individual is responsible for the following activities:
- a) Recommending short- and long-term plans and goals for the HRPP
  - b) Developing and implementing policies and procedures
  - c) Reviewing the HRPP manual and all HRPP policies on an annual basis
  - d) Developing education and training initiatives for the researchers, IRB members, and IRB administrators  
Ensuring the HRPP is operating in accordance with federal and state laws, as well as Chapman University policies and procedures
  - e) Serving as a liaison between the IRB and the University
  - f) Coordinating with and relying upon IRB administrators to ensure IRB Authorization Agreements are executed for cooperative research
  - g) Ensuring the FWA is appropriately renewed and accurate
  - h) Reviewing allegations of noncompliance and assisting IRB Chairs with the investigation, as applicable
  - i) Drafting all correspondence to federal agencies and submitting such correspondence once signed by the IO

## **IRB Administrators**

- 1) IRB Administrators are responsible for the following activities as they relate to the HRPP:
- a) Preparing and maintaining adequate documentation of IRB activities
  - b) Ensuring IRB members (including consultants) are provided with and review submissions (e.g., initial, renewal) to determine whether the proposed research fulfills the criteria for approval
  - c) Pre-reviewing all submissions for completeness and evaluating the expertise needed for member review
  - d) Reviewing administrative modifications according to IRB policy (as assigned)
  - e) Reviewing and approving exempt IRB studies (as assigned)
  - f) Ensuring quorum is maintained during IRB meetings
  - g) Taking minutes during convened board meetings and distributing draft versions to IRB Chairs and others as deemed appropriate

- h) Ensuring meeting minutes are compliant with OHRP/FDA guidance including: attendance of members and others present during meetings; actions taken by the IRB; the vote on agenda items including the number of members voting for, against, abstaining or recusing; the basis for the IRB requiring changes to secure approval of research or disapproving research; any controverted issues and their resolution
- i) Corresponding with researchers, articulating required modifications to study documentation, including informed consent forms, and requesting additional information needed before resubmitting for further review
- j) Participating in training and educational activities on human research protections that are presented to researchers and administrators
- k) Primary point of contact to update and maintain business rules and other non-technical aspects of Cayuse Human Ethics electronic submission system used by the IRB and researchers, including updating applications and templates and notifying the IRB and the community of Cayuse system changes
- l) Providing guidance to researchers and administrators on the use of the Cayuse to manage applications for review
- m) Maintaining the IRB website that describes the impacts of regulations, policies, and ethical norms that are applicable to human research activities
- n) Generating reports and facilitating assessment of the review process and workflow.

### **IRB Chair and Vice Chair (together referred to as the “Chair” or “Chairs”)**

- 1) The IRB Chair’s main responsibilities include but are not limited to:
  - a) Develop and maintain expertise and all human-participant-related federal, state, and local regulations, policies, or guidelines.
  - b) Along with the Director of Research Integrity and Compliance, ensuring that Chapman’s HRPP program is implemented in human research studies reviewed by the IRB.
  - c) Leading convened meetings of the IRB
  - d) Ensuring adequate expertise for review of new submissions
  - e) Ensuring IRB review criteria are met, and determinations made by IRB members are appropriate
  - f) Reviewing initial submissions, renewals, modifications, unanticipated problem and incident reports, and other documentation submitted to the IRB
  - g) Obtaining an individual vote on all IRB actions (e.g., for, against, abstain, recused)
  - h) Voting on each IRB action
  - i) Delegating review responsibilities in writing as necessary and applicable
  - j) Maintaining up-to-date knowledge of human participants regulations and pertinent events
  - k) Consulting with investigators as necessary
  - l) Suspending the conduct of research
  - m) Collaborating with the Director of Research Integrity and the IRB administrator to provide continuing education for IRB members

- n) Collaborating with the Director of Research Integrity to resolve IRB-related issues with researchers or participants
- o) Recognizing and supporting partnership with the Office of Research Integrity to assure IRB efficiency and effectiveness

## IRB Members

- 1) IRB members' responsibilities include but are not limited to:
  - a) Attending and participating in IRB meetings
  - b) Completing in required training for IRB members, and on-going training during meetings and through other channels
  - c) Voting on each IRB action
  - d) Working with PIs to bring their studies into compliance with Chapman policies and procedures
  - e) Presenting their study reviews at IRB meetings
  - f) Complying with IRB policies and procedures, as well as federal, state, and local regulations, policies, or guidelines relating to research involving human participants
  - g) Reviewing submitted proposals as assigned in a timely manner
  - h) Reviewing submissions and other documents in advance of IRB meetings and being prepared for discussion of submitted agenda items
  - i) Acting as a primary or secondary reviewer of submissions when assigned
  - j) Maintaining confidentiality of IRB proceedings
  - k) Disclosing conflicts of interest, if applicable
  - l) Utilizing checklists when completing reviews of research submitted to the IRB.

## Researchers and Research Staff

- 1) Chapman IRB has a [list of responsibilities for principal investigators \(PIs\)](#) available on our website. Unless the PI has appropriately delegated the following activities to a research team member. Although PIs may delegate tasks to members of their research team, PIs retain the ultimate responsibility for the conduct of the study. (Chapman has a separate [PI Eligibility Policy](#).)

## Sponsored Projects Services

- 1) Chapman's Sponsored Projects Services (SPS) serves as Chapman University's central office for research administration. SPS works closely with the Chapman IRB regarding research proposals involving human participants to ensure compliance with all applicable regulations and institutional policies.

## IRBs

### Composition and Appointment of IRB Members and Chairs

- 1) The IRB is composed of primary members and alternate members who vote on matters when their designated primary member is not in attendance at a meeting or assigned to a study. The IRB must include at least 5 members to follow OHRP regulations (45CFR§46.107), and must include one scientist, one nonscientist, and a member nonaffiliated with Chapman. Scientists must represent a number of disciplines, similar to the types of studies reviewed by the IRB. The exact number of members of the IRB is determined by the IO in consultation with the Chairs.



- 2) A quorum is made up of a simple majority of the IRB members, including at least one nonscientist. Nonaffiliated members are strongly encouraged to attend every meeting.
- 3) 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 research activities commonly reviewed by the IRB.
- 4) Scientific members of the IRB as defined by OHRP as those whose training, background, and occupation would incline them to view research activities from the standpoint of someone within a behavioral or biomedical research discipline. These individuals generally have experience in research involving human participants and will be recruited from among active biomedical or behavioral researchers of the University.
- 5) Nonscientific members of the IRB as defined by OHRP as those whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline. These individuals are typically recruited from the faculty and staff at large. The appointment of nonaffiliated (community) members will be done by the IO but the IRB Chair(s), Director of Research Integrity, and IRB administrator and are responsible for determining whether the nominee(s) is truly unaffiliated and/or have appropriate expertise.
- 6) Alternate IRB members are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to that of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the primary member is unable to attend part or all of 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.
- 7) At times, the IRB may not have the necessary expertise to review a research study (e.g., the IRB is unfamiliar with the population to be studied, or it has a lack of understanding regarding a novel procedure). For these research studies, the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may call upon ad-hoc consultants for assistance in with the review. The ad-hoc consultants are not considered members of the IRB; they are utilized only for expert review, have no voting rights, and must disclose whether they have any personal, professional, or financial conflicts of interest with the research study being reviewed. The consultants will submit a written report of their findings 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.
- 8) 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. 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.
- 9) The Director of Research Integrity or designee will report changes in IRB membership to OHRP, as [required](#).
- 10) The IRB has Chairs chosen from IRB members who will typically be members of the faculty of the University and knowledgeable in human participants research, including 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.

## Terms of Appointment, Evaluation, and Reappointment

- 1) IRB members, including Chairs, are appointed to 3-year renewable terms. The IRB Chair(s) are expected to hold the position for several renewable terms.
- 2) IRB members' performance will be evaluated by the IRB Chair.
- 3) The IRB Chairs' performance will be evaluated every 2 years by the IO.
- 4) The composition of the IRB will be periodically evaluated and, if necessary, adjusted to meet regulatory and organizational requirements.

## IRB Functions and Operations

- 1) The [IRB's main responsibilities](#) in safeguarding the rights and welfare of participants involve, but is not limited to, the following roles:
  - a) Conducting review of initial protocol submissions, renewals, and modifications to research involving human participants conducted by Chapman University faculty, staff, students, or agents or overseen by the Chapman IRB, regardless of who is conducting the research.
  - b) Approving, requiring modifications to secure approval, deferring, or disapproving research activities overseen and conducted under the auspices of the University, regardless of location of the research activities.
  - c) Systematically analyzing submissions for benefits to participants and importance of knowledge to be expected and assessing the potential benefits in relation to the potential risks involved in the research.
  - d) Reporting in writing the findings and actions of the IRB to the PIs, IO, and, when applicable, to federal regulatory agencies or departments.
  - e) Determining the interval at which ongoing studies need to be reviewed by the IRB, if any.
  - f) Determining which studies need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.
  - g) Observing, or having a third party observe, consent processes and/or the conduct of research.
  - h) Establishing procedures for ensuring prompt reporting of any changes in research activities to the IRB by researchers.
  - i) Establishing procedures to ensure prompt reporting, by PIs, to the IRB and/or federal agencies or departments (where applicable) of:
    - i) Unanticipated problems involving risks to participants or others
    - ii) Serious or continuing noncompliance with regulations
    - iii) Suspension or termination of IRB approval
  - j) Determining if studies involving investigational devices are exempt, pose significant or non-significant risk, and whether an IDE is required. If an IDE is required, the research cannot be conducted at Chapman.
  - k) Suspending or terminating approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

## IRB Minutes

- 1) The IRB typically meets monthly in person or on-line to review studies, provide training, and to attend to other IRB business as needed.
- 2) IRB meetings are documented in minutes in accordance with [Guidance by OHRP & FDA](#)
- 3) IRB minutes are prepared by the IRB Administrator and are approved by the IRB Chair or the convened IRB and at their next meeting.
- 4) IRB minutes are maintained in accordance with University record retention policies as outlined below.

## Conflicts of Interest of IRB Members, Consultants, and Staff

- 1) Real or perceived conflicts of interest (COI) on the part of any individual conducting research with human participants or responsible for the protection of human participants in research can seriously undermine the credibility of the process and must be avoided.
- 2) The IRB strives to avoid COI when performing its obligations. A COI may take many forms but arises when an IRB member, staff member, or consultant, in relationship to an outside organization, is in a position to influence the University's business, research, or other decisions in ways that could lead directly or indirectly to financial gain for the IRB member, IRB staff, or consultant (or their families) or give improper advantage to others, to the detriment of the University.
- 3) IRB members, consultants, or IRB staff will not be assigned to review a research study if they (and/or their spouse, domestic partner, or dependents):
  - a) Are the principal investigator or another member of the study team.
  - b) Have a significant financial interest in the research (as defined by [Chapman policy](#)).
  - c) Have other personal or professional conflicts that might hamper their ability to perform an impartial review (e.g., are related to the investigator).
- 4) No IRB member, including the Chair(s), shall be assigned to review a research study if the member or a member of his or her immediate family has a COI.
- 5) No member, including the Chair(s), shall participate in the investigation of actual or alleged noncompliance or other misconduct (other than to cooperate with the investigation) if the member has a conflict as described above.
- 6) Prior to each convened IRB meeting, the IRB Chair will determine if any COI exists on any research that is to be reviewed, and if identified, the IRB administrator will note the conflict on the agenda.
- 7) No IRB member, including the Chair(s), may be present for, participate in the deliberations of, or vote on any research for which the member has a conflict as described above. The member may, however, be invited by the IRB to provide information relevant to the board's consideration of the submission.
- 8) The IRB Chair (or acting chair in the situation where the IRB Chair is conflicted) and administrator will ensure that all identified, conflicted IRB members are:
  - a) Excused from discussion except to provide information requested by the IRB.
  - b) Absent from voting.
  - c) Not counted toward quorum.
  - d) Documented appropriately in the meeting minutes.

- 9) To facilitate the identification of any previously unreported conflicts, the IRB Chair shall, at the beginning of each meeting, inquire as to whether any members should excuse themselves from discussion and voting as outlined above.
- 10) Prior to assigning expedited reviews, the IRB administrators will assess submissions, to the best of their ability, for any conflicts with expedited reviewers. IRB administrators will not assign research to be reviewed by a conflicted expediting reviewer.
- 11) If a previously unreported conflict is identified in the course of reviewing a research study, a new reviewer will be assigned to review the research.
- 12) IRB administrators who have an actual or potential COI with any aspect of the research should notify the IRB Chair or Director of Research Integrity to discuss the potential or actual conflict. If a conflict is validated, the staff member will be excused from any IRB duties directly related to the processing, review, or outcome determination of the research, as applicable.

## Liability Coverage

- 1) Chapman University employees and non-Chapman volunteer IRB members are performing official functions on behalf of Chapman University and as such Chapman's general and professional liability policies cover their activities on behalf of the IRB. External consultants and contracted IRB members should look to the terms of their particular signed agreements with Chapman University to determine any relevant insurance coverage responsibilities. For additional information, please contact Legal Affairs at Chapman.

## Confidentiality of the Review Process

- 1) During the process of initial, continuing review, or modification 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.

## IRB Record Retention (See [University's Policy on Record Retention](#))

- 1) To reconstruct a complete history of IRB actions related to the review and approval of protocols, the IRB records include the following:
  - a) Research submission, consent documents, and all other documents submitted for review of proposed human subject research
  - b) Renewal submissions
  - c) Data and safety monitoring reports, if any
  - d) Modifications to previously approved research
  - e) Unanticipated problems involving risks to participants or others
  - f) Documentation of noncompliance or other incidents
- 2) Records related to IRB operations (as well as research related records, including signed consent forms) 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 (e.g., on a password-protected computer or in a secured, locked cabinet). Records may be stored electronically or in paper form. Researchers are encouraged to destroy any identifying participant information as soon as is practicable.

- 3) Additional time periods may be required under state and federal requirements:
  - a) If children are involved, research records will be retained for seven years after all children enrolled in the study reach the age of majority (i.e., the age at which an individual is legally considered an adult based on state definitions)
  - b) If in-vitro fertilization of pregnant women is involved, research records will be retained for 25 years after the closure of the study.
  - c) If regulated by the Food and Drug Administration (FDA), research records will be retained for two years after an approved marketing application; if approval is not received, the research records will be kept for two years after the investigation is discontinued and the FDA is notified.
  - d) If the study is regulated by DHHS-OHRP, study records must be retained for three years after the close of the study unless the project sponsor requires records to be retained for a longer period.

## **Education and Training**

### **Researchers and Research Staff**

- 1) The University requires training for all faculty, faculty mentors, researchers, and students.
- 2) All Chapman investigators who are engaged in the research must complete the required human participants training. To comply with the policy, investigators are required to complete the University's training for biomedical or social and behavioral researchers through the Collaborative Institutional Training Initiative (CITI).
- 3) Based on the type of research conducted, additional training modules may be required (e.g., Good Clinical Practice in the case of clinical trials).
- 4) Training must be completed every three years. All IRB submissions (initial, renewal, modifications) are checked to ensure all Chapman investigators have completed training.

## **Questions or Additional Information in the Manual**

### **Reporting and Management of Concerns regarding the HRPP**

- 1) Faculty, research staff, students, and research participants, or any other person who has a question, concern, complaint, suggestion, or input regarding the HRPP, who feel that they have been subjected to coercion or undue influence, or who feel that they have observed issues of concern regarding research involving human participants, may contact the Office of Research (phone: (714) 628-2805; e-mail: [IRB@chapman.edu](mailto:IRB@chapman.edu); website: <https://www.chapman.edu/research/integrity/index.aspx>).
- 2) 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 for ensuring that all concerns, complaints, and allegations have been addressed appropriately.

### **Approval and Revisions to the manual**

- 1) This HRPP Manual is to be approved by the IO. This plan is intended to be flexible and adaptable to changes in the regulatory environment.

## Revision history:

09May2023:

- Deleted ambiguous statement in the section on appointing nonvoting members to the IRB
- Clarification as to who are authorized to review exempt studies

12Dec2022: Original publication date