CHAPMAN UNIVERSITY

Human Research Protection Program

Sets forth the structure of the Human Research Protection Program at Chapman University and describes the authority and responsibilities of individual researchers, the IO and the IRB in implementing the 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 was 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.

OFFICE RESPONSIBLE FOR POLICY

Name of Office: Office of Research
Contact information for questions about this policy: (714) 628-2805

WEBSITE FOR THIS POLICY

https://www.chapman.edu/research/policies-and-guidance/

WHO APPROVED THIS POLICY

Senior Staff Member submitting the policy: Acting Vice President for Research, Janeen Hill
Date approved by President: Approved by President Daniele Struppa on January 24, 2022

PUBLICATION DATE

Effective: 1/24/2022

RELATED MATERIALS

See the Office of Research, Human Research Protection Program website for more information on carrying out human subject research at Chapman. Chapman's Policy Development and Publication Policy.