HUMAN SUBJECTS PROTECTION PROGRAM POLICY

POLICY STATEMENT

Chapman University maintains a Human Research Protection Program (HRPP) based upon the principles outlined in the Belmont Report, the Declaration of Helsinki (as amended in 1989), and the Nuremburg Code. The program is implemented in accordance with the federal regulations, FDA regulations, and California laws relating to human subjects in research.

REASON FOR THE POLICY

This policy sets forth the structure of the Human Research Protection Program at Chapman University and describes the authority and responsibilities of individual researchers, the Institutional Official (IO) and the Institutional Review Board (IRB) in implementing the program.

POLICY

Through its Code of Ethics, Chapman University established respect for persons as the ideal and fundamental ethical basis in teaching, research and service. The University operates its human research protection program under a Federal wide Assurance (FWA) with the Office of Human Research Protection (OHRP). The FWA represents a fundamental commitment to the protection of human participants and applies to all Chapman University research involving human participants, regardless of the location of the research or its sources of funding, be they governmental agencies, nonprofit organizations, industry, or University funds. In addition, the FWA applies to all research conducted at Chapman University or using Chapman resources regardless of who is conducting the research.

The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- Educate and train students, faculty, and staff who conduct research about the ethical principles and federal regulations guiding research with human subjects.
- To provide efficient and high quality review of human research projects; and
- To facilitate excellence in human subjects research.

Researcher Responsibilities

Researchers have the primary responsibility for the protection of research participants on a given project, including:

- Consulting with Office of Research staff if unsure whether a study meets the definition of research with human subjects;

- Submitting applications for review and approval prior to initiating research;
- Ensuring that research with human subjects is either deemed exempt or conducted according to an IRB-approved protocol;
- Submitting modification requests as needed and waiting to receive written approval before implementing changes;
- Submitting requests for continuing review in accordance with the IRB established timeframe;
- Reporting unanticipated risks, physical or psychological harm, or other problems to the IRB immediately upon becoming aware of them;
- Reporting to the IRB when the research project is completed;
- Retaining research materials for at least three years after the completion of the research; and
- Complying with data retention requirements of funding agencies, as applicable.

In cases of disagreement, the IRB has the final authority to determine what constitutes research and the use of human participants.

Institutional Official Responsibilities

The Vice President for Research is the Institutional Official (IO) with overall responsibility for the HRPP. The IO is authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The responsibilities of the IO include:

- Ensuring that the HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects;
- Ensuring that the IRB functions independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and members if they experience undue influence or if they have concerns about the function of the IRB;
- Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- Oversight of the development and implementation of an educational plan for IRB members, staff, and investigators;
- Serving as the signatory authority related to human subject protections and ensuring compliance with the terms of the FWA to the Office of Human Research Protections;
- Representing Chapman University in communications with the federal OHRP;
- Determining whether protocols with human subjects meet the criteria for exempt determination; and
- As appropriate, delegating responsibilities to the Office of Research staff or IRB member(s).

Institutional Review Board Responsibilities

Chapman University maintains an IRB to protect the rights and welfare of human research subjects recruited to participate in research activities.

The responsibilities of the IRB include:

- To approve, require modifications to secure approval, or disapprove all non-exempt research activities involving human subjects overseen and conducted under the auspices of the institution regardless of location of the research activities;
- To review protocols in accordance with the ethical principles described in the Belmont Report, federal regulations, and institutional policy;

- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB.
- To conduct continuing review of research at intervals appropriate to the degree of risk of the research and as determined by federal regulations
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- To conduct investigations of alleged or suspected non-compliance and submit a report to the IO on the outcome and recommendations of the investigations.
- To review applications in a timely manner, barring any unforeseen problems.
- To accurately document IRB decisions for exempt, expedited and full protocols and minutes of IRB meetings.
- As necessary, to observe, or have a third party observe, the consent process and/or the conduct of research; and
- Submission of an annual report to the IO

Various administrative units (Office of Research, Environmental Health and Safety, Compliance Office) support the HRPP. This includes staff for administering the IRB, as well as managing and handling reports of concerns for human subjects' research.

- The IRB administrator provides support to the IRB and serves as technical advisor to the IRB committee.
- The IRB administrator implements the IRB training programs to ensure campus compliance with policies and human subject regulations.
- The Office of Research collaborates with Environmental Health & Safety to implement an appropriate occupational health program that addresses the participation of Non-Chapman human subject use in research.
- The Chief Compliance Officer collaborates with the Office of Research to handle anonymous reports of human subject concerns.

OFFICE RESPONSIBLE FOR POLICY

Name of Office: Office of Research

Contact information for questions about this policy: Michael Briggs, Director of Research Integrity

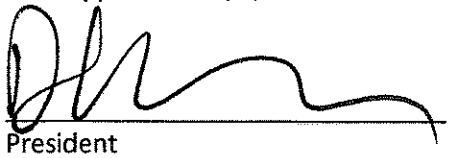
WEBSITE ADDRESS FOR THIS POLICY

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

WHO APPROVED THIS POLICY

Senior Staff member submitting the policy: Tom Piechota, VP for Research

Date approved: 10/9/18



President

PUBLICATION DATES

Effective: 10/9/18

RELATED MATERIALS

Institutional Review Board. Management and Function: Second Edition.

U.S. Department of Health and Human Services Office for Human Research Protections