**Policy Number: P-XXX**

**Effective Date: 7/1/2021**

**Revised Date:** Click or tap to enter a date.

**Department of Origin: Institutional Review Board (IRB), Chamberlain University**

**Policy Approved and Communicated By: Provost, Chamberlain University**

**Purpose:** The Chamberlain University Institutional Review Board (IRB) has established policies and procedures regarding the review, approval, and oversight of research within its jurisdiction. These policies and procedures are informed by federal regulations and guidelines, Chamberlain policies, and ethical standards for the conduct of research. Students conducting research or participating in research as co-investigators or assistants, however, are in unique roles which are poorly addressed in current policies and procedures. Students are typically unfamiliar with the legal/ ethical conduct of research, and therefore, require supervision and guidance from seasoned researchers. Furthermore, additional privacy and confidentiality concerns are present with student researchers when research involves subjects who are themselves students or members of the Chamberlain community. The purpose of this policy is to articulate additional requirements and limits for student-conducted and student assisted research in order to ensure full and appropriate protection for human subjects.

**Area of Responsibility:** The IRB is responsible for implementing and reviewing this policy. All parties involved in student-conducted or student-assisted research are responsible for following this policy.

**Definitions:**

 **Human Subjects Research:** Human subjects research conducted by members of the Chamberlain community (including students)and/or uses Chamberlain community members, programs, structures, or facilities as subjects of the research falls under the jurisdiction of the Chamberlain University IRB. The Office for Human Research Protections (OHRP) defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102). OHRP further defines “human subject” as “a living individual about whom an investigator conducting research a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or b) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.”

**Non-Human Subjects Research:** Research not meeting the definition of human subjects research is considered non-human subjects research and falls under the policies and procedures of the University and individual academic programs.

**Student-Conducted Research**: For the purposes of this policy, student-conducted research is human subjects research primarily developed and implemented by a student enrolled at Chamberlain University, whether the research is in partial fulfillment of an academic requirement or is conducted as an extra-curricular/ co-curricular activity.

**Student-Assisted Research**: For the purposes of this policy, student-assisted research is human subjects research in which a student serves as a co-investigator or research assistant. The student does not have a primary or leadership role in the development and implementation of the research.

**Student**: Any individual enrolled in one or more Chamberlain University academic programs is considered a student. Chamberlain colleagues enrolled in any academic program, Chamberlain or otherwise, are considered students if the proposed research is a component of colleagues’ academic coursework.

**Faculty Advisor/ Supervisor**: The faculty advisor/ supervisor assumes primary accountability for ensuring that a student is developing and implementing research in concordance with all relevant policies and procedures, ethical guidelines, and academic program requirements for student-conducted research.

**Policy Statement and Details:** All persons, including students, engaged in human subjects research must adhere to the policies and procedures governing the conduct of human subjects research. Beyond the policies and procedures applicable to all researchers, students and faculty advisor/ supervisors must adhere to the following additional requirements:

* All students engaged in human subjects research as researchers or research assistants must complete human subjects protections training prior to initiating a research study. This training will be determined by the IRB and may or may not differ from the training required of non-student researchers. Specific content of the training may also differ depending upon the research topic and/or scope.
* Students conducting research must have a designated faculty advisor/ supervisor.
* The faculty advisor/ supervisor must serve as a co-principal investigator for the proposed research study and must co-sign all study materials submitted to any Chamberlain review body. (Note: Serving in the role as co-principal investigator is for research review and accountability purposes only. This role has no relevance to potential authorship of a study’s dissemination materials. How this role contributes to faculty’s personal scholarship productivity is determined by the faculty’s program and the University.)
* The faculty advisor/ supervisor must be included in all communications and actions with the IRB.
* Non-faculty Chamberlain colleagues may serve as an advisor/ supervisor for a student if approved by the student’s academic program and the IRB.
* Students engaged in human subjects research as researchers or assistants may not have access to subjects’ personal identifying information nor an ability to re-identify research subjects if possible. If access is unavoidable (e.g., participating in interviews with research subjects), students may not engage with subjects or subjects’ data from the student’s academic location (e.g., campus) or academic program (for programs delivered online) unless an exception is granted by the IRB.
* For student conducted-research, students must identify themselves as student researchers in recruitment and informed consent materials as well as provide the names and contact information of faculty advisor/ supervisors.

**References and related documents: (Does this policy refer to other documents? If so, list them.)**

**Code of Federal Regulations:** TITLE 45: PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
**PART 46**
PROTECTION OF HUMAN SUBJECTS

Sub-Parts A through E

 Available at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>

*IRB Handbook*, available at <https://library.chamberlain.edu/irb>

**Revision History Table**

|  |  |  |  |
| --- | --- | --- | --- |
| Revision Date | Description | Author | End Date |
| 05-17-2021 | Approved by Provost |  |  |