

**University Policy 3.03.01****Human Research Protections****Policy Approval Date: May 13, 2008****Policy Effective Date: June 1, 2008****Procedure Approval Date: July 25, 2011****Procedure Effective Date: August 1, 2011****POLICY STATEMENT**

All learners conducting academic research under the program requirements at Capella University, including all doctoral learners conducting dissertation or doctoral capstone research and all employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella, are required to obtain Institutional Review Board (IRB) approval prior to beginning research-related interactions with human participants/subjects and/or their records. They are also required to comply with the policies and procedures outlined in Capella University's Research Integrity (RI) Standard Operating Procedures (SOPs). All employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella; researchers unaffiliated with Capella who are conducting academic research involving Capella learners, alumni, faculty, staff, and/or their records; and all research supervisors who are overseeing research activities are also required to comply with the policies and procedures outlined in the SOPs. Academic research conducted outside the purview of Capella as described above is not governed by Capella's IRB.

In the review and conduct of academic research involving human participants and/or their records, Capella University's IRB is guided by the ethical principles established in the Title 45 Code of Federal Regulations, Part 46 ([45 CFR 46](#)), [Nuremberg Code](#), [Declaration of Helsinki](#), and [The Belmont Report](#). In addition, Capella's IRB must review all research proposals in accordance with the policies and procedures outlined in Capella University's RI SOPs.

**RATIONALE**

Capella University is committed to its institutional responsibility to respect and protect the rights and welfare of human participants and/or their records in research, and promote excellence in research through its commitment to ethical and responsible conduct of research. Ensuring the highest standards of ethical conduct in research and the protection of the rights and welfare of human research participants is a shared responsibility between the Capella University research community, the Institutional Review Board (IRB), and the Doctoral Success Center (DSC).

In compliance with the federal-wide assurance on record with the Office of Human Research Protections (OHRP) within the federal Department of Health and Human Services (DHHS), Capella University's IRB is established and maintained to ensure that appropriate provisions exist to protect the rights and welfare of human research participants and/or their records. In fulfillment of these responsibilities, the IRB reviews all academic research and activities that have a direct bearing on the rights and welfare of the human research participants and/or their records.

## **DEFINITIONS**

### Academic Research

Academic research is defined as all research conducted by Capella University learners as part of their degree program requirements, except that which has been designated as courseroom research, and any systematic investigation conducted by Capella University employees or agents that is designed to contribute to generalizable knowledge.

### Agents

Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

### Doctoral Success Center (DSC)

The DSC strives to promote and uphold the integrity of research at Capella University and support Capella researchers in the ethical and responsible conduct of research through its commitment to the following:

- Fostering awareness of and respect for the rights and welfare of Capella University human research participants.
- Fostering ethical research through education, Institutional Review Board (IRB) review, quality assurance and improvement initiatives, and compliance monitoring.
- Building capacity for Capella University researchers to engage in quality and ethical research.
- Informing and educating Capella's research community regarding ethical research and human research protections issues.
- Facilitating IRB review and providing administrative and operational support for Capella's IRB functions to ensure timely and efficient processing, review, monitoring, tracking, and reporting of research protocols and IRB activities.
- Reviewing and monitoring research for compliance with ethical principles and local, state, and federal regulations.

### Human Research Participant

A human research participant is a living individual about whom an investigator (whether professional or student) conducting academic research obtains data through intervention or interaction with the individual or identifiable private information. A human research participant is referred to as a human research subject in federal regulations and guidance material.

- Intervention includes both physical procedures by which data is gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between researcher and subject.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in

order for obtaining the information to constitute research involving human subjects (participants).

### Institutional Review Board (IRB)

An IRB is a committee established in accord with and for the purposes expressed in [45 CFR 46](#).

### Research Integrity (RI) Standard Operating Procedures (SOPs)

The Research Integrity (RI) Standard Operating Procedures (SOPs) outline the procedures by which the Institutional Review Board (IRB) approves proposed academic research and the procedures by which the Doctoral Success Center (DSC) fulfills its institutional responsibility. The SOPs focus specifically on the university's application of ethical principles and compliance with federal guidelines, but do not reiterate principles and procedures otherwise delineated within those guidelines.

## **PROCEDURES**

### I. Scope

- A. All learners conducting academic research under the program requirements at Capella University, including all doctoral learners conducting dissertation research and all employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella, are required to comply with the policies and procedures outlined in Capella University's Research Integrity (RI) Standard Operating Procedures (SOPs).
- B. All researchers must also comply with other applicable university policies, including *3.03.05 Conflict of Interest in Research*.

### II. Institutional Review Board (IRB) Application Submission, Review, and Approval

- A. Prior to submitting an application for a research proposal to the Capella University IRB for review and approval, the researcher works closely with his or her research supervisor (if applicable) to ensure that the application is coherent and complete.
- B. In signing and submitting an IRB application, the researcher and research supervisor (if applicable) certify they will fulfill the roles and responsibilities designated in the Research Integrity (RI) Standard Operating Procedures (SOPs).
- C. IRB Research Proposal Decisions
  1. All research proposals submitted to the university's IRB will be issued a decision. Only academic research designated as "approved," "exempt," or "Not Human Subjects Research" (NHSR) may proceed. Research proposals that are issued any other designation must be resubmitted until approval is granted.
  2. Details about each decision type can be found in the RI SOPs.
- D. All approved academic research may be subject to continuing oversight as directed by the RI SOPs.

### III. Further Institutional Review and Approval of Institutional Review Board (IRB) Actions

- A. All IRB-approved academic research may be subject to further review and approval or disapproval by university officials; however, university officials may not approve academic research that the IRB has previously disapproved (45 CFR 46.112).

- B. The university reserves the right to subject academic research previously reviewed and approved by the IRB to further review.

#### IV. External Researchers

- A. Researchers who are not currently affiliated with Capella University who would like to conduct academic research involving Capella learners, alumni, faculty, or staff, or who are seeking access to Capella University data or records must contact the Doctoral Support Center (DSC). External researchers who wish to recruit Capella University affiliates as participants or access Capella University data or records must be granted university permission.
- B. Capella University will not assume Institutional Review Board (IRB) of record for external researchers, but Capella's IRB may nevertheless review research studies to help determine the appropriateness of granting institutional permission.
- C. Capella University assumes the authority to grant or deny permission for external researchers to use Capella University affiliates, data, or records for research and may disallow requests under university-established guidelines.

#### **POLICY OWNERS**

Academic Owner: Doctoral Success Center

Operations Owner: Doctoral Success Center

#### **RELATED DOCUMENTS**

University policy 3.03.05 Conflict of Interest in Research

*The Belmont Report*

The Common Rule (45 CFR 46)

*Declaration of Helsinki*

*Nuremburg Code*

#### **REVISION HISTORY**

Original Policy Approval Date: April 23, 2004

Revision Dates: 5-13-08

Administrative edits as a result of ongoing review: 5-27-09; 2-22-10; 4-17-12; 8-6-12; 2-10-14; 6-1-16; 8-11-16

Formerly university policies 02.08 Use of Human Participants/Subjects in Research and 3.03.01 Use of Human Participants/Subjects in Research