University Policy 3.03.01 Human Research Protections

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POLICY STATEMENT

All students conducting academic research under the program requirements at Capella University, including all doctoral students 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 data. All employees or agents conducting academic research pursuant to institutionally designated authority or responsibility of Capella; all researchers unaffiliated with Capella who are conducting academic research involving Capella students, alumni, faculty, staff, and/or their records; and all research supervisors who are overseeing research activities are also required to comply with the procedures outlined in this policy. 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*.

RATIONALE

Capella University is committed to its institutional responsibility to respect and protect the rights and welfare of human participants and their data in 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 and the Institutional Review Board (IRB). The IRB reviews all academic research and activities that have a direct bearing on the rights and welfare of human research participants and their data.

DEFINITIONS

Academic Research

Academic research is defined as all research conducted by Capella University students as part of their degree program requirements, except that which has been designated solely as courseroom research. It also includes 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.

Courseroom Research

Courseroom research differs from academic research in that it can be performed without prior Institutional Review Board (IRB) approval. Courseroom research does not meet the federal definition of research as written in 45 CFR 46 and must meet the following criteria. It must be limited in scope. It must not be generalizable and cannot be distributed or used outside of the courseroom. It must have minimal risk to volunteers. It must not be stressful or be about illegal activities. It cannot be used as part of the doctoral project. The research cannot collect personal identifiers, and it cannot use minors or other vulnerable people as volunteers. Data must be destroyed after completion of the course.

Human Research Participant

A human research participant is a living individual about whom an investigator conducting academic research obtains data, identifiable biospecimens, or identifiable private information through intervention or interaction with the individual. 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. It includes information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- Identifiable private information is individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the data, biospecimen, or information).

Institutional Review Board (IRB)

An IRB is a committee established in accord with and for the purposes expressed in 45 CFR 46.

Research Materials

Research materials include signed consent forms, digital and paper surveys, audio recordings, transcripts, data files, and all other documents or communication to or from research participants.

Unanticipated Problems

An unanticipated problem is any event that the researcher did not predict in advance, that is related or potentially related to the research, and that may suggest participants or others are at greater risk of harm than originally assessed.

PROCEDURES

I. Scope of Capella's Institutional Review Board (IRB)
   A. All academic research must be reviewed and approved by Capella's IRB.
   B. The IRB will not review or approve the following types of research:
      1. Research involving tests of food, food additives, or any research that requires oversight by the Food and Drug Administration (FDA).
      2. Research involving investigational new drugs or devices.
      3. Research involving human fetuses or neonates.
      4. Any research with an animal that requires oversight by an Institutional Animal Care and Use Committee.
      5. Research involving greater than minimal risk to minors or to adults who are under legal guardianship.
      6. Research with prisoners falling under 45 CFR 46.306(a)(2)(iii-iv).
   C. Courseroom research does not require IRB review or approval.
   D. The IRB may hold, suspend, place restrictions on, or terminate approval of research when it is necessary for participant protection, when approved procedures are not followed, or during an IRB noncompliance investigation.
   E. The IRB will perform continuing reviews of research at least as often as specified in 45 CFR 46.
   F. 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).
   G. Requests from external IRBs that require Capella's IRB to be the single approving IRB (or "IRB of record") will be reviewed on a case-by-case basis.

II. Researcher Responsibilities
   A. All researchers must apply to the Institutional Review Board (IRB) and obtain approval before they interact with participants for any purpose related to the research.
   B. Researchers must comply with direction from the IRB during the application process and throughout conduct of the research, research audit, or observation by the IRB or designee.
   C. Students may not engage in recruitment, obtain consent, interact with participants, collect data, or analyze identifiable data unless they are enrolled in a doctoral course.
   D. Researchers must report any unanticipated problems or adverse events to the IRB within one business day. During any emergency situation in which a participant may be harmed, researchers will stop the conduct of the research, assist the participant, and report the incident to the IRB within one business day.
   E. Researchers and faculty must complete and maintain currency in Capella University's required research ethics course (Collaborative Institutional Training Initiative/CITI).
   F. Researchers must obtain approval from the IRB before modifying their approved research procedures, sites, or forms.
   G. Researchers must cease performance of research and stop all contact with participants on the expiration date of the IRB approval. If the researcher determines additional time to complete the research is required, researchers must apply for continuing review and reapproval of the research. The continuing review request should occur before the expiration date and allow sufficient time for IRB review and approval.

H. Researchers must maintain all research materials for seven years after completion of a study.
I. Researchers are required to obtain IRB approval before conducting a pilot study. Faculty approval does not supersede the requirement for IRB approval.
J. Researchers, students, faculty, and staff cannot sign a research-related contract or agreement on behalf of Capella University. Researchers must submit these documents to the IRB. The IRB will coordinate additional review by Capella University's legal department.
K. If a study is disapproved, the researcher may appeal the decision in writing within 14 calendar days. All appeals will be reviewed by the full IRB committee. Once the IRB has made a decision about an appeal, the decision cannot be overturned.

III. Compliance

A. Capella University researchers must comply with all Capella University research policies and any applicable international, federal, state, local, or tribal laws that provide additional protection for human participants or their data.
B. Researchers must comply with additional regulations or stipulations made by the research site.
C. Failure to comply with an Institutional Review Board (IRB)-approved research protocol, applicable laws, or site regulations or stipulations will be investigated by a university-designated compliance specialist. When necessary, investigation findings will be presented to the full IRB committee, the Research Compliance Committee (RCC), and/or the appropriate university committee or official.
D. Noncompliance findings will be communicated to the researcher and may be reported to the research site, other approving IRBs, federal agencies, or other Capella personnel as indicated.
E. Following a finding of noncompliance, corrective actions to be implemented by the researcher may be required by the compliance specialist as indicated by the nature of the noncompliance. Failure to complete corrective actions as directed can result in referral to the full IRB committee, the RCC, and/or the appropriate university committee or official.
F. If the IRB noncompliance is found to be "serious" or "continuing," researchers can appeal the finding in writing within 14 calendar days. All appeals will be reviewed by the full IRB committee. Once the IRB has made a decision about an appeal, the decision cannot be overturned.

IV. External Researchers

A. Researchers who are not currently affiliated with Capella University but who wish to perform academic research with Capella students, alumni, faculty, staff, data, or records must contact the Institutional Review Board (IRB) for direction before they begin any aspect of the research at Capella.
B. Capella University assumes the authority to grant, deny, or terminate permission for research requests by external researchers under university-established guidelines.
C. If there are concerns about protocol noncompliance or harm to participants, these concerns will be reported to the appropriate IRB and/or personnel at the external researcher's affiliated institution.

POLICY OWNERS
Academic Owner: Office of Research & Scholarship
Operations Owner: Office of Research & Scholarship

RELATED DOCUMENTS
University policy 3.03.05 Conflict of Interest in Research
University policy 3.03.06 Research Misconduct
The Belmont Report
The Common Rule (45 CFR 46)
Declaration of Helsinki
Nuremburg Code

REVISION HISTORY
Original Policy Approval Date: April 23, 2004
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Formerly university policies 02.08 Use of Human Participants/Subjects in Research and 3.03.01 Use of Human Participants/Subjects in Research