

# Research Integrity Standard Operating Procedures (RI SOPs)

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# PURPOSE AND SCOPE OF THE STANDARD OPERATING PROCEDURES

Capella University is committed to promoting the responsible conduct of research and fostering research which is both sound and ethical. Capella University carries out its institutional responsibility to respect and protect the rights of individuals involved in research as human participants by facilitating review by the Institutional Review Board (IRB), providing education relating to best practices for safeguarding participants, and engaging in monitoring and quality improvement initiatives.

Capella's IRB is guided by the ethical principles set forth in the <u>Nuremberg Code</u>, the <u>Declaration of Helsinki</u>, and <u>The Belmont Report</u>. Capella University requires that all research conducted under the purview of Capella University be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (<u>45 CFR 46</u>) and governed by Capella University's policy <u>3.03.01: Human Research Protections</u>.

The Research Integrity (RI) Standard Operating Procedures (SOPs) outline the procedures by which Capella University fulfills its institutional responsibility to promote human research protections as well as the procedures for IRB approval of proposed research. The SOPs focus specifically on Capella's application of ethical principles and federal guidelines, but do not reiterate principles and procedures otherwise delineated within the federal guidelines. The SOPs do not contain any of the application forms or step-by-step instructions for their completion. Information on the IRB process can be found on iGuide.

## **Revisions to Standard Operating Procedures**

The Standard Operating Procedures (SOPs) contained herein are subject to review and revision on a biennial basis.

#### Amendments to Standard Operating Procedures

The SOPs are subject to amendment if changes are required prior to biennial revision. Amendments will be documented and published on iGuide on an as-needed basis.

# **Limits of Applicability**

Capella University has acknowledged limitations of oversight due to the nature of the university's environment, research education, specializations, programs, and reviewer expertise. Therefore the IRB may not review or approve the following types of research:

• Food and Drug Administration (FDA) & Investigational New Drug or Device (IND)

Capella University does not allow researchers to conduct research that requires FDA oversight and does not allow researchers to conduct research that includes investigational new drugs or devices (INDs).

• Research Involving Human Fetuses & Neonates

Capella University does not allow researchers to conduct research involving human fetuses and neonates as described in <u>45 CFR 46, B</u>.

• Research with Prisoners-Categories 3 & 4

Capella University does not allow researchers to conduct research involving prisoners that falls into <u>45 CFR 46.306(a)[2]iii-iv</u>. Research involving prisoners that falls into <u>45 CFR 46.306(a) [2] i-ii</u> *is* permitted, providing that IRB approval is obtained through the full IRB Committee review process.

• Research with Children Involving Risk

Capella University does not allow researchers to conduct research involving children that falls into <u>45 CRF 46.405</u>, <u>45 CFR 46.406</u>, and <u>45 CFR 46.407</u>. These types of research involve greater than minimal risk to minors.

Researchers need to contact the IRB Office at irb@capella.edu regarding proposed studies that may fall into any of the above categories.

Additionally, Capella University's legal department must review all contracts, site agreements, and data user agreements that require a signature from a Capella representative other than the researcher. This includes agreements in which the mentor is asked to sign as the researcher/principal investigator. If Capella University is unable to enforce or ensure the conditions of the agreement, then Capella University will not enter into an agreement with the organization or owner of data. Researchers in need of a Capella University signature must initiate the review of such documents by contacting the IRB Office.

# A Note on Terms and Definitions

Capella University prefers that its researchers use the term participants in reference to those who consent to be a part of a research study. The federal regulations (and many other institutions), however, refer to participants as subjects.

Throughout this handbook, the term "researcher" will refer to any Capella affiliate engaged in the design and conduct of research, including learners, faculty, staff, and alumni.

The SOPs use federal definitions of research-related terms. Please see Appendix A for a list of these terms and their definitions. Refer to Appendix B for a list of acronyms.

# CAPELLA UNIVERSITY'S HUMAN RESEARCH PROTECTIONS

Ensuring the highest standards of ethical conduct in research as well as 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.)

# Applicability

These SOPs are applicable to all academic research conducted at Capella University. Academic research is defined as all research conducted by Capella learners as part of their degree program requirements, except that which has been designated as courseroom research, and any systematic investigation conducted by Capella employees or agents designed to contribute to generalizable knowledge. Activities which meet this definition constitute research for the purpose of these SOPs. All academic research at Capella University must be conducted in light of best practices relating to the ethical and responsible conduct of research.

#### **Courseroom Research**

Research projects that occur within courses are designed to provide learners an opportunity to practice various research methods such as interview, observation, and survey techniques as well as data analysis. Typically such projects are quite limited in scope and are not intended for dissemination or to contribute to generalizable knowledge.

Course-based research projects and data collection activities may be exempt from IRB review. Such projects should not include sensitive or personal information or otherwise put participants at risk, and the data must be recorded anonymously (i.e., with no name, social security number, or any other code that can be linked to a participant). These projects are considered "courseroom exercises" and are not subject to review by the IRB, unless the learner-researcher anticipates using the results in his or her dissertation, publishing the results or presenting at a professional meeting, or unless the faculty expects to compile all learners' results with the intention of publishing or presenting.

Courseroom research that is exempt from IRB review is subject to Capella University's policy <u>3.01.01 Academic Honesty</u>, but will not be investigated under Capella University's policy <u>3.01.06 Research Misconduct</u>.

Courseroom research must be submitted to the IRB for review and approval under any of the following circumstances:

- The research involves the collection of identifiable data from human participants.
- The research involves more than minimal risk and/or includes sensitive or personal information or topics.
- Research results may be used as part of a learner's dissertation or doctoral capstone.
- Research results may be published or presented at a professional meeting outside the courseroom environment.

Any courseroom research that involves data collection through human interactions that does not meet the criteria for the IRB exemption as noted above will require an IRB application and approval prior to the research being conducted. Courseroom research requiring IRB review will be subject to these SOPs and all Capella University research policies. Courseroom instructors assume the responsibility of oversight for learners engaged in courseroom research. The instructors of courses with data collection or research methods requirements that involve human interactions should complete basic education requirements as required for mentors.

## **Dissertations and Doctoral Capstones**

Capella University requires all doctoral learners to undergo IRB review as part of their dissertation or doctoral capstone milestones for, even if their dissertation or doctoral capstone does not appear to involve human participants and/or their records or meet the federal definition of human subjects research. Learners completing dissertations are expected to submit an IRB application while learners completing doctoral capstones are expected to submit an IRB Screening form, and, if necessary, an IRB application. Mentors assume the responsibility of oversight for learners engaged in doctoral research. Doctoral learners engaged in dissertations or doctoral capstone research and mentors responsible for oversight of such research are responsible for the ethical conduct of research and for meeting HRP expectations for researchers and mentors. Researchers must complete basic education requirements for the protection of human research participants and the ethical conduct of research.

Capella's dissertation and doctoral capstone processes involves a series of milestones whose requirements must be met. IRB approval is one of the required milestones. The milestone is fulfilled once a researcher obtains full IRB approval for his or her study or the study is determined by the IRB not to involve human subjects research.

#### Capella Researchers

All learners conducting research under the program requirements at Capella University, and all employees performing research pursuant to institutionally designated authority or responsibility of Capella, are required to obtain IRB approval prior to beginning researchrelated interactions with human participants and/or their records. All researchers who obtain Capella IRB approval are classified as "Capella Researchers," subject to Capella research regulations and these SOPs. Such researchers may include Capella faculty, learners, staff, and alumni.

Capella faculty or staff conducting research as part of Capella program requirements are considered "Capella Researchers" subject to Capella research regulations and these SOPs.

Capella faculty or staff conducting research as part of the program requirements of another institution are not considered "Capella Researchers" and are not subject to Capella research regulations and these SOPs. However, Capella faculty and staff who wish to recruit Capella University affiliates as participants or access Capella data or records must request and obtain University permission. Capella University will not assume IRB of Record for faculty and staff conducting research to meet program requirements at another institution. However, Capella's IRB may nevertheless review such studies in order to help determine the appropriateness of granting institutional permission.

Capella faculty and staff pursuing research within their own field that is not pursuant to institutionally designated authority or responsibility of Capella or part of the program requirements of another institution may utilize the IRB process at Capella University. All researchers who obtain Capella IRB approval are classified as "Capella Researchers," subject to Capella research regulations and these SOPs.

Research conducted outside the purview of Capella as described above is not governed by Capella University's IRB.

IRB monitoring of research studies concludes once a learner has graduated, discontinued, or been administratively withdrawn from the University. However, serious allegations of non-compliance, reports of adverse events, or allegations of research misconduct may necessitate additional follow up and/or investigation, even after a learner has graduated, discontinued, or been administratively withdrawn from the University.

#### **Conflict of Interest**

Capella researchers are required to ensure that academic, financial, or other personal interests do not compromise the objectivity with which their research is designed, conducted, and reported and that such interests do not put research participants at risk. Conflicts of interest involving the researcher, research team, and mentor(s), including significant financial interests as well as intangible interests involving personal or professional relationships, must be reported to the IRB. Researchers must develop plans to eliminate or mitigate such conflicts of interest, and such plans must be approved by the IRB. Please see Capella University's policy <u>3.03.05 Conflict of Interest in Research</u> and the <u>Guidance on Conflict of Interest</u> for additional information.

#### **Quarters of Inactivity for Doctoral Researchers**

Per <u>University Policy 3.01.10 Doctoral Learners</u>, doctoral researchers may not recruit participants and/or collect data unless registered in a dissertation or doctoral capstone course. Additionally, doctoral researchers may not submit modification or continuing review requests unless registered. If the researchers have not obtained initial IRB approval, IRB approval may not be pursued during a quarter of inactivity. The IRB may require the researcher to notify currently enrolled participants of a period of inactivity that may be lengthy or is unexpected. If the initial IRB approval has expired, continuing review will be required in order to obtain IRB approval.

#### **External Researchers**

Researchers who are not currently affiliated with Capella University, but would like to access Capella data or records or to conduct research involving Capella alumni, faculty, learners, or staff, must contact the IRB. External researchers who wish to recruit Capella University affiliates as participants or access Capella data or records must request and obtain University permission. Capella University will not assume IRB of Record for external researchers.

Capella University assumes the authority to grant or deny permission for research involving Capella participants or data and may disallow requests under guidelines established by Capella University.

#### **Capella University Policies**

All parties adhering to these SOPs must also comply with all other relevant University policies.

# **ORGANIZATION & STRUCTURE**

The promotion of ethical and responsible practices in research as well as protections for human research participants is a shared responsibility. Specific information concerning key roles and responsibilities is below.

# Institutional Official (IO)

The Chief Academic Officer of Capella University is the IO responsible for ensuring that Capella's research community has the resources and support necessary to comply with university policies and with the regulations and guidelines that govern research with human participants. The IO is legally authorized to represent Capella University. He or she is the signatory of the Federalwide Assurance (FWA) and assumes the obligations of the FWA. The IO is the point of contact for correspondence addressing human research with the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (DHHS). The IO appoints IRB Members and Chairs and approves determinations concerning the removal of IRB Members and Chairs. The IO has the authority to delegate such activities as may be necessary in order to fulfill these duties.

# Institutional Review Board (IRB)

The purpose of the IRB is to review research studies to ensure the protection of human research participants in accordance with the principles of the <u>Nuremberg Code</u>, the <u>Declaration of Helsinki</u>, and <u>The Belmont Report</u> and the mandates of the federal regulations (<u>45 CFR 46</u>).

## **IRB** Chair

The primary role of the IRB Chair is to facilitate meetings of the full IRB Committee. The IRB Chair strives to ensure participation of all meeting attendees. The IRB Chair encourages the exchange of a range of perspectives while helping the committee move toward a determination. The IRB Chair also monitors the agenda to ensure there is adequate time for each review. While the IRB Chair does not participate in pre-reviews, he or she must be familiar enough with each study to facilitate dialogue on the ethical concerns identified by the pre-reviewers and committee members. The IRB Chair must vote in the event of a tie. This role may be filled by one or more individuals.

#### **I RB Members**

Capella University's IRB members are responsible for assessing all research proposals involving human participants or records to which they are assigned to ensure that the rights and welfare of human participants are protected.

IRB members serve as designees of the IRB Chair for the expedited review of new or continuing reviews and modifications of ongoing studies and may also serve as primary reviewers when a study requires full IRB Committee review. Capella's IRB members are considered general voting members. Members are expected to attend convened IRB meetings on an assigned basis. An IRB member may also attend as a voting member if he/she is attending the meeting as a pre-reviewer for a full review study.

Responsibilities of IRB members include the following:

- Complete all training and education requirements and participate in other designated educational opportunities.
- Act as the signatory official when conducting expedited reviews.

- Review and evaluate research studies referred to the full IRB Committee for ethical integrity and human participant protections
- Attend and participate in IRB Committee meetings as assigned.
- Notify the chair at least three (3) business days in advance of a planned absence from a meeting if an alternate cannot be arranged.

## **Research Compliance Committee (RCC)**

The purpose of the Research Compliance Committee (RCC) is to ensure that all academic research conducted on or by Capella University learners, faculty, or staff meets the highest ethical standards and complies with the federal regulations for the protection of human participants in research. As such, the mission includes self-reporting violations to the OHRP as required by federal regulations. This mission also includes recommending policy and procedural changes that may impact the institution's ability to comply with federal regulations for the protection of human participants. The role of the RCC is to provide oversight to academic curricula, practice, policy, and procedure related to research and compliance, not to review, overturn, or otherwise question the decisions of the IRB.

The RCC is composed of members representing the IRB, the institution's academic leadership, and school research chairs. Members are appointed on an ad-hoc basis to make determinations and issue recommendations regarding corrective actions for findings of serious and/or continuing non-compliance. The RCC also serves as the committee responsible for assembling a research misconduct investigation panel for the purpose of investigating allegations relating to research misconduct and making recommendations concerning findings and corrective actions to the Deciding Official (IO).

The Compliance Specialist (CS) receives allegations of non-compliance and research misconduct. The CS facilitates inquiries into potential non-compliance and potential research misconduct. The CS is responsible for facilitating meetings of the RCC, communicating decision to researchers, and keeping records of all inquiries and investigations.

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#### Researchers

Researchers include all those who design, conduct and report research under the purview of Capella University and its IRB, whether faculty, learner or staff. Capella expects all those who conduct research under its purview to adhere to the highest ethical standards. Researchers' responsibilities include the following:

- Accept the responsibility to comply with Capella University's policies, these SOPs, and all requirements to protect the rights and welfare of human participants involved in research.
- Comply with all other applicable international, federal, state, and local laws, regulations, and policies that may provide additional protection for human participants in research.
- Complete all education requirements relating to the responsible conduct of research and human research protections required by these SOPs.
- Refrain from interacting with any participants for research purposes prior to receiving IRB approval for the research.
- Acknowledge the responsibility for following the protocol outlined in the approved study and for safeguarding the rights and welfare of each research participant,

and that the participant's rights and welfare must take precedence over the goals and requirements of the research.

- Abide by all the determinations of Capella University's IRB.
- Comply with federal regulations relating to initial and continuing IRB review, administering and documenting informed consent, managing and storing data, safeguarding participants and ensuring their privacy in the conduct of research, submitting modifications for IRB approval, and reporting adverse events and unanticipated problems.
- Cooperate with the IRB as it executes its responsibility for initial and continuing review, record keeping, and reporting for the research study, providing all information requested by the IRB in a timely fashion.
- Cooperate with the IRB and RCC as they execute their responsibility to monitor and review research for compliance with federal, state, and local regulations and to audit studies for quality assurance and improvements, providing all information requested by the IRB Office and/or RCC in a timely fashion.

# **EDUCATION & TRAINING**

Education is vital to ensuring the ethical conduct of research and protection of human participants. Capella University is committed to providing training and ongoing educational opportunities for Institutional Review Board (IRB) members, IRB staff, researchers, mentors, and the Capella community, related to the responsible conduct of research as well as regulatory and institutional requirements for the protection of human participants. Capella ensures that those engaged in the design, review, conduct, and reporting of research and those responsible for supporting such activities have access to education in the responsible conduct of research and demonstrate knowledge of ethical principles and federal regulations concerning research with human participants.

# Collaborative Institutional Training Initiative (CITI)

Capella University has adopted a series of online modules known as CITI to provide mandatory human research protection training to researchers, mentors, IRB Members, IRB Staff, and the IO.

CITI modules may be reviewed and quizzes retaken as many times as needed until a passing score is obtained. A minimum score of 85 percent correct overall is required for researchers and mentors to obtain the certificate of completion for the CITI modules. During IRB review, researchers and mentors may be required to retake individual quizzes that fall below 85%. IRB members and staff are required to receive a score of 100 percent correct to obtain the CITI certificate of completion.

Certificates remain in effect for three years from the date of issue for mentors and two years for IRB members and staff.

#### Researchers, mentors, IRB members, Institutional Official, and DSC staff

Researchers, mentors, IRB members, and DSC staff are required to complete basic training that provides information relevant to their work as reviewers and administrators of research involving human participants:

- Complete basic and optional CITI training modules.
- Read and understand Capella University's policy <u>3.03.01 Human Research</u> <u>Protections</u>, <u>3.03.05 Conflict of Interest in Research</u>, and <u>03.03.06</u> <u>Research Misconduct</u>.
- Read and understand the <u>Nuremberg Code</u>, the <u>Declaration of Helsinki</u>, and <u>The Belmont Report</u>.
- Read and understand the federal regulations <u>45 CFR 46</u>.
- Read and understand the RI Standard Operating Procedures (SOPs) (this document).

# INSTITUTIONAL REVIEW BOARD

Capella University has registered one Institutional Review Board (IRB) with the Office for Human Research Protections (OHRP) (IRB00004629) that is responsible for reviewing all applications that require review as defined within these SOPs.

# Authority of Institutional Review Board (IRB)

The IRB has been established to ensure that all research involving human participants is subject to ethical review. Capella University's IRB is responsible for reviewing all human subjects research protocols in order to ensure that research participants are protected from risk, including but not limited to risk of physical, psychological, social, economic, or legal harm.

The IRB has the authority to review all research involving human participants. All persons conducting human subjects research at Capella University, including all doctoral learners conducting dissertation or doctoral capstone research and all employees performing human subjects research, are required to obtain Institutional Review Board (IRB) approval prior to beginning research-related interactions with human participants and/or their records. Research conducted outside the purview of Capella as described above is not governed by the Capella University IRB.

IRB review focuses on the protection of human participants in accordance with <u>45 CFR 46</u> and the criteria described in these SOPs. Additional school-specific requirements for research must be enforced by the school, and the IRB will not assess the researcher's fulfillment of such requirements.

The IRB may hold, suspend, place restrictions on, or terminate approval of research activities that fall within its jurisdiction when they are not being conducted in accordance with IRB requirements or when they have been associated with serious unanticipated problems, adverse events, and/or noncompliance. The IRB has the authority to observe or have a third party observe the consent process, consent forms, and the research if the IRB determines such observation is necessary.

# **IRB Scope**

The federal regulations offer a narrow definition of research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (<u>45 CFR 46.102</u>). All doctoral learners are required to submit and obtain approval (or a determination of Not Human Subjects Research) for their proposed research to the IRB prior to beginning study activities.

Many of Capella's professional doctorate students undertake dissertation or doctoral capstone research that involves the extension or application of existing research to solve real-world issues within organizational settings. Professional doctorate capstones and dissertations may involve activities such as action research, program evaluation, or needs assessment and might include the use of existing human subjects records or collection of new human subjects data.

Capella has deemed that such activities require independent ethical review by the IRB to ensure the protection of individuals, communities, and organizations who participate.

Capella believes that responsible and ethical practices are important whenever students are engaged in projects that have the potential to impact individuals, communities, and organizations. Capella is committed to educating learners about ethical principles such as

protecting participant privacy and confidentiality, managing conflicting interests, ensuring voluntary consent, and interacting respectfully and responsibly. For this reason, all doctoral learners, whether conducting research that is systematic and generalizable or projects that impact organizations and communities, undertake IRB review as a part of Capella's standard educational practice.

# **IRB** Membership

The IRB Committee includes at least one appointed representative from each school of Capella University in which research with human participants is conducted, at least one external member who has no direct affiliation with the University, and one member whose primary concern is in nonscientific areas.

# **Qualifications & Expertise**

In compliance with <u>45 CFR 106.7(a)</u>, the IRB includes qualified members who represent cultural, ethnic, racial, and gender diversity and offer diverse backgrounds and experience. To become a member of the IRB and conduct reviews of research with human participants, individuals must meet the following qualifications:

- Be a faculty member or employee of Capella University unless serving as a nonaffiliated member, non-scientist, or consultant to the IRB.
- Be able to devote the time needed to conduct thorough reviews of the ethical aspects of proposed research studies.
- Be committed to maintaining high ethical standards for the protection of human participants in research.
- Complete all training requirements as described in these SOPs
- Participate in ongoing ethics and research education.
- Possess a strong working knowledge of Capella's policies and procedures regarding IRB review and of the federal regulations regarding research involving human participants (<u>45 CFR 46</u>).
- Possess a strong understanding of the <u>Nuremberg Code</u>, the <u>Declaration of</u> <u>Helsinki</u>, and <u>The Belmont Report</u>.

# Nomination, Vetting, Appointment & Removal

#### **IRB** members

IRB members, including non-affiliate members, are appointed to the IRB following a nominating and vetting process. IRB member terms are generally for two years.

IRB members are subject to removal from the IRB at any time in accordance with the needs of the IRB committee and at the discretion of the IRB Chair and IRB Administrator. In cases in which an IRB member is found to be in serious and/or continuing non-compliance in the application of federal regulations for the review of research with human participants or with these SOPs, the IRB Chair or Compliance Specialist, in consultation with the IRB member's faculty chair, may remove the IRB member. Examples of situations which may warrant an IRB member's removal include failure to complete basic education requirements, failure to disclose a conflict of interest, failure to maintain confidentiality of IRB proceedings, serious

or continuing misapplication of the federal regulations in the review of research, or failure to consistently conduct reviews in accordance with the IRBs service level agreements. Any change in appointment, including reappointment or removal, requires written notification.

#### **IRB** Chair

IRB members interested in chairing the IRB Committee nominate themselves by completing a statement of interest form. The nominee's faculty chair must confirm the nomination by completing a letter of recommendation form. The IRB chair is expected to serve a two-year term and devote 5 work units per quarter to the administrative functions of the role. These arrangements are subject to negotiation. Individuals interested in extending their service may have an opportunity to renew their appointment, depending on the needs of the IRB, their interest, and performance. The IRB may have more than one individual serving in this role.

Nominees should have a record of research experience involving human research participants and a commitment to ethical and responsible research and the protection of human participants. Nominees should also have prior experience as a participant in Full IRB Committee meetings. Nominees with particular knowledge of sensitive topics, vulnerable populations, community or cultural considerations, or international research are especially welcome.

In addition, nominees should have a record of strong leadership, the ability to foster open and respectful dialogue and achieve consensus, the ability to communicate and interact with diverse individuals and groups, and the ability to manage conflict and engage in challenging dialogue. Effective time management and the ability to juggle multiple responsibilities and tasks are also important skills. The IRB Chair must be willing to work collaboratively with the IRB members and staff to promote ethical research and the protection of human participants and advocate for the importance of IRB review.

The IRB Chair may be required to engage in professional development during their term of service.

#### **Vetting & Determination**

Qualified nominees are interviewed by the IRB Administrator, an acting IRB Chair, and designated IRB members or staff. Candidates for this position are selected based on their qualifications and expertise and the needs of the IRB.

#### Appointment

The IRB chair is appointed by the Institutional Official (IO).

#### Removal

If the IRB Chair is not acting in accordance with the IRB's mission, is not following these policies and procedures, has an undue number of absences, or fails to fulfill the responsibilities of the position, he or she will be removed. The IO will make such a determination. Any change in appointment, including reappointment or removal, requires written notification.

#### **Conflict of Interest**

To ensure that IRB decisions are not compromised by academic, financial, or other personal considerations or obligations, IRB members and others involved in the IRB review process who have conflicts of interests are required to disclose such interests and to recuse



themselves from the review of research or the conduct of audits or compliance investigations, except to provide information requested by the IRB.

All conflicts of interest are managed according to the Capella University's policy <u>3.03.05</u> <u>Conflicts of Interest in Research</u>.

# FEDERALWIDE ASSURANCE (FWA)

Capella University has filed a Federalwide Assurance (FWA 0009640) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) affirming that the University is in compliance with <u>The Common Rule</u>. The FWA is Capella's commitment to comply with federal regulations for the protection of human participants in research.

# Applicability of Federalwide Assurance (FWA)

Capella University has agreed to protect the welfare of all human participants involved in research conducted or supported by a federal department or agency in accordance with *The Common Rule* (45 CFR 46). While the FWA applies to funded or federally supported research, the university agrees to review all research to ensure that the protocol meets ethical standards as described in *The Belmont Report* and <u>The Common Rule</u>. Capella University's Institutional Review Board) is registered under this FWA.

# Institutional Review Board (IRB) of Record

Capella University's IRB has the authority to allow an IRB from a different institution to be the IRB of Record. This determination can be made if Capella's IRB cannot provide adequate oversight for a research study or would like to reduce duplicate efforts of reviewing an IRB submission. Capella University's IRB must confirm that the other institution has the appropriate assurance under the Office for Human Research Protections, obtain a signed IRB Authorization Agreement, and maintain the FWA record regarding the agreement.

Requests from external IRBs that require Capella University's IRB to be the IRB of Record will be reviewed on a case-by-case basis.

# Further Review of Institutional Review Board (IRB) Actions by the Institution

Research approved by the IRB may be subject to further review by officials of the institution. The institution reserves the right to disapprove research approved by the IRB; however, the institution may not approve research that the IRB has disapproved (45 CFR 46.112).

# **IRB REVIEW**

The IRB Office screens all studies to determine that the required documents for review have been submitted. The IRB Office also determines the level of review in accordance with The Common Rule and OHRP Guidance on the Common Rule. Capella University reviews studies determined exempt in order to ensure that they apply the best practice of conducting research.

# **IRB** Committee Meetings

#### **Quorum Requirements**

A simply majority of the regular voting members or their alternates must be present to constitute a quorum for an official meeting. A non-scientist must always be present to constitute a quorum. If research involving prisoners is reviewed, a prisoners' representative must be included in the quorum. The IRB Chair who facilitates the meeting is not counted toward quorum. The IRB Chair will confirm that an appropriate quorum is present before calling the meeting to order and will be responsible for ensuring that the meetings remain appropriately convened. If a quorum is not maintained, the decision must be tabled and the meeting may be terminated.

## Voting

All IRB members designated as primary voting members at a convened meeting have full voting rights except in the case where a member declares a conflict of interest, in which the member must recuse themselves from the vote. IRB determinations (e.g. approvals, deferrals, disapprovals) must receive the approval of a simple majority of those voting members present at the meeting. The IRB Chair votes only in the event of a tie.

Opinions of absent members that are transmitted by mail, telephone, facsimile, or email may be considered by the attending IRB members, but may not be counted as votes or to satisfy the quorum for convened meetings.

#### Guests

At the discretion of the IRB, researchers and mentors may be invited to the IRB meeting to answer questions about their proposed or ongoing research. Researchers and faculty mentors may not be present for the deliberation or vote on their research.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Administrator, IRB Chair, and the DSC Office Manager. Guests who are not part of Capella's research community must sign a confidentiality agreement and a FERPA release must be signed by the researcher in order to share study-related documents

# **Continuing Review**

Federal regulations stipulate that approved projects at the expedited and full review level must be reviewed *at least* once a year as set forth in <u>45 CFR 46.109</u>. At Capella University, the IRB determines the review interval on a case-by-case basis, but no less than annually.

Continuing review and re-approval of research must occur on or before the IRB approval expiration date. Federal regulations do not permit the granting of grace periods extending the conduct of research beyond the expiration of IRB approval. Therefore, researchers must plan ahead to meet required continuing review dates and should allow sufficient time for development and review of renewal submissions.

Researchers are responsible for completing and submitting an IRB Continuing Review Form

and maintaining current IRB approval until all of the following occur:

- Participant recruitment has concluded (i.e., no recruitment is in progress or anticipated).
- All data collection has been completed (i.e. no further collection of data from or about participants is needed).
- All interactions or interventions with participants are completed (i.e. no further contact with participants is necessary or anticipated).
- For research that was reviewed by the fully convened IRB Board, the researcher must maintain IRB oversight during data analysis. Research reviewed at the expedited level is not required to maintain IRB oversight during data analysis unless otherwise determined by the IRB or Compliance Specialist. Researcher will be notified in writing if their study approved under expedited review requires IRB oversight during data analysis.

Although there is no maximum number of continuing reviews a study may receive, the IRB reserves the right to request that the researcher submit a new IRB application if circumstances dictate such a need.

#### Level of Continuing Review

Continuing review of a protocol is generally conducted at the level of the initial review and approval. However, under certain conditions (see <u>45 CFR 46.110</u>; <u>Expedited Categories 8</u> and <u>9</u>), a study initially reviewed and approved at a full IRB Committee meeting may be reviewed through expedited procedures.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories 8 and 9. It is also possible that research activities that previously qualified for expedited review, in accordance with <u>45 CFR</u> <u>46.110</u>, have changed or will change so that expedited IRB review would no longer be permitted for continuing review.

If, during the course of continuing review, the reviewer identifies study procedures which could subject research participants to increased risk of harm, the reviewer may request revisions to minimize the risk or refer the study for full review, even if the study was initially approved under expedited criteria.

#### Lapse of IRB Approval Prior to Continuing Review

IRB approval is considered to have lapsed at midnight on the last day of the approval period. Review of a study modification ordinarily does not alter the date by which continuing review must occur as continuing review is a review of the full study, not simply a change to it.

If a researcher has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, research activities as outlined in the numbered list above must stop unless the IRB finds that it is in the best interests of currently enrolled individual participants to continue participating in the research interventions or interactions (usually applicable only in biomedical research). Enrollment of new participants cannot occur after the expiration of IRB approval.

Failure to maintain current approval may disqualify research data. Continuing to conduct study procedures during lapses in approval may also result in corrective actions.

#### **Studies Approved but Never Started**

Circumstances sometimes dictate that a study is approved yet never started (i.e. no participants were enrolled in the study). In such a situation, a researcher may seek continuing IRB approval through expedited procedures in accordance with <u>45 CFR 46.110;</u> <u>Category 8</u>. Please note that it may be necessary to obtain updated research site permissions and/or make other updates as needed. If the study is finally canceled without participant enrollment, records will be maintained for at least three years after cancellation.

#### **Study Modifications**

Researchers who wish to modify or amend their approved applications must notify the IRB and seek IRB approval **before making any changes** in approved research. Modifications do not extend the original IRB approval data and a modification does not replace continuing review.

#### **Notification of Modifications**

Grammar fixes or corrections of typos in participant facing materials (consent forms, recruitment materials) do not require IRB review and approval. Researchers must contact the <u>IRB Office</u> via email summarizing the proposed changes to the approved IRB application prior to using the revise materials. The IRB Office will notify the researcher if they need to submit an *IRB Modification Form* with required supporting documentation for formal review of the modification. The IRB Office will acknowledge modifications that do not require an *IRB Modification Form* via email.

IRB Office Staff reserves discretion to determine what constitutes a minor change.

In the case of a major modification (change in recruitment strategy, data collection methods, study methodology), the IRB may require the researcher to submit a new application and that the entire study be re-reviewed by the IRB. The IRB may request that a researcher who has proposed significant modifications to study procedures or design resubmit the study as a new project, subject to review by the IRB per its standard review procedures.

#### **Review & Approval of Modifications**

The IRB Specialists will determine the level of review required for proposed changes The IRB Specialist may review administrative or exempt level modifications.

Modifications that require expedited review will be reviewed by the original reviewer when available. Modifications that require full review will be sent to the full committee for review.

#### Modifications Requiring Committee and/or School Approval

If the researcher changes the study methodology, they must obtain school approval of the modification before submitting to the IRB. The researcher must work with their mentor to coordinate the review of the proposed changes. The researcher must submit an updated Research Plan/Proposal/SMART form along with documentation of school approval to the IRB in these instances.

#### Modifications Requiring Site Notification and/or Permission

Modifications that are administrative in nature and do not impact risk to participants require written notification to the research site. Such notification may occur through an exchange of email. Substantial modifications that increase risk to participants, significantly alter study procedures, or impact study design require that researchers obtain updated letter(s) of

permission from the research site(s). Cosmetic modifications do not require site notification or site permission.

#### **Emergency Modifications**

In emergency situations, a change may be necessary to eliminate apparent immediate hazards to the research participants. In such cases, the researcher should inform the IRB of the change following its implementation, ideally within 24 hours. The IRB will review the change to determine whether it is consistent with ensuring the participants' continued welfare.

#### **Participant Notification**

When the IRB reviews modifications to previously approved research, it must consider whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

#### **Exceptions**

Researchers may also request a one-time exception from their IRB-approved protocol in order to temporarily deviate from rather than modify their IRB-approved study procedures. Exceptions may be appropriate when one of several research sites requires a minor change to recruitment procedures or when the researcher would like permission to enroll a participant that does not meet the inclusion criteria. Exceptions may be approved by IRB Staff if they do not increase risk to participants or alter the study design. Researchers seeking one-time exceptions must notify the IRB in writing prior to implementation by emailing <u>irb@capella.edu</u>. IRB Staff will acknowledge the exception request in writing. Requests for exceptions that may increase risk to participants must be reviewed by the IRB.

#### **Study Closure**

The completion of the study is a change in activity that must be reported to the IRB. Although participants will no longer be "at risk" under the study, completing the *IRB Study Closure Form* and submitting it to the IRB allows it to close its files and provides information that the IRB may use in the evaluation and approval of related studies. Continuing oversight from the IRB is no longer necessary once a study is closed.

Closure of a study occurs when one of the following is met:

- The researcher has completed data collection and data analysis, and acknowledges that he or she will no longer contact participants, enroll participants, collect further data for the study, or engage in analysis of identifiable participant data. In this scenario, the investigator must complete the *IRB Study Closure Form*.
- The IRB may close studies that have expired and the researcher has not submitted the Continuing Review Form. The researcher will be notified upon closure.
- In the event that the researcher withdraws from the university or is discontinued from the university and has an active IRB study, the IRB will close the study and notify the researcher of the closure and if any actions are required.

# CRITERIA FOR IRB APPROVAL OF RESEARCH

In the review of research involving human participants, Capella's Institutional Review Board (IRB) is guided by the ethical principles, guidelines and regulations described in these SOPs and Capella University policies.

## Sound Research Design

#### **Scientific Merit Review**

<u>45 CFR 46.111(a) of</u> the federal regulations governing the protection of human participants in research requires that IRBs evaluate the soundness of the research design as a fundamental part of ensuring protection for participants. In reviewing doctoral research, the IRB will rely upon the school's scientific merit review process to ensure soundness of the research design. In studies that present more than minimal risk to participants, the IRB may require changes to the study design if the potential benefits do not justify the potential risks.

#### **Instrument Permission**

Researchers must provide written documentation that permission has been granted to use existing instruments for their data collection. If the author is deceased, the researcher must obtain permission from the publisher of the instrument or the researcher's estate or heirs. Researchers who purchase a published instrument for use in their study must provide a copy of the purchase agreement. Failure to obtain permission to use an instrument represents an unauthorized use of the instrument and is a copyright violation. If the researcher is modifying an existing instrument the permission letter must state clearly the researcher may use and modify the existing instrument.

Permission to use an instrument in a study is not the same as permission to publish the instrument as part of the research findings. Researchers intending to publish the instrument must seek specific permission to do so.

#### **Expert Review**

The IRB may request an expert review of instruments or interview guides when there is concern over their appropriateness for the population.

#### Instrument Reliability/Validity: Pilot Study

A pilot study may not be conducted without IRB approval. If a researcher needs to conduct a pilot study in order to assess the validity of his or her instrument this should be specified in the IRB application. If the pilot study results in changes to the proposed study procedures, researchers must submit a modification to the IRB and obtain approval before beginning study procedures.

#### **Conflict of Interest Assessment**

Researchers are responsible for disclosing any personal relationships or financial interests that may present conflicts of interest and for developing a plan to eliminate or manage potential conflicts of interest. The full IRB Committee or designated reviewer will make a determination as to whether the conflict adversely affects the protection of human participants and whether the conflict management plan adequately protects human participants.

If a conflict of interest develops or changes during the course of a study, the researcher must notify the IRB. The IRB will review this as a modification to the study.

Please see Capella University's Policy <u>3.03.05</u> for additional information.

#### **Minimization of Risk**

In accordance with <u>45 CFR 46.102(i)</u>, <u>45 CFR 46.111</u>, and applicable subparts, the IRB will assess the risk to participants. Risks associated with the research will be classified as either "minimal" or "greater than minimal." The IRB will also determine whether risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk—and, whenever appropriate, by using procedures already being performed on the participants.

#### **Risk/Benefit Ratio**

In accordance with <u>45 CFR 46.111</u>, the IRB will determine whether the risks to the participants are reasonable in relation to anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result.

#### Informed Consent

Capella University requires researchers to obtain informed consent from all human participants or their legal guardians prior to any research-related interactions in accordance with <u>45 CFR 46.111</u>, <u>45 CFR 46.116</u> and <u>45 CFR 46.117</u>, and applicable subparts.

#### Parent/Guardian Permission and Child Assent

Capella University requires researchers to obtain informed parental consent and child assent prior to any research-related interactions with children in accordance with Subpart D of the Code of Federal Regulations: Additional Protections for Children Involved as Subjects in Research (<u>45 CFR 46.408</u>).

#### Waiver of Documentation of Informed Consent

Capella University's IRB may allow for a waiver of documentation of informed consent in accordance with <u>45 CFR 46.117(c)</u>.

#### Deception/Incomplete Disclosure

A study that utilizes deception or incomplete disclosure may require review by the full IRB Committee. Studies involving deception will be reviewed by the IRB in accordance with the ethical principles as described in these SOPs.

#### **Selection of Participants & Recruitment**

The IRB will evaluate the recruitment strategy and selection of participants in accordance with the ethical principles as described in these SOPs, paying particular attention to  $\underline{45 \text{ CFR}}$   $\underline{46.111(a)3.}$ 

#### **Site Permissions**

Researchers must have written authorization from an authorized official to recruit participants, use directory information, or conduct research involving another institution, organization, or corporation. Implied consent does not constitute adequate site permission.

To be considered sufficient, permission letters from outside organizations must

- be written on the organization's official letterhead
- be signed by an IRB Chair (if applicable) or other official within the organization
- be dated within six months of IRB submission

• clearly state that the researcher has the organization's permission to conduct his/her research at the organization

Researchers engaged in research involving participants recruited from schools, Veterans Administration (VA) facilities, military sites and other complex organizations should be aware that multiple permissions are often required (for example from the school district and the individual school or from the commanding officer and the Army Research Office).

It is incumbent on the researcher to determine who has the authority to issue permission to conduct research at the site and to ensure adherence with all policies and procedures relating to obtaining permission to conduct research at the site. In cases in which it is unclear whether appropriate permission has been obtained, the IRB may require researchers to submit documentation (such as organizational charts or policies and procedures) or may consult with the site directly to verify that the appropriate permissions have been obtained.

## Site Permission that Requires a Research Contract

In some cases, a site may require the learner or the university to enter into a contractual agreement in order for the researcher to access records (data) or recruit participants and collect data. These contracts are often (but not always) referred to as Affiliation Agreements, Memos of Understanding, Research Agreements or Data Usage Agreements. Researchers, mentors, and other university stakeholders must follow the appropriate procedures to ensure appropriate review of these agreements.

#### Agreements Requiring Capella University Signature

If the agreement names Capella University as a party to the contract (or requires a mentor, chair, or other university official to agree to conditions of the agreement) the researcher must be aware of the following:

- Capella University legal review is required of all agreements requiring Capella University signature. The researcher must provide a copy of the contract to the IRB Office in order to initiate this review. It is recommended that doctoral researchers initiate this process as early in their dissertation or doctoral capstone process as possible to allow adequate time for the review process or in the event that the contract cannot be signed.
- Learners, mentors, and chairs may not sign on behalf of Capella University and no agreement may be signed without legal review and approval.
- There are certain data usage agreements that Capella University cannot sign due to the data handling requirements. Researchers should consult the iGuide <u>Site</u> <u>Permission</u> guidance for a current list of restricted data sources.

#### **Agreements Requiring Researcher Signature Only**

University legal review is not required, but the IRB is unable to approve any studies in which the agreement contains conditions that go against Capella University policies and practices or which contain clauses that put participants at risk. Therefore, it is strongly recommended that the researcher has the agreement reviewed by the IRB early in the process (prior to submission to the IRB). Additionally, the researcher must provide any contract (signed or not) to the IRB as part of the IRB Application for review.

# **Incentives for Participation**

Capella University recognizes that researchers may sometimes use incentives to encourage participation. Researchers who are planning to provide an incentive must provide specific details about it on the IRB application and in their consent/assent documents. The incentive must be commensurate with the time the participant spends in the study and/or compensation for travel to partake in the study. Incentives may not be coercive in nature and cannot be listed as a benefit for participating in the study. Incentives of \$25-\$50 (or the equivalent in goods and services) are generally considered appropriate for the type of research typically conducted by Capella University doctoral students. However, depending on the nature of the research, more may be approved by the IRB as long as the incentive is not determined to be coercive. State law may also prohibit incentives for prisoners; explicit guidance and permission should be sought from correctional facilities regarding the use of incentives.

# Privacy, Confidentiality, Anonymity

The IRB will assess whether there are adequate provisions to protect the privacy and confidentiality of participants and their data in accordance with <u>45 CFR 46.111(a)</u>. The IRB must ensure that recruitment, screening, enrollment, and data collection procedures protect participant privacy and confidentiality and that plans are in place to manage, store, and destroy the data once it has been collected. In order to ensure participant privacy and confidentiality, researchers must not disclose identifying information of either participants or research sites in their report of findings. Maintaining *confidentiality* means that only the researcher can identify the responses of individual participants. In contrast, providing *anonymity* means that the researcher does not collect identifying information of individual participants and cannot link individual responses with participants unless it is essential to the research design.

# **Records Retention**

Capella expects researchers to maintain and destroy their records in accordance with Institutional Review Board (IRB) approved data storage plans. Generally, Capella's IRB requires that records be maintained for a minimum of seven years after the completion of the study; however, there may be particular circumstances that warrant exceptions. Records include identifiable data, informed consent forms, all communications with participants, and all other documents which could link participants to a particular study.

# Special Categories of Participants/Vulnerable Populations

# Capella University Faculty, Staff, and Learners

Researchers seeking to recruit Capella University's alumni, learners, staff, or faculty for primary research (data collection such as surveys) or utilize Capella University data for secondary research must obtain site permission through Capella's formal review process, which is separate from IRB review. Researchers are encouraged to consult with IRB Staff regarding the feasibility of their proposed plan early in the research design process, as University permission is granted in limited circumstances.

# **Pregnant Women**

The federal regulations define pregnant women as an especially vulnerable population (<u>45</u> <u>CFR 46 Subpart B</u>). Prior to targeting or including pregnant women as participants in a study, researchers must assess whether the research poses particular risk to the pregnant woman or the pregnancy. Pregnant women may be particularly vulnerable to certain research involving direct interventions that may cause physical or psychological distress. However, pregnant women need not be classified as a particularly vulnerable population if studies do not present such risks. Researchers targeting pregnant women in particular should consult with IRB staff.

#### Prisoners

In response to egregious abuse of prisoners in research, the U.S. government has implemented regulations for additional protections for prisoners in research. These regulations, as set forth in <u>45 CFR 46 Subpart C</u>, limit the types of research that can be conducted with prisoners, mandate that prisoner representatives serve on IRBs engaged in review of prison research, require federal review and monitoring of certain types of research with prisoners, and offer additional safeguards for prisoners to prevent coercion and abuse.

Capella University's IRB may approve research with prisoners that falls into <u>45 CFR</u> <u>46.306(a)[2]i-ii</u>, but does not allow researchers to conduct research involving prisoners that falls into <u>45 CFR 46.306(a)[2]iii-iv</u>.

#### Children/Minors

The federal regulations define children as an especially vulnerable population and mandate additional safeguards to protect children and minors involved as participants in research.

Capella University's IRB may approve research that poses less than minimal risk to children and minors as set forth in <u>45 CFR 46.404</u> when adequate provisions are made for soliciting the assent of the child/minor participant and the permission of their parents or guardians, as set forth in <u>45 CFR 46.408</u>.

Research involving greater than minimal risk to children and minors is not supported by Capella University.

# **Other Vulnerable Populations**

While the federal guidelines require additional safeguards for children, pregnant women, and prisoners, other groups may also be particularly vulnerable. Researchers should take extra precautions in ensuring the rights and welfare of socio-culturally or medically vulnerable groups, targeted racial/ethnic groups or genders, individuals targeted because of their sexual orientation, institutionalized individuals, international individuals, soldiers, military personnel, and veterans. In addition, when researchers involve students and workers in research on education and employment, it is important to guard against coercion and to consider the extra vulnerability of these individuals in such situations.

#### State & Local Guide Lines & Regulations

State and local laws relevant to the protection of human participants must be applied when they offer more stringent protections for human participants than federal regulations. State and local laws relevant to research with human participants vary greatly, particularly in regard to the legal age to consent, regulations concerning data retention, and provisions for mandatory reporting. As Capella University's researchers conduct research in all fifty states, Capella University requires researchers to consult their own state and local guidelines and regulations when designing their research and applying for IRB approval.

# **International Guidelines & Regulations**

Capella University researchers seeking to conduct research in international settings must follow international regulations and guidelines for research with human participants. International research often requires additional safeguards to protect the rights and welfare of participants. Such protections include everything from the use of a translator if the researcher is not fluent in the participant's language, to waiving the requirement to obtain written consent due to local custom or because of risks participants may face due to social or political conditions, to changing data retention practices to meet international standards. Researchers must include local community representatives and/or researchers in the design of the research and consent processes to ensure that local concerns about research practices or cultural norms are considered. Capella University requires researchers to consult the <u>OHRP</u> website for a listing of the laws, regulations, and guidelines that govern research in countries outside the United States, to contact local Universities and government agencies for guidance, and to formally secure permission to conduct research at international sites. Capella researchers seeking to conduct research internationally are encouraged to seek out those already engaged in such activities to explore the possibility of collaboration or to seek guidance on responsible practices. It is incumbent on the researcher to obtain sufficient resources and oversight to allow for the responsible conduct of international research and to provide documentation of this to the IRB.

# Health Insurance Portability and Accountability Act (HIPAA)

Researchers who are working with Protected Health Information (PHI) from other institutions that are covered entities will need to comply with the rules on HIPAA including the Privacy Rule and the Security Rule. Additionally, the researcher must obtain the appropriate consent from the potential participant if accessing identifiable PHI.

# Family Education Rights and Privacy Act (FERPA)

Researchers are responsible for meeting <u>Family Educational Rights and Privacy Act</u> (FERPA) regulations when accessing education records. Researchers must also follow the relevant policies and procedures of individual districts and schools. FERPA provides specific protections regarding the privacy of student education records at educational institutions receiving U.S. Department of Education funding. Directory information is not considered part of the education record protected under FERPA. An education record may be obtained for research purposes in one of the following ways:

- The researcher may, with the written approval of the educational institution, contact and obtain written parental or eligible student (18 years old or older) consent to access the record. The consent must specify the record(s) to be disclosed, the specific purpose of the disclosure, and who will have access to the record. This consent does not replace informed consent requirements as outlined in 45 CFR 46.
- A school official with legitimate access to the record may strip the record of identifying information and provide the data to the researcher.
- The educational institution holding the record may invoke an exception to FERPA in order to release the record to the researcher.
- FERPA stipulates that schools have the authority to determine what directory information may be accessed, when parental/eligible student permission is required, and when an exception to FERPA may be granted. Researchers must consult district and school policy relating to FERPA and must obtain written documentation from school officials indicating whether and how the record may be accessed.
- Capella's Institutional Review Board (IRB) has the authority to request additional measures to protect the rights and welfare of human participants which may exceed



the guidelines set forth in FERPA, including requiring student or parental consent even if the school provides documentation to allow for a waiver.

# IRB DECISIONS

All research submitted to Capella's Institutional Review Board (IRB) will be designated as outlined below. Only research designated as "Approved" may proceed. Studies receiving any other designations must be resubmitted until approval is granted.

Although the IRB maintains documentation of studies that are withdrawn, they are not subject to further processing or IRB review.

# **IRB Review Outcomes**

#### Approve

A study that is designated approved meets the ethical standards for research and does not require any changes. Researchers who have obtained IRB approval may begin recruiting and interacting with potential participants. Doctoral researchers who have obtained IRB approval must follow all additional school requirements prior to commencing research activities.

#### **Duration of Approval**

The IRB will make a determination regarding the frequency of review of the research study. Federal regulations require approved studies to be reviewed by the IRB at least once a year in accordance with <u>45 CFR 46.109(e)</u>. However, some studies may require more frequent continuing review.

#### **Approve with Conditions**

Approval with conditions signifies that the proposed study generally meets ethical standards but requires minor changes prior to full approval. Examples include minor corrections to informed consent forms or recruitment materials or documentation of site permission.

Absolutely no research related activities, including recruitment of study participants, may begin until full approval is granted.

#### Defer

A study that is deferred contains elements that are inconsistent with the standards for ethical research and lack sufficient safeguards to protect human participants. Required changes may be minor, requiring only a few revisions, or may be major, requiring substantial revisions. The researcher must submit revisions(s) for review and approval before engaging in any recruitment or research-related interactions with potential participants.

A proposal that qualifies for Exempt or Expedited review that has been deferred will be reevaluated by the reviewer(s) once revisions are made. A proposal that has been deferred by the full IRB Committee must be reevaluated during a convened meeting of the IRB.

If a study submitted by a doctoral learner requires major changes to the research plan, it may be necessary to consult with the school. Revisions to the research plan may be subject to further scientific merit review.

#### Disapprove

A study that has been disapproved does not meet the ethical standards for research and its potential risks are unreasonable in relation to its anticipated benefits. According to federal regulations, only the full IRB committee may disapprove a proposed study (<u>45 CFR</u> <u>46.110[b]</u>).

Doctoral learners whose studies have been disapproved are encouraged to work with the Research Chair or Lead of their school in order to develop a study that meets the ethical standards for research.

#### Exempt

The study meets the criteria for Exemption as set forth in <u>45 CFR 46.101</u> as well as Capella's ethical standards for research.

#### Not Human Subject Research (NSHR)

After an administrative review by an IRB Specialist, the IRB may determine that the research doesn't meet the definition of Human Subject Research as defined in <u>45 CFR</u> <u>46.102(d)(f)</u> and therefore IRB review is not required. The IRB will still ensure that the research has site permission and ensure compliance with other Capella University requirements for the conduct of ethical research during the administrative review before determining the study to be NHSR.

#### Suspend

A decision by the IRB Chair, Compliance Specialist, or full IRB Committee to temporarily withdraw approval for research activities. The IRB Chair or the Compliance Specialist may make the decision to suspend on an emergency basis, but the decision must be confirmed by the full IRB Committee during a convened meeting.

#### Terminate

A decision by the full IRB Committee to permanently withdraw approval for research activities.

#### Notification

All actions and determinations will be communicated to the researcher.

#### Appeal

If the study is disapproved by the fully convened IRB committee, the researcher may appeal the decision. The appeal must be submitted to the IRB within 30 business days.

All appeals must be reviewed by the full IRB Committee. Once the IRB Committee makes a decision concerning a specific appeal, that decision is final and cannot be overturned.



# **IRB Record-keeping Procedures**

The IRB will maintain documentation of its activities in accordance with federal regulations in accordance with <u>45 CFR 46.115</u>.

# **OVERSIGHT & COMPLIANCE**

# **Oversight**

The Institutional Review Board (IRB) maintains its responsibility to protect human participants through each stage of the research process. In addition to continuing IRB review of approved protocols, the IRB will conduct ongoing monitoring of research activities.

# Audit of Approved studies

As part of Capella University's ongoing commitment to ensure compliance with federal regulations and Capella University's RI SOPs, studies may be audited by the Compliance Specialist (or the designee).

# Compliance

Capella University will conduct inquiries and investigations to assess researcher compliance with federal, state, and local regulations as well as Capella University policies.

## Allegations

Institutional Review Board (IRB) Members, IRB Staff, mentors, and others engaged in the design, conduct, or supervision of research are required to report any observed, suspected, or apparent non-compliance to the IRB. This refers to all non-compliance, not just serious or continuing non-compliance. Allegations relating to Research Misconduct will be handled according to Capella University's <u>Research Misconduct Policy 03.03.06</u> while allegations of Academic Dishonesty will be handled according to Capella University. <u>Academic Honesty Policy 03.01.01</u>.

Examples of allegations of non-compliance include but are not limited to:

- The researcher has exerted undue influence while recruiting participants.
- There is an undisclosed/unmitigated conflict of interest.
- Research has been conducted without approval.
- Research has been conducted following lapse of approval.
- Changes were made to the study without IRB approval.
- The researcher failed to report participant concerns, adverse events, or unanticipated problems.
- Researcher changed study materials and/or study procedures without IRB approval
- Researcher did not followed the approved IRB Application (information contained within research proposals to the school including but not limited to research plans, scientific merit review forms, research proposal forms, but not on the IRB application is considered not approved by the IRB.

#### **Inquires & Investigations**

The IRB will investigate (or appoint an individual or entity to investigate) all credible allegations or reports of non-compliance. The level of investigation will depend on the seriousness of the situation and the potential risk to participants.

All allegations of non-compliance will be referred to the Compliance Specialist. Within approximately five business days of receiving an allegation of potential non-compliance, the Compliance Specialist will initiate an inquiry to determine whether the allegation has a basis in fact and/or necessitates further investigation. All inquiries will be fully documented. If the inquiry reveals minor non-compliance, the Compliance Specialist will notify the researcher and determine any necessary remediation. If the inquiry reveals serious or continuing noncompliance, the Compliance Specialist will conduct a full investigation. Investigations of IRB-approved research studies are in response to identified concerns resulting from an initial inquiry. The purpose of an investigation is to identify non-compliance and to determine any corrective actions needed to ensure the protection of human research participants. The Compliance Specialist may choose to consult the IRB Chair, IRB members, the RCC, IRB staff, legal counsel, or other experts in investigating potential non-compliance.

Researchers are required to cease all research-related activities including recruitment, enrollment, data collection, and data analysis while an investigation is underway. Any administrative hold of research must be communicated to the researcher and, if applicable, the mentor. An administrative hold does not constitute a formal suspension.

Those responsible for conducting inquiries and investigations will adhere to the following principles:

- Capella University must vigorously pursue and resolve any allegation of noncompliance with regulations concerning the review and conduct of research involving human participants.
- All parties must be treated fairly, bearing in mind the sensitive nature of academic reputations.
- Confidentiality must be maintained to the maximum practical extent; FERPA requirements must also be upheld.
- Conflict of interest, real and potential, must be minimized.
- All stages of the procedure must be fully documented.
- Capella may be required to inform appropriate agencies of findings of noncompliance.

#### Findings of Non-Compliance

When non-compliance is determined to be minor and sporadic, the Compliance Specialist will make a determination concerning appropriate corrective actions and work directly with the researcher to remediate the issue.

When the non-compliance is determined to be serious (moderate to serious risk to participants/harm done) and/or continuing, the Compliance Specialist will notify the IRB and the RCC. If the study is active, the IRB will convene for the purpose of deliberation and decision-making concerning whether to suspend or terminate IRB approval. The RCC will convene to determine whether any additional corrective actions or sanctions are required.

#### Suspension, and Termination

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to participants. Decisions to suspend or terminate IRB approval of a study may only be made by the IRB committee during a convened meeting.

When the IRB suspends or terminates its approval it will include a written statement of its reasons and report the suspension or termination promptly to the researcher.

The IRB may require the researcher to notify participants that the study has been suspended or terminated. The IRB will consider whether procedures for withdrawal of enrolled participants are necessary to protect the rights and welfare of the participants, and whether alternative procedures such as allowing continuation of some research activities under the supervision of an independent monitor or requiring or permitting follow-up of participants for safety reasons need to be implemented.

#### **Corrective Actions and Sanctions**

The RCC has the authority to determine corrective actions and/or sanctions as a result of non-compliance. Corrective action will depend on the degree (minimal to no harm vs. moderate to serious harm) and frequency (sporadic vs. continuing) of non-compliance.

Possible corrective actions for non-compliance include education and training, notification of site, formal letter of apology to site or participants, termination of research at a particular site, or exclusion of data from the study.

#### **Notification of Non-compliance Findings**

All non-compliance findings will be communicated to the researcher. The extent of further communication will be determined on a case-by-case basis. In studies that had military approvals, disclosures may be necessary to the DoD per Capella University agreements with the DoD. If other IRB's reviewed and approved the research, the Compliance Specialist will report the findings of non-compliance to the other IRBs that approved the research. In the rare circumstance that the researcher obtained federal funding (though an entity other than Capella University) the non-compliance may be disclosed to the Office for Human Research Protections (OHRP) as the regulations require.

#### **Appeal of Non-Compliance Findings**

Once the researcher has been notified of the decision, he or she has 10 business days in which to **respond to the decision in writing** in order to request additional information or clarification. If a decision has been made to suspend or terminate the research, the researcher may also make a request in writing to attend the next IRB meeting to discuss the suspension or termination.

# **PARTICIPANT CONCERNS**

# **Research Participant Questions & Complaints**

Compliance Specialist or a designee will promptly handle, and, if necessary, investigate all complaints, concerns, and appeals from research participants. The confidentiality of participants will be maintained during all such investigations.

## **Adverse Events & Unanticipated Problems**

Incidents occurring during the course of a research study that may constitute unanticipated problems and/or adverse events should be reported to the IRB within 24 hours. The Compliance Specialist will investigate all reports of possible adverse events and/or unanticipated problems.

If an unanticipated problem and/or adverse event occurs that involves risk to participants or others, or that cannot be adequately resolved, the IRB will convene for the purpose of deliberation and decision-making concerning a resolution, which may include suspension or termination or modifications to the approved protocol.

The IRB will also make a determination as to whether past or currently enrolled participants should be informed of the adverse event or unanticipated problem.

# **APPENDIX A: ABBREVIATIONS & ACRONYMS**

# CFR

Code of Federal Regulations

# СІТІ

Collaborative Institutional Training Initiative

## DHHS

Department of Health and Human Services

## **FERPA**

Family Educational Rights & Privacy Act

# FDA

Food & Drug Administration

## FWA

Federalwide Assurance

#### HIPPA

Health Insurance Portability and Accountability Act

#### HRPP

Human Research Protection Program

## 10

Institutional Official

#### IRB

Institutional Review Board

#### NIH

National Institutes of Health

#### OHRP

Office of Human Research Protections (formerly, Office for Protection from Research Risks)

#### PHI

Public Health Information

#### QA or QI

Quality Assurance or Quality Improvement



# CS

Compliance Specialist

# RCC

Research Compliance Committee

# SOP

Standard Operating Procedure

# APPENDIX B: GLOSSARY OF TERMS

#### Adverse Event

Any physical, psychological, or social harm to participants during the course of research.

#### **Allegation of Non-Compliance**

An unproved assertion of non-compliance.

#### Assent

"Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research." (http://www.hhs.gov/ohrp/irb/irb\_glossary.htm).

#### Benefit

A valued or desired outcome; an advantage

#### Children

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

#### **Conflict of Interest**

A situation in which academic, financial, or other personal considerations or obligations have the potential—either actual or apparent—to directly and significantly compromise an individual's or group's professional judgment and objectivity in designing, conducting, reviewing, or reporting research.

#### Deception

In research, the term *deception* refers to deliberately misrepresenting some aspect of the research study or providing false information about it to the participants. Some distinguish deception from "incomplete disclosure," using the latter term to describe situations when the researcher withholds information from the participants about the true nature of the study in order to enhance the validity of the research. Either way, the information that potential participants receive does not accurately reflect the true nature of the study.

#### **Expert Review**

Expert Review may be recommended to assess the appropriateness of interview guides, questionnaires, or other researcher-created instruments. Experts in the field review the questions and offer feedback to the researcher about whether the questions are appropriate for the population, whether they will make sense to the population, and whether they represent the perspectives of the field. Experts in the field typically include faculty, practitioners, or respected researchers. A field test generally does not include people who meet the criteria for inclusion in the study, and expert reviewers are not asked to complete the instrument but rather to provide feedback on the instrument. Expert review may therefore be conducted prior to IRB approval.

#### Finding of Non-Compliance

An allegation of non-compliance that is proven true or a report of non-compliance that is clearly true.

#### Guardian

An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

#### Human participant

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

#### Inquiry

An informal review conducted by the Research, Education & Compliance Specialist, or designee to determine if an allegation has a basis in fact and/or necessitates further investigation.

#### Institutional Official (IO)

A high-ranking administrative officer who is authorized to act for the institution and assume overall responsibility for compliance with the federal regulations for the protection of human subjects.

#### Intervention

Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participants' environment that are performed for research purposes.

#### Interaction

Includes communication or interpersonal contact between investigator and participant.

#### Investigation

An investigation is a process of formal and documented information gathering to determine whether regulations concerning the review and conduct of research involving human participants have been violated and, if so, the degree of harm to participants resulting from the non-compliance.

#### Institutional Review Board (IRB)

An institutional review board established in accord with and for the purposes expressed in this policy.

#### **IRB** approval

The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

#### Minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. It is important to keep in mind that risk is not defined as "minimal" simply because it does not involve physically invasive procedures. There are many kinds of risk, including risk to employment, financial risk, psychological risk, risk to status, risk to reputation,

insurability risk, stigmatization, criminal/civil liability, etc.

#### Non-compliance

Failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

**Continuing non-compliance:** A pattern of non-compliance that, in the judgment of the IRB chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

**Minor or sporadic non-compliance:** Failure to comply with IRB policies, which in the opinion of the IRB chair and director (or designee) are administrative in nature. Examples of minor or sporadic non-compliance could include turning in a report of an unanticipated problem a day late or failure to date a consent form.

**Serious non-compliance:** Failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of either the IRB chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious noncompliance.

#### Parent

A child's biological or adoptive parent.

#### **Pilot Studies**

A pilot study uses actual participants from the population upon which the study will be based to assess the validity of instruments/tools. Pilot studies are typically recommended when a researcher has created an instrument that is intended to measure something, or when a researcher has modified a valid instrument to the point that new validity information is necessary. Pilot studies might also be used to establish whether an intervention or process is valid prior to engaging in a larger study. Often, the intent of a pilot study is to determine whether the instrument measures the construct it is intended to measure. Sometimes, the validation of a new instrument using a pilot study is in and of itself a formal research study; other times, a pilot study would be conducted with a small sample prior to implementing a larger study. Because pilot studies use participants and any study involving human participants or their records requires IRB approval, the pilot study must be approved by the IRB prior to implementation. Preferably, researchers should prepare only one IRB application covering both the pilot study and the actual research study. If a pilot study results in changes to the instrument, the IRB may need to review those changes prior to the instrument's use in a formal study.

#### **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 (for example, 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 participants.

#### Prisoner

Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

#### Research

According to the Code of Federal Regulations, "*research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (<u>§46.102 Definitions</u>).

#### Researcher

The primary individual, whether learner, faculty, or university staff, responsible for the design, conduct, and reporting of research of a given study.

#### Risk

The probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a research study.

#### Significant Financial Interest

Significant financial interest is anything of monetary value held by the researcher or research team members, their spouses, or dependent children exceeding an aggregate threshold of \$10,000 in a 12-month period or five percent ownership of \$10,000 value.

#### **Suspension**

Suspension of IRB approval is a directive of the convened IRB to temporarily stop some or all previously approved research activities. Suspended studies remain open and require continuing review.

#### Termination

Termination of IRB approval is a directive of the convened IRB to permanently stop all activities in a previously approved research study. Terminated studies are considered closed and no longer require continuing review.

#### **Unanticipated Problems**

Any event that (1) was unanticipated (2) is related to the research (3) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.

## Related to the research

An event is "related to the research procedures" if in the opinion of the researcher, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

#### Unanticipated

An event is "unanticipated" when its specificity and severity is not accurately reflected in the informed consent document. Such events may also be referred to as unexpected or unforeseen.