Standard Operating Procedures

Curry College Institutional Review Board (IRB)

May, 2022

Purpose: These Standard Operating Procedures (SOP) are meant to clarify the IRB's role in reviewing research involving human subjects proposed by Curry College students, faculty, and staff, as well as research proposed to take place on campus by Principal Investigators from outside our college campus. These SOP's are built upon the Curry College Charge, which was passed by the IRB and College Senior Staff in January 2019. The "Charge" provides detailed responsibilities for the Board, as well as a working list of defined terms, a Title IX policy, and details for IRB composition and training. The current document provides more detailed procedures for how the IRB operates with respect to types and frequency of reviews, workload for IRB members, potential actions the IRB can take, and reporting for noncompliance.

This document generally follows the organization of the Health and Human Services, Office of Human Research Protections, "IRB Review Board Written Procedures: Guidance for Institutions and IRBs (2018)." The following sections will describe the IRB's scope and authority, the review of research process, the frequency of review, IRB member constitution, reporting of proposed changes to the IRB, and the process for reporting of unanticipated problems and serious and continued noncompliance.

Sections

I. IRB Scope and Authority

a. Defining "research" within the jurisdiction of the IRB at Curry College

The federal definition outlines "research" as:

> "a systemic investigation, including research development, designed to testing and evaluation, designed to develop or contribute to generalizable knowledge."

In addition, this Board will review "research" involving human subjects that may not necessarily be likely to produce generalizable knowledge, but where the methodology or subjects involve some vulnerability to subjects or the researchers.

In determining whether a proposal requires review by the Board, the IRB Chair, an appointee of the Chair, or the entire Board will consider a proposal's risks to human subjects.

This includes research which is a collaboration with other entities/institutions, funded or not.

b. **Distinguishing between classroom assignments and research**.

In general, when distinguishing between "research" and "classroom assignments" which may involve quasi-research, if the participants involve only those inside the class OR if the data collected will only be utilized inside the class (and not be disseminated beyond the class itself), the activity would not qualify as "research" under the IRB authority. If, however, the participants involve those outside the class, or the data collected was intended to be distributed outside of the class, the IRB would retain authority.

c. Research emanating from outside our College

Curry's IRB requires all research which takes place on the campus by reviewed by the Board. Even if another institution's federally recognized IRB has approved the research, we reserve the right to review such research, and if appropriate, require modifications to ensure the safety of human subject participants. While our IRB recognizes that deferral to another IRB ("single IRB approval") is both efficient and recommended by HHS, we also may be aware of institutional circumstances which necessitate additional considerations.

d. Research by Curry Students

All research proposals by undergraduate and graduate students must have a sponsoring faculty or staff member to be considered for IRB approval. No student may submit their own proposal directly to the IRB without both faculty sponsorship and a commitment for ongoing faculty supervision.

d. Research by Curry Part Time Faculty

Any research proposed by part-time faculty (including Senior Lecturers) must be either co-sponsored by a full-time faculty member, or approved by the Department Chair.

e. Research Funded by an External Agency

For any research funded by a federal or any other external funding agency, the IRB will follow the stipulated guidelines to ensure compliance.

f. Exclusions

Under the revisions to the Common Rule (effective January 2019), there are several limited exclusions to the federal definition of "research." These exclusions include some "scholarly activities" involving "oral history, biography, literary criticism, journalism and legal research." Please note that this exclusion involves *activities* (not entire disciplines) that have been deemed not to qualify as research under this definition. OHRP provides the following guidance on this exclusion: "The objective of the activities in this category is to provide an accurate and evidence-based portrayal of the **individuals involved**, and not to develop generalizable knowledge." In addition, there are other exclusions involving mandated public health, criminal justice, or national security officials. For a full list of exclusions see 45 CFR 46.102 (l)(1-4).

To determine whether a proposed study falls under one of these exclusions, Principal Investigators should consult with the IRB Chair.

II. Initial and Continuing Review of Research, Reporting IRB Findings and Actions

Criteria for Review

The IRB will complete their review consistent with 45 CRF 46.111 stipulations, but broadly review will attempt to ensure that risks have been minimized, that risks have been balanced against the anticipated benefits, and that the selection of subjects has been equitable. Our IRB is particularly cognizant when identified subjects may be vulnerable due to age/youth, prisoner/institutionalized status, disability, or those with "impaired decision-making capacity."

As appropriate, the IRB will review proposed monitoring systems to assess clinical or research impact for studies.

The IRB requires that all documentation, including the Informed Consent and interview protocols or recruiting materials, and any other relevant materials, be reviewed as part of the vetting process. Further, the IRB requires all Principal Investigators submit a CV with all proposals.

The IRB shall create a Canvas resource/training site for all students, faculty and staff to utilize to prepare them for research with human subjects. Faculty, staff, and students who submit proposals will be required to familiarize themselves with these resources in order to facilitate submissions. The site will contain resources on informed consent, risk & risk mitigation strategies, the importance of literature reviews to human subjects

research, privacy and confidentiality protections, and creating survey questions considering vulnerable populations and sensitive topics. (3/22)

Consistent with the revised Common Rule (post 2018) guidelines, the Curry College IRB does not require grant proposals to be vetted by the IRB prior to submission. However, the IRB is available to consult on such proposals for informational purposes, at the Principal Investigator's request.

Determination of a proposal's level of risk

The IRB has exclusive jurisdiction in determining what type of review a proposal should have. To be clear: Principal Investigators may not determine Exemption status, even if they perceive low risk in a particular study. The heart of an IRB is to promote objective analysis of risk for the protection of human subjects, and to promote equitable subject selection, and to enhance, as appropriate, the informed consent process. If Principal Investigators have questions about where their research may fall, they should consult with the IRB Chair.

a. Types of Review

1. Exempt Review

The revised Common Rule allows for much research to be designated as Exempt. The first set of criteria pertains to whether there is no or minimal risk involved in the study, the subjects can give free and informed consent, and the release of data could cause no potential harm to subjects. If all of these criteria are met, the second set of criteria look to normal classroom activities or educational tests, benign behavioral interventions, or secondary data review. A detailed list of potential research methodologies is list in our updated Exempt Form Proposal (updated in November 2019).

i. Limited IRB Review

Please note that by mandate the Common Rule is not required to be applied to research determined to be Exempt. With that said, the revised Common Rule allows for a new category of "Exempt with limited IRB review" status. This category abbreviates the IRB review process for projects to ensure that consent is informed, data is protected, and adequate measures are in place to protect confidentiality.

Understanding this, our IRB interprets the phrase "designed to contribute or develop generalizable knowledge" subjectively. We understand that much student research is unlikely to be published or presented—sometimes due to limited resources or time to execute a study—sometimes for other reasons. With that said, the "exempt with limited

IRB" pathway means that even those studies which are unlikely to contribute to generalizable knowledge come through our Board. Our Board's rational for this type of review is to ensure the protection of human subjects. This layer of protection allows our IRB purview even if the design is unlikely to be published. For example, if a student were completing an Honors or thesis project on the prevalence PTSD with veterans. Even if the student had no plans to publish his data, the vulnerability of the subjects and the sensitivity of the topic mandates that our IRB review the methodology and provide appropriate provisions to protect subjects and data, minimizing risk.

The IRB is committed to providing Exempt review feedback within ten business days of receipt of all proposal materials, barring exceptional circumstances.

2. *Full Review Process*

Any research which does not qualify for Exemption or Expedition shall be reviewed by the full Institutional Review Board. Principal Investigators shall submit a full review proposal form (updated in November 2019), the informed consent, and as well all recruitment materials, and the PI(s) CV.

The proposal form requires PI's detail information pertaining to: the selection of subjects and any potential risks or vulnerabilities in such identified group, recruitment methods, the measures suggested to increase/enhance informed consent for participants, the study design, the measures identified to protect confidentiality of participants (as appropriate), and any measures to protect study data. The proposal form requires information whether there is any compensation or any potential benefit that could potentially be coercive in the informed consent process (for example, a large amount of extra credit to participate in a study, etc.). Further, the IRB will pay particular attention to any potential deception of subjects, as well researcher preparation to undertake the study.

In particular, the IRB will closely review the informed consent language and policies to ensure that all subjects will be aware of the risks and benefits in the research.

All IRB members shall review proposals up for full review. Depending upon disciplinary expertise of individual members, the IRB Chair may ask a particular member to lead the discussion for review.

The IRB meets once a month during the fall and spring semesters. PI's should have their materials submit to the Board one week prior to the scheduled meeting in order to have their project reviewed.

In the event of a proposal submit during summer months, the IRB Chair will work with the PI to determine whether the project can be deferred or is eligible for Expedited or Exempt review.

3. *Expedited Review Process*

Expedited reviews are a full review outside of a convened full meeting in accordance with 45 CFR 46.110, to be done by the IRB Chair or by her/his designee when a project has been determined to be "no more than minimal risk." In addition, expedited reviews can be used when a project which had previously obtained IRB approval has a brief update update/modification which does not make a substantial change in the research methods. All of the criteria stipulated in the full review section is germane in the expedited review process, and expedited proposals should be submit on the "Full Review" form.

The IRB is committed to processing Expedited Reviews within ten business days of receipt of all materials, barring exceptional circumstances.

The IRB will be kept apprised of all Expedited reviews and decisions at the next full IRB meeting.

a. Possible IRB Actions

Following a Full or Expedited Review, the IRB has four potential decisions which it can render. For full reviews, a quorum (a majority of voting members) must be achieved to vote on such proposals. Any member who may have a material interest in a proposal shall recuse themselves from any IRB vote; their vote shall not be tallied for the purposes of establishing quorum.

The decision of the Board shall be communicated in writing to the Principal Investigator(s) involved. The potential IRB actions are:

Approval- The IRB approves the project as proposed, and determines that the criteria for research approval have been met.

Approval with minor modifications- The IRB approves the project with minor stipulated modifications. In this event, the Principal Investigator is responsible to make such changes prior to commencement of the project.

Deferral- The IRB has deferred making a decision on the project. This could happen if the IRB requests further information or clarification, or if special circumstances in the environment make rendering a decision not prudent at the current time.

Disapproval- In this instance, the IRB disapproves of the proposal as written. In this event, the IRB Chair will write on behalf of the Board to the PI(s) to explain the rationale about why the project can not move forward. Risks will be outlined.

III. Frequency of IRB Review, Verification Regarding Material Changes

Approval Periods

The IRB may not approve a study for longer than a one-year term. Just prior to the conclusion of one year, Principal Investigators may request an extension to either complete the proposed research, or extend the research in some way beyond the initial scope. This request will be reviewed by the IRB Chair, her/his designee, or, if appropriate, by the full Board.

Verification Regarding Materials

The IRB will vet materials being employed in the methodology through the review process. For materials which may be already established by a third party (such as standardized or copyrighted surveys), the IRB will need verification of the third party's approval to utilize proprietary information. If such materials change during the course of the study, the PI should notify the IRB Chair in writing.

Final Reports

All projects that are reviewed and granted approval by the full Board shall submit a short written report (which may be administered via Qualtrics or other online software) to inform the Board of the progress made on the project, including any adverse events as a result of the research, any premature withdrawals from the research, or any other events/circumstances related to elevated risk.

Meeting Minutes

All meeting minutes will be taken by active members or support staff, in coordination with the IRB Chair. These minutes will be reviewed at the next meeting of the full board, and a vote will take place to approve such minutes, or make amendments as appropriate, determined by the Board.

Minutes may be requested by persons outside the IRB, and if granted, such notes will be redacted to protect any proprietary considerations contained therein. The IRB may share minutes with the Institutional Official (the Provost) if deemed appropriate by the IRB Chair.

These minutes, as well as all proposals and correspondence to PI's, shall be stored on the College's Sharepoint site via TEAMS, which is accessible by all IRB members.

IV. Reporting of Proposed Changes to the IRB; Prior IRB Review and Approval of Changes

Any modifications to any approved protocol must be sent to the IRB Chair in writing, who will then determine whether the changes are minor, or require further review by the full Board. As appropriate, minor study modifications that do not alter the level of risk may be reviewed via Expedited Review. For those modifications which substantially change the methodology or the level of risk, a Full Review by the Board may be necessary.

The IRB's decision on such changes shall be communicated in writing to the Principal Investigators. For those which follow Expedited Review, this will be done within ten business days. For full review, the written communication to the PI will occur within one week of the Board's meeting.

V. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, And Any Suspension or Termination of IRB Approval

Research Misconduct:

Community members should report evidence or reasonable suspicions of research misconduct to the Provost, who is the Institutional Research Officer. Allegations of research misconduct, including but not limited to failure to comply with IRB policy, will be reviewed according to the terms of the College's Employee Handbook and the Collective Bargaining Agreement with the Curry-AAUP, as applicable.

Further, as stipulated in the 45 CFR 46 113:

> "An IRB shall have 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 serious harm to subjects"

In this event of research misconduct, including but not limited to serious or continued misconduct, the IRB Chair, with discussion from the full Board, will work with the Provost (Institutional Officer) to issue appropriate action.

In this event, the Chair and Institutional Official shall notify the Office of Human Research Protections, as required by the Common Rule:

> 45 CFR 46.103(a) & 103(b)5 requires that all unanticipated problems involving risk to subjects or others, serious or continued noncompliance, and suspension or termination of IRB approval be reported promptly to the Office of Human Research Protections.

VI. IRB Membership

Nomination and Faculty Appointments

All members of the IRB will be appointed to the Board by the Institutional Research Officer (the Provost) for a three-year term. There shall be no term limits for Board members.

IRB Member Composition

The IRB will maintain the guidelines as set forth by 45 CFR 46 107, which stipulates that such body must maintain diversity of disciplines, gender and culture, including at least one non-affiliated member, and one non-scientist. The Board shall consist of no less than five voting members.

Ex officio members include the Dean of Faculty and the Institutional Research Director. As appropriate, the Chair may ask for alternate members to serve on the IRB.

Role of the IRB Chair

The IRB Chair shall hold the role for 3 year term, and the selection of Chair shall be made by the Provost, in consultation with the Board.

The IRB Chair shall maintain records for the IRB, and furnish such records as required by HHS.

The IRB Chair shall consult on whether a project is determined to be "activities not deemed research" and thus not subject to IRB authority.

The IRB Chair shall convene and facilitate meetings during the Academic Year on at least a monthly to process proposals. The IRB Chair shall provide notice to the College community by posting the dates for full Board meetings.

Institutional Official

The Provost will serve as the Institutional Official for the purposes of compliance with 45 CFR 46. All appointments to the IRB will be made by the him/her in writing to the IRB Chair.

IRB Member Training

All IRB members shall maintain their training certification through CITI or a comparable training program.

In addition, the Board will periodically be given ongoing training (either through online materials through Health and Human Services or by a training consultant). IRB members are also encouraged to enhance their training through relevant conference attendance (such as PRIM&R or SACHRP functions).

IRB Member Conflict of Interest

Any faculty member who has financial or other relevant stake (see below) in a particular proposal, whether direct or indirect, shall recuse themselves from review of such proposal.

Principal Investigators in research projects may have conflicts of interest on many different issues related to their research; this may involve conflicting interests related to publication, financial gain, benefit to family members, or with the College-related mission. The College maintains a Conflict of Interest Policy in the Employee Handbook (see Section 4.3 for details). This applies to all Curry College employees, including faculty, and requires a disclosure for self-identified conflicts and potential conflicts. Research-related conflicts of interest are covered under this Policy, and as such, a Conflict of Interest Disclosure form should be submitted to both the Chief Financial Officer and to the Provost for any case in which there may be a potential conflict between a researcher's role in executing research and in his/her execution of job responsibilities as an employee of the College.