INSTITUTIONAL REVIEW BOARD

CHARGE

January 2019

The Curry College Institutional Review Board (IRB) serves the College community consistent with our Federalwide Assurance (FWA) from the Office of Human Research Protections (OHRP). As such, we work in compliance with the Common Rule, also known as the Federal Policy for Protection of Human Subjects, generally keeping in place regulatory protections even when the research is not funded through a federal agency. Where there is ambiguity in appropriate measures to respond to research or proposed research, the Board defaults to uphold the protections defined in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). These principles include:

1. **Respect for persons:** Individuals should be treated as autonomous agents, capable of making informed decisions about participating in research activities. This principle recognizes the persons' right to have information about the nature of the research as well as their right to decline participation in the research at any time. Participation in research must be granted via "informed consent" and must be solicited without coercive influence.
2. **Beneficence:** Human research participants must be protected from harm and their overall well-being must be assured. Beneficence carries an obligation to "do no harm" and to maximize possible benefits for the person and society, while minimizing any harmful effects of the research.
3. **Justice:** The principle of justice requires that the burdens and benefits of research be shared to the greatest extent possible. Thus, researchers should endeavor to effectively represent the population of interest in their samples of research participants. In addition, the benefits of research knowledge and practice should be disseminated as widely as possible.

Responsibilities of the Institutional Review Board

The primary responsibility of the IRB is to review all (non-administrative) research involving human subjects at the College, particularly with respect to evaluating and mitigating risk, and enhancing informed consent for participants. Principal Investigators cannot make the determination of risk for their own research projects. In accordance with this, the IRB will:

- Review proposals for compliance with the Common Rule, the Federal Policy on the Protection of Human Subjects.
- Provide guidelines for review of research with human participants at Curry College.
- Provide information on the preparation of informed consent statements.
- Provide information on the protection of safety and confidentiality of research participants.
- Provide a calendar of meetings of the IRB, along with contact information and suggested time frames for submitting documentation and obtaining responses from the IRB.
- Conduct outreach to academic programs sponsoring and conducting research with human participants, including:
    - Consulting with faculty on developing course and program learning outcomes that address IRB procedures and ethical concerns of conducting research with human participants.
    - Serving as a resource for questions related to research with human participants.

The IRB **does not** review:

- Proposals for research that do not include human subjects
- Proposals for research that relate to the administration of the College (exclusively involving improving programming or quality assurance projects which are not intended to build generalizable knowledge). Such proposals are reviewed by the **Institutional Research Steering Committee** (IRSC).

The following material will outline this body's charge with respect to Composition, Training for Members, Processes for Proposals, Policy on Research Misconduct, and a

Statement on Research Conflicts of Interest, as well as a limited Title IX Exception. The next section will define terms.

1. IRB Composition

The constitution of the IRB is guided by regulations specified in 45 CFR 46.107, which mandate that the IRB must be comprised of at least five members who have "...varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution." The composition of the IRB must, 1) have diverse research backgrounds (representing both qualitative and quantitative scientific areas), 2) include at least one scientist and one non-scientist, and 3) have gender, racial and cultural diversity. Lastly, at least one community member must be on the IRB as well. In addition to these voting members, Curry's IRB also has several ex-officio members, including the Director of Institutional Research, the Dean of Faculty, and the Grants Coordinator. The Curry IRB shall be comprised of experienced researchers from many different disciplines.

All IRB members must be appointed by the Institutional Research Representative, who (at Curry College) is the Provost. Terms for IRB members shall be three years. Members are allowed to serve multiple terms.

2. Training for IRB Members

As part of the Federalwide Assurance, the IRB is required to participate in training for research involving human subjects. The College shall maintain membership with the Collaborative Institutional Training Initiative (CITI) (or an equivalent resource) for the purposes of IRB member and Principal Investigator training. IRB members shall be certified by CITI training modules, or a functional equivalent. The institution shall provide funds for ongoing educational opportunities for IRB members, consistent with 45 CFR 46.

3. Processes for Proposals

All faculty or student research (as defined by federal regulations) must be reviewed by the IRB through existing IRB processes, which are in compliance with 45 CFR 46. Faculty members cannot determine the level of risk for their own project. There are three types of review: **Full Board, Expedited, and Exempt** processes.

Generally, **Exempt** research is research where individuals can give free and informed consent, where there is no or limited risk, and the release of data can cause no potential harm to subjects. The 2019 OHRP guidelines both expand the types of research that qualifies as Exempt, as well as outline that even some Exempt research can go through

Definitions:

"Research"

Research is broadly defined as a **"systematic investigation designed to develop or contribute to generalizable knowledge."**

This would include—but is not limited to—any clinical investigations. It does not matter whether a researchers (faculty or student) intend to publish from the study.

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).

Please note that "generalizable information" does not require that the investigator have a plan to present or publish the findings; studies that involve human subjects require IRB review, if only to evaluate and mitigate the risk to the potential participants.

Please note that surveys are included in this definition.

"Human Subjects"

Our IRB follows the federal guidelines for research, which are defined in 45 CFR 46.102(e)(1).

> ***Human subject*** means 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.

"limited IRB review" in an expedited route. For a detailed list of exemptions, please

review the OHRP flowchart.

Generally, **Expedited Review** is appropriate for proposals that present no more than minimal risk. It is actually a **Full Review**, only done by one person (the IRB Chairperson or his/her appointed representative member). Expedited Reviews cannot disapprove any proposal; if there is a question of whether or not a proposal should be approved, it must be reviewed at the Full Board level.

Full Reviews occur for any research that falls outside the limitations stated above for Exempt and Expedited reviews. All of the appropriate forms are posted on the IRB portal.

The IRB maintains more detailed information on the process for proposals, in the **Frequently Asked Questions** document, which is also located on the portal.

The IRB shall meet at least one time per month during the Fall and Spring semesters. The schedule for IRB meetings shall be posted on the College portal.

4. Policies on Research Misconduct

Community members should report evidence or reasonable suspicions of research misconduct to the Provost. 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.

5. Policy on Conflicts of Interest

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.

6. Title IX Limited Exception

The following policy outlines a limited research exception for Title IX reporting around sexual violence, including sexual assault and other forms of interpersonal violence. Research geared toward understanding sexual victimization has the capacity to serve victims in that it may, 1) promote awareness around the various phenomenon of sexual assault, 2) inform the process of improving services for such victims/survivors, and 3) help inform prevention- and discipline-related policies. Without an explicit research-related exception to Title IX reporting, survivors/victims may be less likely to volunteer or participate in research studies to discuss acts of abuse, in that they may not wish to formally report the event(s).

This research-related exception narrowly applies under the following circumstances:

- The exception applies only when the College employee/faculty member *is acting in the role of researcher* in an IRB-approved research protocol. This exception would not cover circumstances outside of such role, including office hours, consulting with students, or during academic advising or any other academic or professional roles.

- The exception excludes disclosures or allegations of faculty/staff-to-student incidents of sexual misconduct or harassment.

- This exception applies to incidents involving persons over the age of 18. Those individuals classified as a statutory Mandated Reporter required by law to report subjected abuse or neglect of a minor (referenced in Massachusetts G.L. c. 119, §51A) are not covered by this exception.

To apply for this exception, the research protocol must include the following components:

- Researchers must submit a proposal to the IRB using the "Full Review" form (consistent with 45 Code of Federal Regulations 46). The IRB will review the proposal and collaborate with the Title IX Coordinator to determine appropriateness of such an exception. <u>This application must take place prior to any data collection.</u> In the proposal to the IRB, the researcher must detail the reasons such an exception is appropriate and necessary for the research design.

- All personnel involved in the research project must be detailed in the IRB proposal. This exception *may apply* to all faculty or staff on a designated project, potentially including student researchers. This determination will be made by the IRB and Title IX Coordinator.

- The Informed Consent form, created by the researcher, shall explicitly detail the limited exception to Title IX created by this policy so that the potential participants are aware the exception to mandated reporting does not extend to other roles the researcher may have as an advisor or professor, or any other professional capacity, where federal and state requirements remain in effect.

- The IRB shall require that the researcher has a list of counseling and trauma and support resources available for every participant.

- Both the Informed Consent form and the list of resources provided by the researcher shall have contact information for the College's Title IX Coordinator, should the participants want to follow up voluntarily with this office.

- The researcher will document their academic/professional preparation to undertake the study. In addition, the Principal Investigator's Title IX training must be current.

For further information, please contact the Chairperson of the Institutional Review Board, or the College Title IX Coordinator.