BELLIN COLLEGE RESEARCH AND INSTITUTIONAL REVIEW BOARD (IRB) POLICY

02/23, 01/24

PURPOSE:

The purpose of this policy is to provide guidance on the IRB process for research and QI/process improvement projects conducted by faculty, staff, students, or others as part of employment or an academic program at Bellin College. The second purpose is to describe the qualifications and duties of the Bellin College IRB representative to the Bellin Health IRB.

POLICY:

Bellin College has one voting board member on the Bellin Health Institutional Review Board. Board members must have a terminal degree to serve. The BC IRB board member nomination is submitted to the Bellin Health IRB Chair, voted on, and then approved by the Bellin Health System Board of Directors. Once approved, the BC board member is appointed to serve a three-year term with the possibility of serving additional terms as described in the Bellin Health Institutional Board (IRB) bylaws. An alternate may be identified.

Duties of the BC Board Member

Duties of the BC board member include but are not limited to:

- Review of exempt and nonexempt research proposals in accordance with 45 C.F.R. Part 46 and 21 C.F.R. Part 56 as assigned by the IRB Chair or designee.
- Attend IRB meetings in person or virtually. If unable to attend, notify the IRB Chair.
- Serves as a resource to faculty, staff, and students conducting research or QI projects.
- Serve as a conduit for information from the IRB to the College and the College to the IRB.
- Report updates and changes to the Faculty of the Whole.
- Ensure BC research and QI projects comply with IRB policy and procedure.
- Advocate for the College in the IRB process and with updates to the Bellin Health System IRB Bylaws and IRB Policy and Procedures.
- Participate in the CAP review process.

Research

All research at Bellin College involving human subjects conducted by faculty, staff, students, or others must comply with applicable policies for the protection of human subjects, including a review by the Bellin Institutional Review Board (IRB). Projects must be reviewed whether they are funded, unfunded, sponsored, or unsponsored.

Under a formal assurance made by the health system and approved by the federal Office for Human Research Protections (OHRP), and per federal regulations, the Bellin IRB is given authority and responsibilities for ensuring the ethical and legal conduct of human subject research at Bellin Health Systems. This Board reviews, monitors, and facilitates research activities for the general advancement of health care and to protect the rights and welfare of human subjects within BHS, including Bellin College. Bellin College provides representation to the Bellin Health System IRB.

Current Human Subjects training is required for all research/project team members.

There are three types of review processes:

- 1. Full Application IRB review conducted by Bellin's IRB
- 2. Expedited Application IRB review conducted by Bellin's IRB, and
- 3. Exempt Application review of evidence-based practice and/or quality improvement projects deemed non-research.

Investigators may consult Bellin's IRB for advice about whether a project must be reviewed. The final authority for making this determination rests with the IRB. All communications with the IRB should go to IRB-Coordinator@bellin.org.

All projects must be reviewed and approved by the IRB in writing before starting the project.