

Organization of ORIC

Policy Title

Office of Research Integrity & Compliance (ORIC)

Policy Text

Institutional Official

The Associate Provost of Health Sciences serves as the Institutional Official (IO) for oversight of the ORIC at Harding University. In this role, the IO is responsible to ensure the following:

- a culture of ethical conduct, review, and oversight of research
- independent functioning of the IRB, IACUC, and IBC, free from coercion and undue influence
- adequate resources to support all entities in the ORIC

In addition, the IO has the following responsibilities:

- serves as signatory authority for assurances or agreements involving research projects as needed by the OSP
- appoints members of the IRB, IACUC, and IBC, including appointment of committee chairs based on recommendations from the academic deans and the provost
- removes members from the IRB, IACUC, and IBC, in consultation with the committee chairs, other members, and the provost
- reports issues of serious noncompliance and unanticipated problems to federal agencies and sponsors with the assistance of OSP staff
- may disapprove, suspend, or terminate IRB, IACUC, or IBC approval of research projects
- is prohibited from approving a project previously disapproved, suspended, or terminated by the IRB, IACUC, or IBC
- may require additional investigation or corrective actions for any issues of noncompliance or unanticipated problems involving risks to participants or others reviewed by the IRB, IACUC, or IBC

ORIC workforce

Qualified individuals, usually faculty members, are charged with leading and managing the day-to-day functions of the IRB, IACUC, IBC, and OSP. The specific roles that make up the ORIC workforce are as follows:

- chair, Institutional Animal Care and Use Committee
- chair, Institutional Biosafety Committee
- chair, Institutional Review Board
- director, Office of Sponsored Programs

- administrative staff assigned to support the chairs and director

These individuals serve as a communication link between board/committee members, investigators, and the IO, and are responsible for doing the following:

- maintain a thorough knowledge of federal regulations, Harding University policy, state and local laws, including best practice standards pertaining to the type of research overseen
- complete orientation, training, and continuing education appropriate for their role
- receive and process submissions for proposed and ongoing research
- serve as a resource for investigators and members with questions about IRB, IACUC, or IBC procedures
- certify protocols eligible for exempt status; ensure appropriate review of protocol submissions
- disclose any protocol-related conflict of interest having the potential to bias decisions relating to research protections
- communicate review determinations to investigators and issue approval notices as appropriate
- maintain appropriate IRB, IACUC, and IBC membership composition in conjunction with IO
- maintain records of all IRB, IACUC, and IBC activities and approved protocols
- maintain required federal and sponsor assurances and registrations
- maintain a program for initial and continuing education of IRB, IACUC, and IBC members and investigators
- conduct random and directed audits of research
- maintain a manual of IRB, IACUC, IBC, and OSP procedures
- participate in review of noncompliance and reports of unanticipated problems
- receive and address any complaints, in conjunction with IRB, IACUC, and IBC members or sponsored researchers as appropriate
- ensure research community is kept informed of policies and procedures regarding research protections
- support evaluation of the effectiveness of the ORIC
- ensure review and certification of funding proposals involving research
- serve as point of contact for auditors and inspectors from internal or external entities

Rationale

Harding University's responsibility to ensure integrity and compliance in all research endeavors is shared by many groups on campus and overseen by the Office of Research Integrity & Compliance (ORIC). The (ORIC) is a division of the Office of Accreditation & Institutional Effectiveness and manages the activities

of the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Office of Sponsored Programs (OSP).

Governance

Authority: Institutional

Responsible Office: Accreditation & Institutional Effectiveness

Responsible Committee: Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Office of Sponsored Programs (OSP)

Document History

Effective date: Version 1 Date: June 20, 2017

Revisions:

Version 2 date: February 8, 2019

Version 3 date: June 18, 2019