



## Institutional Review Board By-Laws

The Arizona College of Nursing Institutional Review Board (hereinafter called "IRB") is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Arizona College (hereinafter called "College") or involving any College student, faculty, staff, or administrator as either the researcher or subject for any study. The IRB is responsible for reviewing all research involving human subjects conducted at the College or using any College data or accessing any faculty, staff, and students affiliated with the College. IRB Oversight is to ensure compliance with and fulfillment of: (1) the policies contained in the IRB document entitled "Arizona College Statement of Principles," (2) the U.S. Department of Health and Human Services Office for Human Research Protections' *Institutional Review Board Guidebook* (hereafter, HHS OHRP *IRB Guidelines*), and (3) federal and state regulations related to research with human subjects.

### 1. The Institutional Review Board

#### A. Membership and Appointment:

**Voting Members:** The IRB shall consist of the IRB Chair, IRB Co-Chair and a minimum of six (6) and a maximum of ten (10) additional voting members, inclusive of one or more members of the community who are otherwise unaffiliated with the College other than their IRB membership. Elevated alternate members are authorized to vote. All voting members shall be recorded in the minutes of each meeting.

**Alternate Members:** A minimum of two alternates are to be appointed. Alternates may attend all meetings but serve in an advisory, non-voting status unless elevated to be a voting member. Such elevation occurs when voting members recuse themselves for conflict of interest or when a voting member is absent from either a stated meeting or special meetings of the IRB. In such cases, the IRB Chair may elevate any alternate member present to voting status.

Responsibility for appointing the IRB Chair and IRB members and alternates rests with the Arizona College Provost (IRB Signatory Official) or designee. In compliance with OHRP regulations, the membership represents the breadth of scientific and scholarly specialties at the College, and at least one member whose primary concerns are in a non-scientific area and at least one member who is otherwise currently unaffiliated with the College must make up the IRB membership. Appointments are for two-year staggered terms and are renewable. Member terms are staggered to assure committee continuity.

The IRB Chair and all IRB members serve at the pleasure of the Provost. Members may be removed from service at any time by the Provost for failure to complete required IRB training and certification, attend stated IRB meetings, fail to fulfill the oversight obligations of IRB membership, or on the recommendation to the Provost by a majority vote of the Board.

Any full-time member of the College community holding an earned graduate degree; and who has the research record and background that would qualify them for IRB membership is eligible to serve. Anyone who would like to serve on the IRB as either a voting or an alternate member should indicate their interest to the Campus Executive Director of Academic Operations for approval, and send a notice of interest to the IRB Chair at [irb@arizonacollege.edu](mailto:irb@arizonacollege.edu) who will then submit all notices of interest to the Provost or designee for appointment.

#### **B. IRB Member Duties:**

- Attend Board meetings
- Review and evaluate all assigned “full review” protocols in advance of each meeting
- Review and evaluate all assigned “expedited review” protocols within 72 hours
- Serve on any assigned *ad hoc* IRB taskforce
- Complete CITI and/or other required IRB member development for human subjects research

### **2. The IRB Chair**

**A. Appointment:** The Provost or designee shall appoint an IRB Chair who will continue to serve until a replacement is designated. The Chair serves at the pleasure of the Provost or designee and may be removed from service at any time by the Provost or designee, with or without cause.

#### **B. IRB Chair Duties:**

- Serves as the IRB Executive Officer and the IRB Liaison with the Office of the Provost, or designee
- Oversee and monitor the activities of the IRB Administrator to assure IRB records compliance
- Chair all stated and special IRB sessions. If the Chair is unable to attend any meeting, the IRB Co-Chair shall serve as Chair Pro tempore for that meeting and shall have the authority to elevate an alternate member to vote for the IRB Chair.
- Vote and perform all other functions of an IRB member
- Review all incoming applications and determine if the application is exempt, eligible for expedited review, or requires a full review at the next stated or special meeting
- Evaluate any application(s) eligible for expedited review or assigns such evaluation(s) to another voting or alternate IRB member
- Temporarily suspend research that is not in compliance with IRB guidelines, collaborate with Provost to process termination or suspension appeals, and report final decision and required actions to be taken by the Principal Investigator to the IRB at the next full board meeting
- Authorize emergency changes to a protocol to avoid an immediate hazard to subjects and report such changes to the Provost or designee and to the IRB during the next meeting
- Receive all notices of “Unanticipated Problems and Adverse Effects”
- Participate in or designates others to participate in sessions designed to inform and educate College faculty, staff, and students about IRB responsibilities and activities
- Stay informed regarding the latest changes in federal and state guidelines for research with human subjects and communicates that information to other IRB members and to the College community
- Appoint and oversee the activities of any needed *ad hoc* Taskforce
- Collaborate with Provost to authorize payment on all honoraria, stipends, contracts, professional development, and other budgeted IRB-related expenses and report out during next full board meeting
- Perform all other duties necessary for efficient IRB operations

### **3. The IRB Co-Chair**

**A. Appointment:** The Provost or designee shall appoint an IRB Co-Chair who will continue to serve until a replacement is designated.

#### **B. IRB Co-Chair Duties:**

- Serve in the absence of the IRB Chair and inherits all the duties and responsibilities of the Chair, until the IRB Chair is able to fulfill the responsibilities of the role.

### **4. The IRB Administrator**

**A. Appointment:** The IRB Chair shall appoint an IRB Administrator. Alternately, the Provost in consultation with the IRB Chair can appoint the IRB Administrator. The IRB Administrator serves at the pleasure of the Provost.

**B. IRB Administrator Duties:**

- Remain current on federal and state human subjects research guidelines and communicate that information to the IRB Chair, IRB members, and to faculty, staff, and students who do human subjects research
- Complete IRB Administrator CITI training
- Organize and participate in educational activities related to IRB policies and procedures
- Post IRB guidelines, forms, minutes, logs, and related materials electronically
- Maintain records for all protocols
- Distribute protocols appropriately to IRB members
- Post meeting notices to the College community
- Record meeting minutes for all expedited, ad-hoc taskforce, and standing IRB meetings.
- Archive IRB correspondence, guidelines, forms, minutes, logs, human research training certificates, and all other relevant information
- Participate in on-site reviews by federal inspectors
- Provide assurances to federal agencies of approval of protocols to be supported by federal funds
- Act as liaison between federal agencies and investigators regarding human subjects issues
- Submit an annual report on IRB activities to the IRB, IRB Chair, and Provost

**5. Special Consultants:**

**A. Appointment:** The IRB Chair may designate a consultant with special expertise to assist in the review of a particular protocol and, in consultation with the Provost authorize payment for such consultation services. The consultant does not vote on protocols. The contract ends upon completion of the protocol review.

**6. Meetings**

**A. Stated Meetings:** The IRB Stated Meetings shall be held in the second week of every 8-week term. Dates, times, call-in numbers, and deadlines will be announced College-wide by the IRB Chair and posted on the IRB website. In case of holidays or other unforeseen circumstances, the monthly stated meeting may be held during the third week of an 8-week term.

**B. Special Meetings:** The IRB Chair may call a special meeting if needed. The same quorum and attendance requirements shall be maintained as in any Stated Meeting. All business of the IRB may be conducted at a Special Meeting.

**C. Agenda:** The Board will receive a report on all exempt and expedited reviews and discuss and act on all protocols requiring full IRB review and approval, as well as conduct other business on the agenda.

**D. Voting:** A quorum, consisting of more than one-half the IRB membership (including a non-scientist member) is required to conduct business. A majority of voting members present is required for Board action. If there is no dissenting or abstaining vote on a matter before the IRB, the IRB Administrator will list the name of all members in attendance and note that they voted in favor of the proposal. If a vote is not unanimous, the minutes shall list each member and how they voted or abstained.

**E. Minutes:** Minutes shall be kept in accordance with OHRP guidelines. The minutes shall reflect the substance of all discussions, the members, alternates, guests and others in attendance, and the IRB members name and vote on each matter that comes before the IRB. The IRB Administrator shall distribute all meeting minutes to members via email before the meeting for additions and corrections. The IRB will approve the amended minutes at the next stated meeting, and the IRB Administrator will archive the amended minutes for audit and post notice of actions to the College community.

## 7. Action on Research Proposals

**A. Full Review:** The IRB shall review research proposals that require full Board review and shall periodically conduct ongoing review of approved research projects.

**B. Expedited Review:** The Chair may review and approve proposals that involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. Also, such review and approval may be conducted by one or more experienced members of the board designated by the Chair. All expedited reviews will be reported to the full IRB at the next stated meeting.

**C. Exempt Research:** The IRB Chair shall review all submissions and may determine that the study is exempt from further IRB oversight. The Chair shall notify the applicant within 3 business days of that determination. Even though the researcher believes the submission is exempt, the research may not go forward until approved, in writing, by the IRB Chair. All exempt reviews will be reported to the full IRB at the next stated meeting.

**D. Adverse Consequences/Unanticipated Effects:** If adverse consequences or unanticipated side effects are encountered during a study, or new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the IRB Chair immediately. The IRB Chair may immediately suspend the research on a temporary basis or require modifications, pending full IRB review. The Chair is authorized to take immediate steps to protect the research subjects or their information or provide support for research subjects from such research consequences/effects. The Chair shall report all such actions to the Provost. The full IRB will make the final determination regarding any permanent protocol changes that may be required due to the adverse consequences or unanticipated side effects at the next stated or special meeting.

**E. Administrative Restrictions and/or Disapproval:** Research that has been reviewed and approved by an IRB may be subject to further review and administrative restrictions. Upon further review, the research protocol may be disapproved by Arizona College officials through the Provost. Arizona College officials may not, however, approve research if it has been disapproved by the IRB. (HHS OHRP *IRB Guideline*, 3)

**F. Continuing Review:** Approved research is subject to continuing IRB review and must be re-evaluated at least annually. (HHS OHRP, *IRB Guidelines*, 3)

## 8. Changes to the Guidelines and Bylaws

Changes to the guidelines that are mandated by the federal government or other regulatory agency, or accreditor will be made, effectively immediately upon passage.

The IRB will adopt, by a majority vote of the Board, any proposed revisions to the adopted By-Laws. The Office of the Provost must also approve all revisions. Notice will be given to any research underway that may be impacted by such changes.

The IRB Administrator will post any rules, regulations, or operating procedures revisions on the IRB Website and Arizona College of Nursing Catalog.