



Clayton State University Institutional Review Board

Bylaws and Board Governance

Identifying Information

- **Name:** Clayton State University Institutional Review Board
- **Federalwide Assurance (FWA) Number:** FWA00011633
- **IORG Number:** IORG0004989

Mission

The mission of the Clayton State University (CSU) Institutional Review Board (IRB) is to process all research proposals that require human subject participation. The CSU IRB also serves to encourage, educate and promote faculty, students, staff and administration to conduct all types of research, including grants and contracts, that contribute to the enhancement of teaching, literature and community service in accordance with federal guidelines. In all deliberations, the IRB will adhere to the Belmont guidelines, and require that research involving human subject participation be conducted to protect the rights of individuals against harm. The IRB will maintain a federally registered IRB status to ensure compliance with federal statutes and regulations, and to encourage federal research as well as state and local research.

Membership

Federal regulations require that membership of the IRB include at a minimum, one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, numerous members representing more than a single profession, and at least one individual not affiliated with CSU. The CSU IRB membership shall, at a minimum, consist of:

- two (2) members from each of the schools and colleges (voting members)
- one (1) staff council representative (voting member)
- one (1) a representative from IACUC (voting member)
- one (1) administrative representative (voting member)
- one (1) external members (voting member)
- University IRB Officer-in-Charge (designated by the Provost) (non-voting member)
- two (2) ex officio members (Provost and University President) (non-voting members)

Election, appointment and term length

College and school representatives will be elected from each college and school for initial 2 or 3 year terms and subsequent three year terms. The school or college will determine which member will serve which term length. The intention for this requirement is that each college maintain membership continuity, ensuring that the IRB has one experienced (minimum one year IRB service) at all times.

Staff Council, IACUC, and Administrative representatives will be appointed for three year terms.

External members (community representative) serve three year terms.

IRB officers are elected to one-year terms during the last scheduled meeting of an academic year (typically at the end of Spring Semester). Officers serve a one-year term from the beginning of Fall Semester to the beginning of the following Fall Semester, at which time the new officer corps assumes their roles.

Chair:

- Nominated by the IRB members for a term of one year
- Serves as advisor during the year following term as Chair

Vice Chair:

- Nominated by the IRB members for a term of one year and act as Chair-elect
- Serves as Chair in the year following term as Vice Chair

Secretary:

- Record minutes of meetings
- Prepare minutes for distribution by IRB chair, no more than two weeks after meeting conclusion, but prior to next scheduled meeting

Advisor:

- The Chair will serve a one-year term as Advisor after being Chair
- In the event that the immediate past Chair cannot serve, the current Chair may make a special appointment of a qualified individual
- Provides guidance and advice to current IRB chair as appropriate

Institutional Officer

- The Institutional Officer is appointed by the Provost and is not a voting member of the board

The University President and Provost serve as ex-officio members with no term limits or voting rights.

Term limits

With the exception of ex-officio members, members may serve two consecutive terms. A member becomes eligible for service after one year off the board.

Alternate Members:

At least one alternate will be elected from each member School or College, and one alternate each for the staff, administrative and community representatives. Only alternates elected for each member's school or college, staff, administrative, or community representative may serve for the absent member.

Member Roles and Responsibilities

IRB Members, General:

- execute their responsibilities in accordance with University policies and applicable federal, state, and local and laws

- Complete required training and keep member file up to date with required documents (Curriculum Vitae, Member Training Verification Form, Human Subjects training completion certificate, and licenses.)
 - Members must complete the Human Subjects training approved by the CSU IRB within the first 30 days of a new appointment to the CSU IRB
 - Human Subjects training completion certificates for members will remain valid until a break in IRB service; any subsequent re-appointment to IRB requires new training completion
- Identify as a scientist or non-scientist and list area(s) of expertise
- maintain confidentiality for all matters before the IRB, all expedited reviews, and IRB consultations
 - sign a confidentiality agreement at each IRB board meeting
- ensure that the seven criteria for IRB approval at 45 CFR 46.111 are met for all review assignments including expedited and full committee reviews
- when assigned as primary, secondary, or expedited reviewer, review and assess recruitment materials and procedures, and use of recruitment incentives when applicable to confirm the equitable selection of participants
- complete the relevant review checklists when assigned as primary, secondary, or expedited reviewer for a project
- comply with the University or Affiliate institution's conflict of interest policy
- disclose conflict of interests for a project subject to IRB review at a convened meeting; refrain from the discussion except to provide information requested by the IRB, and leave the room during voting
- when she/he has a conflict of interest for a project she/he has been asked to review by expedited procedures, disclose the conflict interests and decline the review

Member Responsibilities During Study Reviews:

- follow the appropriate review checklist, documenting decisions and comments as appropriate; include the signed, completed checklist with your feedback to the IRB Chair or Vice Chair
- consider the adequacy of inclusion/exclusion criteria to enroll individuals most likely to benefit from and least likely to be harmed by the research
- determine if the inclusion/exclusion criteria have an ethical basis
- verify the adequacy of the consent document for informing subjects about the research, including risks and benefits
- evaluate the clarity and appropriateness of the information in consent documents with consideration for the sample populations
- verify the consent documents are consistent with IRB protocols

IRB Participation Requirements:

- attend at least 80% of scheduled IRB meetings when a primary member

- notify IRB Chair or Vice Chair in advance if there is a need to be absent from a scheduled meeting, and ensure that the designated alternate member is available for attendance; work with IRB Chair for acceptable alternative if designated alternate member is not available
- arrive promptly and stay at convened meetings until all committee business and training has been completed
- review the complete package (including recruitment and consent materials) for all projects on the agenda for IRB meetings in which she/he is attending as a voting member
- participate in IRB discussions of protocols
- complete expedited reviews (including the relevant review worksheets) in a timely manner (within 10 business days of receipt).
- Assist researchers in school, college, or organization being represented in the preparation and review of IRB application materials prior to application submission to IRB
- may act as resources for researchers in the design of human subjects protection aspects of protocol development; and
- are encouraged to support IRB training opportunities for represented organization
- Unaffiliated IRB members (i.e., IRB Community Members) have the responsibility of bringing the perspective of research participants to the review process

Additional IRB Member Responsibilities for Research Involving Sharing Data or Specimens:

When University or Affiliate investigators plan to conduct non-exempt research that involves providing data/specimens to or obtaining data/specimens from an external entity, AND the data-set includes *Protected Personally Identifiable Information* or *Protected Health Information*, the Primary or expedited reviewer must confirm the following before approving the research:

- The submission includes a fully-executed research agreement that specifies the responsibilities of both the Data Provider and the Data Recipient.
- The research agreement confirms that the *Data Provider* complied with DHHS requirements for informed consent as it relates to the use of the data/specimens as specified in the agreement.

Alternate Member Duties:

- Complete required training and keep member file up to date with required documents (Curriculum Vitae, Member Training Verification Form, Human Subjects training completion certificate, and licenses.)
 - Alternate members must complete the Human Subjects training approved by the CSU IRB within the first 90 days of a new appointment to the CSU IRB, or prior to their first IRB board meeting attendance, whichever is first
 - Human Subject's training completion certificates for alternate members will remain valid until a break in IRB service; any subsequent re-appointment to IRB requires new training completion
- Identify as a scientist or non-scientist and list area(s) of expertise
- Attend board meeting if designated member is unable

- Fulfill other responsibilities of replaced member as appropriate, until an appropriate information exchange and activity handoff can occur back to the replaced member

Chair and Vice Chair Additional Responsibilities:

The Chair and Vice Chair are voting members of the IRB and assumes all responsibilities of IRB Members. In addition to their responsibilities as voting IRB members, the IRB Chair and Vice Chair oversee IRB meetings to ensure reviews and approvals comply with regulatory requirements, the Belmont Report, state laws, and University policy.

The IRB Chair and Vice Chair are authorized to sign all documents relevant to the review and approval of human subject research projects (e.g., waivers of HIPAA authorization) and documents submitted for post-approval monitoring (e.g., safety reports that are not unanticipated problems; acknowledgement of and notifications from external IRBs), except IRB Institutional Agreements, which are signed by the Institutional Official or designee). The chair is responsible for the maintenance of IRB documents and records in accordance with applicable university, USG, state, and federal records-retention policies and procedures. The Chair may designate one or more voting IRB members to facilitate records storage and retrieval, including access to IRB email account and shared drive storage.

The IRB Chair and Vice Chair may designate signature authority to qualified IRB members who are voting members of the IRB, as appropriate. In all cases individuals sign their own name.

During IRB meetings, Chairs and Vice Chairs

- remind members who have a conflict of interest to leave the room during deliberation and voting
- ensure ample time is allowed for discussion for each study
- ensure the criteria for IRB approval and other relevant requirements (e.g., consent waivers/alterations, waivers of signed consent, determinations for vulnerable populations) are met before projects/packages are approved
- ensure a determination is made and voting takes place for each action item on the agenda
- Ensure that confidentiality agreements are signed and maintained for each IRB board meeting
- provide guidance to IRB members during and outside of meetings as appropriate

For reportable events, the IRB Chair and Vice Chair

- may review investigator problem reports when referred by reporting official, to assess for possible noncompliance or unanticipated problem involving risks to participants or others and Full Committee Review
- review reports of initial allegations of serious and/or continuing noncompliance to determine whether to refer the incident for Full Committee Review

The IRB Chair and Vice Chair work with the IRB OIC to

- review IRB policy, documents (e.g., forms and worksheet), and correspondence
- provide consultation and guidance to university administrators, faculty, and staff

- Assist the OIC in the preparation and submission of FWA and IRB renewal applications in accordance with submission timelines
- consult with the OIC regarding IRB member performance and needs
- The chair will prepare (with the assistance of the Vice Chair and other IRB members as required) and submit to the OIC a summary of all IRB activities for the term of service, within 30 days of the end of the elected term

Removal of Members

The board may recommend removal of members who fail to fulfill duties, fail to follow by-laws, policies, or procedures of the IRB, violate CSU policies, violate applicable laws, or do not act in the interests of the board. In the event of a member's removal an alternate from the member's College or School will serve for the remainder of the removed board member's term. The College or School will elect a new alternate to fill the remainder of the promoted alternate's term.

If a member misses two regularly scheduled meetings in one academic year and does not send an alternate to the scheduled meetings or does not have an alternate member, the member will be replaced by the next IRB meeting, the member will be replaced by the next IRB meeting.

The IRB OIC has the final decision-making authority to remove a member or alternate member.

The Institutional Officer (OIC) may remove the Chair or Vice-Chair at any time if they fail to fulfill duties, fail to follow by-laws, policies, or procedures of the IRB, violate policies of Clayton State University, violate applicable laws, or do not act in the interests of the board. If the Chair is removed the Vice-Chair will assume the Chair position for the Chair's remaining term and a new Vice-Chair will be elected by majority vote of the board to complete the term of the Vice-Chair. In the event the Vice-Chair cannot assume the duties of the Chair the IO may appoint an interim Chair until election and installation of a new chair. If the Vice-Chair is removed the Chair will conduct an election of a new Vice-Chair from among current board members. In the event a Vice-Chair cannot be elected the IO may appoint an interim Vice-Chair until election and installation of a new Vice-Chair.

Consultants

If the board does not have the appropriate expertise for review of an application the board can request a consultant. The IRB Chair or Vice-Chair will consider CSU faculty for available expertise with preference for faculty who have previous service to an IRB. If no faculty can conduct an expert review then consultants from outside universities may be considered.

Consultants will review applications and complete the appropriate reviewer check list.

Consultants will disclose any COI prior to performing the review and those with a COI will not review the application. Consultants will be bound by confidentiality and sign a form agreeing to maintain confidentiality and stating no COI exists.

Meetings

Date and Time:

The IRB will be required to meet at least monthly unless no activity is before the IRB whereby the Chair or Vice Chair may cancel the meeting. A called meeting by either the Chair or Vice Chair may occur beyond the monthly meetings.

Agenda and Minutes:

The IRB Chair and Vice Chair will ensure that an agenda is provided and meeting minutes are approved by a majority of the IRB members. The IRB Chair or Vice Chair may discuss with the Institutional Officer IRB agenda items and pending policies/procedures changes at an IRB meeting. All meeting agendas and approved minutes will be converted to pdf format and placed in the appropriate shared folder.

Voting:

A majority of members which includes the Chair or Vice Chair, the community representative or staff representative as a non-scientist, and representatives of at least two Colleges, must be present to constitute a quorum and conduct IRB business. The President and Provost serve as ex-officio members, without voting rights. The IRB members will report their decisions to the IRB Institutional Officer. Decisions are documented in the minutes of the meeting corresponding to the vote.

Electronic Voting:

IRB administrative activities requiring vote may be conducted electronically if deemed necessary by the IRB chair. Examples of administrative activities include, but are not limited to, changes to policies, guidelines, bylaws, IRB support materials, training materials, and website updates. IRB full reviews, including votes, may be conducted electronically if deemed necessary by the IRB Chair. A vote is counted if it is accompanied by a completed IRB checklist for the appropriate review type (exempt, expedited, or full), including selection of the recommended decision and signature of the IRB member.

Review Procedures

It is the responsibility of the IRB to protect the rights of individuals involved in research and ensure that human subjects research conducted at Clayton State or by Clayton State representatives adheres to applicable ethical principles, laws, and regulations. All investigators must seek IRB approval for research involving humans.

Exempt and Expedited applications require that the Chair reviews the application. The Chair may also assign 1-2 committee members to review these applications. Full Reviews require review by the full IRB. The Chair gathers member comments. When quorum is established, members vote to grant or deny approval.

When committee review is complete, and an application has been approved or denied, a formal notification will be sent to the Primary Investigator. Research may not begin without formal decision from the IRB regarding IRB monitoring status.

Formal Procedures for conducting IRB reviews and issuing IRB decisions are to be maintained in a separate IRB Policies and Procedures document, and accessible to CSU faculty and staff.

IRB Records

It is the responsibility of the IRB chair to ensure that IRB records (agendas, minutes, application materials, decision letters, forms, and other documents as deemed appropriate by the majority of the IRB) are updated and stored in accordance with CSU records storage and retention policies. The current system of record for storing application materials and completed decision letters is the IRB Shared Drive. All hard copies of documents received, including but not limited to signed confidentiality statements, IRB member administrative materials, and application materials, will be converted to electronic copy and stored on the IRB shared drive. Originals may then be destroyed in accordance with CSU records policies.

The IRB public-facing website (<http://www.clayton.edu/provost/IRB>) will, at a minimum, provide the following information:

- IRB overview
- Current IRB Membership
- Meeting Schedule
- IRB contact information
- Federal Regulations
- Ethical Principles
- Policies & Guidelines
- Human Subjects Training
- Submission Information
- Forms & Applications

IRB agendas and minutes will not be maintained on the IRB website, but will be maintained on the IRB shared drive and distributed to all IRB voting members and OIC.

The IRB Chair may establish a website maintenance subcommittee of 1-3 members to make changes to the IRB website as appropriate. Any website changes will be disclosed to the IRB Chair in advance of implementation, and summarized for the IRB and included in the minutes of the next scheduled IRB meeting.