

OPERATING CODE

Institutional Review Board (IRB)

Purpose:

1. Oversee clinical research involving human subjects at Sonoran University and its affiliates;
2. The IRB reports to the Faculty Senate and the Department of Health and Human Services;
3. The IRB is a standing committee, and will continue to operate as long as the University is associated with human research;

Functions:

1. The IRB is a Standing Committee of the University;
2. The IRB oversees ethical aspects of human clinical research at the University, including ethical and safe treatment of research subjects, patient confidentiality, fairness and informed consent.

Membership:

1. Membership of the IRB reflects current federal guidelines, and is mandated by The University's MPA (multiple project assurance of compliance);
2. The IRB must have a minimum of five (5) members including the following:
 - i. one clinician, (minimum of 1 year experience in clinical related activities)
 - ii. one scientist, (minimum of 1 year experience in research related activities)
 - iii. one non-scientist
 - iv. one outside member
3. All members are to be nominated by the faculty senate or IRB chair with input from all IRB members and are to be approved by membership by a majority vote of the current members of the IRB;
4. All members serve a three-year term with rotating time limits. Members can be re-elected by the membership of the IRB, with approval of the faculty senate, and can serve more than one term. There is no limit to the number of terms a member may serve;
5. Members may be added according to those interested in research at Sonoran University and who have some experience in research and IRB functions;
6. Members are required to complete an ethics training course and receive certification, course available from the OHRP.

Leadership/Officers:

1. The Chair is the only officer;
2. The Chair is elected from current membership of the IRB;
3. The Chair must be a full-time employee of the University and have significant experience in research and IRB activities either at SONORAN or at another institution; Research, Ethics, Compliance, and Safety Training, as needed is required.
4. The Chair's first term is for two years, and then may be annually re-elected;
5. Repeated terms are allowed;

6. Terms may be continuous;
7. The Chair must be elected every year during the Summer term no later than September 31st;
8. The Chair may be replaced at any time by a majority vote of the IRB;
9. Anytime there is a vacancy in the Chair's position, it may be filled by a vote of the IRB members;
10. When the Chair resigns, a new Chair will be elected from the remaining members of the IRB;
11. The Chair may resign from being the Chair but continue to serve on the IRB;

Major Functions of the Chair:

1. Presides over all the formal meetings of the IRB and also establishes the agenda;
2. Keeps IRB records of all clinical research projects;
3. Available to research subjects as needed.
4. The trial PI reports to the Chair who collaborates with the IRB members to make collective decisions.
5. Monitors and over-sees ethical aspects of all clinical research projects and tracks any and all adverse events.
6. Reports any and all adverse events to the IRB and the Vice President of Academic Affairs in a timely manner.
7. Review annual reports of ongoing studies.

Meetings:

1. Meetings are held once a month as needed;
2. Meetings are called by the Chair via e-mail;
3. Meetings are called in response to new protocol submissions and problems;
4. A quorum consists of minimum of 5, required to take a vote

Changes to Operating Code: Changes in the IRB Operating Code will be passed by a simple majority of the members and will be in force upon approval of the faculty senate.

Date operating Code was last revised: 8.2.2024