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12. **Introduction**

Each IRB must be appropriately constituted for the volume and types of human research to be reviewed, in accordance with federal regulations. An IRB will include members with diverse experience and expertise to assure the professional competence necessary to review the University’s research, as well as knowledge of community attitudes and training in protecting the rights and welfare of human subjects. The purpose of this policy is to describe the membership requirements and responsibilities for The LSUHSC-NO (HSC-NO) IRB.

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1. **Definitions**

**Affiliated:** IRB membership status designating association with the University.

*A member (or alternate) is considered to be affiliated if he/she or a member of his/her immediate family is a current or past (within the last 2 years):*

* *employee (full or part-time);*
* *clinical, adjunct, or visiting faculty member or instructor;*
* *paid or unpaid member of a university governing panel or board (not including the IRBs);*
* *healthcare provider holding credentials to practice at LSU Health;*
* *volunteer working at the university (unrelated to IRB service);*
* *or university consultant or advisor (paid or unpaid).*

*An emeritus faculty or retired staff member is also considered to be affiliated if he/she has been retired or involved in paid or unpaid university activities (including research or service) within the last 2 years. Current undergraduate, graduate, and postdoctoral students are also considered to be affiliated.*

**Alternate:** An individual appointed to the IRB to serve in the same capacity as the specific IRB member(s) for whom the alternate is named, who substitutes for the member at convened meetings when the member is not in attendance.

*IRB members and alternates have equal responsibilities in terms of required education, service, and participation. (See below for additional information about alternates.)*

**Non-Scientist:** An individual appointed to the IRB who (due to training, background, and/or occupation) is inclined to view research activities from the standpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves.

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1. **IRB Composition**
   1. In appointing IRB members, the Chancellor in consultation with the Institutional Official (IO) and/or Executive Director of the Office of Research Services (ORS) will ensure that all of the following conditions are met for the HSC-NO IRB:
      1. IRB members will have varying backgrounds, experience, expertise, and professional competence as necessary to promote complete and adequate review of research activities commonly conducted by HSC-NO.
      2. Each IRB will be sufficiently qualified through the experience, expertise, and diversity of its members, including considerations of race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
      3. Each IRB will include persons knowledgeable about institutional commitments and regulations, applicable laws, and standards of professional conduct and practices.
      4. If the IRB regularly reviews research that involves a category of participants that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the Chancellor will appoint one or more individuals who are knowledgeable about and experienced in working with these categories of participants.
      5. Each IRB will consist of at least five members
      6. Each IRB will include at least one member whose primary concerns are in scientific areas.
      7. Each IRB will include at least one member whose primary concerns are in non-scientific areas, at least one member who represents the perspective of research participants, and at least one member who is not otherwise affiliated with HSC-NO and who is not part of the immediate family of a person affiliated with HSC-NO.

***Note:*** *In many cases, the same member will satisfy the three roles. The IRB may, on occasion, meet without representation of the unaffiliated member; however, this should be the exception. Attendance of the unaffiliated member and the member who represents the perspective of subjects at convened meetings will be monitored and assessed through documentation in the minutes (e.g. minutes indicate attendance at greater than 50% of meetings).*

* 1. The IRB may invite individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available on the IRB. These individuals (consultants) may not vote with the IRB.
  2. Other individuals also attend convened meetings as necessary. These individuals advise the IRB on the acceptability of proposed research in terms of regulatory requirements, institutional commitments, applicable laws, and standards of professional practices and conduct. Examples include, but are not limited to, representatives from the Conflict of Interest Office, Office of Sponsored Programs, Office of Compliance Programs, and Office of Chief Counsel. ***Note:*** *Individuals responsible for business development or grants and contracts (e.g., Office of Sponsored Programs, Office of Innovation & Partnerships) do not serve as IRB members or alternates.*
  3. All IRB members, alternates, and IRB Office staff receive human subjects protections education related to federal regulations and guidance, HRPP policies and procedures, and IRB review processes. Minimally, initial training in human subjects protection, with continuing education every three years is required (*e.g.*, completion of Collaborative Institutional Training Initiative modules). IRB members and IRB Office staff also receive additional education/new information via newsletters, email announcements, website postings, webinars, and in-person training sessions.

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1. **Quorum**
   1. IRB Office staff attending IRB meetings are responsible for determining that meetings are appropriately convened before the discussion and vote for each review. For convened IRB review, a quorum is defined as follows:
      1. The necessary number (*i.e*., more than half) of the IRB members listed on the membership roster are present.
      2. At least one member is present whose primary concerns are in nonscientific areas.
      3. At least one member is present whose primary concerns are in scientific areas.
      4. For FDA-regulated research, a member is present who is a licensed physician.
      5. For research involving a category of participants vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, a member is present representing the vulnerable population’s interests.
   2. If both an IRB member and his/her respective alternate(s) are present, only one may vote and be counted toward quorum.
   3. Comments from members unable to attend a meeting that have been provided in advance (*e.g.*, by fax or e-mail) may be considered by the attending IRB members, but may not be counted as votes or toward the quorum for convened meetings.
   4. Any member may participate by teleconference or videoconference, provided he/she has received all materials and can actively and equally participate in the discussion.
   5. Assuming all applicable composition requirements are satisfied, the number of IRB members necessary for a quorum is calculated by dividing the number of members in half and “rounding up” when there is an odd number of members or “adding one” for an even number. For example:
      1. If an IRB has 15 members, the quorum is 8.
      2. If an IRB has 20 members, the quorum is 11.
   6. If quorum is not met, then IRB voting cannot take place; and the items on the agenda will be tabled until the next convened IRB meeting.
   7. If quorum is lost during a convened meeting (*e.g.*, due to a member leaving the meeting), then no further voting can take place; and the remaining items on the agenda will be tabled until quorum is restored or the next convened IRB meeting.
   8. IRB Office staff attending IRB meetings are responsible for recording the attendance of members as they enter and leave the room. If quorum is lost, IRB Office staff will notify the IRB Chair or Vice-Chair that no further actions can be taken until/unless quorum is restored.
   9. IRB members with potential conflicts of interest must leave the room before discussion of the research, except to provide information requested by the IRB. Members with potential conflicts of interest may not be present for the vote and are not counted toward quorum for review of the research for which the potential conflict exists.

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1. **IRB Membership Roles and Responsibilities** 
   1. **IRB Chair(s)**

The Chair(s) is/(are) appointed by the Chancellor in consultation with the IO and selected based on experience and expertise from among current and former IRB members. The IRB Chairs have primary responsibility for the following:

* + 1. Providing leadership to the IRB to help ensure the rights and welfare of human subjects participating in research reviewed by the IRB;
    2. Conducting convened meetings and reviewing and approving the minutes documenting IRB discussions and findings;
    3. Leading discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct;
    4. Completing the annual ***Conflict of Interest***disclosur*e* and disclosing any potential conflicts prior to IRB review of the research for which a conflict may exist;
    5. Managing conflicts of interest by ensuring that IRB members with conflicts are not present for review of research for which a conflict may exist;
    6. Maintaining confidentiality of IRB-related information ;
    7. Administering Board decisions and maintaining the independence of the IRB;
    8. Signing correspondence communicating and documenting IRB decisions;
    9. Reviewing and approving research by expedited procedures;
    10. Participating in the development of meeting agendas, policies, procedures, and educational efforts to support the human research protection program;
    11. Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects;
    12. Regularly consulting with the ORS Director and staff regarding IRB issues;
    13. Assisting with investigations and review of alleged noncompliance with human subjects protections requirements as specified by HRPP policy;
    14. Participating in the development of policies, procedures, and institutional efforts to promote a culture of shared responsibility for the safety and welfare of research participants.
  1. **Vice-Chair(s)**

The Vice-Chair of each panel:

* + 1. Is appointed by the Chancellor in consultation with the IO and IRB Chair and selected based on experience and expertise from among current and former IRB members.
    2. Supports the role and responsibilities of the IRB Chair. The Vice-Chair attends IRB meetings and chair convened meetings when required. The Vice-Chair assume duties as delegated by the Chair.
    3. Works with the Chair, IRB members, and IRB Office staff to develop and implement policies and procedures to assure the efficiency and effectiveness of the human research protection program.
  1. **IRB Members**

Each IRB member is appointed by the Chancellor in consultation with the IO and IRB Chair. IRB member responsibilities include all of the following:

* + 1. Attending IRB meetings and actively participating in the review of research, unless arrangements have been made for the alternate’s attendance;
    2. Completing initial training in human subjects protection for IRB members prior to voting on any research, with continuing education every three years and as provided;
    3. Understanding and applying the principles of the Belmont Report and the federal regulations related to the protection of human subjects;
    4. Providing timely written comments on research undergoing IRB review, when required;
    5. Completing the annual ***Conflict of Interest***disclosur*e* and disclosing any potential conflicts prior to IRB review of the research for which a conflict may exist;
    6. Maintaining confidentiality of IRB-related information;
    7. Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects;
    8. Working with investigators to resolve matters relating to research approval and participating in educational efforts for investigators, research staff, and new IRB members;
    9. Participating in the discussion of issues affecting the human research protection program and contributing to policy development, as appropriate;
    10. Reviewing and approving research by expedited procedures, when designated by the IRB Chair to perform this review.
  1. **Alternates**

Federal regulations allow organizations to appoint an alternate(s) to substitute for an IRB member(s) who is unable to attend so that IRB business may move forward in a timely manner.

* + 1. Alternates are appointed by the same process as IRB members.
    2. IRB alternates function as regular Board members when they are in attendance. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities (*i.e.*, “job-share”) in terms of required education, service and time commitments, and participation.
    3. Each alternate member is paired with one or more regular members with comparable experience and expertise, as possible. The IRB roster identifies the primary member(s) for whom each alternate may substitute. Minimally, alternates and members are paired by scientific “class,” as physician scientists (when applicable), other scientists, and non-scientists. The IRB roster will identify the member(s) for whom each alternate can substitute.
    4. When an alternate substitutes for a regular IRB member, the alternate receives and reviews the same materials that the regular member received (or would have received), and IRB minutes document that an alternate replaced a primary member.
    5. Senior staff of the IRB Office, as designated on the IRB registration maintained with OHRP, may be designated as alternates.

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1. **Terms of Service**

All Board members, including Chairs, Vice-Chairs and alternates, are initially appointed to a term of three years.

When a member has successfully completed his or her term and wishes to remain on the IRB, a letter of reappointment is sent by the Chancellor, thanking the member for his/her contribution, stating the duration of the new term of three years and the continued expectation regarding attendance at IRB meetings. Reappointment is based on the recommendation of the IO, Chair and/or ORS Director after assessing the member’s contribution over the course of the term and the current and future needs of the IRB.

If a member declines full membership, s/he may be asked to become an alternate member. Reappointed members will be asked to provide an updated CV.

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1. **Consultants**
2. For research that requires expertise beyond or in addition to that available on the IRBs (including application of laws outside the state of Louisiana), or involves a vulnerable population where no IRB member knowledgeable about or experienced in working with these participants will be present at the meeting, one of the following will occur:
   1. IRB Office staff may identify the need for review by a consultant during the screening of a protocol submission. The IRB Office staff member will invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.
   2. The primary reviewers or IRB membership may identify the need for a consultant during their review. The primary reviewer(s) will work with an IRB Office staff member and/or IRB Chair to invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.
3. Consultants with potential conflicts of interest may not provide information to the IRB.
4. The use of a consultant and the result of the consultant’s review will be shared with the IRB by either having the consultant attend and present to the convened IRB or by having the consultant provide a written report to the IRB.
   1. If the consultant presents at a convened meeting, the IRB minutes will document key information provided by the consultant. The consultant will not vote with the IRB.
   2. If the consultant provides a written report, the report will be included in the protocol records.

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1. **Membership Documentation & IRB Roster(s)**
2. The IRB Office is responsible for maintaining documentation of IRB membership. Rosters for each IRB contain the following information for each member and alternate:
   1. Name
   2. Earned degree(s)
   3. Chief anticipated contribution (board certifications, licenses, etc.)
   4. Special representation
   5. Scientist status (physician, other, or non-scientist)
   6. Affiliation status (yes or no)
   7. Employment or other relationship with the university (e.g., paid or unpaid member of a university governing panel or board member (not including the IRBs), consultant, hospital volunteer, etc.).
3. Information for alternates also includes the member(s) for whom the alternate may substitute.
4. The IRB Office also is responsible for maintaining other member records including, but not limited to, the member’s curriculum vitae, any letters of appointment, and renewal or recognition.
5. Records relating to past members are stored according to Federal regulations and University policies regarding storage of IRB records.

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1. **Review of IRB Composition and Performance**
   1. **IRB Composition**

The composition of the IRB is reviewed at least annually by the IRB Chair and IRB Office staff to determine if adjustment of the membership or composition is necessary to meet regulatory and organizational requirements, including whether or not membership reflects the expertise for appropriate scientific and ethical review of research.

1. The IRB Chair and IRB Office staff evaluate, at least annually, various characteristics of IRB operations and performance including both the composition of the Board and the source of studies reviewed by the Board as a function of Schools and Departments.
2. The IRB Chair recommends, when appropriate, changes in the composition of the Board to the IO and Chancellor.
3. IRB members are notified in writing by the Chancellor or the IO when their services are requested or if they are no longer needed to serve.
4. IRB Office staff will promptly update the roster when changes in IRB membership are made.
   1. **IRB Members**

IRB members are evaluated on an ongoing basis by the IRB Chair and Vice-Chair. However, formal evaluations occur annually.

* + On an annual basis, each IRB member will complete a self-evaluation survey assessing his/her understanding of regulations and policies, review and preparation of materials prior to meetings, participation in meeting discussion, interactions with investigators and IRB staff, and areas for improvement.
  + The completed surveys will be reviewed by IRB Chair, Vice Chair and/or ORS Director, with input from the IRB Office staff to assess performance.
  + Written feedback will be provided to each member about his/her performance within one month of submission of the self-evaluation. The letter also will include several metrics including rate of attendance, volume of IRB assignments, and timeliness of reviews for the evaluation period.
  + If any significant concerns are identified, the IRB Chair or Vice-Chair will address these confidentially with the individual committee member and then provide necessary guidance materials or educational sessions.
  + The self-evaluation and attendant discussion is used to determine areas of focus, if needed, and decisions about continued membership.
  1. **Chairs/Vice-Chairs & IRB Staff**

Chairs/Vice-Chairs are evaluated on an ongoing basis by the IO and/or ORS Director; IRB staff is evaluated by the Chair and/or ORS Director. Formal evaluations, however, occur annually.

* + 1. On an annual basis, IRB members will complete an anonymous survey assessing the performance of the Chair(s)/Vice-Chair(s) and IRB staff.
    2. Both parties will be assessed on their knowledge of regulations and institutional policies; efficacy of communication and interaction among and between key stakeholders including Chairs/Vice-Chairs, IRB members, IRB Staff and Investigators; and preparation for Board meetings. In addition, Chairs/Vice-Chairs will be assessed according to leadership ability, management of convened meetings, engagement in the review process, and effectiveness as representatives of the IRBs; whereas IRB Staff will be evaluated also for preparation and maintenance of meeting records.
    3. The anonymous survey results will be aggregated and shared with the full committee so that any necessary discussions and improvements can be made.
    4. This information also will be shared with the IO and the ORS Director. The IO and/or ORS Director are responsible for addressing, at least annually, performance issues with the IRB Chairs/Vice Chairs and for selecting new Chairs and Vice Chairs when necessary. The ORS Director is responsible for annual evaluations of IRB Staff members.

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1. **Other Terms & Conditions** 
   1. **Confidentiality:** IRB members agree not to discuss, disclose, or reproduce any confidential IRB information, except as necessary to carry out IRB membership responsibilities or as required by law.
   2. **Indemnification:** IRB members and alternates fulfill their administrative and institutional service responsibilities to the University, in part, by serving on an IRB committee. Accordingly, the University will indemnify IRB members in the event of a legal dispute relating to the actions of the committee, provided that the IRB member has acted in good faith and in accordance with federal requirements, state and local laws and University policy.
   3. **Resignation:** Resignation of IRB membership status, based on the wishes of the IRB member, will be submitted, in writing, to the Institutional Official and copied to the IRB Chair.
   4. **Suspension or Termination:** IRB Membership status may be suspended or terminated by the IRB Chair due to failure to attend and/or otherwise actively participate in IRB functions, provided that such member is given reasonable notice of the grounds for the suspension or removal and an opportunity to be heard. Termination of any individual from IRB membership will be reported to the Institutional Official to include a written justification for the termination.

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1. **References and Regulations**
2. **DHHS Regulations**
3. IRB Membership: [45 CFR 46.107](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%2346.107)
4. IRB Review of Research: [45 CFR 46.109](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%2346.109)
5. **FDA Regulations**
6. IRB Membership: [21 CFR 56.107](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.107)
7. IRB Review of Research: [21 CFR 56.109](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.109)
8. **LSUHSC Policies**
9. Conflicts of Interest in Research **-** [Chancellor’s Memorandum #35 (CM-35)](https://www.lsuhsc.edu/administration/academic/ors/docs/cm-35.pdf)

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| **Version Number** | **Version Date** | **Summary of Changes** |
| 3.0 | 11.20.2020 | Consolidated separate policies and added details about IRB member evaluations |
| 2.0 | 2.07.2020 | Separated section in Guidebook into multiple online policies |
| 1.0 | 3.35.2019 | N/A |