202.1 Scope of UH IRB Authority

The IRB derives its authority from both regulatory and institutional sources (e.g., EP 12.301 and AP 12.301). IRB provides reports to the Institutional Official through the HSP Director. No UH Human Subjects Research can commence without the approval of the IRB.

The IRBs operating under the HSP have the statutory and institutional authority to take any action necessary to protect the rights and welfare of human research participants involved in research. Along with conducting reviews of human participant research, the IRB authority includes, but is not limited to, the following:

- Assess suspected or alleged deviations from regulations or approved protocol;
- Address participant complaints;
- Investigate violations of external regulations or UH policies; and
- Monitor research conduct and report on noncompliance (45 C.F.R. parts 46.109, 46.112, 46.113)

The IRB has the authority to suspend or terminate the enrollment or ongoing involvement of research participants and research as it determines necessary for the protection of those participants.

Upon request, the IRB shall review and comment on proposed external regulations dealing with human research. When appropriate, the IRB will formulate draft policies and procedures for approval by the appropriate UH administration.

202.2 Composition and Membership

IRB Composition

Each UH IRB meets the following IRB composition requirements:\[\text{\textsuperscript{11}}\]:

1. Has at least five (5) regular members;
2. Possesses varying professional backgrounds to appropriately and adequately review research activities commonly conducted at the UH;
3. Is sufficiently diverse relative to ethnicity, gender, cultural background, and sensitivity to community attitudes;
4. Includes members knowledgeable of institutional commitments, applicable law, and standards of professional conduct to determine the acceptability of a proposed study;
5. Includes both male and female members at any given time;

\[\text{\textsuperscript{11}}} 45 \text{C.F.R. § 46.107; IRB Registration Instructions, HHS (June 15, 200), http://www.hhs.gov/ohrp/assurances/forms/irbregisinstruct.html\]
6. Includes at least one member whose primary concerns are scientific, and at least one member whose primary concerns are nonscientific;
7. Includes at least one member who, or whose immediate family member, is not affiliated with the UH; and
8. If the IRB regularly reviews studies that involve a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration is given to include one or more individuals who are knowledgeable about and has experience in working with these populations.

Alternate Members

Each alternate IRB member, who votes in the place of a regular member at the IRB meeting when the regular member is absent or recused from voting, has the experience, expertise, background, professional competence, and knowledge equivalent to that of the regular IRB member who the alternate replaces.

Membership: Length of Term, Responsibilities, Attendance, Compensation, and Removal

An IRB consists of regular and alternate members. This section applies equally to regular and alternate members unless stated otherwise.

Appointment

The IRB Chair and the Director nominate and appoint individuals for IRB membership. Investigators and faculty or entities outside the HSP may recommend, but are not involved in the appointment of IRB members.

Members are selected based on the following qualifications:
1. Knowledge of applicable federal regulations;
2. Experience in performing research;
3. Experience in serving on an IRB or other research committees;
4. Knowledge of community values and norms; and/or
5. Other qualifications determined to be important in maintaining a diverse and qualified IRB.

Length of Term

IRB members serve two (2)-year terms, and are eligible for reappointment.

Responsibilities

All IRB members are responsible for reviewing and monitoring research involving human subjects and protecting the rights and welfare of subjects. Members vote to approve, require modifications in, or disapprove research submitted to the IRB. Duties of members and alternate members include:
1. Attending IRB meetings on a regular basis;
2. Reviewing received meeting materials prior to the meetings;
3. Serving as a primary or secondary reviewer as assigned;
4. Serving as general reviewers on all research discussed at convened meetings;
5. Conducting expedited reviews on behalf of the IRB when so designated by the IRB Chair;

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6. Maintaining confidentiality of IRB decisions and materials;
7. Keeping abreast of regulations and policies on human research; and
8. Completing the necessary orientation and required educational requirements.

Attendance Requirements

Regular IRB members are expected to attend at least six (6) of all convened meetings in a year. If a member cannot attend a scheduled meeting, the member shall notify the Director or the Director's designee at least one week before the meeting.

At least one unaffiliated member must be present in at least six (6) out of twelve (12) meetings in a calendar year.

Compensation

UH IRB members do not receive financial compensation.

Removal

A member may renew their term in the IRB indefinitely until the member steps down voluntarily or involuntarily. A member may be removed because of conflicts in time or interest. A member also may be removed for improper conduct, such as not acknowledging a conflict of interest, not maintaining confidentiality of the proceedings, failure to fulfill training requirements, or lack of regular attendance or meaningful participation in IRB meetings. A decision to remove a member is made collaboratively between the IRB Chair and the HSP Director.

IRB Chair and Vice Chair

IRB Chairs and Vice Chairs are appointed by the HSP Director and the ORC Director.

Selection of the Chair and Vice Chair are based on, but not limited to:
1. Comprehensive knowledge of the human subjects regulations,
2. Experience as an Investigator,
3. Uses sound ethical judgment which can be evidenced by past practices,
4. Experience as a Chair or member of an IRB,
5. Willingness to commit as a Chair/Vice Chair, and
6. Status, experience, or reputation consistent with upholding the independence of an IRB

The Chair and Vice Chair serve a two (2) year term and may be reappointed.

Responsibilities of the IRB Chair and Vice Chair

In addition to the responsibilities as a member, the Chair has primary responsibility for conducting IRB meetings and ensuring that the IRB operates within all applicable regulatory requirements. The duties of the Chair include:

1. working with IRB members, the Director and staff, and Investigators to ensure that the rights and welfare of research participants are protected;
2. ensuring that IRB minutes are recorded accurately;
3. reviewing and approving protocol applications that may be expedited or delegating the authority to experienced members of the IRB;
4. ensuring that IRB members having a conflict of interest with a particular protocol abstain from voting on the protocol;
5. ensuring a quorum is maintained when voting;
6. participating in the resolution of controversial, substantive or procedural matters; and
7. participating in monitoring and improving the operation of the IRB.

The IRB Vice Chair assumes all responsibilities of the Chair when the Chair is unavailable. If the Chair is unable to perform Chair duties, the Vice Chair assumes all responsibilities of the Chair until the Director and the Assistant Vice Chancellor of Research Compliance (AVCRC) appoint a replacement IRB Chair. It is not required for an IRB to have a Vice Chair.

### 202.3 IRB Member Scientific and Scholarly Expertise

Having the diverse scientific or scholarly expertise, IRB members can review a broad range of UH-engaged research. Policy requires IRB members to be knowledgeable about all relevant regulatory requirements, while remaining impartial and objective to the best of their ability during protocol review, deliberation and voting. The IRB includes members who are particularly knowledgeable about research ethics and the vulnerable research participants included in UH research.

However, in situations where the IRB lacks members who have the expertise in a particular research, outside experts may be consulted. Consultants may provide comments in writing. The written comments are retained in the study files. An IRB may also consult the Investigator about the study.

The consultants may be asked to attend a convened IRB meeting, or assist in providing information to the designated reviewer in an expedited review. Consultants do not vote and are not counted towards a quorum; they are excused from the meeting before the vote. If a consultant attends an IRB meeting, meeting minutes document the attendance and describe the consultant's role in the review.\(^\text{13}\)

### 202.4 Members’ Conflicts of Interest

No IRB member participates in the IRB’s review of any research where the member has a conflicting interest, except to provide information requested by the IRB.\(^\text{14}\) The IRB members, including the Chair, who have conflicting interests in the research, must disclose those conflicts before the IRB’s review of the study, and recuse themselves from the deliberation, quorum count, and vote on the research.\(^\text{15}\)

Individuals responsible for business development\(^\text{16}\) do not serve on the IRB as members nor are involved in the day-to-day operations of the IRB. This restriction is to ensure the IRB review process is free of conflicting interests so that the members' obligation to protect participants is not compromised.

See **SOP 106: IRB Member Conflicts of Interest** for procedures for reporting and managing IRB

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\(^{14}\) 45 C.F.R. § 46.107(c); 21 C.F.R. § 56.108(c).
\(^{15}\) Note: abstention is not due to conflicts of interest and abstained members may be counted towards quorum. [*Id.*]
\(^{16}\) Examples of individuals responsible for business development are the Director for the Office of Research Services, Vice President for Research, or Vice Chancellor for Research. Those individuals are responsible for raising funds or garnering support for research.
member conflict of interests.

202.5 Training of IRB Chairs and Members

Before assuming responsibility as a voting member of the IRB, newly appointed IRB members participate in an orientation and are given copies of relevant policies and procedures and other documents appropriate to their role.

New members are also paired with experienced members for the first few protocols that are assigned to them as reviewers. New members may seek assistance from HSP staff and experienced IRB members regarding questions about regulations and review process at any time during their term.

Continuing Education

IRB members, the HSP Director and other subject matter experts conduct educational presentations to the convened IRB. Longer policy discussions or special topic seminars are scheduled as needed. IRB members periodically receive copies of books, articles, newsletters and other information in electronic format or through materials distributed at IRB meetings on the most current information on human participant research as it relates to IRB review. Topics, identified by the QIU to require more attention, will be reviewed during special training sessions. The HSP maintains reference materials in its office, which are made available to IRB members.

202.6 IRB Roster and Quorum Requirements

IRB Roster

UH IRB Rosters are created to meet the requirements specified under 45 C.F.R. §§ 46.107 and 108; and 21 C.F.R. §§ 56.107 and 108.

An IRB Member database is maintained by the HSP and used as the data source for all IRB membership roster needs. The IRB Member database includes all information required under the HHS and FDA regulations and Office for Human Research Protection (OHRP) guidance (45 C.F.R. §§ 46.107 and 108; 21 C.F.R. §§ 56.107 and 108) including:

- Members’ names
- Names of alternate members (and regular members who whom they substitute)
- Gender
- Earned degrees and licenses
- Scientific status (see definition on “scientist” vs. “non-scientist”)
- Representative capacity (e.g., prisoners, children, pregnant women)
- Affiliation (see definition on affiliation)
Changes to IRB membership are reported to OHRP. The HSP Director (or delegate) revises and registers its membership list to OHRP whenever membership or member information changes occur; and whenever a new IRB is formed or eliminated.

UH graduate students may serve as IRB members to represent the perspective of participants in many social & behavioral sciences research. A UH student may be nominated by experienced IRB members who are also UH faculty or administrators that have witnessed a student’s potential to appropriately and objectively review human participant research. Senior IRB administrative staff may also be appointed as an alternate member of the IRBs.

Quorum and Voting Requirements:

The IRB Chair and Vice Chair are voting members of the IRB. The Chair determines that quorum is established and maintained, chairs the meeting discussions, and calls for votes as appropriate.

Maintaining quorum and voting at convened meetings is based on the following for each meeting, unless otherwise indicated:

1. A majority of the (voting) IRB members (or their designated alternates) including at least one member with a non-scientific background must be present to conduct a convened meeting. For research to be approved, it must receive the approval of the majority of members present at the meeting.

2. If an IRB reviews research that involves categories of participants vulnerable to coercion or undue influence such as children or prisoners, one or more individuals knowledgeable about or experienced in working with such participants must be present;

3. If an IRB reviews research involving prisoners, a prisoner representative must be present to vote, and a majority of the members present must have no association with the prison involved.

4. Members recusing themselves from a particular review due to conflicts of interest may not be counted towards quorum for the particular review. Recusal is due to conflicts of interest while abstention is due to reasons other than conflicts of interest. An IRB may not count recused members, but may count abstained members, towards quorum.

5. Members may participate in meetings by being physically present or via telephone or virtual, synchronous audio-visual teleconference, with the same standards and opportunity to participate fully in IRB discussions. Meeting minutes documents each individual’s mode of participation. Use of electronic devices to access meeting materials is allowed and encouraged during the meetings.

6. Individuals who are not listed on the official IRB membership roster may not vote with the IRB. These include non-voting ex-officio members, ad hoc consultants, and HRPP staff.

7. When a member and their alternate both attend a meeting, either person (but not both) may vote on each protocol or proposal.
8. Proxy votes are not allowed.

9. If the quorum is lost during a meeting, the IRB cannot take any further actions or vote until the quorum is restored.

10. The HSP staff is responsible for monitoring the members present at a convened IRB meeting to ensure that at the beginning of the meeting and for each subsequent vote the meeting is appropriately convened.

### 202.7 IRB Meeting Schedule and Materials

#### Scheduling of the Meetings

During the academic year (September through May), the IRB meet once a month; during the summer months (June and August), it may convene less frequently.

The annual meeting schedule is distributed about one month before the new calendar year, and posted on the HSP website. Changes in dates, times, and locations of scheduled IRB meetings are communicated to all IRB members before the meeting or at the beginning of a meeting during the announcement portion. Investigators are notified of rescheduling or cancellation of IRB meetings if their application is queued for review.

#### Review and Preparation Time

**Application Materials**

The IRB Coordinators assigns applications to the primary and secondary reviewers in sufficient time for them to be reviewed before the meeting, usually at least two weeks prior to the upcoming meeting. All other members are granted access to the presented application materials, usually at least two weekends prior to the upcoming meeting.

The HSP provides materials for IRB members before each scheduled convened meeting. For the list of materials provided to members, see [SOP 105: IRB Meeting Preparation and Conduct](#).