UCLA Research Administration
Human Research Protection Program

Guidance and Procedure: UCLA IRB Chair and Vice-Chair Responsibilities (updated 8/31/2011)

General Responsibilities of IRB Chair and Vice-Chair

In addition to the responsibilities described in the guidance document UCLA IRB Member Standards and Responsibilities, the UCLA IRB Chairs and Vice Chairs have additional responsibilities to help ensure the safety and welfare of human research participants. They are appointed not only because of their leadership abilities but also because of their high level of knowledge of human research regulations and UCLA OHRPP policy and procedures. This guidance document describes these additional responsibilities.

Full Committee Meetings and Review of Expedited Submissions and Post-Approval Reports

UCLA IRB Chairs and Vice Chairs have the following responsibilities with respect to protocol reviews:

- Direct the proceedings and discussion of Full Committee meetings to ensure review and approval of Full Committee submission in accordance with the ethical principles of the Belmont Report, the regulatory requirements (i.e., 45 CFR 46.111, and 21 CFR 56.111 when the research is regulated by the Food and Drug Administration), state laws and University policies. This includes but it not limited to making sure that
    - Ample time is allowed for discussion for each study.
    - Regulatory determinations are made as required.
    - Voting takes place for each study.
    - Members who have a conflict of interest leave the room during deliberation and voting.
    - Studies are approved only if the regulatory criteria for approval have been met.
- Review and approve Expedited submissions in accordance with the ethical principles of the Belmont Report, the regulatory requirements of 45 CFR 46.111, state laws and University policies.
- Seek outside consultation when needed.
- Review Post-Approval Reports to determine whether the risk-potential benefit profile of the study has changed and whether review by the Full committee is warranted.
- Review initial allegations of serious and/or continuing noncompliance to determine whether to refer the incident for Full Committee deliberation.
- Reviewing Single Subject Exception to determine whether it is acceptable for the investigator to deviate from the approved protocol for a single subject.
- Conferring with investigators who wish to apply the FDA Emergency Use provisions and reviewing post-emergency use reports.
- Reviewing and approving IRB correspondence to be issued to investigators.
- Reviewing investigator responses to correspondence.

- Providing guidance to investigators as needed.
- Reporting both up the hierarchy of the University and out to federal regulators and others as described in OHRPP IRB Reporting Procedures for Unanticipated Problems, Noncompliance, Suspension or Termination.

Additionally the UCLA IRB and IRB Chair/Vice Chair have the authority to suspend all or parts of the research when it is suspected or determined that the following has occurred: an unanticipated problem associated with unexpected serious harm to research participants, the research is not being conducted in accordance with the IRB requirements with possible risk of harm to research participants, and/or serious or continuing noncompliance has taken place.

Orienting, Evaluating and Guiding IRB Members

UCLA IRB Chairs and Vice Chairs serve a particularly critical role with respect to their relationships with the other IRB Members and are asked to.

- Whenever possible, participate in initial orientation of new members,
- Formally evaluate the IRB members on their committee at least once a year.
- Provide guidance to IRB members during the review process at the meetings and outside of meetings when appropriate.
- Discuss with the Director any additional needs of the committee for additional members or if there are any issues with member performance.

Working Closely with OHRPP Administrative Staff

The UCLA IRB Chairs and Vice Chairs are asked to:

- Work closely with the Administrator for the panel they are assigned to make sure the agendas are the appropriate and the best reviewers are assigned to studies.
- Review correspondence as requested.
- Provide consultation and guidance to the staff as needed.
- Keep the Director informed of any additional support that may be needed, any concerns with staff as well as any outstanding performance.

Identifying, Developing and Implementing UCLA IRB Policies

UCLA IRB Chairs and Vice-Chairs are responsible for

- Identifying areas of the Human Research Protection Program which require developing and implementing policies, guidance and/or procedures.
- Reviewing and providing comments about proposed policies.
- Assisting in the training of IRB members about new policies and guidance.
- Serving on the IRB Executive Committee when asked by the Vice Chancellor.

UCLA IRB Chairs are asked to participate in the UCLA Human Research Policy Board (HRPB) as a voting member.

References

- Policy and Guidance: Suspension and Termination of Research
- Post-Approval Reporting Requirements for Investigators: Reporting of Unanticipated Problems, Including Adverse Events as well as Protocol Violations, Deviations and Incidents and the Reporting of Updated Study Safety Information
- Human Research Policy Board
- Referral to the IRB Executive Committee