

Guidance and Procedure: OHRPP Staff Responsibilities

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General Responsibilities of OHRPP Staff

OHRPP staff members are responsible for performing a variety of duties to support and facilitate the work of the **three units that make up the UCLA Office of the Human Research Protection Program (OHRPP)**. The program consists of the following three units:

- Protocol Review,
- Education and Training, and
- Quality Improvement.

OHRPP staff members are also required to fulfill human subject training requirements and to keep current with regulations and guidance pertaining to the protection of human subjects protection. This guidance document describes OHRPP staff member responsibilities in supporting and facilitating the UCLA Human Research Protection Program.

Protocol Review Unit

OHRPP staff members who are part of the Protocol Review Unit coordinate and support the activities of the five UCLA IRBs responsible for reviewing all research protocols that involve human subjects. The Protocol Review unit staff members' responsibilities include but are not limited to the following:

- Supporting the IRB members and Chairs in their responsibilities to conduct a timely review of all applications for the use of human subjects in research.
- Notifying investigators and appropriate UCLA officials in writing the IRB decisions to approve or withhold approval of applications or modifications of ongoing activities.
- Providing guidance to investigators in interpreting and applying federal requirements for IRB approval ([45 CFR 46.111](#) and [21 CFR 56.111](#)), university policies and procedures, and federal and state laws applicable to the research.
- Assisting investigators in the preparation of IRB applications.
- Responding to investigators' inquiries by telephone or e-mail within a timely manner.
- Being as supportive and flexible as possible in responding to researchers.
- Performing pre-review to ensure completeness and accuracy of protocol submission prior to review by the Full Board or by the expedited procedures.
- Preparing and distributing Full Board meeting agendas, including assigning primary and secondary reviewers to each submission.
- Coordinating with the Quality Improvement Unit to include any allegations of noncompliance or unanticipated problems on the Full Board meeting agendas.

- Coordinating with the Education Unit to include items for educational activities on the agendas.
- Documenting Full Board deliberations by taking minutes and recording any controverted issues.
- Providing regulatory guidance to facilitate Full Board deliberations and determinations.
- Providing regulatory guidance to facilitate review by the expedited procedures.
- Communicating the IRB discussions by drafting correspondence to describe any ethical concerns, regulatory requirements or revisions requested by the Full Board. The Committee Chair or designee reviews the correspondence before it is forwarded to the researcher.
- Preparing correspondence to be forwarded to the researcher for the expedited reviewer(s) as needed.
- Issuing IRB approval letters.
- Reviewing and certifying studies that may qualify for exempt certification. Preparing any related correspondence and/or issuing Exempt Certifications.
- Meeting time-to-completion standards established by the OHRPP Director.
- Ensuring that the IRB records comply with the federal requirements outlined in [45 CFR 46.115](#) and when the research is regulated by the Food and Drug Administration [21 CFR 56.115](#).
- Assisting with keeping current and adding to the [OHRPP](#) website.

Education and Training Unit

The Education and Training Unit, which may include staff members from other units of the OHRPP, in collaboration with the IRB Chairs, is responsible for the training and education of the UCLA research community. Though many others throughout the University also contribute to this training through classroom activities, seminars, workshops and lectures, the Education and Training staff member responsibilities include but are not limited to the following:

- Developing and coordinating training and education activities on topics pertaining to the IRB review process and conduct of human subject research.
- Conducting lectures and workshops for the research community on various topics pertaining to the IRB review process and conduct of human subject research such as the federal requirements for IRB approval ([45 CFR 46.111](#) and/or [21 CFR 56.111](#)), including the ethical principles of the [Belmont Report](#), and university [policy and procedures](#).
- Conducting training sessions for the research community on the use of the web-based electronic IRB submission and review system (webIRB).
- Maintaining, disseminating, and updating educational and institutional review guidance materials.
- Working with the Quality Improvement Unit to develop training materials based on the outcomes of their reviews.
- Working with the Protocol Review Unit to develop training materials based on the evaluation and needs of the IRB members.
- Developing and implementing the use educational assessment materials.
- Coordinating with other human research educational outreach activities at UCLA, local and statewide.
- Keeping current and contributing to the [Certification, Education and Training](#) section of the OHRPP website as well as the information on the [webIRB Home Page](#).

Quality Improvement Unit

The Quality Improvement Unit, in collaboration with the IRB Chairs, monitors and measures the effectiveness and quality of the HRPP. Quality Improvement staff members' responsibilities include but are not limited to the following:

- Conducting both for-cause and not-for-cause on-site reviews of human research activities.
- Processing and reviewing all post-approval reports submitted to the IRB and performing quality assurance monitoring of research protocols.
- Referring any reports of unanticipated problems involving risks to study participants or others as well as incidents or allegations of serious and or continuing noncompliance to the IRB for review and management.
- Processing, reviewing and inquiring into all complaints and concerns that are brought to the attention of the OHRPP/IRB regarding human subjects research conducted at UCLA.
- Reviewing and assessing subjects' opinions and assessment of their experience in participating in human subject research at UCLA.
- Responding to PI requests for emergency use of an investigational drug or device.
- Conducting consent monitoring.
- Routinely reviewing and assessing IRB and OHRPP operations and procedures.
- Developing and conducting quality improvement activities to improve human research protections at UCLA.
- Coordinating activities with other QI units at UCLA.
- Coordinating with the Education Unit to provide feedback about topics or areas that need additional education.
- Identifying topics for education related to clinical research.
- Keeping current and adding to the [Clinical Research Toolkit](#) on the OHRPP.

Maintaining and Improving Knowledge and Skills

OHRPP staff members are required to complete all training described in the [List of References for IRB Members and Staff](#) and OHRPP Education and Training guidance documents. In general OHRPP staff members expect to:

- Being knowledgeable about the information on the [OHRP](#), the [FDA](#) and [UCLA OHRPP](#) websites.
- Using or having a working knowledge of the UCLA IRB Checklists for the criteria for reviewing and approving IRB applications and for preparing consent forms.
- Attending ongoing training and continuing education opportunities.
- Participating in regulatory and professional meetings and conferences.
- Completing and keeping current training and certification programs, [CITI](#) for all staff and [Certified Institutional Review Board \(IRB\) Professional \(CIP®\)](#), when eligible.
- Taking advantage of professional development activities when offered or provided.

References

- DHHS Regulations for the Protection of Human Subjects in Research: [45 CFR 46](#)
- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)
- [Public Responsibility in Medicine and Research](#)
- [UCLA List of References for IRB Members and Staff](#)