1. PURPOSE
This policy describes the training and educational requirements for COMIRB staff, panel members and chairpersons.

2. POLICY
Training of COMIRB staff, panel members and chairpersons is critical if the COMIRB is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout the University of Colorado Denver and its Affiliates.

COMIRB chairpersons, panel members and staff charged with responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics and policies applicable to human subject research. Such training is fully supported by the management of the COMIRB, UCD Assistant Vice Chancellor for Regulatory Compliance, and the CEO and Office of Research Compliance at each Affiliate.

3. SPECIFIC POLICIES

3.1 Training

3.1.1 COMIRB chairpersons, panel members and staff who are overseeing research on human subjects, as defined in 45 CFR 46.102(f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an institution under the jurisdiction of COMIRB will receive initial and ongoing training regarding the responsible review and oversight of research and COMIRB policies and accompanying procedures.

3.1.2 The Director and Assistant Director under the direction of the Vice Chancellor for Research establish the educational and training requirements for COMIRB chairpersons, panel members and staff who review biomedical and social behavioral research involving human subjects and/or who perform related administrative duties. Initial and ongoing training is documented by COMIRB in the appropriate training logs. The Senior IRB Staff is responsible for ensuring that these requirements are tracked and followed.

3.1.3 Panel Members:
3.1.3.1 The panel Chair, the Director, and/or COMIRB staff identifies a need for a new or replacement member, or alternate member. Panel Chairs and members may nominate candidates and sends the names of the nominees to the COMIRB Office. Department Chairs and others may forward nominations to the Institutional Official or COMIRB. Faculty members may also self-refer to COMIRB, and the Director contacts the nominee. If there are no nominees, then appropriate Department Chairs or Program Directors will be contacted in writing by the Institutional Official, or the Director, concerning the vacancies and solicit nominees from the Department Chairs or Program Director. The decision to select a new member is made by the Director, in consultation with the IO, Senior IRB Staff, and/or Chairs as appropriate.

3.1.3.2 The new panel member will discuss with the Director or Assistant Director for an orientation session to discuss IRB service. This orientation session should be conducted prior to the new member attending a panel meeting or following their first observational meeting.

3.1.3.3 The Director or Assistant Director then forwards the nominee to the IRB Panel Manager who will provide the following documents:

a) A copy of the Belmont Report;
b) UCD COMIRB Policies and Procedures for the Protection of Human Subjects (CP-001);
c) SOP - training and education (CP-011);
d) Indemnification of COMIRB Community Members (community member only);
e) Member Information Sheet (CF-027);
f) Link to the COMIRB website for more information on policies and regulations.

3.1.3.4 All new Panel Members must:

a) Provide a current CV or resume
b) Complete the Member Information Sheet (CF-027) outlining their expertise, any significant financial conflicts of interest, non-financial conflicts of interest, and confidentiality agreement.
c) Complete or update their Conflict of Interest Declaration on file with the UCD Conflict of Interest and Commitment Office.

3.1.3.5 The new panel member is required to complete the following online training:

a) CITI HIPAA module
b) CITI Basic course (one of the following modules: Biomedical Investigators (Group 1), Social Behavioral Research (Group 2), Good Clinical Practice and ICH (Group 4)

Recommended: COMIRB Panel Members (Group 3) at the CITI site.

3.1.3.6 The IRB Panel Manager will add the new panel member as a consultant in InfoEd.

3.1.3.7 The Panel Coordinator coordinates the meeting schedule of the new panel member. The new panel member is asked to attend three training meetings. The first two meetings are observational. At the third meeting, the new panel member will conduct a mentored review, in which the new panel member reviews a protocol (initial or continuing review) in the area of his/her expertise, whenever possible, under the guidance of a mentor who is an experienced panel member and present at the meeting. The Panel Coordinator, after consultation with the Senior IRB Staff and/or Chair, assigns a protocol and mentor to the
new panel member. The Panel Coordinator provides the appropriate evaluation forms (see below, 3.1.3.8) to the new panel member and his/her mentor prior to the meeting.

3.1.3.8 After the mentored review, the forms listed below are completed by the new panel member and the mentor and returned to the Panel Coordinator.

- CF-024 COMIRB Training Mentor New Lay Member Evaluation Form (for non-scientific member)
- CF-025 COMIRB Training Mentor Evaluation Form (for scientific member)
- CF-026 COMIRB Training New Panel Member Trainee Evaluation Form

3.1.3.10 All training documents are given to the IRB Panel Manager who verifies completion of the training, maintains the New Panel Member Training Record (CF-020), and drafts the appointment letter. Once the Panel Manager verifies completion of all requirements, all of the required documents are given to the Director.

3.1.3.11 The Director sends the Appointment Letter to the new panel member as a new member on the appropriate panel roster(s).

3.1.3.12 The Director will add new panel members to the IRB roster as an alternate or full Member and updates InfoEd with the new members on the appropriate panel(s).

3.1.3.13 On-going commitment for panel members:

- Update their conflict of interest declaration in accordance with UCD policy or more frequently as needed. This is completed by Panel Members in InfoEd.
- Update the non-financial conflicts of interest yearly or as needed. The Director sends out an email requesting the update. Panel Members are expected to respond to the email. The form can also be brought to a panel meeting by the Senior IRB Staff if necessary.
- Complete all appropriate checklists for each protocol reviewed as much as necessary to complete reviews. Checklists are provided by the Panel Coordinators.
- Attend at least six panel meetings a year for biomedical panels or 25% of social and behavioral meetings held.

3.1.3.14 On-going training requirements for panel members:

- Review articles and guidance documents provided by COMIRB Staff in the monthly continuing education email and/or at panel meetings.
- Read information/educational materials distributed by COMIRB administration.
- Community members will be asked to attend an annual education day.

Additional optional training includes attending:

- PRIM&R, OHRP, AAHRPP, or other professional conferences
- PRIM&R, OHRP, AAHRPP, or other professional webinars
- Ethics Grand Rounds
- Annual Ethics Conference(s)
• Guest speaker lectures

3.1.3.15 The articles and guidance documents provided monthly by email are documented in the meeting minutes.

3.1.3.16 Resignation of a Panel Member:

This should be communicated in writing to the Director who will then forward the revised roster to the Senior IRB Staff.

The Director is responsible for updating the IRB roster. An appropriate replacement will be identified according to the procedures described above in Section 3.1.3.1.

3.1.3.17 Poor Attendance:

If an issue of poor attendance or lack of availability is brought to the attention of the Director, the matter is discussed with the appropriate panel Chair and Senior IRB Staff.

The Director or Assistant Director will discuss the situation with the panel member. The Director, who will consult with the panel Chairs, Institutional Official, and Senior IRB Staff when necessary, will make a decision. Any change in the panel member’s status will be communicated to them in writing.

The Director is responsible for updating the IRB roster. An appropriate replacement will be identified according to the procedures described above in Section 3.1.3.1.

3.1.4 Chairs:

3.1.4.1 Any new full board Chair must first complete the new panel member training before commencing additional training to be a full board Chair and have at least 12 months experience as a panel member before beginning the training. This requirement can be waived only by the Director in consultation with the panel members and other Chairs.

3.1.4.2 The Chair trainee will receive additional training in areas that pertain to their additional responsibilities including:

• The Chair trainee is expected to attend three mentored panel meetings as an ‘acting Chair’ under the guidance of an experienced Chair. The Panel Coordinator will schedule these meetings.

• For a new Panel S Chair, the trainee may attend any panel meetings for training purposes.

• The Chair trainee is expected to train with an experienced Chair on expedited review for at least 16 hours.

• The Chair trainee is expected to attend at least two panel meetings at two different panels and meet with the Chairs at these two panels.

• The IRB Panel Manager will update the New Chair Training Record (CF-022) and maintain this information in their file.

• The Director is responsible for updating the IRB roster and sending a new Appointment Letter to document this roster change.
3.1.4.3 On-going commitment for Chairs:

- Update their conflict of interest declaration in accordance with UCD policy or more frequently as needed.
- Update the non-financial conflicts of interest yearly or as needed. The Director sends out an email requesting the update annually. Chairs are expected to respond to the email promptly.
- Complete all appropriate checklists for each protocol reviewed as much as necessary to complete reviews for protocols reviewed at panel meetings. Checklists must be fully completed and returned to COMIRB staff for exempt/expedited reviews.
- Attend at least 12 biomedical panel meetings a year or 50% of social and behavioral panel meetings held.
- Attend at least eight Chair/Compliance Board meetings a year.
- In conjunction with the Senior IRB Staff, ask about conflict of interests for the current meeting and ensure minutes are approved if present.
- Before approving the minutes at Full Board meetings, ask the panel members if they have any questions or concerns.
- If articles of interest or guidance documents have been included in the packets or presented at the meeting, ask the panel if they have any questions or would like to discuss. Ask them if they have any additional discussion items.

3.1.4.4 On-going training requirements for Chairs:

- Review articles and guidance documents provided by COMIRB staff in the monthly continuing education email and/or at panel meetings.
- Read information/educational materials distributed by COMIRB administration.
- Review and stay current with regulations, guidance documents, and COMIRB policy.
- Attend PRIM&R, OHRP, or AAHRPP conference/training on a rotating basis; OR
  Attend at least two seminars, webinars, training workshops, or other educational opportunities supportive of their functions within COMIRB; OR
  Complete two additional CITI modules; OR
  Participate in COMIRB Office hours regularly to teach/mentor junior faculty on research protocols.

As these requirements are completed, documentation must be given to the IRB Panel Manager who will update the Chair Training Record (CF-021) and maintain this information in their file.
3.1.5 Exempt/Expedited Reviewers:

3.1.5.1 A senior panel member or panel Chair can become a reviewer for Requests for Exemption/Expedited reviews. All exempt/expedited reviewers must be panel members on a panel roster.

Non-Human Subject Research and Requests for Exemption reviews can be reviewed by designated COMIRB staff as well as senior panel members and panel Chairs on a panel roster.

The panel member reviewer is required to have completed the panel member training and be current with panel member on-going training requirements. The COMIRB staff must complete required training as described below in Section 3.1.5.2.

3.1.5.2 A new panel member exempt/expedited reviewer is expected to complete the following mentored reviews during training:

- Three Requests for Non-Human Subject Research Initials
- Three Requests for Exemption Initials
- Three Requests for Expedited Review Initials

A new COMIRB staff reviewer is expected to complete three Non-Human Subject Research initials and three Requests for Exemption Initial reviews during training.

Once the mentor determines the new exempt/expedited reviewer is adequately trained to perform initial reviews alone, then both the mentor and new reviewer review initial protocols as often as necessary to ensure the quality of reviews by the new reviewer. The frequency and length of the quality assurance process will be determined by the mentor at her/his discretion.

3.1.5.3 After reviewing initial submissions and reaching an appropriate level of comfort (usually a minimum of two months), the new reviewer can begin training for continuing reviews for expedited protocols followed by training for amendment reviews for exempt/expedited protocols. The new reviewer is expected to conduct three mentored reviews for each type of submission.

Once the mentor determines the new reviewer is adequately trained to perform continuing reviews or amendment reviews alone, then the mentor and new reviewer together review both types of submissions as often as necessary to ensure the quality of reviews by the new reviewer. The frequency and length of the quality assurance process will be determined by the mentor at her/his discretion.

3.1.6 Vulnerable population reviewers

3.1.6.1 A panel member or panel Chair can become a reviewer for a vulnerable population (children/neonates, pregnant women, decisionally challenged, and prisoners). A vulnerable population reviewer must be knowledgeable about or experienced in working with the applicable vulnerable population to be qualified as a vulnerable population reviewer. All vulnerable population reviewers must be panel members on a panel roster.

3.1.6.2 COMIRB staff or Chairs will identify a need for a new or replacement vulnerable population reviewer. A new vulnerable population reviewer can be identified by referral, including self-referral. The potential new vulnerable population reviewer is...
asked to submit a CV or resume demonstrating that s/he is qualified to be a vulnerable population reviewer. Senior IRB Staff will review this information to determine whether the potential vulnerable population reviewer is qualified to be a vulnerable population reviewer.

3.1.6.3 Once determined to be qualified, the new vulnerable population reviewer is required to complete, at minimum, one mentored review for the applicable vulnerable population (e.g., decisionally challenged) using the applicable checklist (e.g., decisionally challenged checklist). The mentored review is recorded in the minutes. Both the mentor and trainee will complete an evaluation form for this review.

3.1.6.4 Once the mentor affirms the competency of the new vulnerable population reviewer, completion of the training is documented in the minutes. The reviewer's CV/resume and completed evaluation form will be filed in their file.

3.1.7 COMIRB staff:

3.1.7.1 Newly hired COMIRB Staff will receive individualized training specific to their job responsibilities by their supervisor and designated experienced COMIRB staff according to the Standard Operating Procedures on New Hire Training (CP-030).

3.1.7.2 The new employee is required to complete the following online training:
  - CITI HIPAA Research Module
  - CITI Basic course (one of the following modules: Basic Biomedical Investigators, Basic Social Behavioral Investigators, GCP, and Responsible Conduct of Research)
  - UCD required courses depending on the position

3.1.7.3 On-going requirements for COMIRB staff:
  - Attend Monthly staff meetings
  - Stay current with COMIRB policies and procedures
  - Attend at least two seminars, training workshops, or other educational opportunities supportive of their functions within COMIRB OR complete two additional CITI modules
  - Attend/complete any mandatory COMIRB training(s)

3.1.7.4 All initial and continuing education/training courses attended and completed are logged by the employee on their COMIRB Staff Training Record (CF-019) in the COMIRB Training (Staff) binder maintained by the Senior IRB Staff.

3.2 Evaluation

3.2.1 Chairs:
The Director, in consultation with the Institutional Official and Assistant Vice Chancellor for Regulatory Compliance, reviews the performance of all panel Chairs on an annual basis. The appropriate Panel Coordinators and Senior IRB Staff may also be consulted when appropriate in evaluating Chairs’ performance.
The feedback will be provided to the Chairs individually in writing. The Director annually meets with each individual Chair for an evaluation. A copy of the evaluation letter will be kept in each Chair’s file.
3.2.2 Panel Members:

The Director, in consultation with the panel Chairs, Senior IRB Staff and Panel
Coordinators, reviews the performance of individual panel members on an annual basis.

The feedback will be provided to each panel member in writing. A copy of the evaluation
letter will be kept in in each panel member’s file.

3.2.3 COMIRB Director:

The Institutional Official, in consultation with the Assistant Vice Chancellor for Regulatory
Compliance, will review the performance of the Director and COMIRB office on an annual
basis.

The feedback will be provided to the Director in writing. A copy of the evaluation letter will
be kept in their file.

3.2.4. COMIRB staff:

The supervisor of COMIRB staff, in consultation with the Director, will review the
performance of the COMIRB staff at least annually and more frequently as needed.

The annual evaluation is provided to the COMIRB staff in writing prior to a scheduled
evaluation meeting. During the evaluation meeting, the supervisor and staff discuss the
evaluations and set goals for the following evaluation cycle. A copy of the signed
evaluation form will be kept in their file.

4. RESPONSIBILITY

The Director and Assistant Director are responsible for establishing, conducting
and/or supervising all relevant training programs for IRB members and COMIRB staff.

Chairpersons and the Director are responsible for guiding the development of COMIRB
member training programs in collaboration with the Research Compliance Office.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107
45 CFR 46.107
OHRP IRB Guidebook - Membership Section
NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research
Participants

6. ATTACHMENTS

Membership” (Section 5)
Institutional Review Board Guidebook
Staff Evaluation documents
CF-019  COMIRB Staff Training Record
CF-020  New Panel Member Training Record
CF-021  Chair Training Record
CF-022  New Chair Training Record
CF-024  New Lay Member Mentor Evaluation Form
CF-025  Mentor Evaluation Form
CF-026  New Panel Member Trainee Evaluation Form
CF-027  Member Information Sheet

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY
<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>Institutional Official and</td>
<td>Evaluates the performance of the COMIRB Director and COMIRB office at least annually.</td>
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<tr>
<td>Assistant Vice Chancellor for</td>
<td>Establish training, educational requirements, and content for COMIRB Staff.</td>
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<tr>
<td>Regulatory Compliance Director and Assistant Director</td>
<td>Based on requirements and budget, determine training &amp; education schedule. Schedule speakers, acquire outside publications, schedule attendance at professional development conferences and seminars as budget allows.</td>
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<td>Review (annually) the Chairs knowledge, understanding, and experience relevant to their roles.</td>
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<tr>
<td>Senior IRB Staff</td>
<td>Facilitate the training and on-boarding for new panel chairs, members, and vulnerable population(s) reviewers.</td>
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<td>Provide individualized training and professional development to direct reports.</td>
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<td>Maintain documentation of all training and education completed.</td>
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<td>Provide articles for the monthly educational materials sent to panel chairs and members.</td>
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<td>Perform annual performance evaluation for direct reports.</td>
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<tr>
<td>Chair and Director</td>
<td>Review (annually) IRB Panel Member’s knowledge, understanding, and experience relevant to their roles.</td>
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<tr>
<td>Panel Coordinators</td>
<td>Communicate all training and educational opportunities to panel members.</td>
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