1. PURPOSE
This policy is to provide internal communication and feedback on required procedures and processes necessary for COMIRB to maintain a strong human research protection program.

2. POLICY
It is important for the UCD human research protection program that COMIRB maintains an effective and efficient human subject protection program. To enhance the existing program, it is necessary to have objective data to ensure quality of work and critically evaluate the system. A related SOP, "Audit and Improvement" (CP-023) addresses global Quality Assurance and improvement of COMIRB function.

3. SPECIFIC POLICIES

3.1 Assessment of the panel meeting

3.1.1 Prior to a panel meeting, the IRB Coordinator and Senior IRB Staff review the quorum requirements for each protocol to be reviewed at the meeting.

3.1.2 Quorum – the IRB staff documents quorum is attained for each protocol by reviewing the assignment sheet to ensure adequate quorum. At least one scientific reviewer, one non-scientific reviewer, and one non-affiliated reviewer, and at least five voting members must be present at a convened meeting to attain adequate quorum. Additionally, the following members must be present at the meeting as part of quorum: an MD if an FDA regulated protocol is reviewed and a VA representative for any VA protocols. An RDRC Safety Officer must also be present at the convened meeting if a protocol involving RDRC procedures is reviewed at the meeting; however, the RDRC Safety Officer is not considered part of the quorum.

3.1.3 The IRB Coordinator and Compliance Officer confirm during the meeting that adequate quorum is maintained for each protocol reviewed.

3.2 Minutes Review

3.2.1 The Senior IRB Staff is responsible for performing a Quality Assurance check of all draft minutes.

3.2.2 This review evaluates if each meeting has been appropriately recorded in accordance with federal regulations and COMIRB policies.
3.2.3 Feedback is provided by the Senior IRB Staff and errors are rectified by discussing with the IRB Coordinators and panel Chairs, when necessary.

3.2.4 The Senior IRB Staff builds the final minutes within the Program Tools function of eRA(InfoEd). The Senior IRB Staff manually corrects attendance display, when necessary, and manually adds a signature lines for Chair signature and page numbers.

3.2.5 The Senior IRB Staff or coordinator ensures that the minutes are then sent to the next available panel meeting for approval. Once approved by the panel, the paper copy is signed by the panel chair.

3.2.6 The signed copy of the minutes is returned to the Senior IRB Staff who maintains the official record. A copy is also sent to the VA for review by the R&D committee, for all VA panels. This process is tracked, for internal purposes, if applicable, on the minute tracking sheet maintained by the Senior IRB Management.

3.3 Expedited Review
To maintain consistency of review among expedited/exempt reviewers, any questions on Expedited reviews are brought by IRB Coordinators to the panel's Senior IRB Staff.

The Expedited / Exempt reviewers meet at least monthly to discuss policy, concerns, and/or issues raised by recent reviews. Any policy impacted by the expedited/exempt team is reviewed and agreed upon at this meeting prior to review by the full Compliance Board.

3.4 WIRB

The WIRB coordinator collates any feedback from investigators and/or affiliates and generates a six monthly report. Any issues are then discussed at the bi-annual meeting between the Institutional Official, Director, WIRB coordinator and representatives from WIRB.

3.5 Panel Members

3.5.1 The COMIRB Director and Assistant Director meet annually with each panel's Chairs and staff to discuss performance of all of the panel's regularly-attending members. Panel members are given assessments of "Areas for Improvement," "Adequate Performance," or "Special Commendation" for the performance over the past academic year.

3.5.2 Each panel member is sent an evaluation letter summarizing the feedback at the end of the academic year.

3.5.2 Each panel Chair's performance is evaluated by the Director and Assistant Director, in consultation with the Senior IRB Staff and panel coordinator of the relevant panel. The evaluation feedback and areas for improvement are provided to the Chairs in an annual face to face evaluation meeting. Each Chair is then sent a letter summarizing the feedback at the end of the academic year.

3.6 Investigators and potential or actual subjects
Investigators have the opportunity to provide feedback, suggestions, and criticism either directly by contacting the Senior IRB staff (including the Director), or indirectly via an online survey process. All direct communication is responded to by the Senior IRB staff. Feedback is also
3.7 Maintaining open communication

3.7.1 COMIRB Compliance Board Meeting
This is a monthly meeting of the panel chairs, Associate Vice Chancellor for Regulatory Compliance, COMIRB Director, COMIRB Assistant Director, and Senior IRB Staff to discuss potential compliance issues, interpretation of the regulations, inconsistencies, policies and procedures or administrative concerns. The Institutional Official also attends when possible. Other members of the UCD HRPP are invited as needed to ensure open communication. There are formal minutes from this meeting and a key point summary, if applicable, from the meeting taken to the panel meetings.

3.7.2 COMIRB Staff Meetings:
This is a monthly meeting of the COMIRB staff to discuss issues or concerns with process, provide education opportunities and plan projects. There are formal minutes from this meeting.

3.7.3 COMIRB Staff Process Training:
Additional ad hoc training sessions are held with staff to review SOPs and revisions to SOPs.

3.7.4 COMIRB Managers’ Meeting:
COMIRB Director, COMIRB Assistant Director, and Senior IRB Staff meet bi-weekly to discuss issues, analyze data and/or reports of the preceding month, and strategize on quality improvement, panel problems, key priority issues, quality assurance tasks, IRB compliance documentation, and process improvements. Key points from these meetings are disseminated to coordinators through the Senior IRB Staff through their weekly team meetings, or at the monthly Staff Meeting.

3.7.5 The Associate Vice Chancellor for Regulatory Compliance and the COMIRB Director meet at least monthly to update the institution on COMIRB, discuss issues or concerns relating to the institution’s human research protection program and provide a report on the activity of COMIRB and its on-going relationship with the other offices under the HRPP. The Associate Vice Chancellor for Regulatory Compliance and the Institutional Official meet regularly to review significant issues, as well as a quarterly snapshot of research reviewed by COMIRB.

3.7.6 The Associate Vice Chancellor for Regulatory Compliance and the WIRB Coordinator will conference call with representatives from WIRB at least every 6 months.

3.7.7 The COMIRB Director communicates with Compliance Officers from each affiliated institution on a regular basis to discuss issues or concerns relating to the institution’s human research protection program and provide a report on the activity of COMIRB.

4. RESPONSIBILITY

4.1. It is the responsibility of the COMIRB Director, Assistant Director and Senior IRB Staff to oversee the day to day of this SOP and ensuring that there is a safe environment in which to share ideas.
4.2. All COMIRB Staff should read and understand this SOP and be encouraged to critically evaluate their role.

5. **APPLICABLE REGULATIONS AND GUIDELINES**

None

6. **REFERENCES**

<table>
<thead>
<tr>
<th>CF-057</th>
<th>Minute Tracking Sheet (internal document only)</th>
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<tbody>
<tr>
<td></td>
<td>Staff SOP Training Sheet</td>
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<td>COMIRB Top 20 sheet</td>
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<thead>
<tr>
<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>Associate. Vice Chancellor for Regulatory Compliance</td>
<td>Works with the COMIRB panel members and staff to strategize and evaluate the COMIRB HRPP. Provides institutional feedback to the Institutional Official.</td>
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<tr>
<td>Director, Asst. Director, Senior IRB Staff, and panel Chairs</td>
<td>Evaluate the current program using the feedback obtained to strive for improvements in compliance, efficiency and service. Ensure that staff, investigators and research subjects have different ways to communicate easily with the COMIRB Office.</td>
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<tr>
<td>Director, Asst. Director, and Sr. IRB Staff</td>
<td>Create the data reports and analyze data to ensure that the quality of work is maintained. Use the quality assurance data to assess the current work environment and develop ways to improve the procedures and process flow.</td>
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<tr>
<td>COMIRB staff</td>
<td>Participate productively and professionally in meetings to develop a dynamic atmosphere where ideas can develop.</td>
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