Human Subjects Research Office
Temporary Business Process for IRB System Downtime
August 12, 2022 – August 28, 2022

The IRB system will be down for two weeks during the transition from IRB8 (eProst) to IRB10. During this time, the Human Subjects Research Office (HSRO) will ONLY accept emergency or urgent submissions related to Modifications (MODs) and Reportable New Information (RNI). If a MOD or an RNI is received and is deemed to be a non-urgent submission, HSRO will kindly request that this submission be placed on hold and resubmitted in IRB10. All Continuing Reviews (CRs) should have been completed prior to the system downtime as was stated in previous communications. All new study submissions should be placed on hold and submitted in IRB10 once the system goes live on Monday, August 29, 2022. If there are any questions or concerns, please contact Stephanie Venero at sdv19@miami.edu.

*Link to the Qualtrics submission form will be shared prior to August 12, 2022.

**Modifications (MOD)**
Urgent / Emergency Submissions ONLY

1. Study team member will complete the temporary MOD submission form in Qualtrics.
2. HSRO will receive an email with the completed form.
3. HSRO staff will review the submission and assign an IRB Coordinator.
4. The IRB Coordinator will conduct a Pre-Review and contact the study team via email if there are any clarification requests.
   a. Clarification responses should be submitted to the IRB Coordinator via email.
      i. Clarification responses will be documented on the Pre-Review form in Qualtrics.
5. The IRB Coordinator will submit the Pre-Review form in Qualtrics.
6. Once the IRB Coordinator has completed the Pre-Review, the submission will move forward to a full committee review or an expedited (designated) review.
   a. Clarification requests (if any) will be sent via email to the study team.
   b. Clarification responses should be submitted to the IRB Coordinator via email.
      i. Clarification responses will be documented on the Committee Review or Designated Review form in Qualtrics.
7. The IRB Coordinator will submit the Committee Review or Designated Review form in Qualtrics.
8. Once the final determination has been made, the IRB Coordinator will notify the study team via email.
   a. The email will include a Determination Letter that will be completed manually.
9. HSRO staff will add a Comment in IRB10 to manually document this MOD and include all pertinent dates and information on the submission.
10. Once IRB10 is live, the PI/study team will need to create and submit a modification submission to upload the documents that were approved offline into the parent study workspace, if applicable.

**Reportable New Information (RNI)**

*Urgent / Emergency Submissions ONLY*

1. Study team member will complete the temporary RNI submission form in Qualtrics.
2. HSRO will receive an email with the completed form.
3. HSRO staff will review the submission and assign an IRB Coordinator.
4. The IRB Coordinator will conduct a Pre-Review and contact the study team via email if there are any clarification requests.
   a. Clarification responses should be submitted to the IRB Coordinator via email.
      i. Clarification responses will be documented on the Pre-Review form in Qualtrics.
5. The IRB Coordinator will submit the Pre-Review form in Qualtrics.
6. Once the IRB Coordinator has completed the Pre-Review, the submission will:
   a. Transition to a closed and acknowledged state; or
      i. If the submission is being acknowledged, an email will be sent to the study team that includes a manually completed Determination Letter.
   b. Move forward to a full committee review or an expedited (designated) review.
      i. Clarification requests (if any) will be sent via email to the study team.
      ii. Clarification responses should be submitted to the IRB Coordinator via email.
        1. Clarification responses will be documented on the Committee Review or Designated Review form in Qualtrics.
7. The IRB Coordinator will submit the Committee Review or Designated Review form in Qualtrics, if applicable.
8. Once the final determination has been made, the IRB Coordinator will notify the study team via email.
   a. If an Action Plan is required, the IRB Coordinator will include all relevant information in an email to the study team and responsible party.
      i. An Action Plan response should be submitted to the IRB Coordinator via email. The submission will then move back to Step 6 above.
b. If the submission is being acknowledged, the email will include a Determination Letter that will be completed manually.

9. HSRO staff will add a Comment in IRB10 to manually document this RNI and include all pertinent dates and information on the submission.

10. Once IRB10 is live, the PI/study team will need to create and submit the RNI submission in the new system.