UNIVERSITY OF MIAMI
OFFICE of the VICE PROVOST
for RESEARCH & SCHOLARSHIP

# 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 via Qualtrics. Due to system limitations, the IRB is unable to process major documents in the submission (informed consents, protocols, investigator brochures, etc.) during the system downtime. All documents can be submitted in IRB10 beginning Monday, August 29,2022. If a submission is received (via Qualtrics) 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 on or after Monday, August 29, 2022. If there are any questions or concerns, please contact Stephanie Venero at sdv19@miami.edu.

**Below you will find additional guidance related to urgent submissions the HSRO will accept during the system downtime:**

1. **Protocol exception:**
    a. Deviation from protocol requirements to protect subject from imminent harm* and the patient's condition doesn't allow time for prior IRB approval - Please report to the IRB with the study number and justification for the exception via Qualtrics within 5 business days ***after*** the procedure/intervention.
    b. Deviation from protocol when the patient's condition allows time for IRB review/approval - Please report to IRB with the study number and justification for the exception via Qualtrics ***in advance*** of procedure.
2. **Post emergency use report:** Please report the information to the IRB via Qualtrics (required within 5 business days of use).
3. **Personnel update:** The PI needs to ensure that the individuals complete the required training per HRP-103 – Investigator Manual and conflict of interest is cleared before having new personnel participate in the research. The PI is required to keep the delegation log, including training records and COI status, available for inspection purposes. If there is a conflict of interest per the University's Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy, the individual cannot participate in the research until the new IRB system is live and the PI can subsequently submit a modification for the IRB to review the management plan.

4. **New risk information:** The current eProst system will be available for reporting the new risks until 5:00 pm on Friday, August 12, 2022. Please ensure that any and all risk-relevant information received on or before that date are reported in the current system (via RNI). For new risks received during the downtime, verbally notify any subjects of the information (this must be well documented in the research record) and report the information in the new system (IRB10) according to HRP-103 (page 60) on/after Monday, August 29, 2022.
5. **Other type of urgencies:** Please email the HSRO inbox at HSRO@miami.edu for further guidance.

**Please note, you may implement changes before IRB approval if it is necessary to eliminate an apparent hazard to subjects at imminent risk. [21 CFR 312.30 (b) ii]. Please inform the IRB of the practice within 5 business days as described in section 2.*

***As best practice, during the system downtime, the investigator should notify participants of any newly identified risk ASAP.***

***The IRB would like to remind the PI that they should not enroll new subjects until s/he has an IRB-approved consent document that is compliant with federal regulation 21 CFR 50.25. Therefore, if there is new risk information, changes to procedures, or changes that could affect a subject's willingness to participate during the system downtime, the PI should voluntarily hold new enrollment and verbally inform current participants of the new information.***

## How to Submit Urgent / Emergency Submissions:

1. Study team member will complete the form in Qualtrics.
2. HSRO will receive an email with the completed form.
3. HSRO staff (screening team) will review the submission, determine urgency, and assign to either full board or expedited team via email.
4. The assigned IRB Coordinator will conduct a Pre-Review and contact the study team via email if there are any clarification requests.
5. The IRB Coordinator will complete their Pre-Review.
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. Further clarification requests (if any) will be sent via email to the study team.
    b. Further clarification responses should be submitted to the IRB Coordinator via email.
7. The IRB Coordinator will complete the Committee Review or Designated Review.
8. Once a determination has been made, the IRB Coordinator will notify the study team via email. The email will include a Determination Letter.