UMass Boston Post-Approval Monitoring (PAM) Review Checklist
Version 9/26/2024

Study Information

- Principal Investigator (PI): Click or tap here to enter text.
- Study Title: Click or tap here to enter text.
- IRB Protocol Number: Click or tap here to enter text.
- Department: Click or tap here to enter text.
- Date of Review: Click or tap here to enter text.
- PAM Reviewer(s): Click or tap here to enter text.

Section 1: Pre-Review Information

1. Has the study been previously monitored?
    - ☐ Yes (Date: Click or tap to enter a date.)
    - ☐ No
2. Study Funding Source:
    - ☐ Federal
    - ☐ Institutional
    - ☐ Private
    - ☐ Other (Specify: Click or tap here to enter text.)
3. Study Phase:
    - ☐ Recruitment
    - ☐ Data Collection
    - ☐ Data Analysis
    - ☐ Closed to Enrollment
    - ☐ Other (Specify: Click or tap here to enter text.)

Section 2: Subject Recruitment Procedures

1. How are participants identified for this study? Click or tap here to enter text.
2. Are there recruitment materials for this study?
    - ☐ Yes
    - ☐ No
3. Are all recruitment materials IRB approved?
    - ☐ Yes
    - ☐ No
4. Are all currently approved recruitment materials on file?
    - ☐ Yes
    - ☐ No

Section 3: Informed Consent Process:

☐ Section not applicable (consent waived)

1. Is written consent required to be obtained by the IRB approved protocol?
    - ☐ Yes

- ☐ No

  1.1 If yes, how many versions of the consent form are there? Click or tap here to enter text.

Section 4: Consent Process and Documentation

1. Informed Consent Process:
   - a. Is the informed consent process being conducted as described in the approved protocol?
     - ☐ Yes
     - ☐ No (Describe deviations: Click or tap here to enter text.)
   - b. Are the consent forms signed and dated by all participants?
     - ☐ Yes
     - ☐ No (Describe issues: Click or tap here to enter text.)
   - c. Is the consent form version being used consistent with the latest IRB-approved version?
     - ☐ Yes
     - ☐ No (Describe issues: Click or tap here to enter text.)
2. Documentation:
   - a. Are all consent forms appropriately filed and stored as per university policies?
     - ☐ Yes
     - ☐ No (Describe issues: Click or tap here to enter text.)
   - b. Are participant confidentiality and privacy being maintained as described in the protocol?
     - ☐ Yes
     - ☐ No (Describe issues: Click or tap here to enter text.)

Section 5: Protocol Adherence

1. Compliance with Approved Protocol:
   - a. Are all study procedures being followed as per the approved protocol?
     - ☐ Yes
     - ☐ No (Describe deviations: Click or tap here to enter text.)
   - b. Are any protocol modifications reported and approved by the IRB?
     - ☐ Yes
     - ☐ No (Describe unreported changes: Click or tap here to enter text.)
2. Adverse Events Reporting:
   - a. Have there been any adverse events?
     - ☐ Yes (Describe: Click or tap here to enter text.)
     - ☐ No
   - b. If yes, have these events been reported to the IRB?
     - ☐ Yes
     - ☐ No (Explain why not: Click or tap here to enter text.)

Section 6: Data Management

1. Data Collection:
    - a. Is data being collected as outlined in the protocol?
        - ☐ Yes
        - ☐ No (Describe issues: Click or tap here to enter text.)
    - b. Is the data securely stored in compliance with university policies?
        - ☐ Yes
        - ☐ No (Describe issues: Click or tap here to enter text.)
2. Data Analysis:
    - a. Is data analysis being conducted as described in the protocol?
        - ☐ Yes
        - ☐ No (Describe deviations: Click or tap here to enter text.)

Section 7: Education and Training

1. Research Team Training:
    - a. Are all research team members up to date with required training?
        - ☐ Yes
        - ☐ No (Specify who is out of compliance: Click or tap here to enter text.)
    - b. Are there opportunities for additional training to enhance compliance?
        - ☐ Yes (Specify: Click or tap here to enter text.)
        - ☐ No

Section 8: Findings and Recommendations

1. Summary of Findings:
    - a. Overall compliance status:
        - ☐ Compliant
        - ☐ Minor Issues Identified
        - ☐ Significant Issues Identified
    - b. Areas of excellence:
        - Click or tap here to enter text.
    - c. Areas for improvement:
        - Click or tap here to enter text.
2. Recommendations for Corrective Actions:
    - Click or tap here to enter text.
3. Additional Comments:
    - Click or tap here to enter text.

Section 9: Follow-Up Actions

1. Is follow-up required?
    - ☐ Yes (Specify actions and timeline: Click or tap here to enter text.)
    - ☐ No
2. Date for Follow-Up Review (if applicable): Click or tap to enter a date.

Reviewer Signature: _____ Date: _____

PI Signature (Acknowledgment of Findings): _____ Date: _____