MONTANA STATE UNIVERSITY
Office of Research Compliance
Institutional Review Board
101 Lewis Hall 406-994-4706

Post Approval Monitoring Checklist

IRB#: _____ PI: _____ Date: _____

Project title: _____

Person/s performing PAM: _____

Related protocols (i.e., IBC, etc.): _____

Approval and Record Keeping	Yes	No	NA	CTI	Comments
The project has current IRB approval.					
Are all personnel listed on the protocol?					
Have protocol personnel completed training - including a base human subjects research course, study-specific, etc.? Is there documentation?					
All IRB related records (approval letters, protocol form, consent forms, recruitment material, correspondence, etc.) are retained in an accessible location for protocol personnel.					
Are there procedures in place to retain records for 3 years after the research is complete? Show current storage for existing subject records.					
Consents	**Yes**	**No**	**NA**	**CTI**	**Comments**
Are the enrollment numbers less than or equal to the number approved by the IRB in experimental (research) and control (normal) groups?					
Does the consent process match the latest IRB approved procedure?					
Do the subjects receive a signed copy of the consent form or at a minimum offered the opportunity to do so?					

Verify signed and dated consent form on file for a sub-set of subjects enrolled in the study using approved version (number of checks will vary depending on sample size).					
Have you consistently received similar types of questions or concerns from subjects? If so, how have these been addressed? Has a change to the Consent Form been considered?					

Additional reviewer notes:

Recruitment/Payments	Yes	No	NA	CTI	Comments
Were subjects recruited according to the methods approved by the IRB and following recommended best practices? (i.e., IRB# on flier)					
Verify that inclusion and exclusion criteria as listed and approved by the IRB were met.					
If subjects received compensation, is there documentation? What Personal Identifiable Information (PII) is gathered to deliver compensation, and where is this information stored?					
Research Protocol	**Yes**	**No**	**NA**	**CTI**	**Comments**
Verify research conducted complies with the protocol and procedures as approved by the IRB. View data collection location, equipment, and devices as applicable.					
Certify that all data collection instruments were/are approved by the IRB.					
Study-Specific Elements as Applicable	**Yes**	**No**	**NA**	**CTI**	**Comments**
External Collaboration: The status, procedures, and relationship with an external entity or partner is accurately reflected in the protocol. The documentation demonstrating their willingness to participate in MSU research is active.					

Reliance: Where MSU IRB is the IRB of record, study protocols, amendments, and relevant updates have been shared with relying institutions in a timely manner.					
Minors: Research practices adhere to the *IRB Guidelines for Working with Children in Research.* Background checks and signed guidelines for each personnel are recorded.					
Biospecimens: Continued use of human materials are handled or destroyed in accordance with the Consent Form.					
Clinical Trials: The study is registered at clinicaltrials.gov. A Data Safety Monitoring Board is in place where required.					
Non/Investigational Drugs, Substances, and Devices: Source, dosing, administration, testing phase, and commercial status match the protocol. Associated reports are up to date.					
Other:					
Data Storage and Confidentiality	**Yes**	**No**	**NA**	**CTI**	**Comments**
Paper/Physical Documents as Applicable: Is data stored on paper (e.g., consent forms and data forms) in a secure, locked location as approved by the IRB? Is access limited to approved personnel?					
Electronic Data as Applicable: Is electronic data stored on a secure and protected computer/server as approved by the IRB? Is access limited to approved personnel?					
Are coding and/or deidentifying procedures being followed as described in the approved protocol?					
Is any data being shared outside of MSU? If so, are appropriate DUAs or contracts in place?					
HIPAA: PHI and related health records are accessed and transmitted as described and with appropriate security measures.					

FERPA: Student education records are accessed and utilized as described per regulations.					
Continuing Review	**Yes**	**No**	**NA**	**CTI**	**Comments**
Is **funding** information still current and accurate?					
Have there been any changes that would affect the **conflict of interest** status of this project? Consider personal interests related to this research (applies to the PI, protocol personnel, and their family members).					
Have there been any new findings in the project or field of study that change the **risk - benefit ratio**?					
If there were any changes to the approved project/forms since the last review, was an amendment submitted to the IRB?					
Have there been any lapses in IRB approval? If yes, was any research activity done during the lapse reported?					
Have there been any adverse effects while conducting this research? If yes, have all been reported to the IRB within 3 days of occurrence?					
Have there been any withdrawals, unanticipated problems, or complaints while conducting this research? If yes, have all been documented by the research team?					
Closure	**Yes**	**No**	**NA**	**CTI**	**Comments**
Are remaining study activities limited to performing data analysis only? (If yes, protocols can remain open in their 5 year cycle or move into a lower review level.)					
Additional reviewer notes:					