Information
This form is used for Post-Approval Monitoring (PAM) by the Office of Research Compliance of all laboratories that have a current IBC protocol at Montana State University. MSU has made a commitment to maintain a program in accordance with the current edition of the Biosafety in Microbiological and Biomedical Laboratories, the NIH Guidelines, USDA/APHIS permitting requirements, OSHA Bloodborne Pathogens Standard, and all MSU biosafety policies.
Questions/Concerns/Comments: Please call MSU Biosafety Officer Ryan Bartlett Phone: 406-994-6733 E-mail: ryan.bartlett@montana.edu
References: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules MSU Biosafety Manual

1.0 Protocol Information
1.1 Are all personnel performing work on the protocol are listed? (If human-derived materials are used, all staff who are present during work are listed.)
1.2 All IBC related records (CITI or in-person training, risk assessment, etc.) are retained in an accessible location for study personnel.
1.3 Are all building and room numbers where work with biological agents listed on the protocol?
1.4 Is the protocol associated with any other protocols (IACUC, IRB, IBC, RAD)?
1.4.1 Are associated protocols listed in TOPAZ?
1.5 If there were any changes (personnel, procedures, etc.) to the approved protocol since the last review, was an amendment submitted to the IBC?
1.6 Has the study been audited by a funding or other agency (NIH, NSF, CDC, USDA)?
1.6.1 Is there documentation?
1.6.2 Have any corrective actions been completed?

2.0 Biological Agent Information
2.1 Are all biological agents being used listed on the protocol with accurate Genus, species, and strain?
2.2 Are the biological agents being worked with at the appropriate physical containment level (i.e., biosafety level)?
2.3 Are all relevant pathogen safety data sheets (PSDS) available for lab staff?
2.4 Are any biological toxins listed on the protocol?
2.4.1 Are the amounts possessed within limits?
2.5 Is any work with recombinant or synthetic nucleic acid molecules performed for this protocol?
2.5.1 Are all hosts, vectors, and genes of interest listed?
2.5.2 Are all relevant NIH Guidelines being followed?

3.0 Biological Material Storage Information
3.1 An accurate inventory of biological materials is available.
3.2 Containers are labeled in accordance with MSU requirements.
3.3 If required, biological materials are stored in a locked location.

4.0 Procedural Risks
4.1 Are there Standard Operating Procedures for each method of analysis with training documentation?
4.2 Are personnel listed on the protocol trained in the proper procedure processes (e.g., pipetting, vortexing, centrifuging, other aerosol generating procedures, lab specific procedures)?
4.3 Are personnel trained on proper use of biosafety cabinets (BSC)?
4.4 Do personnel know who to contact in case of an emergency (e.g., injury, accidental exposure)?
4.5 Do personnel know who to contact in the event of a spill involving recombinant/synthetic materials?
4.6 Are the approved disinfection procedures being used?
4.7 Is the approved PPE being used?
4.8 Are special equipment (e.g., flow cytometer) listed and approved by the IBC?

5.0 Continuing Review
5.1 Have there been any injuries association with this protocol?
5.1.1 Was a First Report of Injury form completed?
5.1.2 Was a Corrective Action Plan (CAP) completed and submitted?
5.2 Have there been any incidents/spills associated with this protocol?
5.2.1 Incidents/spills were preported to the lab manager and PI. Spill invloving recombinant/synthetic nucleic acids have been reported to the BSO.
5.3 Have there been any new findings to change the risk assessment?
5.3.1 Has the IBC Protocol been updated to reflect these changes?
5.4 Amendments have been submitted when required by IBC policy.