Monitoring and Compliance Tools Coversheet

This cover sheet gives a brief explanation of the UNM OIRB MAC Tools.

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It is the responsibility of the Principal Investigator to ensure that human research is conducted ethically and according to IRB determinations. It is also their responsibility to monitor the on-going conduct and compliance of the research. The UNM OIRB has created Monitoring and Compliance (MAC) tools that may be used by researchers to meet these responsibilities. Below is a brief explanation of the each tool so that you can decide which tools are relevant to your research.

TOOLS	PURPOSE
CITI – COI Tracking Log	To track project team required training and COI disclosures.
Compensation Log	To track compensation given to participants. It may be useful for projects that compensate participants with money or gift cards.
Complaint Report	Complaints can come from participants or others and this form helps to record the details of the issue, investigation, and resolution.
Event Reporting Log	To keep track of events that have occurred, even if they did not require reporting to the UNM IRB.
Informed Consent Process Checklist	To document that the consent process includes all of the required components and that it is following the approved process in the protocol. This checklist can be used randomly or with every participant.
Linking and Screening Log (Excel spreadsheet)	To keep track of participant names and participant codes. This file should be protected and stored separately from signed consent forms and coded data. For projects that involve screening, it can be used to track the screening process.
Note to File Template	To document the ongoing conduct of a research project. This template should be used to ensure that all of the necessary details are included in the note. Examples of appropriate use of a note to file includes failure of research team to sign and/or date a signed consent form, documenting a missed time point to complete a survey, etc.
Participant Contact Information (Excel and Word)	To organize and store participant contact information. These files should be stored separately from signed consent form, linking logs, and coded data. Contact information should not be written on the consent form; instead, use a separate document to collect that information.
Protocol Deviation Report	To document the occurance of protocol deviations over the course of a research project. Note that if a protocol deviation causes or increases harm to participants, an Event Report must be submitted for IRB review.
Regulatory Files Checklist	To establish organizational compliance for research documentation at the beginning of the project. Checklist includes all of the documents that should be monitored and referenced throughout the project as well as what the IRB would expect to see during an audit.
Research Staff Training Log	To document that project staff have completed all required and necessary trainings to ethically and accurately conduct the research. Use one log per staff member and remember to update the log over time as staff aquires additional training.
UNM Participant Receipt Forms	These receipt forms are required to document compensation for research participation. Use one form when compensation is under $600 and the other form when it is $600 or more. For a copy of this form as well as additional information about UNM policies regarding participant compensation, see UNM Policy 2480.