Detailed DSM Plan Checklist

Was Item included in the DSM Plan?	Included?	
	Yes	No
1. Heading		
Title, Grant number, PI and Medical Monitor name		
2. Summary of the protocol		
Brief description of the protocol, procedures and table for schedule of events		
Primary, secondary objectives and outcome measures		
Inclusion and Exclusion criteria		
Sample size and power calculation		
3. Trial management		
List of participating/enrolling clinics or data collection centers		
Planned enrollment timetable (graph showing time vs. projected cumulative enrollment)*		
Target population dsitribution (gender, minorities, etc.)		
4. Data management		
Data acquisition and transmission, data entry methods		
Data security and protecting confidentiality		
Statistical analysis plan		
5. QA and QC plan		
Procedures in place to ensure the integrity and validity of the data		
Procedures to guarantee the accuracy and completeness of the data set		
6. Regulatory		
Reporting process for AEs and SAEs		
SAE reporting in medication trials: FDA, IRB and NIDA		
SAE reporting in non-medication trials: IRB and NIDA		
Process of reporting IRB actions to NIDA		
Process of changes or amendments made to the protocol**		
7. Trial safety		
Potential risks and benefits for participants		
Risk mitigation plan (management of SAE and other study risks)		
Trial stopping rules		
Process of AE/SAE collection, assessing by PI and/or medical monitor and reporting		
AE/SAE follow up plan		
8. Trial efficacy		
Plan for interim analysis (if applicable)		

9. Administration of DSM plan		
Responsibility of data and safety monitoring		
Frequency of monitoring		
Conflict of interest		
DSM report (***to be submitted to NIDA PO annually***)		
Content of DSM report		
Brief description of progress		
Enrollment update (participants who are randomized in the trial)		
Retention and dsiposition of participants (active, completed, and terminated)		
AE/SAE listings		
Regulatory issues (amendments, protocol deviations, IRB reports, QA issues)		
10. DSM Board (if applicable DSMB plan)		
Members and affiliations		
Conflict of interest		
Frequency of meetings		
Monitoring activities (initial and ongoing reviews)		
Reporting DSMB minutes to IRB, NIDA and FDA (if applicable)		

*Enrollment: participants who are randomized and received treatment in the trial

**Changes made to protocol must be pre-approved by NIDA PO