## Detailed DSM Plan Checklist

<table>
<thead>
<tr>
<th>Was Item included in the DSM Plan?</th>
<th>Included?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
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### 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 distribution (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

<table>
<thead>
<tr>
<th>Responsibility of data and safety monitoring</th>
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<td>Frequency of monitoring</td>
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<td>Conflict of interest</td>
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**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 disposition 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)

<table>
<thead>
<tr>
<th>Members and affiliations</th>
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<tbody>
<tr>
<td>Conflict of interest</td>
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<tr>
<td>Frequency of meetings</td>
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<tr>
<td>Monitoring activities (initial and ongoing reviews)</td>
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<tr>
<td>Reporting DSMB minutes to IRB, NIDA and FDA (if applicable)</td>
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*Enrollment: participants who are randomized and received treatment in the trial

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