Data and Safety Monitoring Plan (DSMP) Checklist

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Trial Safety	
☐ Yes ☐ No ☐ N/A	Potential risks and benefits for participants
☐ Yes ☐ No ☐ N/A	Adverse Event and Serious Adverse Event Collection and Reporting
☐ Yes ☐ No ☐ N/A	Protection Against Study Risks
☐ Yes ☐ No ☐ N/A	Protocol compliance/adherence
Interim Analysis	
☐ Yes ☐ No ☐ N/A	Plans for interim analysis
☐ Yes ☐ No ☐ N/A	Trial stopping rules
Data and Safety Monitoring	
☐ Yes ☐ No ☐ N/A	Investigators' data and safety monitoring responsibilities
☐ Yes ☐ No ☐ N/A	Frequency of data and safety monitoring
☐ Yes ☐ No ☐ N/A	Plans for distribution of data and safety monitoring reports
☐ Yes ☐ No ☐ N/A	DSMB membership, affiliation, and responsibilities
☐ Yes ☐ No ☐ N/A	Data protection of confidentiality
Data Entry Guidelines	
☐ Yes ☐ No ☐ N/A	Description of use of data entry system
☐ Yes ☐ No ☐ N/A	Explanation of single or double data entry process
☐ Yes ☐ No ☐ N/A	Data validation process (who checks for consistency, how are data queries communicated and resolved)
☐ Yes ☐ No ☐ N/A	Data back-up and archiving process