Data Safety and Monitoring Plan Checklist

NHLBI requires IRB approval of an appropriate Data and Safety Monitoring Plan (DSMP) for all clinical research proposals. Your DSMP must also be reviewed by your Program Director prior to enrolling patients into your study. This checklist may help you to determine if you have included the necessary elements into your plan.

Is Item Included in the DSMP	Yes	No
An appropriate monitor (person or group)	☐	☐
Monitoring procedures	☐	☐
Frequency of monitoring	☐	☐
Content of DSM report	☐	☐
Collection and reporting of SAEs and AEs	☐	☐
Reporting mechanisms of AE/SAEs to the IRB, FDA and NHLBI	☐	☐
Reporting mechanisms of IRB actions to NHLBI	☐	☐
Reporting mechanisms for changes or amendments to the protocol or consent form	☐	☐
Potential risks and benefits to subjects	☐	☐
Management of SAEs or other study risks	☐	☐
IND or IDE information (if applicable)	☐	☐
Conflicts of interest	☐	☐
Data acquisition and transmission	☐	☐
Data analysis plans	☐	☐
Trial stopping rules	☐	☐
Plans for interim analysis	☐	☐
DSMB/OSMB Plan (if applicable)	☐	☐