DSMB

DSMB

Requirements

- Copy of all Data Safety Monitoring Board (DSMB) reports
- Additional correspondences with DSMB (e.g. meeting minutes, information provided to the DSMB, emails)

Tips / Additional Information

Submit a copy of the most recent DSMB report to the IRB at the time of continuing review.

Refer to ResearchGo for Data and Safety Monitoring guidance and templates to assist sites in developing a monitoring plan to ensure subject safety and data integrity:

- IRB Guidance and Procedure: Data Safety Monitoring Plan
- NIH Policy and IC Guidance for Data and safety Monitoring of Clinical Trials
- FDA Guidance-Establishment and Operation of Clinical Trial Data Monitoring Committees
- DSMP Checklist

Applicable GCP sections:

- 8.3.10
- 5.19.3

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