Decision Tree for Data and Safety Monitoring for Clinical Trials

Human Subjects involved? (even if exempted under 45 CFR 46)?

YES

NO

Data and Safety Monitoring Policy and Guidance do not apply

Is a Clinical Trial proposed (any Phase) ?

YES

NO → *Plan not required*

Is the Data and Safety Monitoring Plan Acceptable?
1. Entity responsible for monitoring is identified? **and**
2. Policies and procedures for adverse event reporting are described? **and**
3. Plan is appropriate with respect to risks to participants, complexity of study design, and methods for data analysis?

NIH requires a Data and Safety Monitoring Board for multi-site clinical trials of interventions with potential risk to participants.

YES

ABSENT

No Information

NO

ACCEPTABLE

Explain why the data and safety monitoring plan is scientifically acceptable.

UNACCEPTABLE

Contact

Scientific Review Administrator

UNACCEPTABLE
Negative impact on score.

Explain why the data and safety monitoring plan is scientifically unacceptable.