**Decision Tree for Data and Safety Monitoring for Clinical Trials**

1. **Human Subjects** involved? (even if exempted under 45 CFR 46)?
   - **YES**
   - **NO**

2. **Is a Clinical Trial** proposed (any Phase)?
   - **YES**
   - **NO**

3. **Data and Safety Monitoring** Policy and Guidance do not apply

- **Plan not required**

4. **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.

5. **YES**
6. **ABSENT** No Information
7. **NO**

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

- **UNACCEPTABLE**
  - Contact
    - Scientific Review Administrator
  - Negative impact on score.
  - Explain why the data and safety monitoring plan is scientifically unacceptable.

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