

What is a Data and Safety Monitoring Plan and how do I get one?

Human Research Protection
Program
ETSU

For a study to be approved, one of the criteria that must be met is:

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.



The ETSU/VA IRB and ETSU IRB have determined that “when appropriate” means when a study is more than minimal risk and involves an intervention.

- When appropriate (when study is more than minimal risk and involves an intervention), the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.



If a study is more than minimal risk and involves an intervention, a data and safety monitoring plan must be included in the proposal.

- For a submission for initial review, this information must be provided on the narrative, section 11C.



What is minimal risk?

- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 and 21 CFR 56.102).*

* note: studies involving prisoners have different definition of minimal risk



Who decides if the study is minimal risk ?

- The IRB (usually the IRB Chair) makes the final determination. Studies that are determined to be more than minimal risk are “full” studies and require review by the convened board.
- Studies in which a subject will be experimentally assigned to an investigational drug or device treatment intervention are considered to be more than minimal risk. Other studies may also be determined to be more than minimal risk. Contact the IRB office for questions.



What is data and safety monitoring?

- Data and safety monitoring is the process for reviewing data from an ongoing study to monitor the progress of the research and the safety of participants.

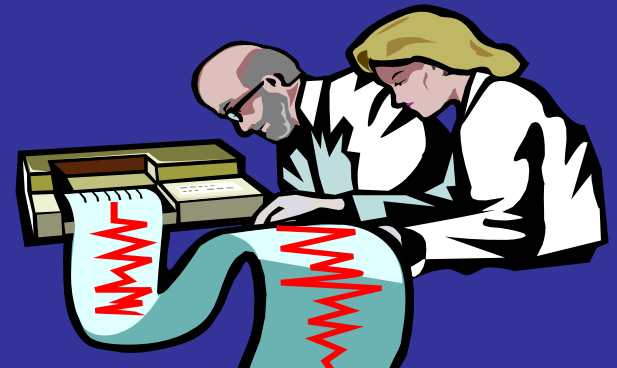


The frequency of review and the intensity of the monitoring required depend on factors such as the study risk, complexity and size.



What should be included in the plan?

- Description of how risks are minimized and how risks are reasonable in relation to anticipated benefits and the importance of the knowledge that is expected to result (narrative questions 11 and 12)
- The type of data or events that will be monitored
- Who will be monitoring the data/events
- How events will be reported
- How often the assessments will be made
- What procedures are in place to ensure protocol adherence



The type of data or events that will be monitored

Considerations:

- Prompt detection of unanticipated problems involving risks to subjects or other
- Data accuracy
- Protocol compliance
- Recruitment, accrual, retention
- Criteria for suspension or termination of study

Who will be monitoring the data/events?

Considerations:

- Is there a Data and Safety Monitoring Board (DSMB)/ Data Monitoring Committee (DMC) that will be monitoring the data/events? (for example, if the study is part of a multi-center clinical trial) If so, the DSMB/DMC generally will fulfill the requirement for a data and safety monitoring plan.
- Who will be monitoring and collecting the adverse events?

How will events will be reported?

Considerations:

- Time frame for reporting unanticipated problems involving risks to the subjects or others to the sponsor, IRB, etc.
- If study is multi-center and the local PI is the lead investigator, describe how communication will be assured among the sites (see narrative question 3B)
- If the study has DSMB/DMC, how findings will be reported to the IRB
- Plan for reporting of adverse events at continuing review

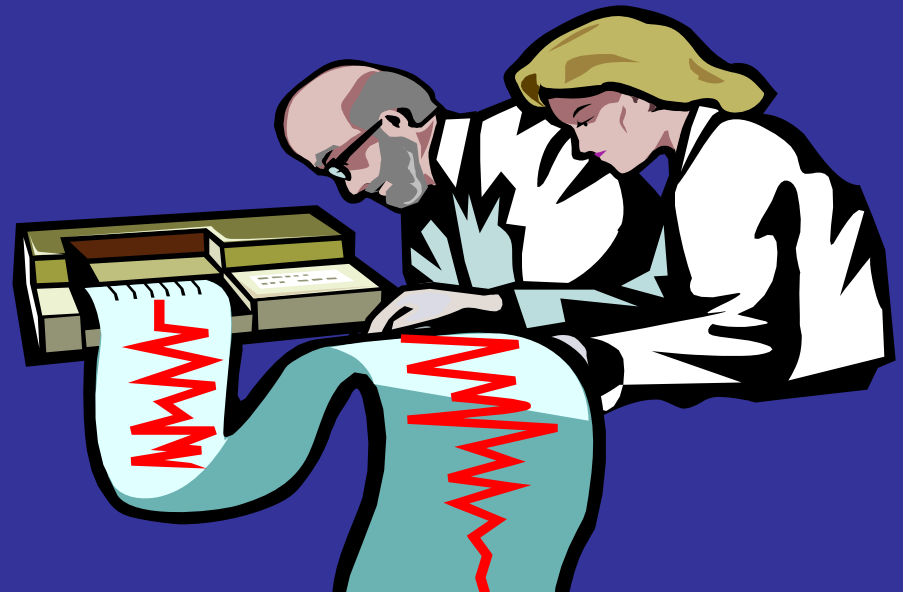
How often will the assessments will be made?

Considerations:

- When assessments will be made, (for example, after a certain number of participants are enrolled or at a specific point in the study)



- A sample data safety monitoring plan is available at:
<http://www.etsu.edu/irb>



REMEMBER:

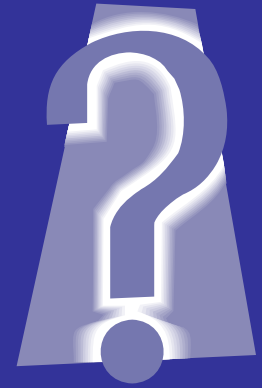
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Questions?

Contact the IRB.



ETSU/VA IRB (Medical): Teresa Doty at
439-6055

ETSU IRB (Campus): Ari Vasquez at 439-
6002