

# Data Safety and Monitoring Boards for Behavioral Studies

Dennis G. Fisher, Ph.D.  
Center for Behavioral Research &  
Services  
California State University, Long Beach

# What is a Data Safety and Monitoring Board?

- A Data Safety and Monitoring Board (DSMB) aka Data Monitoring Committee (DMC) is an independent group who periodically reviews a study involving human subjects.

# When Should You Use a DSMB?

- 45 CFR 46.111 (a) (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- The IRB has the authority to require formal data monitoring.
- PI may include DSMB in protocol presented to IRB.
- High-risk studies, vulnerable populations (e.g. children, prisoners, mentally ill), large impact

# Who Should be on the DSMB?

- Multidisciplinary
- Relevant clinical experience
- Methodological expertise
- Statistical expertise
- Ethics or client population representation

# How are DSMB meetings conducted?

- Should be written charter, procedures, or bylaws for the written record
- Minutes must be taken and kept
- Open session
- Closed, executive session

# Do behavioral scientists do high-risk studies?

- Needle exchange
- HIV or other disease prevention
- Domestic violence
- Rape
- Sexual abuse
- Collecting information on stigmatized or illegal behavior
- Suicidal behavior - depression

# What is statistical power?

- The ability to reject  $H_0$  when  $H_0$  is false
- Determination of required sample size
- A study may have too little power or too much power
- If a study does not have sufficient power, it will not be able to answer the research question

# What are some issues that the DSMB should examine?

- Review of study protocol
- Review of dependent variables (primary endpoints)
- Review of statistical hypothesis statements
- Assess participant accrual and whether changes are needed
- Decide whether to terminate study
- Adequacy of randomization – need to change?

# Confidentiality

- Executive session is confidential
- Interim analysis results by study arm is to be kept confidential
- Adverse events and safety data (reported to IRB, but not by study arm)
- DSMB open minutes can be reported to IRBs on a regular basis

# Independence and Conflict of Interest

- Individuals with important conflicts of interest (coi) should not serve
- COI can be financial, intellectual, or emotional
- Complete coi elimination is usually not possible
- The higher the risk, the more independent