**What is a DSMP?**
A DSMP describes how the Lead Researcher plans to oversee the research participant’s safety and welfare, and how adverse events will be characterized and reported. (Some DSMPs include a DSMB.)

**What is a DSMB?**
A DSMB (or DMC) is a formally appointed group that will conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study and integrity of the accumulating data.

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**Does this Project Require a DSMB?**
(Under NIH or FDA)

- The Protocol is a Phase III Clinical Trial.
  - NIH - Yes
  - FDA – No

- The Protocol involves planned emergency research.
  - NIH - Silent
  - FDA - Yes

- The Protocol is a Phase I or Phase II Clinical Trial that has multiple clinical sites, employs particularly high risk interventions, or involves vulnerable populations.
  - NIH - Recommends
  - FDA - Silent

- The Protocol is a controlled trial that compares rates of mortality and major morbidity.
  - NIH - Silent
  - FDA - Recommends

- The Protocol involves early stages of product or novel device development, or addresses lesser outcomes (i.e. relief of symptoms), unless the population is at elevated risk or highly vulnerable.
  - NIH - Silent
  - FDA – Generally Not Required

- The Protocol is considered minimal risk.
  - No

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**Stanford IRB Considerations:**

**What is the Risk to Participants?**
- Is the study population at elevated risk of death or other serious outcomes?
- Is there prior information suggesting the possibility of serious toxicity from the study treatment?
- Is the procedure for administering treatment of particular safety concern?
- Is the study population potentially fragile such as children, pregnant women, elderly, terminally ill or of diminished mental capacity?
- Is the study large, of long duration, and multi-center?

**Is DSMB/DMC Review Practical?**
- Will the trial be done too quickly for the DSMB to have meaningful impact?
- If so, is there a possibility to build in “pauses” so that interim data may be reviewed before additional cohorts would be enrolled?

**Other Points:**
- Consider whether an adequate data safety monitoring plan (DSMP) with defined or stringent stopping rules would be sufficient, rather than requiring a DSMB.
- Consider a shorter approval period and/or restricting the number of participants to be enrolled during the approval period.
- Is there an appropriate regulatory structure in place that allows for independent review that would have efficient and effective flow of information back to the IRB, allowing for meaningful interpretation?
- The IRB should determine the necessity/feasibility of a DSMB (when not otherwise required by the NIH or FDA) on a case-by-case basis for novel, high-risk studies, especially those which are Investigator-Initiated where the Stanford investigator holds the IND/IDE.

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**References:** FDA “Guidance for Clinical Trial Sponsors” and NIH “NIDCD Guidelines for Data and Safety Monitoring of Clinical Trials”