If yes to any of the below, bring to IRB Chair's attention for further discussion at convened meeting to consider whether a DSM BOARD should be required, or if a robust DSM PLAN would be adequate.

Consider:

- is the study a novel/high-risk Phase I/II cell or gene transfer trial
- whether the existing data safety monitoring **plan** (DSMP) with stopping rules would suffice
- whether a regulatory structure is in place that would provide flow of information to the IRB
- whether requiring a shorter approval period or restricting number of participants during approval period is appropriate
- is the trial Investigator-Initiated where Stanford holds the IND/IDE
- is Stanford the only site
- whether vulnerable participants are involved:
    - are participants at an elevated risk of death or other serious outcome due to their vulnerable status
    - are there concerns due to the mental capacity or fragile status of the participants

(Based on Discussion at 9/12/17 Chairs' Meeting)

*DSM Boards are *required* for:

- NIH Phase III trials, and
- FDA regulated planned emergency research

DSM Boards are *recommended* for:

- NIH Phase I or II trials that have multiple clinical sites, employ high-risk interventions, or involve vulnerable populations, and
- FDA regulated controlled trials that compare rates of mortality and major morbidity