Institute for Clinical and Translational Research
UNIVERSITY OF WISCONSIN–MADISON

ICTR's Data & Monitoring Committee Decision Tool

This tool is designed to assess whether your clinical trial requires a Data & Monitoring Committee (DMC) to ensure subject safety, research integrity, and compliance with federal regulations and local policies. If you have additional questions, please contact Theresa Lins at tlins@wisc.edu.

Please refer to the information below to determine if you need an independent DMC without conflict of interest for your trial

You are REQUIRED to use a DMC if any of the following apply:

- Your trial is intended to provide clinically useful information about effectiveness and/or safety of a medical or bio-behavioral intervention.
- There's prior data to suggest that the intervention in your trial has the potential to induce potentially unacceptable toxicity.
- It would be ethically important for your trial to stop early if the primary question addressed has been definitively answered, showing either substantial benefit or harm, even if secondary questions or complete safety information were not yet fully addressed.
- Your intervention is regulated by the FDA.
- Your trial is considered "high risk".
    - For this discussion, "high-risk" refers to trials of interventions associated with substantial side effects to subjects (e.g., side effects that could result in serious morbidity or death, or are irreversible), trials of diseases associated with high mortality or morbidity, and trials of highly experimental therapies (e.g., gene therapy).
    - As a general guideline, DMCs are needed for clinical trials of diseases with high mortality or morbidity, for clinical trials involving high risks, and for large, multicenter clinical trials.
- Your trial is blinded. (Phase I, II, III only)

You are NOT required to use a DMC but it is RECOMMENDED in the following situations:

- Your trial has a minimal risk intervention but studies a vulnerable population(s). (Phase I, II, III only)
- For some studies involving particularly vulnerable study participants (e.g., children or persons with impaired ability to consent), it may be beneficial to utilize a DMC as an additional measure of subject protection.
- Your clinical trial is Phase III, which generally require a DMC.

You are NOT required to use a DMC but could be helpful in the following situations:

- Your trial considered "minimal risk" because subjects are expected to experience only minor side effects, and interim analyses are not crucial for the protection of the subjects.
- Your multicenter, high-risk Phase I clinical trial has very clear rules for stopping the trial.
- Your clinical trial is a single center open label Phase I or II trial.

Clinical Trial 'Phase' Information:

Clinical trials are conducted in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.

Phase I trials: Researchers test a drug or treatment in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.

Phase II trials: The new drug or treatment is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.

Phase III trials: The new drug or treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.

Phase IV trials: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.

Please refer to the NIH Policy for Data and Safety Monitoring for additional information