Studies the WCMC DSMB Will Monitor

1) All studies for which the PI or WCMC is sponsor or holds IND

2) All human gene transfer studies

3) Any other studies in which there is a high risk of physical harm from the intervention and DSMB review of interim results can add a safety margin. There have to be enough subjects in the study and treated long enough to justify interim looks.

4) Low risk studies will be monitored by the DSMB when there are special circumstances that make full DSMB monitoring necessary.

5) The DSMB will review any study not otherwise being monitored by the DSMB upon IRB request for a review.

For all studies, a DSMB member shall serve as a primary reviewer and monitor of the protocol. For most phase 1 and 2 studies, and other studies when appropriate, the DSMB will delegate monitoring to the primary reviewer who shall serve as an Independent Medical Monitor (“IMM”). This monitor can request full DSMB review at any time.

Monitoring Schedule Guidelines According to Phase

Phase 1:

If a phase 1 study involves dose ranging for a dose limiting toxicity (DLT), the DSMB will perform a Periodic Review when toxicity or an adverse event occurs at a dose one level less than the DLT, irrespective of the attributed cause of the event. The DSMB will perform its next review after the next dose level is completed and a higher dose is planned. If the phase 1 study does not involve dose ranging for a DLT, then the DSMB will review Immediate Reports only, excluding protocol deviations.

Phase 2:

If a phase 2 study is open label, the DSMB will monitor Immediate Reports only, excluding protocol deviations. If a phase 2 study is blinded and controlled, the DSMB will perform a Periodic Review when an interim look is planned.

Phase 3:

If a phase 3 trial is open label, the DSMB will monitor Immediate Reports only, excluding protocol deviations. If a phase 3 trial is blinded and controlled, the DSMB will perform a Periodic Review when an interim look is planned.
WCMC DSMB Review of Immediate Reports

For all studies monitored by the DSMB, the DSMB will review Immediate Reports, excluding protocol deviations. The DSMB will perform a review of protocol deviations only upon IRB request.