CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

DMC members will be completely independent of study investigators and must have no financial, scientific, or other conflict of interest with the sponsor of the clinical trial. The DMC must not actively conduct any of the studies under the Board's review, and may not have any significant financial interest in the study's conduct or outcome.

Additionally, DMC members must disclose any potential conflict of interest involving, e.g., pharmaceutical companies, manufacturers or distributors, contract research organizations, and the like. Conflict of interest may be determined by assessing any financial arrangement, consultancy agreement (either directly or through a third party), research support, or other relationship that could be construed as introducing bias.

Members must advise the sponsor and the other members of the DMC of any existing or arising conflict of interest, including financial interests. If this conflict is considered by the sponsor to be significant and likely to impact objectivity, sponsor will find a replacement member. If this conflict is considered significant and likely to materially impact objectivity, the sponsor may ask the member to resign from the DMC. Where the DMC member resigns, the sponsor will identify a replacement and decide whether to approve the candidate.

The sponsor is free to appoint replacement DMC members.

COMPENSATION

A contract specifying fees to be paid to DMC members for each meeting, or for each data review, will be provided by *PharmaDrug* to DMC members. In addition to the payment of fees, the sponsor will reimburse all travel and other reasonable expenses incurred while attending DMC meetings.

BOARD MEETINGS AND REPORTS

DMC meetings will be held via teleconferences or in person. *PharmaDrug* or its designee will be responsible for arranging all meetings.

ORGANIZATIONAL MEETING

The first DMC meeting will be an organizational meeting, and will allow members to discuss logistic issues relating to future DMC meetings, e.g., frequency of data reviews, content of data reviews, and the meeting format. The DMC Charter will also be reviewed and finalized at this meeting, with input from the Sponsor. Conflicts of interest will also be addressed. In addition to DMC members, representatives from *PharmaDrug* including the medical monitor, data managers, project managers, statisticians, pharmacovigilance staff, may also participate in the organizational meeting.

INTERIM REVIEW MEETINGS

Regularly scheduled safety review meetings will be conducted after approximately ____ subjects, and after approximately ____ subjects have completed at least ____ cycles of treatment. The frequency of interim review meetings may be changed, as desired, by the DMC or by the sponsor.

FORMAT

Interim review meetings will be conducted in three consecutive sessions:

- An Open Session for reviewing administrative aspects of the study and the safety data.