

DSMPs and DSMBs at UCLA

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The UCLA Human Research Protection Program requires an adequate data and safety monitoring plan (DSMP) for all interventional research studies involving greater-than-minimal risk. Please review <u>Guidance and Procedure: Data Safety Monitoring Plan</u> for more information.

The <u>CTSI DSMB</u> offers oversight for those investigator initiated trials that do not have an external DSMB oversight mechanism. The DSMB advises investigators regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The CTSI DSMB performs the following general functions:

- Objectively appraise a study's progress
- · Assess data quality via a formal and planned process
- Provide analytical expertise and rigor
- · Determine the statistical significance of efficacy and/or risk?benefit ratio

Jonsson Comprehensive Cancer Center DSMB

In response to the National Cancer Institute mandate, the JCCC DSMB was constituted in January 2001 and meets monthly. The JCCC DSMB reviews all Serious Adverse Events (SAEs) occurring in JCCC protocols. In addition, the JCCC DSMB serves as the DSMB for institutional research studies at UCLA that do not have an external DSMB. The JCCC DSMB helps to ensure that adequate safety monitoring will be carried out for all cancer interventional trials offered at the JCCC. The DSMB oversees the implementation of the data monitoring plans approved by ISPRC and on file with the JCCC. The chairman of the JCCC DSMB is Dr. Sven De Vos.

Please contact the Office of Regulatory Affairs for more information.

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