

## Getting Started with Data and Safety Monitoring at KUMC

This document provides an **Overview** of the data and safety monitoring review process, including links to relevant forms to be used when a protocol is referred to the Data and Safety Monitoring-Executive Committee (DSM-EC) for monitoring. Additional details about the process can be found in the standard operating procedures at <http://www2.kumc.edu/researchcompliance/dsmbpolicies.htm>.

The data and safety monitoring review process has three stages:

1. **The monitoring plan.** In the first stage, the DSM-EC works with the investigator to develop a Data and Safety Monitoring Plan (DSMP).
2. **Protocol monitoring review.** Following acceptance of the Plan by the DSM-EC, a protocol-specific monitoring board (PSMB) will be established to conduct the primary review of safety and trial progress. The PSMB may be an Independent Study Monitor, a Clinical Study Oversight Committee, or a Data and Safety Monitoring Board. (See “Protocol Specific Monitoring Options” document at <http://www2.kumc.edu/researchcompliance/dsmbpolicies.htm> for additional details.) After each meeting of the protocol-specific monitoring board, a summary of its deliberations and recommendations regarding the protocol’s status are forwarded to the DSM-EC for consideration and review.
3. **DSM-EC review.** The DSM-EC reviews the deliberations of the PSMB and then makes a recommendation to the referring body regarding the status of the protocol.

### The monitoring plan.

Pre-Monitoring Approval All protocols must have the conditional approval of the HSC before the DSM-EC will carry out an initial review to create a monitoring plan.

The DSM Plan. Once a protocol has been referred to the DSM-EC for monitoring, the DSM-EC Chair or designee contacts the principal investigator and requests that a DSMP be submitted to the Office of Compliance. The required template for the DSMP can be found at <http://www2.kumc.edu/researchcompliance/dsmbforms.htm>.

As part of the DSM Plan, the principal investigator must nominate individuals with protocol-specific expertise to serve on the PSMB and assist the DSM-EC in monitoring the protocol. These protocol-specific members must have relevant expertise and must be free of conflict of interest with the to-be-monitored protocol. They may be from any institution as long as they have the appropriate expertise and are willing to serve. The principal investigator must contact the proposed experts prior to nominating to assure their willingness to serve if they are approved by the DSM-EC. Nominations should be forwarded to the Office of Compliance using the PSMB member nomination form found at <http://www2.kumc.edu/researchcompliance/dsmbforms.htm>

Honoraria for these experts will be the responsibility of the principal investigator (see document “Honoraria for PSMB Members” at

<http://www2.kumc.edu/researchcompliance/dsmbsubprocess.htm> for details on these costs and methods of payment).

In addition to the investigator's DSMP, the DSM-EC may request that KUMC's Research Institute Clinical Research Administration Division conduct a periodic quality indicator visit (QIV) to assure that data are being collected and recorded according to protocol. The reports coming out of these record reviews will be reviewed by the PSMB as part of its regular protocol review. If the results of the QIV indicate the need for a further review, a detail visit may be requested by the PSMB or the DSM-EC to review further study details.

The PSMB or DSM-EC may also identify additional variables that they wish to review as part of the monitoring process, and the investigator will be required to provide those data.

Initial Review of the DSMP. Once the investigator submits a DSMP to the Office of Compliance, DSM-EC members will review the plan and supporting materials. Following this review, the DSM-EC chair will write a *Report of Initial Review* to the protocol PI, documenting any concerns with the DSMP including any requests for changes or additions.

If no issues are raised in the initial review processes regarding the protocol specific experts, these individuals will be contacted by Office of Compliance staff as part of the initial review to confirm their willingness to participate in the on-going protocol review process and if so, to obtain their signed confidentiality agreement and Committee Conflict of Interest Disclosure before reviewing any protocols. If concerns or conflicts are identified during the initial review phase regarding the proposed protocol-specific experts, the principal investigator may be asked to supply additional names or the DSM-EC will recruit additional experts.

Principal investigators are encouraged to work closely with the Office of Compliance during this period of initial review so that Plan approval can be accomplished in a timely manner.

DSM-EC Plan Review And Approval. Following the initial review, the plan is scheduled for full review at the next scheduled DSM-EC meeting. If any Plan changes are requested by the DSM-EC, the DSM-EC will not recommend initiation of the protocol until those changes have been made or negotiated to the satisfaction of the DSM-EC.

When the recommendation is that the protocol be initiated, a *Letter of Agreement* is sent to the protocol PI stating the frequency of monitoring review and the responsibilities of the protocol PI for providing information to the PSMB. The protocol PI is required to sign the letter and return it to OC staff for their records.

## **PSMB Review**

Investigator's Reporting Responsibilities. In advance of each scheduled PSMB meeting, the Investigator will be required to submit to the OC an "Investigator's Interim Data and Safety Monitoring Report" (found at <http://www2.kumc.edu/researchcompliance/dsmbforms.htm>), current enrollment data, adverse event summary data, and any other data requested by the

PSMB or DSM-EC. Deadlines for the submission of materials will be determined by the scheduled PSMB meetings and will be communicated to the investigator by OC personnel.

PSMB Ongoing Protocol Review. The protocol-specific monitoring board will meet at regularly scheduled intervals to review trial progress, adverse event data, and any other relevant information such as significant amendments or reviews from HSC submitted by the principal investigator. Monitoring reviews assess protocol elements as described in the Interim Monitoring Report. Following their review, the PSMB makes a recommendation to the DSM-EC regarding continuation of the study which is then forwarded to the DSM-EC for review.

### **DSM-EC Review**

DSM-EC Ongoing Protocol Review. Before each DSM-EC review, the PSMB report of ongoing review will be distributed to all DSM-EC members, along with a protocol summary, adverse event data, and any other relevant information.

Based on its review and discussion of the PSMB recommendation to continue, suspend, or terminate a protocol, the DSM-EC in turn recommends continuation, suspension, or termination of the protocol to the HSC and the referring body (if different than the HSC) following each review meeting. The DSM-EC recommendation is conveyed to the investigator by letter following each review meeting.

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