I. Organization
The External Data and Safety Monitoring Board (EDSMB) is an autonomous group of experts whose primary responsibility is to protect study participants through independent analyses of study data collected over time. An EDSMB is required to manage any study for which The University of Texas at MD Anderson Cancer Center has a financial conflict of interest with a sponsor/supporter of a research study.

II. Purpose
The Purpose of the EDSMB is to:

(a) Ensure that the interests of research study participants are protected.

III. Responsibilities
The EDSMB has the following responsibilities to accomplish the above Purpose:

(a) To review protocol specified interim analyses of outcome (toxicity and efficacy) data prepared by the study statistician or other responsible person at the time points defined in the study and additional time points as determined by the EDSMB;

(b) To determine whether, and to whom, outcome results should be released prior to reporting of study results;

(c) To consider study specific data, as well as background information about the disease, test agent or patient population applicable to the study and to communicate information and recommendations regarding the continuation, modification or termination of the study. If inadequate data or no data has been submitted to the committee, refer to Recommendations Part C.

(d) To serve as representatives of study participants and their interests, and not of the institution and its interests.

(e) To review protocol amendments, and if necessary, make suggestions on how the proposed amendments can be corrected or enhanced before giving approval for the amendment to be reviewed by the IRB of record. The EDSMB review will be conducted by the EDSMB Chair or designated EDSMB member.

(f) Once EDSMB has been made aware of a conflict of interest, the OPR staff notifies the PI of EDSMB monitoring and his or her responsibilities.

(g) If a conflict of interest with the sponsor is dissolved during EDSMB oversight, the protocol will be turned over to the MD Anderson DSMB for a determination regarding continued DSMB oversight.
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IV. Membership
The EDSMB shall consist of up to five (5) members (including the Chair) for each fiscal year. Appointment of EDSMB members will be based on breadth of background and experience. The EDSMB members will not have any affiliation with the institution of the principal investigator of the study.

(a) Voting:
A quorum, defined as two (2) or more members in addition to the Chair, is required for any EDSMB vote to take place.

(b) Recusal of Members:
Members associated with a study will excuse themselves from EDSMB discussions concerning such study and will not receive EDSMB reports concerning such study.

V. Meetings

(a) The EDSMB shall meet at least once a year, and more often if necessary.

(b) Study information to be provided to the EDSMB will include: title of the study, study principal investigator, study start date, expected study termination date, expected total number of study participants, number of participants currently enrolled in the study, results of interim analyses, dates of interim analyses, toxicity concerns, and the next formal monitoring date as specified in the study.

(c) It is recommended that a written report outlining the current status of each study to be monitored by the EDSMB be sent to the EDSMB members by the Office of Protocol Research (OPR) prior to an EDSMB meeting.

(d) EDSMB review of each study may include three parts.

1) First, the principal investigator will be invited to an open session to answer the members’ questions and add any further information s/he deems necessary. In this part, the focus will be on study accrual, compliance and toxicity issues.

2) Second, the study biostatistician will present study results in a closed session, during which the EDSMB will discuss interim outcome results by study treatment arm and determine any action that may need to be taken. The report of the results of the second part may contain recommendations on whether to close the study, whether to report study results, or whether to continue study accrual and follow-up.

3) Third, the EDSMB members will vote on the study in an executive session.

(e) A copy of the study statistician’s report will be sent via email to the EDSMB Chair, members, and the EDSMB ethicist (if any) for review prior to an EDSMB meeting.

(f) The EDSMB shall communicate their findings with the University of Texas
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Executive Vice Chancellor for Health Affairs, the external Institutional Review Board (IRB), and MD Anderson as necessary.

VI. Minutes
Minutes will be taken at each meeting and submitted to the EDSMB Chair for approval. The meeting agenda, along with reports, will be deleted at the conclusion of the meeting. Members receiving an electronic agenda, but who do not attend a meeting, are expected to permanently delete the meeting agenda as soon as possible. One (1) copy of each EDSMB meeting agenda (and any reports) will be kept at MD Anderson within OPR. No other copies will be kept at any location.

VII. Recommendations
EDSMB recommendations should be based upon results for the study being monitored as well as upon data available to the EDSMB from other related studies. The study principal investigator will ensure that the EDSMB is advised about relevant non-confidential results from other related studies that become available.

The EDSMB will provide recommendations in writing to the study principal investigator.

(a) In the event that a study change is recommended, the principal investigator will act to implement the change as expeditiously as possible to ensure the safety of all study participants.

(b) If the EDSMB provides a recommendation to the study principal investigator and/or biostatistician, it is their responsibility to respond to the EDSMB concerning such recommendation.

(c) If inadequate or incomplete data (i.e. an incomplete EDSMB report or no EDSMB report) is submitted to the EDSMB, the committee can administratively close the protocol to new patient entry until all information is received, reviewed, and approved by the committee.

VIII. Confidentiality Procedures
All documents, investigative reports or information and conversations relating to the EDSMB’s work are strictly confidential and are not to be shared with anyone other than Board members and OPR Staff. Although documents are subject to legal privileges as set forth in statutory and case law and generally are not subject to discovery during litigation, such privileges may be lost if any such documents are given to, shown to, or discussed with non-EDSMB members without an official EDSMB request to do so.

No communication of the deliberations or recommendations of the EDSMB, written or oral, should be made outside of the EDSMB except as expressly set forth in these By-Laws. Additionally, all study outcome (efficacy) results are strictly confidential and should not be divulged to anyone outside the EDSMB until after an EDSMB recommendation to report the results and the subsequent reporting of those results.

IX. Conflict of Interest
Individuals invited to serve on the EDSMB will disclose to the EDSMB Chair any potential,
real, or perceived conflict of interest at any time. Such conflicts of interest will include professional interest, proprietary interest and other miscellaneous interest considerations.

X. **NCI Oversight and Cancer Center Program**
In order to satisfy its objectives of protecting study participants, ensuring study integrity and providing public confidence in the conduct of research studies, it is essential that the EDSMB function in a manner that demonstrates competence, experience and independence of institutional, career, or financial interests.

XI. **Amendments**
These By-Laws may be amended or repealed or new By-Laws may be adopted by a vote of two-thirds (2/3) of the EDSMB members at any regular or special meeting, upon notice given prior to the meeting, and upon approval of the Vice President for Clinical Research.

APPROVED: _______________ DATE: _1-21-2016_
Aman Buzdar, M.D.
Vice President, Clinical Research Administration