DRAFT DSMB Charter

Title: Improving medical decision making for older patients with End Stage Renal Disease

Shortened Title: Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD)

Grant #: 1 R01 AG066892

Principal Investigators: Michael Paasche-Orlow and Angelo Volandes

Institution: Boston Medical Center

1. Introduction

This DRAFT Charter is for the Data and Safety Monitoring Board (DSMB) for the Video Images about Decisions for Ethical Outcomes in Kidney Disease (VIDEO-KD) study. One of the first acts of the DSMB would be to edit, finalize, and the Charter. In addition, the DSMB may wish to review and further edit the Charter at regular intervals to determine whether any changes are needed.

2. Responsibilities of the DSMB

The DSMB will act in an advisory capacity to the National Institute on Aging (NIA) Director to monitor participant safety, data quality and progress of the study by the Principal Investigators Michael Paasche-Orlow, MD, MA, MPH and Angelo Volandes, MD, MPH for the VIDEO-KD grant 1 R01 AG066892 and any successor grants, funded by the National Institute on Aging.

In addition, the DSMB may be asked to make recommendations, as appropriate, about:

- Efficacy versus futility of the study intervention in relation to enrollment and power to discern effects
- Benefit/risk ratio of procedures and participant burden
- Selection, recruitment, and retention of participants
- Adherence to protocol requirements
- Completeness, quality, and analysis of measurements
- Data and statistical analysis plan
- Amendments to the study protocol and consent forms, including whether any new data from other sources affect the equipoise of the study being monitored
- Participant safety, including review of consent form
- Notification of and referral for abnormal findings
- Participant burden

3. Communications, Organization, and Interactions

The DSMB will meet yearly throughout the study to receive an update and discuss ongoing study procedures. The project coordinator and data manager will share information with the DSMB as requested.

To avoid appearance of conflict of interests, neither the investigators nor the DSMB members should directly communicate on any study-related issues. This includes any protocols, manual of procedures, reports, recommendations and other study-related correspondence.

All such communications should be conducted exclusively through the NIA Program Official as described elsewhere in this document.

4. DSMB Members

DSMB members and their expertise are listed in Appendix A.

5. Conflict of Interest Reporting

All DSMB members will complete conflict of interest reports. Prior to the beginning of each DSMB meeting, all members will be asked to report any new conflicts of interest.

6. Scheduling, Timing, and Organization of Meetings

DSMB meetings will usually be held by video conference call. The initial DSMB meeting will be held prior to initiation of participant enrollment. If applicable, IRB approval of any protocol revisions that emerge from response to this meeting would need to be obtained prior to initiation of the protocol.

Subsequent meetings will be held via video teleconference at least every six months with additional meetings or conference calls scheduled as needed. The study coordinator in collaboration with the PIs will schedule meetings and conference calls.

The agenda for DSMB meetings and calls may be drafted by the study coordinator and the PIs. The study coordinator will send a draft of the agenda to the Program Officer and the chair of the DSMB for their review. Based on feedback on the draft agenda, the study coordinator will finalize the agenda and distribute the agenda two weeks before each meeting. All meeting and follow-up materials (agendas, reports, minutes, responses) will be distributed electronically.

The purpose of the first meeting will be to:

- Convey expectations for DSMB operations
- Provide an overview of study activities
- Review and accept the protocol or make recommendations for changes related to human subjects safety and ethics
- Review this Charter, confirm any edits to the Charter, and ratify the Charter

In subsequent annual meetings, the DSMB will review study-related adverse events, data quality and completeness, adherence to the protocol, and enrollment data to ensure proper trial conduct. Study personnel should provide any new literature particularly pertinent to the trial, along with their recommendation as to whether it affects the trial conduct or design. The DSMB will review the informed consent form when it reviews the protocol. The DSMB will review the consent periodically and/or as needed and consider whether the consent form requires revision in light of any new findings or amendments.

No interim analyses or early stopping rules are planned. In addition to regular meetings, it may be necessary to convene the DSMB urgently or on an *ad hoc* basis to discuss any information that raises questions about equipoise, safety, or anything else that would compromise the trial.

It is expected that all DSMB members will attend every meeting. The Board may wish to decide if particular expertise is needed within the quorum for a particular meeting or if additional members are needed to add to augment the expertise represented in the DSMB in an *ad hoc* fashion. All standing Monitoring Board members are voting members. The Board may decide in advance whether *ad hoc* members can vote.

7. Discussion of Confidential Material

DSMB meetings and calls will be organized into open, closed, and executive sessions.

During the **open sessions**, information will be presented to the DSMB by the study investigators, with time for discussion.

During the **closed sessions** (as needed), the DSMB will discuss confidential data from the study, including information on efficacy and safety by treatment arm. If the closed session occurs on a conference call, steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the closed session. The NIA Program Official, who is considered to be Executive Secretary, can participate in the closed session. The Project Scientists do not participate in the closed session.

The DSMB may hold an **executive session** in which only the DSMB members are present (i.e., without NIH representatives or Investigators). The DSMB Chair will be responsible for summarizing the DSMB's discussion and recommendations for executive sessions.

Each meeting must include a recommendation to continue or to terminate the study made by a DSMB majority or unanimous vote. Should the DSMB decide to issue a termination recommendation, the full vote of the DSMB is required. In the event of a split vote, majority vote will rule and a minority report should be appended. The DSMB Chair provides the tiebreaking vote in the event of a 50-50 split vote.

A recommendation to terminate the study may be made by the DSMB at any time by majority vote. The Chair should provide such a recommendation to the NIA immediately by telephone and email. After the NIA Director makes a decision about whether to accept or decline the DSMB recommendation to terminate the study, the PIs will be immediately informed about the decision.

At the conclusion of the closed and executive sessions, the DSMB chair may provide a summary of the preliminary recommendations to the lead investigators to provide an opportunity for study investigators to ask questions to clarify the recommendations.

8. Reports of DSMB Deliberations

Following review by the Principal Investigators, the study manager will send the minutes to the DSMB members for review. After receiving the DSMB members' input, the study manager will finalize the minutes and transmit them to the DSMB Chair for final review and approval. The DSMB Chair may sign the minutes or indicate approval electronically via email. The final, approved minutes will be sent electronically to the Principal Investigators and will be stored in electronic versions at BMC. A response to action items contained in the minutes will be included in the report for the subsequent DSMB meeting. The Principal Investigators will distribute the meeting minutes to study investigators. It is the responsibility of each clinical center to forward this information to their local IRB.

When a closed session of the DSMB is held, the procedure for reporting the minutes will be similar. However, the minutes from the closed session will be created and stored separately from the session minutes. The minutes from the closed session (drafts of final versions) will not be sent to the Principal Investigators.

The study manager is responsible for preparation and transmission of the formal DSMB minutes 14 calendar days after each meeting or call. Minutes will document whether there is conflict of interest on the part of Board members and will summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting. The minutes are sent to the DSMB Chair, who will approve them on behalf of the DSMB. The minutes from the closed session (drafts of final version) will not be sent to the Principal Investigators.

9. Reports to the DSMB

The DSMB should discuss at the first or subsequent meetings what data they wish to review and how the data should be presented. The study team will be responsible for sharing data with the study team.

10. Statistical Monitoring Guidelines

The DSMB will review the adequacy of the statistical monitoring plan. Because potential adverse effects associated with the planned intervention are likely to be minor, uncommon, and anticipated, no interim analysis of the data is planned. If the DSMB request interim analyses, guidelines should be provided in advance for early termination for benefit, futility, or safety reasons.

11. Confidentiality

All materials, discussions and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

DSMB Charter, Version 2.0 11.11.2020

Appendix A: DSMB Members

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