National Institutes of Health (NIH)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Data and Safety Monitoring Board (DSMB) Charter

[STUDY/TRIAL NAME]
Grant No: [GRANT NO]
Contract No: [CONTRACT NO]
Cooperative Agreement No: [COOPERATIVE AGREEMENT NO]
[PI NAME AND CREDENTIALS], Principal Investigator
[INSTITUTION]

Last Approved Date: TBD

INTRODUCTION

This Data and Safety Monitoring Board (DSMB) acts in an advisory capacity to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH) to review safety data and [study/trial] progress for "[STUDY/TRIAL NAME]." This clinical [study/trial] is funded partially or in whole by the NIAMS and [OTHER NIH IC]. However, the NIAMS is responsible for oversight of the data and safety monitoring of this [trial/study]. The purpose of this document is to outline the NIAMS charge to the DSMB regarding its responsibilities, composition, and processes for "[STUDY/TRIAL NAME]." The NIH mandate requires safety oversight and monitoring for all interventional studies to be commensurate with the risks, nature, size, and complexity of the clinical [study/trial]. The Charter is intended to be a living document to be modified at any time. Annual review, modification, and approval of the Charter are facilitated by Navitas Clinical Research, Inc. (NCR), the Executive Secretary.

NIAMS RESPONSIBILITIES

NIAMS staff have stewardship responsibilities for oversight of the data and safety monitoring of its clinical [studies/trials]. Responsibilities of the NIAMS include, but are not limited to:

- Ensuring that a monitoring system is in place and is appropriate for the clinical [study/trial].
- Selecting DSMB members that have relevant expertise for the clinical [study/trial].
- Providing DSMB members access in a timely manner to study documents and milestones, and masked/unmasked data.
- Attending all DSMB meetings and meeting sessions. A limited, designated number of NIAMS staff attend the meetings. NIAMS staff are not members and do not have voting

privileges. The NIAMS may not influence or provide input into the DSMB recommendations. They may, however, raise questions to or seek clarification from the DSMB and the investigators during the meeting.

- Serving as the final decisional authority and accepting or rejecting recommendations from the DSMB. The NIAMS may also add an addendum to the formal written recommendations to provide further clarity or feedback as to their decision associated with the recommendations.

Other NIH program staff who attend the DSMB meetings are held to the same responsibilities.

EXECUTIVE SECRETARY

A NIAMS contractor, NCR, serves as the Executive Secretary and drafts meeting agendas in consultation with the DSMB Chairperson and the NIAMS Program staff. The Executive Secretary coordinates the DSMB meetings as well as any ad-hoc web-conferences, and provides logistics support and meeting summaries. The Executive Secretary transcribes the meeting recommendations and minutes and distributes them to the NIAMS, the DSMB, and the study team. The Executive Secretary is the primary contact point for DSMB communication with the NIAMS and the Principal Investigator (PI).

DSMB RESPONSIBILITIES

Responsibilities of the DSMB are to:

- Review the research protocol, Data and Safety Monitoring Plan (DSMP), Manual of Operating Procedures (MOP), and informed consent documents, including all proposed revisions.
- Evaluate the progress of the clinical [study/trial] on an ongoing basis, as needed, including periodic assessments of data quality, participant recruitment, accrual and retention, participant risk versus benefit, performance of [study/trial] site(s), and other factors that can affect the outcome.
- Evaluate safety throughout the course of the clinical [study/trial] through the routine review of aggregated adverse event safety data, in addition to expedited review of unanticipated problems, serious adverse event reports, and protocol deviations that impact participant safety. The DSMB Safety Officer reviews the documentation provided by the study team and makes recommendations to the NIAMS regarding protection of the clinical [study/trial] participants.*

*Questions from the investigators regarding individual study participants, such as those involving eligibility, patient care, or unblinding, are outside the purview of the DSMB. The PI is encouraged to consult with a designated study medical monitor and/or the IRB for guidance in these cases.

- Evaluate proposals of new clinical sites (that differ from the approved application) and make a recommendation to the NIAMS as to whether the enrollment at the site(s) is expected to enhance overall enrollment. Activities include evaluating the patient population pool, catchment area description, recruitment plan, and target enrollment for any new clinical sites.
- Consider the impact of factors external to the clinical [study/trial] when new information, such as scientific or therapeutic developments, becomes available and may affect safety of participants, their willingness to participate in the clinical [study/trial] or the ethics and conduct of the [study/trial].
- Assist the NIAMS by commenting on any problems with study conduct or performance.
- Ensure that the plan for maintaining the confidentiality of the clinical [study/trial] data and the results by the investigative team is appropriate.
- Review and evaluate requests for protocol modifications.
- [Review data after completion of each cohort to approve dose escalation.]
- Review in advance of the clinical [study/trial] initiation the [study/trial] specific stopping rules and any plans for interim analyses as established by the PI and selected members of the study team. These plans outline the conditions under which a clinical [study/trial] may be stopped (e.g., difficulties in recruitment, retention, obtaining outcome measures, or other issues).
- Review the interim analyses and/or accumulating data at the specified interval(s) (if applicable), and as appropriate, make a recommendation to continue, terminate, or modify the clinical [study/trial] based on observed benefit or harm in accordance with the planned stopping rules.

The NIAMS may discharge one or all of the DSMB members from their duties when:

a) "[STUDY/TRIAL NAME]" is complete;
b) a member is not able to fulfill the DSMB responsibilities as outlined in the Charter;
c) the NIAMS no longer has oversight responsibilities of the clinical [study/trial] and/or;
d) a member is found to have a real or perceived conflict of interest.

Additionally, a DSMB member may resign at any point during the clinical [study/trial], when a member:

a) is not able to fulfill the responsibilities of the position as outlined in the Charter;
b) believes a real or perceived conflict of interest exists.

DSMB MEMBERSHIP

This DSMB consists of [NUMBER] members who have been appointed by the NIAMS. [NUMBER] members will constitute a quorum for voting. In the event quorum is lost during the meeting, the NIAMS and the DSMB will discuss whether to continue with the remaining members or adjourn the meeting. If quorum is lost during the meeting, a vote may not take place and must be conducted electronically after the meeting with all members. The NIAMS holds the final decision-making authority.

Membership consists of persons independent of the clinical [study/trial] who have no financial, scientific, or other conflict of interest with the PI or any Co-Investigators. This DSMB includes experts in or representatives from the fields of: [e.g., Orthopedics, Dermatology, etc.)]

Ad Hoc Membership

Individuals with additional expertise may be invited by the NIAMS to participate as non-voting members in the DSMB meeting in certain situations. These members do not constitute quorum for voting. Non-voting members must also be independent of the clinical [study/trial] and have no financial, scientific, or other conflict of interest with the PI or any Co-Investigators.

DSMB Chairperson

The DSMB Chairperson is appointed by the NIAMS and confirmed by DSMB vote at the first meeting. The DSMB members must provide a full consensus vote when electing the DSMB Chairperson. The Chairperson is responsible for overseeing the meetings, reviewing and providing input on the agenda, and summarizing all DSMB recommendations in the Executive Session to the DSMB, NIAMS, and the Executive Secretary, with input from the other DSMB members. The Chairperson is the primary contact person for the DSMB.

Dr. [NAME] has been appointed as the DSMB Chairperson for this clinical [study/trial].

DSMB Safety Officer

The DSMB Safety Officer is appointed by the NIAMS and confirmed by DSMB vote at the first meeting. The DSMB members must provide a full consensus vote when electing the DSMB Safety Officer. The Safety Officer is the DSMB contact person for expedited reportable events (i.e., serious adverse events (SAEs), protocol deviations impacting participant safety, and unanticipated problems). The DSMB Safety Officer provides an assessment of SAEs and unanticipated problems on relatedness and expectedness, as well as recommendations for further action, if any (i.e., collection of follow-up information).

Dr. [NAME] has been appointed as the DSMB Safety Officer for this clinical [study/trial].

CONFLICT OF INTEREST

Individuals invited to serve on the DSMB must disclose any potential conflicts of interest, whether real or perceived, to the NIAMS. Conflicts of interest can include, but are not limited to, professional, proprietary, and personal interests. Any real or potential conflicts that develop during a member's tenure on a DSMB must be disclosed for the NIAMS consideration at the time the potential conflict is realized. In addition, written documentation attesting to an absence of conflict of interest is required annually.

Confidentiality

Each member of the DSMB must sign a statement of confidentiality annually. All materials, discussions, and proceedings of the DSMB are completely confidential. Members and other participants in DSMB meetings are expected to maintain confidentiality.

DSMB PROCESSES

Prior to commencement of recruitment, the study team drafts or revises [study/trial] materials (i.e., the protocol, MOP, DSMP, consent/assent form, report templates, and any other materials required for the DSMB's review). The study team submits relevant materials to the Executive Secretary, who facilitates the review process with the NIAMS and the DSMB through email and a secure website. The DSMB is requested to review the [study/trial] materials in preparation for the first meeting (referred to as the introductory meeting), which is scheduled between the PI, key study team members, and the DSMB, the NIAMS, and Executive Secretary. The DSMB has the opportunity to raise any questions or comments regarding the [study/trial] materials to the study team during the meeting.

The first meeting is held either by web-conference or in-person before initiation of the clinical [study/trial] to discuss the materials and whether the [study/trial] is ready to commence, establish guidelines for monitoring, and determine the format for future meetings. The NIAMS and the Executive Secretary prepare the agenda to 1) review the study materials, 2) appoint the DSMB Chairperson and Safety Officer, 3) discuss the plan and timing for safety monitoring, 4) make recommendations to initiate the clinical [study/trial] and/or modify the [study/trial] materials, and 5) review the Charter. During the introductory DSMB meeting, a NIAMS representative provides a training session outlining the DSMB process, roles and responsibilities for all meeting participants (i.e., DSMB members, study team, NIAMS staff, and the Executive Secretary).

Routine DSMB meetings are generally held semi-annually (or at other intervals determined by the DSMB), in-person or via a web-conference. Attendance at all meetings is highly critical for all DSMB members. Each DSMB member is specifically selected for his/her expertise and thus the member's consistent participation ensures rigorous monitoring throughout the course of the clinical [study/trial]. To facilitate its role as the decisional authority, NIAMS staff attends all DSMB meetings and meeting sessions (i.e., open, closed, and executive sessions) as an objective observer, not a DSMB member. The Executive Secretary also attends all DSMB meetings and

meeting sessions in order to provide logistical support and transcribe meeting summaries. All meetings are closed to the public because of participant confidentiality considerations.

An ad-hoc meeting of the DSMB may be called at any time by the Chairperson or by the NIAMS should ethical or participant safety issues arise. The suggestion to convene an ad-hoc meeting should be transmitted to the Executive Secretary, who will notify the NIAMS and the Chairperson. Depending on the situation, this meeting may include the Chairperson alone, a quorum of the DSMB, or the full DSMB.

Meeting Format

DSMB meetings may consist of open, closed, and executive sessions. All invited meeting participants, including the investigators and study team, the DSMB members, the NIAMS staff, and the Executive Secretary, may attend the **open session**. All sessions are normally attended by a minimum of [quorum #] voting DSMB members. The PI and the study statistician must be present. The number of NIAMS staff attending DSMB meetings should be minimized and only include experienced and trained Program Officials, Medical Officers, and Clinical Research Managers. Other NIAMS staff may be invited to attend only when appropriate. Open session discussion focuses on the conduct and progress of the clinical [study/trial], including participant accrual, protocol compliance, and problems encountered. **Unmasked data are not presented in the open session.**

The **closed session** is normally attended by the DSMB members, the NIAMS staff, the Executive Secretary, and the unmasked study statistician or unmasked study team designee. Any study team members, including the PI, or any NIAMS staff who are not privy to unmasked data should not attend this session. **If necessary, all unmasked safety data and efficacy data by treatment group may be presented during the closed session.** The DSMB determines in advance in what format it wishes to see the data during the closed session.

The **executive session** will be held after the closed session to identify and discuss the DSMB's recommendations to the NIAMS. It is attended by DSMB members, the NIAMS staff, and the Executive Secretary.

If necessary, a second **open session** to clarify any questions that arise from the DSMB may be held with the study team. A second **closed or executive session** may also be held, if needed.

Each meeting, whether routine or ad-hoc, must include a recommendation made by a formal DSMB majority or unanimous vote in the Executive Session to initiate, continue, place on hold, or terminate the clinical [study/trial]. The decision is ultimately made by the NIAMS, taking into consideration the recommendation(s) from the DSMB. The vote may be postponed until further information is acquired. In case of a tie vote, both positions will be reported. Discussions and recommendations will be documented by the Executive Secretary. The DSMB Chairperson provides the tiebreaking vote in the event of a 50-50 split vote.

Should the DSMB decide to issue a termination recommendation, the full DSMB must vote. In the event of a mixed vote, majority vote will rule and a minority report will be appended. A recommendation to terminate the study may be made by the DSMB at any time by majority vote. The NIAMS Institute Director makes the final decision about whether to accept or decline the DSMB recommendation to terminate the study. The Executive Secretary will transmit the NIAMS' decision to the PI as soon as possible. Specific recommendations will be transmitted in writing at a later date.

Meeting Materials

DSMB report templates are prepared by the study team, typically the statistician and/or the data coordinating center in consultation with the [study/trial] PI, to be reviewed by the DSMB during the introductory meeting; modifications to the reports can be requested at any time throughout a clinical [study/trial]. The reports list and summarize safety data, as relevant, and describe the status of the clinical [study/trial]. All meeting materials must be sent to the Executive Secretary at least two weeks prior to the meeting for distribution to the DSMB and the NIAMS. The Executive Secretary posts the meeting materials on the NIAMS Monitoring Bodies Materials website for access by the DSMB members, the study team, and the NIAMS staff. Materials are divided into two parts: Part 1 contains open session materials, which will be shared with all meeting participants and may be referenced during any session of the meeting; Part 2 contains closed session materials, which contain sensitive or unmasked data and should be discussed in closed and executive sessions only.

Part 1 – Open session materials include administrative study reports by [study/trial] site that describe participants screened, enrolled, completed, and discontinued, as well as baseline characteristics of the clinical [study/trial] population. Listings and summaries of adverse events and SAEs, along with any other information requested by the DSMB, may also be in the open session report, but none of the data should be presented in an unmasked manner.

Part 2 – Closed session materials contain study safety data in aggregate, by masked treatment group (A/B presentation), by unmasked treatment group, or in other formats as requested by the DSMB. The closed session reports should not be shared with any individuals who do not attend the closed session. Printed copies of the closed reports should be destroyed immediately following the meeting. If hard copies are distributed during an in-person meeting, they will be collected by the Executive Secretary at the conclusion of the meeting and destroyed.

It is important that access to outcome data, when necessary, be limited to the study statistician and/or unmasked study team designee and the DSMB to protect the clinical [study/trial] from bias in participant entry and/or evaluation. Any unmasked study personnel should be pre-designated and described in the MOP.

Meeting Recommendations

Meeting recommendations are drafted by the Executive Secretary within two working days after the meeting and are distributed for review to the full DSMB. The Executive Secretary receives comments from DSMB members within two working days. The Executive Secretary will send one reminder to DSMB members who have not provided a response and will be given an additional two-day window to respond. After the second two-day window has passed, the Executive Secretary will send DSMB comments and the recommendations to the NIAMS for review and acceptance. The NIAMS may request the Executive Secretary to follow-up with any DSMB member who has not responded to the request for review of the recommendations.

The NIAMS carefully considers all DSMB recommendations and accepts them at its discretion. The NIAMS has the final decisional authority and may add an addendum to the recommendations prior to finalization. Once finalized, the recommendations are posted to the NIAMS Monitoring Bodies Materials website and circulated to the study team.

Once received in writing, the PI has 30 calendar days to submit a formal, written response to the recommendations, which will then be circulated to the DSMB and the NIAMS for their electronic review by the Executive Secretary. In some cases, the recommendations from the introductory DSMB meeting may indicate that the clinical [study/trial] cannot begin enrollment until the PI's response to the recommendations has been submitted, reviewed, and accepted by the DSMB and the NIAMS. Therefore, recruitment initiation may be contingent upon the DSMB's and the NIAMS' review of the PI's response and the study materials, if further revisions are required.

If the DSMB and the NIAMS have any further questions or concerns upon review of the PI's response to the recommendations, the Executive Secretary will notify the PI for further clarification via email. It is the responsibility of the PI and at his/her discretion to distribute the DSMB recommendations or other information from the meeting to all co-investigators and to assure copies are submitted to all the IRBs associated with the clinical [study/trial]. The PI's response will also be reviewed at the following DSMB meeting and formal acceptance will be documented in the minutes.

Meeting Minutes

The Executive Secretary drafts the full meeting minutes within five working days after the meeting and distributes the full meeting minutes to the full DSMB for review and approval. The DSMB has three working days to review and provide comments. The Executive Secretary will send one follow-up reminder to the DSMB members who have not responded allowing them an additional two days to respond. After two days, the Executive Secretary will send DSMB comments and the full meeting minutes to the NIAMS for review. The NIAMS may request the Executive Secretary to follow-up with any DSMB member who has not responded to the request for review of the minutes. The minutes are typically finalized no later than 30 calendar days after the meeting. Once approved by the DSMB and accepted by the NIAMS, the Executive Secretary posts separate versions (open, closed (if applicable), and executive) of the approved minutes to the NIAMS Monitoring Bodies Materials website and notifies all participants according to the

session(s) they attended. Note: Masked study team members will only have access to open session minutes, whereas unmasked study team members will have access to the closed session minutes. A formal vote to approve the minutes is held at the next DSMB meeting.

Additional Reporting

Monthly Status Updates (pre-enrollment)

A status update regarding recruitment/enrollment start-up should be provided to the NIAMS by the study team through the Executive Secretary on a monthly basis until the first participant is enrolled. These updates are also shared with the DSMB for their reference following the introductory meeting.

Monthly Enrollment Reports (during active enrollment)

All clinical trials must provide monthly enrollment reports by the 5th of each month once the first participant is enrolled into the study. These reports will contain an Actual versus Expected graph along with a CONSORT diagram and should be submitted to the NIAMS through the Executive Secretary. The reports will be shared with the DSMB for their reference.

Unanticipated Problems

Unanticipated problems are 1) unexpected events that are 2) related or possibly related to participation in the research and 3) place participants or others at a greater risk of harm than was previously known or recognized. All three criteria above must be met to qualify the event as an unanticipated problem. The Office for Human Research Protections (OHRP), the Department of Health and Human Services (HHS) provides a complete definition and the following guidance for reporting unanticipated problems to the Institutional Review Board(s) (IRBs): *Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)* (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html).

Unanticipated problems must be reported to the NIAMS and the DSMB Safety Officer through the Executive Secretary within 48 hours of the investigator becoming aware of the event. The DSMB Safety Officer reviews and provides an independent assessment of the unanticipated problems, as well as determines if further action is required.

Serious Adverse Events

All SAEs (regardless of expectedness, relatedness, or if they meet the definition for unanticipated problems) must be reported to the DSMB Safety Officer and the NIAMS through the Executive Secretary within 48 hours of the investigator becoming aware of the event. The report will include a description of the event, the investigator's assessment of expectedness and relatedness, and other relevant information, including any actions taken. The DSMB Safety

Officer will review this information and provide an independent assessment, as well as recommendations for further action, if any.

While the NIAMS requires expedited reporting of SAEs through the Executive Secretary, the DSMB Safety Officer and NIAMS do not provide real time assessment of SAEs. It is the responsibility of the investigator(s) to provide real time assessment and take the necessary, immediate action with regard to participant safety.

Please note that if the study is testing an intervention that is regulated by the Food and Drug Administration (FDA), there may be additional reporting requirements to the FDA and the IRB that are not part of the NIAMS reporting process and are the PI's responsibility.

Discrepancies with Assessments Concerning SAEs and Unanticipated Problems

On occasion, there may be disagreements between the investigator and the DSMB regarding the assessment and/or management of an SAE or an event that qualifies as an unanticipated problem. The following excerpt gives guidance for cases where there is a difference of opinion among the DSMB (referred to as the "monitoring entity" in the excerpt below) and the investigator on unanticipated problems (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q4).

> *If the investigator determines that an adverse event is not an unanticipated problem, but the monitoring entity subsequently determines that the adverse event does in fact represent an unanticipated problem (for example, due to an unexpectedly higher frequency of the event), the monitoring entity should report this determination to the investigator, and such reports must be promptly submitted by the investigator to the IRB (45 CFR 46.103(b)(5)).*

Please note: The DSMB and the investigator may have iterative discussions regarding the assessment and may later come to an agreement regarding the assessment and/or management of an SAE or unanticipated problem. In cases where the DSMB and investigator come to an agreement after discussions and the event is determined not to be an unanticipated problem, the investigator is not required to report the event as an unanticipated problem to the IRB. Such discussions should take place promptly so as not to delay appropriate reporting to the IRB.

As it relates to SAEs, if resolution cannot be achieved after the investigator has had the opportunity to provide a rationale for their assessment of the event and does not agree to amend the report to match the NIAMS' and DSMB Safety Officer's assessment, the DSMB Chairperson may be requested by the NIAMS to weigh in and provide their feedback on the conflicting assessments by the investigator and the NIAMS/DSMB Safety Officer. If for any reason a mutually agreed upon assessment still cannot be reached, the NIAMS will further discuss the appropriate action that should be taken to resolve the difference in assessment between the parties. If a resolution cannot be accomplished over email, an ad-hoc meeting will be coordinated

between the parties, including but not limited to the investigator, DSMB Safety Officer, DSMB Chairperson, and the NIAMS.

Dependent upon the outcome of the ad-hoc meeting, one of the following may occur:

- The investigator will update the report to reflect the NIAMS' and DSMB Safety Officer's adjudication and resubmit it to the DSMB Safety Officer and the NIAMS for review. If the updated adjudication changes the reporting requirements for the event (e.g., an SAE now meets the criteria for an unanticipated problem), these new reporting requirements should be met.
- The investigator will leave the report as is with their original adjudication and notify their IRB of the difference in the adjudication of the event, as well as provide a copy of the IRB communication to the NIAMS.

As the DSMB is advisory to the NIAMS, the NIAMS makes the final decision regarding the recommended adjudication of the event being shared with the investigator. Once the NIAMS makes a final decision about the adjudication of the event, further discussion with the monitoring body will not be needed. During this process of determining the adjudication of the event, the investigator should adhere to all applicable (IRB, FDA, etc.) reporting requirements and timelines for the event based on their original assessment.

Protocol Deviations

Protocol deviations that impact participant safety should be reported to the NIAMS and the DSMB Safety Officer (through the Executive Secretary) within 48 hours of the investigator becoming aware of the event. Protocol deviations that occur but do not affect participant safety are submitted in aggregate as part of the routine DSMB meeting report. The investigator must also adhere to the Institution's policy on reporting protocol deviations to the IRB.

Please note: Additional reporting may be required if the deviation meets the definition of an unanticipated problem as described in the OHRP guidance linked above.

Protocol Amendments

All protocol amendments should be reviewed and approved by the NIAMS, DSMB, and the IRB prior to implementation. Requests for protocol amendment approvals may be submitted by the PI for review by the NIAMS and the DSMB between regularly scheduled meetings. Approvals may be conducted via email correspondence, deferred until the next regularly scheduled DSMB meeting, or a web-conference may be scheduled if immediate discussion is warranted. The PI and study team (and any other internal study committees such as a Steering Committee) should ensure that they have come to an internal consensus with any proposed changes prior to submitting the amendment to the NIAMS and the DSMB for review. The PI is notified by the Executive Secretary of the approved changes. IRB review of protocol amendments are separate from this process and are the PI's responsibility.

Communication with the DSMB

To maintain the independence of the DSMB, the PI and study team shall only communicate DSMB-related requests, questions, or concerns through the NIAMS or the Executive Secretary. The DSMB members should only communicate with the PI through the Executive Secretary and the NIAMS.

Release of Clinical [Study/Trial] Data

Publications and abstracts containing primary clinical [study/trial] results are the responsibility of the investigator(s), and prior review or approval by the NIAMS or the DSMB is not required. However, the perspective of the DSMB and NIAMS staff can add value to such publications/abstracts, and their comments may be useful to the investigator(s). Therefore, the PI is strongly encouraged to provide the NIAMS with a copy of all abstracts or manuscripts reporting primary clinical [study/trial] results well in advance of submission to a journal or scientific meeting. The NIAMS will distribute the manuscript/abstract to the DSMB members and collect and provide their comments to the PI. The PI may then consider changes to the abstract or manuscript based on comments received from the NIAMS and the DSMB.

NIAMS DSMB Ombudsman

Any concerns related to the NIAMS staff attendance or participation in DSMB meetings may be directed to the NIAMS Deputy Director.