

# Protocol Review & Monitoring System

## Standard Operating Procedures

Title: **Observer Attendance at PRMS Committee Meetings**

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**PURPOSE:** The purpose of this procedure is to describe the standard process and requirements for observer attendance at a Protocol Review & Monitoring System (PRMS) Committee meeting.

**SCOPE:** This SOP applies to the Scientific Review Committee (SRC), Data and Safety Monitoring Committee (DSMC), and Audit Committee (AC), and describes department specific activities, as well as expectations for observers in attendance at convened committee meetings,

**PERSONNEL RESPONSIBLE:** The Manager of PRMS and OnCore Oncology is responsible for reviewing attendance requests and approving observer attendance at any PRMS committee meeting.

### **DEFINITIONS:**

- **Observer:** An individual, defined as neither PRMS staff nor PRMS committee member, attending a PRMS committee for the purposes of orientation, education, or otherwise.

### **PROCEDURES:**

- Prior to attendance at an SRC, DSMC or AC meeting, a request must be submitted to [prmsoffice@unmc.edu](mailto:prmsoffice@unmc.edu) and must include name, contact information, title, justification for the request, and number of meetings requested. This request will be forwarded to the Manager of PRMS and OnCore Oncology for approval. The observer will be notified of the status of the approval, the next meeting date, a confidentiality agreement, as well as any restrictions regarding their attendance.

#### PRMS Staff

- The PRMS Staff responsible for coordinating the meeting will ensure a signed confidentiality agreement has been received before providing all necessary meeting details to the observer for each of the approved meetings.
- The presence of an observer will be recorded in the appropriate committee meeting minutes.

#### Observer

- The observer will be required to sign the confidentiality agreement prior to the scheduled meeting(s). The signed confidentiality agreement must be received by the PRMS staff prior to attending the first meeting.
- In general, observers will not participate in the discussion of agenda items.
- The observer may be required to leave the room during any discussion or vote as determined by the Chair, Vice Chair, or their designee.
- At the conclusion of the approved number of meetings, a new request must be submitted to attend additional meetings.