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| **Figure 6.7** | **Medical Staff Committee Meeting Minutes** | | |
| Study Oversight Committee Meeting Minutes  Held on: October 29, 2019, Conference Room B | | | |
| **Members (Present)** | | **Affiliation** | **Scientist?** |
| Physician A, MD (Chairman) | | Private Physician | Yes |
| Physician B (Member) | | Private Physician | Yes |
| Community Member A (Member) | | Community | No |
| Physician C (Member) | | Private Physician | Yes |
| Attorney A (Member) | | Community | No |
| Community Member B (Member) | | Community | No |
| **Staff Present** | | **Affiliation** | **Scientist?** |
| Medical Staff Services Director | | Hospital | No |
| Hospital Staffer (Member) | | Hospital | No |
| **Researchers Present** | | **Affiliation** | **Scientist?** |
| Researcher A, CMA | | State Infectious Disease Dept. | No |
| Researcher B, MD | | State Infectious Disease Dept. | Yes |
| **Members (Excused)** | | **Affiliation** | **Scientist?** |
| Physician E, MD (Member) | | Private Physician | Yes |
| Physician F, MD (Member) | | Hospital | Yes |

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| **Figure 6.7** | **Sample Committee Meeting Minutes (cont.)** |
| Call to Order: The meeting convened at 12:03.  September 2019 Minutes: Approved. Review Board Addition  The addition of the Quorum Review Board as a central Institutional Review Board was approved. Hospital staffer to obtain MEC chair approval and submit revised assurance form.  **Initial Review**  Principal Investigator: Researcher A, CMA  Coinvestigator: None  Subinvestigator: None  Sites: [Hospital name]  Street Address City, State, ZIP Telephone number  Second location (if applicable) Street Address  City, State, ZIP Telephone number  **Company:** ABC Co.  **Study Name:** Randomized, observer-blind, placebo-controlled, multicenter, multinational Phase III trial in 1,500 adult subjects age 59 years or older who are at risk for *C. difficile* infection (CDI).  **Use Summary:** To assess the efficacy of the CDI vaccine in preventing the onset of symptomatic primary CDI confirmed by polymerase chain reaction (PCR) in adult subjects age 50 years or older who are at risk for CDI and have received at least one injection. | |

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| **Figure 6.7** | **Sample Committee Meeting Minutes (cont.)** |
| **Discussion:**  **General:** Patients enrolled in the study will be enrolled in one of two risk strata across treatment groups. **Scientific Design:** A randomized, observer-blind, placebo-controlled, multicenter, multinational Phase III trial. **Risk/Benefit Level:** Minimal risks.  **Central IRB:** Quorum.  **Subject Selection:** Adult subjects age 50 years or older who are at risk for CD).  **Additional Safeguards for Vulnerable Subjects:** None.  **Privacy and Confidentiality:** Medical records will be maintained according to current legal requirements.  **Consent Form:** Accepted with no revisions.  **Recommendations:** Provide copies of the screening for adverse events (SAE) and the recruitment plan to chair for review.  **Decision and Vote:** The study was approved following review of the documents listed above.  **Adjournment**  Researcher A, CMA, and Researcher B, MD, were excused for the final discussion and voting process.  The meeting was adjourned at 12:50.  Submitted by Director, Medical Staff Services, 10-31-19  Approval:    Signature, Chair Date | |