

IRB SOP 402
IRB Meeting Minutes

1.0

3.0 Information Documented

The minutes of IRB meetings shall be compiled by the IRB Administrator, following the IRB meeting minutes template. The following specific information shall be recorded in the meeting minutes:

1. Attendance recorded by name
2. Approval of previous minutes
3. Adverse Events action
4. Protocol Deviations
5. List of closed/expired protocols
6. List of approved exempt and expedited approved protocols and specific citation for the category of expedited review.
7. Actions taken by the IRB on initial, amendments, and continuing review applications. If applicable, specific measures taken to protect vulnerable populations and request for waiver of informed consent.
 - Votes on these actions
 - Basis for requiring changes in or disapproving research
 - Summary of controverted issues
 - Required IRB findings and determinations
8. Information/Education
9. Research Compliance
10. Quality Assurance and Quality Improvement
11. Old/New Business
12. WCG (v)7 (e)3 (r)14a (s)1era wrote AA (B)HD#BA1 .atiaR il4 (u)-4 bm (ti)i3 (CG-8(w.01 0 Td(/C20 Td

Procedures

1.0 Development of IRB Meeting Minutes

The IRB Administrator identifies all reviews and comments from the meeting and utilizes this information to prepare the Board minutes.

2.0 Meeting Minutes Approval