Minutes of IRB Meetings

Minutes of a convened IRB meeting should include:

- Attendance at meeting, including guests.

- Key points of any deliberations, actions, and votes; 1) Initial review 2) Continuing review 3) Change of protocol review 4) Review of adverse events, potential noncompliance, Unanticipated problems. Include number of members voting:
  _____ for _____ against _____ abstaining

- Abstention due to COI: _____ Names of IRB members who abstain due to COI.

- Summarize discussion of controverted issues.

- Determinations by regulations and policy for any applicable HIPAA or FERPA regulations.

- Determinations and justifications required by regulations and protocol specific findings:
  ___ Level of risk; minimal
  ___ Waiver or alteration of informed consent and justification for it.
  ___ Research involving vulnerable populations; a) Pregnant women, human fetuses and neonates
      b) Prisoners c) Children.
  ___ Additional safeguards and documentation protecting vulnerable populations and why they are considered vulnerable.
  ___ Appropriate determination of Continuing Review

- Use of a consultant. Expertise of consultant should be noted and his/her comments cited and no conflict of interest noted.