

## 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.