



## **#16 Documentation of IRB Activities**

The IRB Office is responsible for preparing and maintaining adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; recruiting materials; and progress reports submitted by investigators.
- Reports and results of subsequent reviews by the IRB of injuries to subjects and/or other adverse events.
- Records of continuing review activities including the timeliness of progress reports, and the IRB decision to append, terminate, or allow study continuance as previously approved.
- Copies of all correspondence between the IRB and the investigators.
- Notification to the full IRB, by inclusion on the IRB agenda, of protocols that have been approved via the expedited review process.
- Agendas and minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the fact that an LLNL IRB member with a conflicting interest in a study refrained from voting; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and any other matters that may come before the Board during the meeting.
- A list of IRB members identified by name; earned degree; representative capacity; indication of experience such as board certifications, licensures, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.

