

IRB approval does not end the relationship with the IRB. The relationship continues to the end of the study *and beyond*.

CONDITIONS: With every study approval there are conditions.

- No subject may be approached until IRB approval is received.
- No activity may continue after the expiration date.
- Informed consent must be obtained
 - using an established process unless the consent process is waived
 - and documented using an IRB approved consent document unless documentation is altered or waived.
- Adverse events must be recorded.
- Adverse events that are serious *or* unanticipated *and* are possibly or probably related must be reported immediately.
- Unanticipated problems to subjects or others must be reported.
- The protocol must be followed.
- Modifications must be pre-approved unless subjects safety is involved
- Violations of protocol must be reported immediately if
 - There is any increase in subject risk
 - The study design is compromised
 - The violation is a second occurrence.
- Investigators must be knowledgeable about
 - the study protocol
 - background information and literature
 - responsible conduct of research and ethics
- Investigators must have completed a course in the responsible conduct of research within the past two years.
- All data analysis and subsequent use of the data must conform to the promises and conditions set forth in the approved protocol.

