

## Request for Continuance Guidelines

Institutional Review Board (IRB) approval is granted for one year, at the end of which, the principal investigator of an ongoing project must submit a request for continuance. Investigators are required to submit as part of their request for continuance a status report on the progress of the research to date that includes:

- ✓ title of project, principal investigator, date of initial IRB approval
- ✓ the number of subjects accrued
- ✓ a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure)
- ✓ a summary of any withdrawal of subjects from the research since the last IRB review
- ✓ a summary of any complaints about the research since the last IRB review
- ✓ a summary of any recent literature that may be relevant to the research
- ✓ a summary of any amendments or modifications to the research since the last IRB review
- ✓ any relevant multi-center trial reports (if applicable)
- ✓ any other relevant information, especially information about risks associated with the research
- ✓ a copy of the current informed consent document and any newly proposed consent document

Please note that it is the investigator's responsibility to know when IRB approval will expire and to submit a request for continuance to the IRB prior to the end of the current approval period. As per federal standards for conducting a continuation review, the IRB uses "Full Committee Review" procedures unless the research meets the expedited review criteria. This means that investigators may need to submit their request for continuance one or more months prior to the end of the current approval period to ensure that their request is available for a full committee review that coincides with a scheduled IRB meeting time. Upcoming meeting times can be viewed at the IRB committee's website: [www.anselm.edu/IRB](http://www.anselm.edu/IRB)

Also note that if a protocol's approval expires before the IRB completes its continuation review, the investigator must stop all procedures that are not needed to ensure the health and safety of the research subjects.

To apply for continuation of an ongoing research study submit the following:

1. status report as outlined above
2. proof of current IRB ethics training certificate(s) for all investigators involved with the project

These materials can be sent electronically via e-mail to [irb@anselm.edu](mailto:irb@anselm.edu) or mailed to the committee secretary, Robin Allard, Campus Box 1662.