Regulatory Issues

If the proposal involves Human Subjects, Vertebrate Animals, and/or Biohazards or Recombinant DNA research, then the Transmittal Checksheet must indicate this in items #24 through #29.

Humans
Principal Investigator prepares and submits applications for use of Human Subjects. The application should be submitted to the Committee Secretary.

Human Subjects Protection Program
610 Purdue Mall
West Lafayette, IN 47907-2040

The Committee on the Use of Human Subjects in Research reviews the application. Once approval is obtained, a Protocol Approval Number is assigned to the P.I. and is good for up to one (1) year.
For more information see: **http://www.purdue.edu/Research/ORA/humans/humans-main.shtml**

Animals
Principal Investigator prepares and submits an application for use of Vertebrate Animals. The application should be submitted to the Purdue Animal Care and Use Committee (PACUC), VAHF. Once the PACUC approves the application, a Protocol Approval Number is assigned to the P.I. and is good for up to three (3) years. For more information see: **http://www.purdue.edu/Research/ORA/animals/animals-main.shtml**

R-DNA and Biohazards
Principal Investigators prepare and submit an application for use of R-DNA and/or Biohazards. It is suggested that P.I.'s develop an umbrella application describing their research projects. This umbrella application would ideally encompass all of the P.I.'s current & anticipated research design. Applications should be submitted to Purdue's Institutional Biosafety Committee (IBC), Office of Research Administration, 300 Hovd. R-DNA and Biohazard approvals are good for up to three years. For more information see:
http://www.purdue.edu/Research/ORA/rdna/rdna-main.shtml

Definition of Good Laboratory Practices:
Compliance with Federal Good Laboratory Practices or GLP regulations involves complex record keeping/archiving and is generally only required for projects producing data for regulatory activities (registration of pesticides or drugs or devices by EPA or FDA). Whenever anyone thinks that GLP compliance is required, The Assistant Vice President for Research Compliance needs to speak with him or her to determine why and how he or she plan to comply.

When the Account Manager in SPS reviews the original proposal, he/she reviews the appropriate items (#24-#29) regarding regulatory approvals and verifies that they are marked on the transmittal checksheet according to the proposal. If the transmittal checksheet does not match what the P.I. has indicated in his/her proposal, the Account Manager contacts The Assistant Vice President for Research Compliance.