Protocols and Amendments Submission

Mechanisms of Approval

Submitting New Protocols

For preliminary review, the Principal Investigator shall submit new protocols along with the required IACUC Forms to the IACUC office for review by the Committee.

• Any concerns or requested changes will be communicated to the Principal Investigator two weeks after reception of the protocol by the Committee.
• Addressing these concerns or the requested changes by the Principal Investigator does not guarantee that additional changes or clarifications will not be requested at a later time.
• The Principal Investigator modifies the protocol based on the preliminary evaluations by the IACUC and resubmits the protocol for IACUC review within one week of receiving the preliminary evaluation memo.
• The modified protocol is assigned a designated reviewer who presents his findings to the Committee for approval, further modifications of the protocol for approval, or rejection.
• If there are no concerns or requested changes, the Principal Investigator will receive an approval from the IACUC.
• New protocols with the following elements are automatically assigned for full Committee review, without preliminary review:
  – Major survival surgery (e.g. brain, chest, bone etc…)
  – Death as an endpoint
  – Unrelieved pain and distress

Submitting Amendment(s) to already approved protocols

An amendment to an already approved protocol may be submitted at any time by the Principal Investigator.

• Amendments containing the following elements will be assigned automatically for full committee review and will be processed as described under New Protocols:
  – Major survival surgery
  – Death as an endpoint
  – Unrelieved pain and distress

• If the amendment does not contain the above criteria, it is assigned to the IACUC Chair/designee for review. The IACUC Chair/designee may:
  – Approve
  – Require modifications in order to approve the amendment
  – Request full-board review