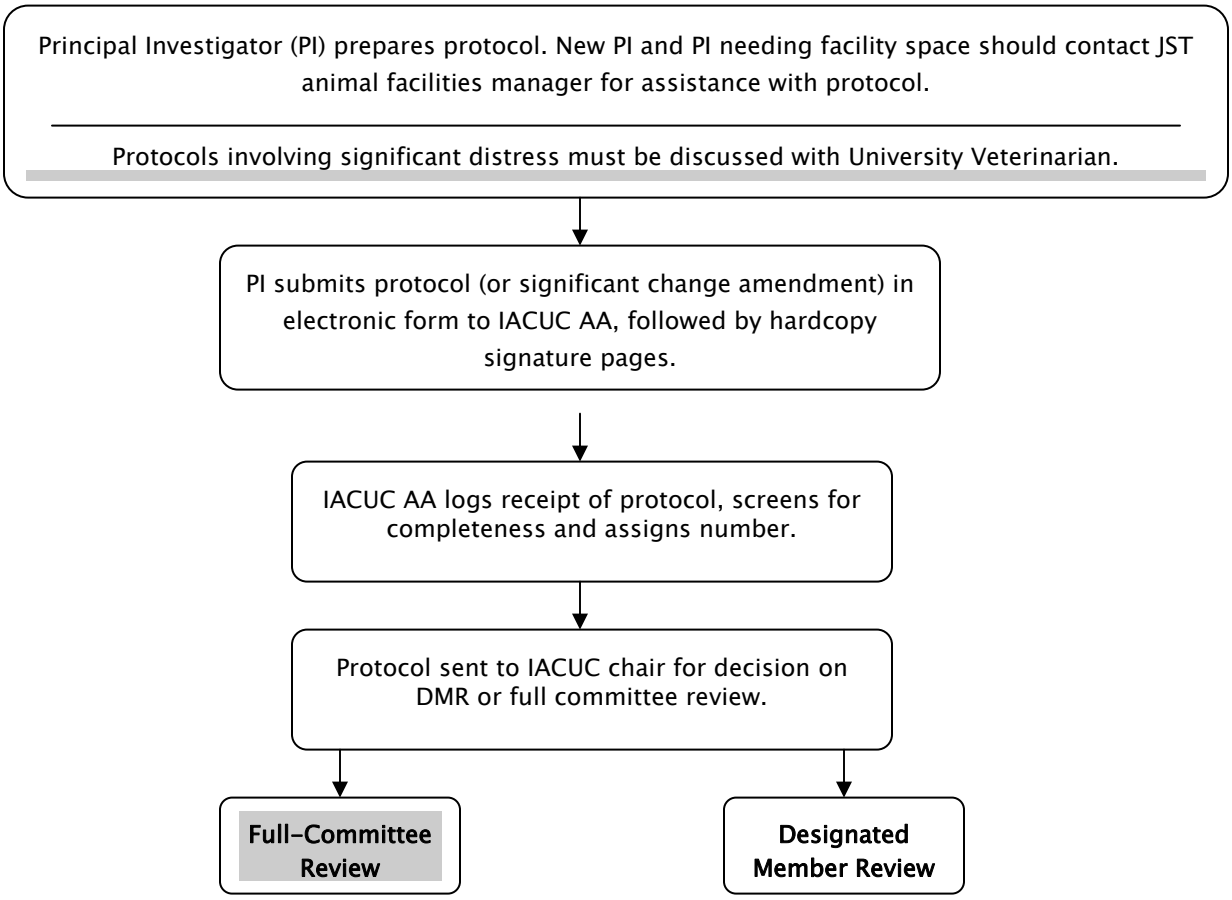New Protocol or Significant Change Amendment Submission