



**OFFICE OF RESEARCH & SPONSORED PROGRAMS
BSU-INSTITUTIONAL REVIEW BOARD (IRB)**

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PROTOCOL MODIFICATION SUBMISSION FORM

Federal Regulations require BSU-IRB approval before implementing the proposed changes listed below. Complete and sign the form and submit electronically via email to irb@bowiestate.edu for review. The Office of Research and Sponsored Programs staff will send a written notification of the BSU-IRB decision. The Principal Investigator may implement protocol changes to decrease immediate risks to subjects prior to submitting the change document to the BSU-IRB.

Name of Principal Investigator (First, Last):	
Name of Primary Contact (First, Last):	
E-mail Address of Primary Contact:	
Phone Number of Primary Contact:	
Protocol Number:	
Study Title:	
IRB Approval Expiration Date:	
Date Form Completed:	

TYPE OF MODIFICATION

Principal Investigator Transfer of Responsibility:

Provide detail and attach supporting documentation on a separate sheet, if applicable.

Protocol Change Increasing Risk to Subjects:

Provide detail and describe the increased risk and how subjects will be informed. Provide detail and attach supporting documentation on a separate sheet, if applicable.



Study Enrollment Status:

- Study has not begun (no subjects consented)
- Open to subject enrollment
- Closed to subject enrollment

Modification to Informed Consent Document: Documentation Checklist

Have you attached a copy of the revised informed consent document with tracked changes, AND an additional clean copy to irb@bowiestate.edu ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have subjects been consented previously?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the research team plan to re-consent subjects?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Modification to supportive materials:

Is the modification to a questionnaire, survey, recruitment materials, study brochure, or other supportive materials?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Have you attached a rationale for the modification to this form?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please provide additional details regarding the modification to supportive materials in the space provided below. Use an additional sheet, if applicable.	

Submitted by:

Principal Investigator Name (Printed):	
Principal Investigator Signature:	
Date:	