



SOP Title:	Procedure for Modifying Research Protocol Registrations	SOP No.	10
		Revision	0
Effective Date:	5/18/2022	Page	1 of 1

Purpose: This standard operating procedure (SOP) explains the procedure for modifying an existing approved research proposal.

Conditions:

1. An approved research proposal must be on file with the Institutional Biosafety Committee (IBC).
2. The modification must still be in concert with the original proposal’s objectives.
3. The modification cannot increase the risk group rating of the research.

Procedures:

1. To submit an amendment, go to <https://era.jmu.edu>. Please note that signing into this site from off campus requires registration through Pulse Secure:
https://www.jmu.edu/researchintegrity/irb/SSLVPN_Pulse_Secure_Guide.pdf.
2. A more detailed user guide for helping to fill out the protocol is available here:
https://www.jmu.edu/researchintegrity/eramaterials/eProtocol_Investigator_Training-Manual_IBC.pdf but help can also always be obtained by consulting with the Office of Research Integrity or someone from the IBC committee.
3. Click on the Protocol ID under “Approved Protocols” on the Investigator Dashboard.
4. Click on “Start Amendment.”
5. Complete the form and update the protocol registration as necessary.
6. Recertify the protocol under “Certifications” then “Submit Form.”
7. Depending on the nature of the amendment, it will either be processed administratively, designated member, or by the full committee.
8. The possible outcomes are: approve as written, approve pending minor revisions, or disapprove. Amendments that cannot be approved under designated review will be sent to the full committee.