



SOP Title:	Filing a Non-Exempt Protocol Registration	SOP No.	5
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Purpose: This standard operating procedure (SOP) explains the procedure for review of research proposal involving biohazardous materials.

Conditions:

1. The applicant must be a faculty member at JMU.
2. The applicant must complete the protocol registration in the electronic research administration system (eRA).
3. The applicant should complete a risk assessment to determine applicable biosafety level based on agent and proposed procedures.
4. The applicant may consult with a member of the IBC for guidance on the process.
5. The applicant can expect protocol approval to take no more than 30 days from time of submission if the protocol is submitted during the school year. Submission over the summer months may take longer.
6. Applicant approval will require an initial lab inspection.

Procedures:

1. To create a protocol 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/eramanuals/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.

The project will have several pages to fill out:

- a. Expect to start by filling out a project title and your personal information.
- b. The next page is Personnel Information – here you should add any students or other faculty or staff working with you on the project. Student information should be recorded under “other personnel” at the bottom of the form. Use the binoculars and the student email username to look up your students and add them to your protocol. Remember you do need to get permission to share your students email addresses with us.
- c. Protocol Registration is next – first you will check the type of protocols you will be doing and then you will fill out your funding information.
- d. Next you will need to put together a protocol summary to explain what you are doing, your rationale for doing it and all of the basic procedures you are using. Please also explain in this document how you will train your students and what records will be kept of this training. If you need to, you may continue this in the attachment section.



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- e. You will need to let us know next all of the places your research will take place. If you find you cannot find the room numbers you need already in the system contact the Office of Research Integrity to have them put additional room numbers.
 - f. The next few pages, biological agents, recombinant or synthetic nucleic acids, and biological toxin usage should be filled out based on what you are doing. All biological agents and their risk group needs to be listed both in the protocol and in the table under number 1 on the biological agents page.
 - g. Facilities, Security and Safety- helps you walk through basic biological safety questions that are needed to fill out for the protocol.
 - h. Once you are finished you will want to check for completeness of this form.
3. Once the protocol is finished, the protocol first must be approved by the Academic Unit Head (AUH).
 4. Once it is approved by the AUH it needs to be submitted to the IBC.
 5. Once the protocol is submitted to the IBC, it will be sent to the committee members for review. IBC members will be given a maximum time of 21 days to review the protocol and submit comments during the academic school year. More time may be required over the summer semester.
 6. The IBC may 1) Request addition Information, 2) May approve the protocol or 3) May reject the protocol as being untenable at JMU (in which case safety reasons will be cited).
 7. In addition to the review an inspection of the lab space must be conducted by at least two IBC members using the IBC inspection checklist. This inspection will be scheduled within 30 days of the protocol submission. At least two IBC members will conduct the inspection using the IBC inspection protocol. You are asked to please be at this initial inspection. A copy of the inspection results will be sent to your lab within 30 days of your inspection. (An SOP with more details about the inspection process can be found in SOP No. 7.)
 8. The protocols are approved for 3 years as long as a yearly update is submitted and inspection reports reflect compliant conditions. Protocols may also be amended or updated during the three years but this often requires reinspection by the IBC (an SOP with more details about amending a protocol can be found in SOP No. 7).