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Biosafety Protocol Approval Letter: A Tool for Risk Assessment & Post-Approval Monitoring

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{Objectives}

Emory University's Environmental Health and Safety Office (EHSO) critically examined and edited their Biosafety Protocol Approval Letter to meet the following objectives:

- Improve the letter so that it communicates the outcomes of biological risk assessments in a more clear and concise way.
- Modify the letter so it can be used as a tool for post-approval monitoring.

{Methods}

1. Critically examined the existing approval letter.
2. Benchmarked with other institutions.
3. Edited the existing letter. Used an addendum to include discovered gaps and opportunities.
4. Conducted a beta test with principal investigators (PIs), members of the Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), Division of Animal Resources (DAR), and EHSO.
5. Incorporated edits from the beta test.
6. Began using the new letter across Emory's campus.

Teamwork...
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Out with the old...

The original approval letter included:

- Overall biosafety level (BSL) / animal biosafety level (ABSL)
- List of animals, agents, and human material
- *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) classification (ex: III-D-1, III-E-1)


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Research Administration | Institutional Biosafety Committee
Research Involving Biological Safety

Date
PI Name
Address 1
Address 2

Biosafety File #: (File #)
Proposal title: (Protocol Title)

Dear Dr. PI Name:

This is approval is valid until (Renewal Monthly 1, 2013.

The proposal to work with biological toxins, infectious agents, and or recombinant DNA molecules referenced above was reviewed by the Institutional Biosafety Committee and approved on Date.

Laboratory activities should be conducted utilizing laboratory practices, safety equipment and facilities recommended for Biosafety Level

Animal related research activities should be conducted at Animal Biosafety Level

Animals approved for research:

Human blood, cell lines/CRPM:

Agents approved for research:

NIH Guidelines Recombinant DNA Classification: (cDNA)

For any additions or changes to the protocol, an amendment form needs to be submitted. Forms are available at www.ehso.emory.edu

The Biosafety assigned file number is

... and in with the new!

The new letter includes two parts: a formal letter and an addendum. The formal letter contains the NIH Guidelines classification, renewal dates, and personnel listing. The attached and referenced addendum provides a concise view of the approved research, along with requirements (administrative controls, work practices, engineering controls, and personal protective equipment) that the PI must follow in order to maintain their approval status.

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BIOSAFETY PROTOCOL APPROVAL LETTER - ADDENDUM

The table outlines the requirements that must be maintained in order for the approved research to be conducted at Emory University:

PROTOCOL INFORMATION			
Principal Investigator			
Protocol Number		*Approval Date*	

GENERAL REQUIREMENTS					
Training	*Minimum requirements include annual Laboratory Safety Training, Biosafety Training every 3 years, Lab Specific Training, and monthly Lab Rat Newsletter Training. Additional training requirements include:* ☐ BBP (annual) ☐ Laser Safety (annual) ☐ BSO Consultation – BSL-3/ABSL-3 ☐ Herpes B (annual) ☐ BARS: ☐ DAR/Yerkes Training – ABSL-2 ☐ DAR/Yerkes Training – ABSL-3 ☐ Other:				
Occupational Health Requirements	Vaccinations	☐ None	☐ Hepatitis B	☐ Tetanus	☐ Influenza ☐ Other:
	Tests	☐ None	☐ PPD	☐ Medical Clearance for Respirator	
	Other				

☐ IN VIVO STUDY REQUIREMENTS

Animal Biosafety Level	*Agents*	*Animals*	*PPE Requirements* ➢ *For work conducted at Yerkes, follow Yerkes Policies for PPE*
☐ ABSL-1			Gloves, Button Front Gown *Additional:*
☐ ABSL-2			Gloves, Solid Front Gown, Hair Cover, Surgical Mask, Shoe Covers *Additional:*
☐ ABSL-2 for 72 hours, then ABSL-1			Requirements for ABSL-1 & ABSL-2 listed above *Additional:*
☐ ABSL-3			Double Gloves, Solid Front Gown, Hair Cover, Double Shoe Covers *Additional:*
Engineering Controls	☐ Work in a Biosafety Cabinet ☐ Other:		
Other			

☐ IN VITRO STUDY REQUIREMENTS

Biosafety Level	*Agents*	*PPE Requirements*
☐ BSL-2		Gloves, Button Front Lab Coat & Eye Protection (when performing activities with a splash or impact potential) *Additional:*
☐ BSL-3		Double Gloves, Solid Front Lab Coat, & Eye Protection (when performing activities with a splash or impact potential) *Additional:*
Engineering Controls	☐ Work in a Biosafety Cabinet ☐ Centrifuge Safety Caps ☐ Other:	
Solid Biohazard Waste Disposal	☐ Dispose of untreated waste through Stericycle ☐ Autoclave, then Stericycle disposal ☐ Other:	
Other		

Statement at the top of the page informs researchers that the approval is conditional.

Ability to select specific trainings, vaccinations, and medical tests as prerequisites to working on the protocol.

In vivo section allows EHSO to set multiple biosafety levels and conditions for protocols that involve varied animal models and agents. It also is used to specify controls for each type of experiment.

In vitro section also allows for approvals to be set at multiple biosafety levels. Separating the *in vivo* and *in vitro* materials provides greater clarity for post-approval monitoring.

{Conclusions}

The Biosafety Protocol Approval Letter is used by multiple groups (PIs, EHSO, IACUC, DAR, Institutional Review Board [IRB]) to maintain and monitor the approval for laboratories to work with biological/infectious material and/or recombinant/synthetic nucleic acid molecules. Prior to a recent revision, the letter presented certain challenges. The original letter only listed an overall biosafety level and list of material. Therefore, if a protocol had some work conducted in a BSL-2 lab and other experiments in a BSL-3 lab, the approval letter would only list BSL-3. Also, the letter did not include detailed requirements from the biological risk assessment. This made it difficult for PIs to adhere to the safety requirements and for members of EHSO, IRB, DAR and IACUC to use the letter during post-approval inspections and study reviews.

The new letter uses an addendum to resolve these issues through the use of tables broken into four sections: protocol information, general, *in vivo*, and *in vitro* study requirements. These sections allow for easy indication of requirements for each type of experiment and improved communication of the approval status to all affected players.

The new letter is a valuable tool during post-approval monitoring. Electronic versions are accessible to EHSO in the field during inspections on iPad tablets and to the IRB, IACUC and DAR via an access-controlled web-drive. Sharing the letters through real-time electronic systems ensures that all users have access to the most current versions, thus streamlining the approval maintenance process.