A. Purpose
This policy describes the work that EH&S performs in conjunction with the Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB). To ensure compliance with animal welfare and human health and safety regulations, all research protocols for animals or human subjects involving the use of hazardous materials require review of a hazardous materials appendix by EH&S. EH&S is also represented on the membership of the IACUC.

B. Applicability/scope
This is an internal EH&S policy that may also be referenced by the IACUC and IRB.

C. Responsibilities
EH&S is represented on the membership of the IACUC. IACUC and IRB are represented on the Institutional Biosafety Committee (IBC). Investigators are responsible for protocol and hazardous materials appendix submission, and meeting any associated training requirements. EH&S, IACUC, IRB and IBC are responsible for protocol and hazardous materials appendix submission review. EH&S and IACUC are responsible for providing training and monitoring compliance.

D. Definitions
Appendix – Hazardous material use by investigators typically requires that a series of controls are identified and documented. These include administrative (authorized users and their training), engineering controls (certified fume hoods and biosafety cabinets), personal protective equipment as well as the procedures that will be employed with the hazard, including how to respond to an exposure.

IACUC - Institutional Animal Care and Use Committee
IBC- Institutional Biosafety Committee
ICM – Institute for Comparative Medicine
IRB - Institutional Review Board
LION – Laboratory Online Information Network
NIH - National Institutes of Health
OPIM – Other Potentially Infectious Materials
RASCAL – Research Compliance and Administration System

E. Procedures
1. Appendix Submission
   i. Introduction of recombinant or synthetic DNA into animals or humans subjects must be in compliance with the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). A RASCAL Appendix A must be attached to the associated animal protocol. See Policy 2.17 - Recombinant DNA Policy: Requirements for Submission, Approval and Use. For human gene transfer protocols complete and sign form “Application for the use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer” and follow the submission instructions on the form.
ii. Use of infectious agents in animals or humans subjects, or isolation of infectious agents from animals or humans subjects requires submission of an Appendix B.

iii. Introduction of human tissues, cells, cell lines, or other potentially infectious materials (OPIM) into animals requires submission of an Appendix C. Collection or introduction of human tissues, cells, cell lines, or other potentially infectious materials (OPIM) from/into human subjects in IRB protocols is covered by an attestation that all study personnel have received appropriate training.

iv. Use of lasers requires submission of an Appendix D

v. Use of hazardous chemicals or toxins in animals requires submission of an Appendix E

vi. Use of radiation in animals requires submission of an Appendix G

vii. Use of radiation in human subjects requires submission of an Appendix H

viii. Use of controlled substances in animals requires submission of an Appendix I


2. Appendix Review
   The IACUC or IRB staff receives the hazardous materials appendices associated with animal protocols and add them to a queue in RASCAL for EH&S review. Appendix A, B, and “Application for the use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer” submissions are screened by the Biosafety Officers and also require review by the IBC. Appendix C are reviewed by Biosafety Officers, Appendix E are reviewed by Occupation Safety Officers. Appendix D, G and H are reviewed by the Radiation Safety Officers. Appendix I are reviewed by the Biosafety or Research Safety Officers. Reviewer (“hold”) comments for investigators are directed through RASCAL. Final approvals are recorded in RASCAL and immediately viewable by the Investigators.

3. Animal protocol-related lab surveys and facility inspections
   Approval of an animal protocol hazardous material appendix, and hence the animal protocol itself, may be contingent on a satisfactory lab survey that pertains to safe use of the particular hazardous material. EH&S IACUC members also participate in IACUC semi-annual inspections of ICM vivaria and investigator laboratories.

4. Committee work
   EH&S is represented on the membership of the IACUC. IACUC and IRB are represented on the IBC. This ensures a thorough and consistent evaluation of each protocol.

F. Emergency contacts
   N/A

G. Medical Surveillance
   N/A

H. Recordkeeping
   Animal and human subject protocol records are maintained in RASCAL and survey reports are maintained in the LION.

I. Appendices
   None
J. Forms
N/A

K. References
RASCAL https://www.rascal.columbia.edu/
IACUC website http://www.cumc.columbia.edu/dept/iacuc/
Hazardous Materials Appendix – When is one required?