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**Modification/Annual Review Form**

**REGISTRATION FORM FOR PATHOGEN, SELECT AGENTS and HUMAN CELLS/TISSUES**

**Please complete for annual review or prior to changes in personnel or project and submit MS Word file to** **research@etsu.edu** **When completing the form using the Mac version of Word, place the cursor in front of the box and tap the space bar. Please return original, signed affirmation form to: Vice Provost for Research, Box 70565. The forms have been revised; please review the instructions prior to completing the forms.**

**Please indicate all changes by highlighting in yellow the corresponding text and information (hint: use the  button).**

|  |
| --- |
| Biosafety Registration Number that was assigned to this project -- **REQUIRED**:  |
| Principal/Responsible Investigator:  | Phone number:  |
| Department Name and Box #:  |
| Alternate Contact Person:  | Phone & e-mail:  |
| Laboratory Location(s):  | Project Period:  |
| Project Title:  |
| Do you have a Materials Transfer Agreement? [ ]  Yes [ ]  No |

[ ] No changes since last submission

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

 (See section E)

* Complete section F and route original to Vice Provost for Research, Box 70565

[ ] Changes in personnel only

* If containment level requires BSL-2 conditions, provide location and most recent date of certificate.

 (See section E)

* Complete sections F & G and route signed original documents to the Vice Provost for Research, Box 70565

[ ] Changes in project

* Complete all sections of the Annual Review Form (sections A-G)
* Route completed original affirmation form to the Vice Provost for Research, Box 70565

**Please mark the box(es) for the Parts being completed:**

[ ]  **Part A: Pathogenic Microorganisms:** Agents capable of causing disease in immune-normal, healthy adults and includes organisms classified as requiring work at BSL-1 or higher in the latest edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition.

**Registration is required for BSL 2 organisms or higher.**

[ ]  **Part B: Human Blood, Human Cell Lines and Tissues or Other Potentially Infectious Materials (OPIM):**

Includes established cell lines of human/primate origin (including those obtained from commercial sources) and OPIM (material with the potential for transmission of HIV, HBV, HCV, and other bloodborne diseases, including tissue from animals known to be infected with any of these agents, microbial stocks and cultures, certain body fluids, unfixed human tissue, primary tissue/cell cultures). These must be handled under BSL-2 conditions as if they were primary cells or tissues.

[ ]  **Part C: “Possession, Use and Transfer” of Select Agents, Toxins, High Consequence Livestock or Plant Pathogens.** The use of these agents, toxins or pathogens is regulated by the [Select Agent Regulation, 42 CFR 73.0](http://www.cdc.gov/od/sap/docs/42cfr73.pdf), and the [Agricultural Bioterrorism Protection Act of 2002](http://www.cdc.gov/od/sap/docs/btarule.pdf) **.** Facility Registration is required and is administered by the [Centers for Disease Control](http://www.cdc.gov/od/sap/addres.htm), and/or the [USDA](http://www.aphis.usda.gov/vs/ncie/bta.html). If you anticipate obtaining these materials complete **Part C** of this form. Additional requirements of the "USA Patriot Act" and the "Public Health Security, Bioterrorism and Response Act of 2002" must also be satisfied. ANY USE OF SELECT AGENTS MUST BE APPROVED AND PROCESSED BY THE BIOSAFETY AND CHEMICAL SAFETY COMMITTEE. Approval of use of select agents will take several weeks.

[ ]  **Part D: Administration to animals of any of the above selections:** Administration of any of the above agents to animals requires approval of the UCAC and may also require that the animals be housed in microisolator or filtered, ventilated cages and handled under BSL-2 conditions.

**☒ Part E: Safety Measures: This section must be completed for all registrations.**

**☒ Part F: Principal Investigator Affirmation: This section must be completed for all registrations.**

**☒ Part G: Project Personnel Affirmation: THIS DOCUMENT MUST BE COMPLETED FOR CHANGES IN PROJECT OR PERSONNEL**

**Part A - Pathogenic Micro-organisms:** To be completed by the Principal Investigator for all laboratories handling or storing pathogenic microorganisms (agents capable of causing disease in immune-normal, healthy adults and includes organisms classified as requiring work at BSL-2 or higher in the latest edition of either the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* or the NIH's *Guidelines for Research Involving Recombinant DNA Molecules*. Complete Part A for each organism used in the lab. Like organisms can be grouped on a single form.

|  |  |
| --- | --- |
| 1. Name of Organism(s) (genus, species, strain description)

 Is organism attenuated? [ ]  Yes [ ]  No  | 2. Is a toxin produced? [ ]  Yes [ ]  No Work with toxin? [ ]  Yes [ ]  No |
| 3. Is drug resistance expressed? [ ]  Yes [ ]  No | 4. Where is organism stored? Room/location: \_\_\_\_\_\_ Are Biohazard Warning Labels in use? [ ]  Yes [ ]  No |
| 5. Largest volume used: \_\_\_\_\_\_\_\_ liter(s)  | 6. Is organism inactivated prior to use? [ ]  Yes [ ]  No Specify Method:  |
| 7a. Do you concentrate the organism in your protocol? [ ]  Yes [ ]  No | 7b. Specify method: [ ]  centrifugation [ ]  precipitation [ ]  filtration [ ]  other: |
| 8a. Building and room where organism is used? 8b. Source of Organism: \_\_\_\_\_\_\_\_\_\_8c. CDC Shipping permit #: \_\_\_\_\_\_\_\_\_\_\_\_\_ | 9. Does the laboratory work with human blood or blood products, unfixed human tissue, or human or other primate cells?[ ]  Yes [ ]  No **(if yes, fill out Part B below**) |
| 10. Are cultures, stocks, and items contaminated items decontaminated prior to disposal? [ ]  Yes [ ]  No  Method: [ ]  autoclave [ ]  chemical disinfectant [ ]  other (specify):  |

|  |
| --- |
| **Brief description of proposed research (please include enough information to describe project’s specific aims):** |

**Part B - Human Cells and Tissues:** (includes ATCC established cell lines of human/primate origin or OPIM)

|  |  |  |
| --- | --- | --- |
|  | 2.  | 3.  |
| 4.  | 5.  | 6.  |
| 7.  | 8.  | 9.  |

|  |
| --- |
| **Brief description of proposed research (please include enough information to describe project’s specific aims):**  |

**Part C: Possession, Use or Transfer of "Select Agents, Toxins, High Consequence Livestock/Plant Pathogens".** The university is required to register with the CDC or USDA for possession, use or transfer of any of these agents, toxins or pathogens. These agents are regulated by [Select Agent Regulation, 42 CFR 73.0](http://www.cdc.gov/od/sap/docs/42cfr73.pdf) andthe [Agricultural Bioterrorism Protection Act of 2002](http://www.cdc.gov/od/sap/docs/btarule.pdf). If you anticipate obtaining these materials complete **Part C** of this form. Additional requirements of the ***"USA Patriot Act"*** and the ***"Public Health Security, Bioterrorism and Response Act of 2002"*** must also be satisfied.

**Are, or will, any of the following agents, toxins or pathogens be used in your laboratory:** [ ]  **Yes** [ ]  **No**

If "yes", please indicate which by marking the box next to the item with a check (✓) or an “X”.

# SELECT AGENTS, TOXINS, HIGH CONSEQUENCE LIVESTOCK/PLANT PATHOGENS

|  |  |  |  |
| --- | --- | --- | --- |
| Viruses (HHS and USDA) | **✓** | Bacteria (HHS and USDA) | **✓** |
| Akabane virus |  | Bacillus anthracis |  |
| African swine fever virus |  | *Brucella abortus* |  |
| African horse sickness virus |  | *Brucella melitensis* |  |
| Avian influenza virus (highly pathogenic) |  | *Brucella suis* |  |
| Blue tongue virus (Exotic) |  | *Burkholderia mallei (formerlyPseudomona mallei)* |  |
| Bovine spongiform encephalopathy agent |  | *Burkholderia pseudomallei* |  |
| Camel pox virus |  | *Botulinum neurotoxin producing species Clostridium* |  |
| Classical swine fever virus |  | *Cowdria ruminantium* (Heartwater) |  |
| Crimean-Congo hemorrhagic fever virus |  | *Coxiella burnetti* |  |
| Eastern Equine Encephalitis virus |  | *Francisella tularensis* |  |
| Ebola viruses |  | *Mycoplasma capricolum*/ M.F38/*M. mycoides capri* |  |
| Foot and mouth disease virus |  | *Mycoplasma mycoides mycoides* |  |
| Goat pox virus |  | *Rickettsia prowazekii* |  |
| Cercopithecine herpesvirus 1 (Herpes B virus) |  | *Rickettsia rickettsii* |  |
| Japanese encephalitis virus  |  | *Yersinia pestis* |  |
| Lassa fever virus  |  | **Fungi** | **✓** |
| Lumpy skin disease virus |  | *Coccidioides immitis* |  |
| Malignant catarrhal fever virus (Exotic) |  | *Coccidioides posadasii* |  |
| Marburg virus |  | Toxins (HHS and USDA) | **✓** |
| Menangle virus |  | Abrin |  |
| Monkeypox virus |  | Botulinum neurotoxins |  |
| Newcastle disease virus (VVND) |  | Conotoxins |  |
| Nipah and Hendra Complex viruses |  | *Clostridium perfringens* epsilon toxin |  |
| Peste Des Petits Ruminants virus |  | Diacetoxyscirpenol |  |
| Rift Valley fever virus |  | Ricin |  |
| Rinderpest virus |  | Saxitoxin |  |
| Sheep pox virus |  | Shigatoxin |  |
| *South American Hemorrhagic fever viruses* |  | Shiga-like ribosome inactivating proteins |  |
| Junin | Staphylococcal enterotoxins |  |
| Machupo | T-2 toxin |  |
| Sabia | Tetrodotoxin |  |
| Flexal | USDA Plant Pathogens | **✓** |
| Guanarito | *Liberobacter africanus* |  |
| Swine vesicular disease virus |  | *Liberobacter asiaticus* |  |
| *Tick-borne encephalitis complex (flavi) viruses* |  | *Peronosclerospora philippinensis* |  |
| Central European Tick-borne encephalitis | *Phakopsora pachyrhizi* |  |
| Far Eastern tick-borne encephalitis | Plum Pox Potyvirus |  |
| Russian Spring and Summer encephalitis | *Ralstonia solanacearum* race 3, biovar 2 |  |
| Kyasanur Forest disease | *Schlerophthora rayssiae* var *zeae* |  |
| Omsk Hemorrhagic Fever | *Synchytrium endobioticum* |  |
| Variola major virus (Smallpox virus) |  | *Xanthomonas oryzae* |  |
| Variola minor virus (Alastrim) |  | *Xylella fastidiosa* (citrus variegated chlorosis strain) |  |
| Venezuelan Equine Encephalitis virus  |  |  |  |
| Vesicular stomatitis virus (Exotic) |  |  |  |
| **Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:** \* If your research involves rDNA, you must submit a registration form with the IBC. Contact ETSU Biosafety and Chemical Safety Committee.  | **✓** |
| (1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses. |  |
| (2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in if the nucleic acids: (i) are in a vector or host chromosome; (ii) can be expressed in vivo or in vitro; or (iii) are in a vector or host chromosome and can be expressed in vivo or in vitro. |  |
| (3) Viruses, bacteria, fungi, and toxins listed that have been genetically modified. |  |

**Part D: Animal Use:**

Will biohazardous materials be administered to animals? [ ]  Yes [ ]  No

|  |  |
| --- | --- |
|  If yes, what species: |  |

Is the material an animal pathogen? [ ]  Yes [ ]  No

|  |
| --- |
| Is the material a human pathogen? [ ]  Yes [ ]  No |
| Will the material or organism be inactivated prior to use in animals? [ ]  Yes [ ]  No |
| Experimental administration route, volume, titer: |  |
| Caging: microisolator cages? [ ]  Yes [ ]  No Other? |  |
| Special procedures needed for containment: |  |
| Work in biosafety cabinet? [ ]  Yes [ ]  No Other? |  |
| Animal Biosafety level requested: |  |
| UCAC #: |  |  UCAC Approval date: |  |

UCAC Approval Pending? [ ]  Yes [ ]  No

(attach detailed procedure if biohazards do not fit conventional Animal Biosafety Level 1 or 2 work practices)

Reference CDC/NIH BMBL Animal Biosafety Levels: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

**Part E: Safety Measures:**

Research will be conducted at **Biosafety Level \_\_\_\_\_**

 (Contact Biosafety and Chemical Safety Committee if you need assistance in determining the appropriate classification).

 Reference CDC/NIH BMBL4th Edition. Web address: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

**Engineering controls:** available to control significant aerosol generating steps for work requiring BL-2 containment or higher (e.g., centrifugation, vortexing, sonication, egg harvesting), check all that apply:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| [ ]  | Biological Safety Cabinet and Location (BSC): Class I |  |  Class II |  |
|  | Last date of BSC Certification (Mo/Yr) |  |  |
| [ ]  | Centrifuge Are centrifuge safety cups available and used? [ ]  Yes [ ]  No |
| [ ]  | Containment suite |
| [ ]  | Other:  |  |

**Sharps**: (e.g., syringes, scalpels, glass) used with BSL-2 and higher organisms must be minimized.

Will (syringes, scalpels, glass) be used? [ ]  Yes [ ]  No

Has the research protocol been reviewed to minimize the use of sharps where possible? [ ]  Yes [ ]  No

Are sharps with integrated safety devices available? [ ]  Yes [ ]  No

|  |  |
| --- | --- |
|  If yes, please describe device (Type, Model, Brand): |  |

**Personal protective equipment:**  check all that are recommended and available for your work:

 [ ]  Lab coat

 [ ]  Gloves: [ ]  nitrile [ ]  non-powdered latex (powdered latex not recommended) [ ]  vinyl

 [ ]  Safety glasses with side shields

|  |  |
| --- | --- |
|  [ ]  Other (specify):  |  |

**Disinfectant(s) which will be used for routine cleaning and spills**:

 [ ]  1/10 bleach [ ]  povidone-iodine [ ]  70% ethanol [ ]  other: \_\_\_\_\_\_\_\_

**Describe the Infectious Waste Handling procedures to be used (note, all laboratory ware and culture media that contacts BL2**

**organisms or recombinant materials are to be inactivated prior to disposal).**

Solids - Disinfection method: [ ]  autoclave [ ]  1/10 bleach [ ]  povidone-iodine [ ]  70% ethanol [ ]  other: \_\_\_\_\_\_\_\_

Liquids - Disinfection method: [ ]  autoclave [ ]  1/10 bleach [ ]  povidone-iodine [ ]  70% ethanol [ ]  other: \_\_\_\_\_\_\_\_

**Medical Surveillance**  (check all that apply):

[ ]  1) No medical surveillance necessary

[ ]  2) Employees have been provided Bloodborne Pathogens (BBP) training within the past year. All potentially exposed employees have received Hepatitis B vaccine or proven immunity. (Basic OSHA BBP compliance adequate for BSL-2 work.)

[ ]  3) Additional vaccination/surveillance required for work on this project.

[ ]  4) Individuals at increased risk of susceptibility to agent (e.g., preexisting diseases, medications, compromised immunity, pregnancy or breast feeding) have been referred to appropriate personnel for counseling.

**Project Personnel:** Principal Investigators, use the following table to list all personnel in your laboratory who handle or may otherwise be exposed to any of the microorganisms (add more rows if necessary).

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |
|  |  |
|  |  |

**Part F –Principal Investigator AFFIRMATION:**

I accept responsibility for the safe conduct of work with this material. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and the level of containment required to perform this research safely. I will report to Biosafety and Chemical Safety Committee any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing recombinant DNA or other potentially hazardous materials into the environment.

|  |  |
| --- | --- |
| Principal/Responsible Investigator (please type): |  |

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Grant Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Award #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part G – Project Personnel AFFIRMATION: a separate document (see website)**

**For Committee Use Only:**

**Approval:**  [ ]  Yes [ ]  Yes, approved with modifications **\***(see notes below) [ ]  No

**Signatures:**

IBSC Chairman / Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Biological Safety Officer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department Chairperson: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee Health Physician (as appropriate):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Veterinarian: (as appropriate) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\* Modifications**:

[ ]  IRB approval required – check one: [ ]  IRB approval pending [ ]  IRB approval received, IRB #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  UCAC approval required

**For Committee Use Only:**

**Approval:**  [ ]  Yes [ ]  Yes, approved with modifications **\***(see notes below) [ ]  No