ARKANSAS DEPARTMENT OF HEALTH

RULES AND REGULATIONS PERTAINING
TO BIOLOGICAL SELECT AGENTS AND TOXINS REGISTRY
ARKANSAS DEPARTMENT OF HEALTH
RULES AND REGULATIONS
BIOLOGICAL SELECT AGENTS AND TOXINS

SECTION I. AUTHORITY
The following Rules and Regulations pertaining to Arkansas Biological Select Agents and Toxins Registry are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas, Ark Code Ann.§ 20-36-101.

SECTION II. PURPOSE
To establish a Biological Select Agents and Toxins Registry to identify those agents possessed and maintained by any person in the state of Arkansas.

SECTION III. DEFINITIONS
The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates.

SECTION IV. GENERAL REQUIREMENTS
(Listed in the attached Rules and Regulations of the Arkansas Department of Health pertaining to Biological Select Agents and Toxins.)

SECTION V. REPEAL
All Regulations and parts of Regulations in conflict herewith are hereby repealed.

CERTIFICATION
This is to certify that the foregoing Rules and Regulations for Biological Agents Registry in Arkansas were adopted by the Arkansas State Board of Health at a regular session of said Board held in Little Rock, Arkansas on the 22nd day of January, 2009.

Signature on original
Paul K. Halverson, DrPH, FACHE
Director and State Health Officer
Arkansas Department of Health
Secretary of Arkansas State Board of Health

The foregoing Rules and Regulations, copy having been filed in my office, are hereby approved on the ___2nd___ day of ___February______, 2009.

Signature on original
Mike Beebe
Governor
SECTION I. AUTHORITY

The following Rules and Regulations pertaining to Arkansas Biological Agent Registry are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas, Ark Code Ann. § 20-36-101.

SECTION II. PURPOSE AND SCOPE

To establish a Biological Agent Registry to identify the biological agents possessed and maintained by any person in the state of Arkansas.

SECTION III. DEFINITIONS

A. Biological agent means:

1. Any select agent that is a microorganism, virus, bacterium, fungus, rickettsia, or toxin listed in Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003;

2. Any genetically modified microorganisms or genetic elements from an organism on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003, shown to produce or encode for a factor associated with a disease; or

3. Any genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed on Appendix A of Part 72 of Title 42 of the Code of Federal Regulations, as in effect on January 1, 2003, or their toxic submits;

B. Person is any association, business, corporation, facility, firm, individual, institution of higher education, organization, partnership, society, state agency or other legal entity.

SECTION IV. REGISTRATION

Any person required to register must apply for a certificate of registration as outlined in Title 42 of the Code of Federal Regulations §73.7.

SECTION V. RESPONSIBLE OFFICIAL

Any person listed under Section 3-B must designate an individual to be a responsible official who must be approved by the Secretary or the Administrator of the Health and Human Services, following a security risk assessment by the Attorney General outlined in Title 42 of the Code of Federal Regulations §73.9.
SECTION VI. SECURITY, BIOSAFETY AND TRAINING

A. Security

Any registered person must develop and implement a written security plan outlined in Title 42 of the Code of Federal Regulations §73.11.

Any registered person may not provide another person access to a select agent or toxin, unless the access is approved by Secretary of Department of Health and Human Services or Administrator, following a security risk assessment by the Attorney General outlined in Section 42 of the Code of Federal Regulations §73.10.

B. Biosafety

Any person required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of agent or toxin, given its intended use as outlined in Title 42 of the Code of Federal Regulations §73.12 and must develop and implement a written incident response plan as outlined in §73.14.

C. Training

Any person required to register under this part must provide information and training on biosafety and security outlined in Title 42 of the Code of Federal Regulations §73.15.

SECTION VII. HHS SELECT, OVERLAP AGENTS AND TOXINS

HHS SELECT

Permissible Toxin Amounts

<table>
<thead>
<tr>
<th>HHS Toxins</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Botulinum neurotoxins</td>
<td>0.5 mg</td>
</tr>
<tr>
<td>Clostridum prefringens epsilon toxin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Conotoxins</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Diacetoxyscirpenol</td>
<td>1,000.0 mg</td>
</tr>
<tr>
<td>Ricin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Saxitoxin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Shigatoxin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Shi-like ribosome inactivating proteins</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>Staphylococcal enterotoxins</td>
<td>5.0 mg</td>
</tr>
<tr>
<td>Tetrodotoxin</td>
<td>100.0 mg</td>
</tr>
<tr>
<td>T-2 toxin</td>
<td>1,000.0 mg</td>
</tr>
</tbody>
</table>

OVERLAP AGENTS AND TOXINS

(a) Except for exclusions under paragraphs (d) and (e) in the Federal Register, the HHS Secretary has determined that the biological agents and toxins listed below have the potential to pose a severe threat to public health and safety. (See rule 73.3 HHS select agent and toxin for further information).
Abrin
Cecopithecine herpes virus 1 (Herpes B virus)
Cocciidioides posadasii
Crimean-Congo hemorrhagic Fever virus
Diacetoxyscirpenol
Ebola Virus
Lassa fever viruses
Marburg virus
Monkey pox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments
Ricin
Rickettsia Prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Haemorrhagig Fever Viruses
(Junin, MAchupo, Sabia, Flexal, Guanarito)
Tetrodotoxin
Tick-borne encephalitis complex (flavil)
viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease Omak hemorrhage Fever)
Variola major virus (Smallpox virus) and Vaiola minor virus (Alastrim)
Yersinia pestis
(a) Except for exclusion under paragraph (d) and (e) the Federal Register the HHS Secretary has determine that the biological agents and toxins listed below have the potential to pose a severe threat to public health and safety, to animal health, or to animal product.

(b) Overlap select agents and toxins (See Rule 73.4 further information).

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia pseudomalleia(formerly Pseudomonas)
Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah Virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

SECTION VIII. EXEMPTIONS

The regulations listed in Title 42 Code of Federal Regulations §73 and Section 9 Code of Federal Regulations Part 121 establishes a procedure by which attenuated strains of select biological agents or toxins that do not pose a severe threat to public health and safety, animal health or animal products may be excluded from list of select biological agents and toxins.

SECTION IX. DENIAL, REVOCATION OR SUSPENSION OF REGISTRATION

A. An application may be denied or a certificate of registration revoked or suspended as outlined in Title 42 of Code of Federal Regulations §73.8.
B. Any person may appeal a denial, revocation or suspension of registration as stated in Title 42 of Code of Federal Regulations §73.20.

SECTION X. CIVIL MONEY PENALTIES

The Arkansas Department of Health shall impose a civil penalty for a willful or knowing violation of this section in the amount of up to one thousand dollars ($1,000).
I, Jerry Jones, P.D., Branch Chief of Pharmacy Services for the Arkansas Department of Health, do hereby certify that the documents attached hereto are true and correct copies of the current Rules and Regulations adopted by the Arkansas State Board of Health in accordance with Arkansas state law.

Signature on Original
Jerry Jones, P.D., Branch Chief
Pharmacy Services Branch

STATE OF ARKANSAS )
COUNTY OF _Saline_ )

I, _Marcia Middleton_, do hereby certify that Jerry Jones, P.D., well known to me, appeared before me and signed the above referenced document.

Sworn and subscribed to before me this _26th_ day of _January______, 2009.

Signature on Original______________
Notary Public

04/25/2015
My commission expires on