

University of Colorado

Denver and Health Sciences Center

Select Agents Registration and Use

Policy and Procedures

University of Colorado, Denver and Health Sciences Center

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Policy and Procedures

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This manual will be revised as necessary.

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**University of Colorado Health Sciences Center
Select Agents Registration and Use
Policy and Procedures**

I. PURPOSE, REFERENCE, AUTHORITY AND RESPONSIBILITY	5
A. PURPOSE	5
B. SCOPE	5
C. REFERENCES	5
D. RELATED POLICIES	6
E. INSTITUTIONAL AUTHORITY	6
F. RESPONSIBILITY	6
1. Office of the Chancellor and Office of the Vice Chancellor for Research	6
2. Responsible Facility Official	6
3. Environmental Health and Safety Committee	7
4. The Institutional Biosafety Committee (IBC)	7
5. The Principal Investigator	8
6. Health and Safety Division	9
II. APPLICABILITY AND DEFINITIONS	9
A. APPLICABILITY	9
B. DEFINITIONS	9
III. INSTITUTIONAL APPROVAL FOR USE OF SELECT AGENTS	10
A. REQUEST FOR SELECT AGENTS REGISTRATION	10
B. ROUTING AND DOCUMENTATION REQUIREMENTS	10
1. Submission to the UCDHSC IBC and RO	19
2. Institutional Review	10
IV. CONDUCTING SELECT AGENTS RESEARCH	11
A. MANIPULATION OF SELECT AGENTS MATERIALS	11
B. FACILITIES AND SECURITY	12
C. TRAINING OF RESEARCH STAFF	13
D. SELECT AGENT DISPOSAL OR TRANSFER	14
E. REPORTING OF NONCOMPLIANCE	14
F. CONTINUING REVIEWS	14
V. RECORDS MANAGEMENT	15
A. REGULATORY DOCUMENTATION	15
B. RESEARCH DOCUMENTATION	15
C. CLOSING OF PROTOCOLS	15
D. TERMINATION DATES AND EXTENSIONS	15
E. PRINCIPAL INVESTIGATOR--RECORDS RETENTION RESPONSIBILITIES	15

APPENDICES

For further information:

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**University of Colorado Health Sciences Center
Select Agents Registration and Use
Policy and Procedures**

I. Purpose, Reference, Authority and Responsibility

A. Purpose

The purpose of this policy is to set forth the guidelines and procedures, at the University of Colorado at Denver and Health Sciences Center (UCDHSC), in accordance with federal law, for the proposal, approval and management of research involving federally regulated Select Agents (SA).

Federal law provides that in the case of violations of the law, individuals are subject to federal criminal penalties, to include prison and fines.

B. Scope

1. This policy refers to those infectious agents, biologically-derived toxins, and those genetic elements from any Select Agents as identified by the federal Dept. of Health and Human Services (DHHS) and the Dept of Agriculture (USDA). A current list of the Select Agents is found in Appendix A.
2. All materials that are known to, or reasonably suspected of containing one of the Select Agents, including tissue samples, unless specifically exempted per federal regulations, are subject to this policy.
3. This policy will cover all proposals for the possession, storage, use, *ex vivo* and *in vivo*, transfer and disposal of federally regulated Select Agents at UCDHSC campuses and by UCDHSC investigators at off-campus locations.
4. All uses of federally regulated Select Agents by UCDHSC investigators must comply with these defined procedures for use of Select Agents. Failure to comply may result in prohibition of further use and/or confiscation of said substances.

C. References

1. Public Law 107-188, The Public Health Security and Bioterrorism Preparedness and Response Act of 2002
2. Public Law 107-56, the USA PATRIOT Act
3. Code of Federal Regulations, Title 42 CFR Part 73, Possession, Use and Transfer of Select Agents
4. Code of Federal Regulations, Title 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins
5. CDC/NIH, Biosafety in Microbiological and Biomedical Laboratories (BMBL) Current Edition
6. OSHA, 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories

D. Related Policies

1. UCDHSC Institutional Biosafety Committee (IBC) Policy and Procedures
2. UCDHSC Fiscal Policy, Chapter 4, <http://www.uchsc.edu/fbsvcs/fiscal.html>
3. Chancellor's Policy On Identification Badges (Appendix B)
4. COMIRB Policies (For Investigational New Drug Research)

E. Institutional Authority

1. The Office of the Chancellor has primary responsibility for regulatory compliance and policies for the UCDHSC campuses. This responsibility has been delegated in turn to the Office of the Vice Chancellor for Research (OVCR).
2. The Environmental Health and Safety (EHS) committee is the faculty and staff advisory committee to the Office of the Vice Chancellor for Research (OVCR) for all safety, public health and environmental compliance matters, including the use of Select Agents.
3. The Institutional Biosafety Committee (IBC) is the faculty and staff advisory committee to the Office of the Vice Chancellor for Research, for all safety, public health and environmental compliance matters for work with infectious materials, recombinant DNA and, as discussed herein, Select Agents materials.

F. Responsibility

1. Office of the Chancellor and Office of the Vice Chancellor for Research
 - a. The Office of the Chancellor has primary responsibility for regulatory compliance and policies for the UCDHSC campus.
 - b. The Chancellor has delegated this responsibility to the Office of the Vice Chancellor for Research (OVCR).
 - c. The Vice Chancellor for Research, in keeping with the federal regulation, will appoint a Responsible Official (RO) and alternate RO (ARO).
2. Responsible Official
 - a. The Responsible Facility Officer (RO), appointed by the Office of the Vice Chancellor for Research, will exercise management oversight of the regulations and compliance with the federal Select Agents program at the UCDHSC campus.
 - b. The RO will retain the authority and responsibility to immediately bring to the attention of the Office of the Vice Chancellor for Research, any errors, omissions and discrepancies in the application of these policies and compliance with the Select Agents regulations.
 - c. The RO will retain the authority and responsibility to notify and request assistance from the UCDHSC Police and federal agencies, as required for compliance with the federal law.

- d. The RO will retain the authority and responsibility to confiscate any SA materials, as required for compliance with the federal law.
 - e. The RO will review and update relevant internal policies/procedures as necessary to maintain compliance with this federal law and communicate changes to employees to assure compliance.
 - f. The RO will:
 - i. As an ad hoc member of, and in conjunction with the IBC, review the proposed plan of investigation/research for each Principal Investigator to include proposed plans for security and containment for the laboratory;
 - ii. review the findings and recommendations of the IBC on the proposed plan of research and physical containment of the biohazards;
 - iii. make the final approval or disapproval for authorization to use SA materials
 - iv. sign off on each request for transfer of Select Agents in compliance with the Select Agents act;
 - v. submit to CDC any amendments of the Select Agents Registration whenever agents/toxins need to be added or deleted; and
 - vi. review any compliance audits conducted internally by the HSC.
3. Environmental Health and Safety Committee
- a. The RO will be an ad hoc member of the UCDHSC Environmental Health and Safety Committee.
 - b. The EHS Committee will work with the RO to assure appropriate training of campus personnel in Select Agents programs.
 - c. The EHS Committee will work with the RO to measure program effectiveness and to assure compliance.
 - d. The EHS Committee will work with the RO and the Health and Safety Division to document that effective compliance, registration and disposal plans are in place.
4. The Institutional Biosafety Committee (IBC)
- a. The IBC has responsibility to monitor work with recombinant DNA, infectious materials, and in this case work with Select Agents materials for the UCDHSC campuses.
 - b. It is the responsibility of the IBC to review such projects for physical containment of materials and protection of the public and environment from exposures. The IBC will seek out Infectious Disease and/or Toxicology expertise as necessary to provide complete review of such submissions.
 - c. In accordance with this policy, the IBC will forward to the RO, a recommendation to approve, require modifications in (to secure approval), or disapprove biomedical research involving SA, and to forward that information to the RO for final action.

- d. The IBC will advise the RO and the PI on the appropriate biosafety and containment levels for research protocols involving Select Agents.
 - e. Risk Group (RG) 1, 2 and 3 agents may be used at the HSC after appropriate review and approval. RG 4 agent use is not permitted at the HSC at this time.
 - f. The IBC will collaborate with the IACUC on any animal studies with Select Agents materials as appropriate.
 - g. The IBC will collaborate with the COMIRB on any human use studies/Investigational New Drug studies
5. The Principal Investigator (PI)
- a. It is the responsibility of all Principal Investigators, throughout UCDHSC, to comply with this policy.
 - b. Only a Principal Investigator holding the position of Assistant Professor or higher in the Health Sciences Center may request authorization for obtaining and using any Select Agent materials.
 - c. Any UCDHSC investigator intending to use any material on the list of Select Agents biologicals and toxins, (Appendix A) must register the laboratory through the RO, Health and Safety Division (HSD) as outlined in this policy.
 - d. The Principal Investigator will conduct and document in writing a laboratory assessment of risk based on the most current edition of the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) guideline, Biosafety in Microbiological and Biomedical Laboratories (BMBL) for Select Agent usage.
 - e. The risk assessment for toxins must be based on 29 CFR § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories. The HSD Biosafety Office is available to help in this risk assessment.
 - f. The PI must ensure appropriate security for the CDC Select Agents to prevent unauthorized use/access. The UCDHSC Security Plan outlines specific requirements for security of laboratories using SA.
 - g. The PI must ensure appropriate use of approved inactivation and disposal procedures for the CDC Select Agents. The Health and Safety Division is available to help in determining disposal procedures for toxins.
 - h. The PI is responsible for maintaining a current inventory of all CDC Select Agents (biological and toxins) in the laboratory and maintaining written documentation of all Standard Operating Procedures (SOPs), on-the-job training, and other documentation as required by this policy and federal law.
 - i. The PI is responsible for obtaining the Responsible Official signature whenever there is a Form EA 101 transaction to be completed.

j. The PI is responsible for making their laboratory and all related SA documents available to inspection by representatives of the federal agency (CDC or designee) and the RO at all times.

k. The PI is responsible for immediately reporting by telephone or in person, any unauthorized access to Select Agents in their possession to the Responsible Official.

6. Health and Safety Division

The Health and Safety Division will manage the day-to-day operations of compliance with the Select Agents act by:

a. Keeping current with the relevant regulations and legislation as it applies to the use or transfer of Select Agents.

b. Accepting authorization requests for the use of Select Agents and distributing those requests to the IBC and the RO.

c. Assisting in laboratory risk assessment as requested by investigators or directed by the RO.

d. Advising on the collection, destruction and disposal of select agent materials and wastes.

e. Conducting periodic audits to ensure that transactions are properly conducted.

f. Managing the hazardous materials inventory database, used to cross-reference the presence of CDC Select Agents/Toxins.

g. Coordinating shipping and receiving of all SA materials to and from the campus.

h. Managing required records-keeping in accordance with SA rules and other regulations and policies as appropriate.

II. Applicability and Definitions

A. Applicability

This policy applies to all possession, storage, use, transfer and disposal of Select Agents (SA) administered by, conducted by, or under the direction of, any employee or agent of the UCDHSC in connection with his or her UCDHSC responsibilities.

B. Definitions

A glossary with definitions is provided at Appendix C.

III. INSTITUTIONAL APPROVAL FOR USE OF SELECT AGENTS

A. Request for Select Agents Registration

1. Research proposals involving the possession, use and disposal of any materials on the federal list of Select Agents must be submitted to, and considered through a review process, involving the UCDHSC Institutional Biosafety Committee (IBC), and the UCDHSC Responsible Official (RO) and appropriate federal agencies.
2. The Principal Investigator(s) for the study must submit the relevant information on the proposed Select Agents experiments through the department chair, to the UCDHSC Biosafety Office, for distribution to the IBC and the Responsible Official (RO). Submission of Select Agents protocols will be in the format described in Appendix D, Submission Requirements -- Select Agents Authorization.
3. The IBC will make a recommendation to approve, require modifications in (to secure approval), or disapprove biomedical research involving SA, and forward that information to the RO for final action.
4. The RO will make the final approval, sign and submit the application packet to the CDC on behalf of the PI.
5. Once approved by the RO and the CDC, all laboratories and related SA documents must be ready and available for federal inspection (the CDC or designee) at all times.

B. Routing and documentation requirements

1. Submission of protocols for concurrent IBC and RO review will be on the CDC Application for Laboratory Registration and the UCDHSC Biosafety Information Form (BSF-001) and Appendix A for Use of Select Agents (BSF-002). (see Appendix D for details)
2. All submissions for possession and use must be accompanied by a statement of support from the department/division chair. A sample letter is provided in Appendix E.
3. Submissions must include the CV or biosketch of the Principal Investigator, the Personnel Qualifications Form, (Appendix F) of any other individuals to be authorized access to Select Agents and evidence of the adequate training of all members of the research team. Background investigations, as required by federal regulation are also required, as administered by the Department of Justice, through the Responsible Official..
4. These documents will be submitted to the Biosafety Office, Mailstop F484 for distribution to the IBC and RO.

C. Institutional Review

1. A minimum of two reviewers will be assigned by the IBC.
2. Inspection of and acceptance of the physical facility, biosafety containment, training of personnel and other safety features in conjunction with the federal regulations must be documented by the committee and the RO.
3. Upon review by the UCDHSC IBC and the RO, letters of approval will be issued. Application with the CDC or other federal agency will be through the RO office.
4. Only upon notification of approval by the CDC may work begin. Evidence of approval by the CDC or other federal agency will be submitted by that agency directly to the RO.
5. To conduct research at facilities other than the Fitzsimons campus, the 9th and Colorado campus e.g., at one of the UCDHSC affiliates, requires separate submission of and approval of registration by the administration of that institution. Inspection of and acceptance of the physical facility, biosafety containment, training of personnel and other safety features in conjunction with the federal regulations must be documented by that facility.
6. No shipment of Select Agents materials shall be permitted, per the federal regulations, until the following documentation has been submitted to the RO:
 - a. Institutional Biosafety Committee approval;
 - b. IBC inspection of and acceptance of physical containment and security measures;
 - c. Curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format);
 - d. Department/division chair letter of support
 - e. RO approval
 - f. CDC or other federal agency approval for registration
 - g. SRA (FBI/Dept. of Justice) clearance for the PI and other individuals as applicable

IV. Conducting Select Agents Research

A. Manipulation of Select Agents Materials

1. Additional specific requirements for handling toxins subject to this law must be met and are found in the OSHA document, 29 CFR § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories
2. To work with SA Toxins, a laboratory and experimental procedure-specific Chemical Hygiene Plan (CHP) must be prepared by the Principal Investigator. This document is subject to inspection and review by the RO and the CDC.
3. Laboratory and procedure -specific Standard Operating Procedures (SOPs) for work with any SA materials, will be documented in writing for the laboratory

and immediately available to all lab personnel, the RO (or designee) and CDC or other federal inspecting agency

4. The Principle Investigator must provide and document in writing job and task specific on-the-job training for all lab personnel handling these materials. (see more on Training, below)
5. The Principle Investigator must provide appropriate Personal Protective Equipment (PPE) for handling these materials, and provide and document in writing on-the-job training for the use of PPE.
6. The Principle Investigator must provide and document in writing all decontamination and disposal SOPs for work with the specific SA in their laboratories. Decontamination and disposal procedures will be in compliance with all federal, state and local regulations concerning the infectious and/or hazardous wastes generated.

B. Facilities and Security

1. There are specific facility, containment, and security issues for Select Agents materials. Inspection of the applicant's laboratory facility will be made at the discretion of the IBC and/or the RO. Note that there is a separate and specific UCDHSC Security Plan that compliments this policy. Adherence to the procedures and requirements of the Security Plan are required
2. Facilities are subject to inspection by federal agencies (the CDC, USDA, or designees) as well as internal inspection by the RO or ARO.
3. The RO (or designee, e.g. UCDHSC IBC, Biosafety Officer) will make a determination of the appropriateness of the physical facility, the needed and available containment for Select Agents materials and the needed and existing security and emergency spill response protocols for SA submissions by UCDHSC faculty.
4. Follow-up inspections of the laboratory facility by the RO (or designees, e.g. IBC or Biosafety Officer) may be made as appropriate, to ensure the facility continues to meet approved standards and record-keeping requirements.
5. Withdrawal of SA materials from stock materials, for use in procedures will be documented by inventory records in accordance with this policy. Record keeping issues are addressed in Section V.

6. Authorization for possession, use and manipulation of SA may be denied or withdrawn by the RO if:

- a. Evidence exists that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;
- b. Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;
- c. Evidence that the facility has failed to comply with any provisions of the law or has acted in a manner in contravention of the law; or
- d. Evidence that the facility has failed to comply with any aspect of this policy;
- e. Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans.

C. Training of Research Staff

1. General training in UCDHSC policies and procedures governing work with any infectious or recombinant DNA or RNA materials is provided through the Biosafety Office, Health and Safety Division, Office of the VC for Research. This is a minimum requirement for all personnel with potential exposure to these materials. This general training must be accomplished prior to authorization to work with any infectious or recombinant DNA or RNA materials.
2. Training requirements for Select Agents are specific to the agent(s) authorized for use. Appropriate training for the SA use will be explained in detail in the submission to the IBC.
3. The Principal Investigator must demonstrate to the satisfaction of the IBC that he, or she, is adequately trained for the specific techniques of Select Agents. (generally by the CV and Personnel Qualifications Statement)
4. Furthermore, the Principal Investigator must instruct and train all staff participating in Select Agents research in the practices and techniques required ensuring safety, including the procedures for dealing with accidents or spills.
5. There may be specific training issues and needs for other support staff in administration of the Select Agents Rules. The Principal Investigator retains the responsibility for assuring the adequacy and documenting the actual training of research and other support staff. All personnel associated with the work must be informed of the nature of the materials, the appropriate procedures for the management of the materials, any potential risks from exposure to the materials and proper disposal of all materials.
6. The PI will provide documented, specific training and methods for the proper decontamination and disposal of waste materials. The UCDHSC Health and Safety Division will work with the Principal Investigator(s), to develop the appropriate decontamination and disposal methods in accordance with federal, state and local regulations.

D. Select Agent Disposal or Transfer

1. Upon termination of the need to use the specific Select Agent, that fact will be reported immediately to the RO, by the PI.
2. All cultures and stocks of that SA will be:
 - a. securely stored in accordance with prudent laboratory practices;
 - b. transferred to another registered facility in accordance with CDC rules, or
 - c. destroyed on-site by autoclaving, incineration, or another approved sterilization or neutralization process.
3. When an agent, previously transferred to a UCDHSC facility in accordance with the law, is consumed or destroyed, the Responsible Official (RO) must formally notify the registering entity. Formal notification must be noted on CDC Form EA-101 and a copy kept on record by the RO for a period of five (5) years.
4. Intra-facility transfers must be requested in writing of the RO and the UCDHSC lab receiving the materials must be in compliance with this policy and procedure, (i.e., a registered laboratory) before any materials are transferred.

E. Reporting of Noncompliance

Investigators must notify the RO immediately of any incidents of noncompliance which occur during the course of Select Agents possession, use, or study. This notification must be by telephone or personal contact. If the RO is unavailable, the Alternate RO will be advised. If neither individual is available, or it is after normal work hours, the UCDHSC Police Department will be notified to contact the appropriate individuals at their homes.

F. Continuing Reviews

1. Continuing reviews for Select Agents research will be conducted concurrently by the RO and the IBC, at intervals not to exceed 12 months.
2. The Biosafety Office will notify the PI of the continuing review and provide the PI with all appropriate forms not less than 60 days prior to the review deadline. It will be the responsibility of the Principal Investigator to provide all documents to the IBC (Mailstop C275) for the concurrent review.
3. Failure to meet a continuing review deadline or to obtain re-approval within the approval period will result in immediate suspension of all work with the Select Agent. The Investigator will be required to turn in all remaining SA materials to the Health and Safety Division, for storage (if approval is pending) or destruction and disposal.

V. Records Management

A. Regulatory Documentation

A copy of any regulatory communications, records, reports or correspondence from inspections, audits or other agency (CDC, NIH, etc) communications associated with the study must be provided to the RO and the IBC upon receipt.

B. Research Documentation

1. All records for Select Agents research must be kept a minimum of 5 years, per federal regulations.
2. All Select Agents research must be performed in conformance with generally accepted standards of good laboratory practice and with all applicable local, state and federal laws and regulations and guidelines governing the performance of Select Agents research, including but not limited to the references in para. I, B. of this document.

C. Closing of Protocols

Investigators will provide a final report to both the RO and the IBC at the closure of the study. Transfer of ownership of the materials and/or final destruction must be documented.

D. Termination Dates and Extensions

1. Research records will be set up in the IBC records management system with a three-year life unless a different end date is specified by the RO and/or the IBC.
2. If the study will not be completed within three years, the IBC will request documentation from the Principal Investigator, on the status of the study and request an extension for the appropriate period of time, with ongoing annual continuing reviews.

E. Principal Investigator--Records Retention Responsibilities

1. In addition to other record retention requirements, SA research may produce records that are maintained by the Principal Investigator for future reference and review.
2. At a minimum the investigator's file must include the original signed authorization forms and a list of participating laboratory personnel, along with documentation of Standard Operating Procedures.
3. Other items for the investigator's file include written, documented on-the-job training for laboratory personnel.

Appendix A

Current List of Select Agents and Toxins

Please review the most current list from the DHHS-CDC and USDA at the following web link:

<http://www.selectagents.gov/agentToxinList.htm>

Appendix B

ID Badge Policy

-----Original Message-----

From: James H. Shore [<mailto:J.Shore@UCHSC.edu>]

Sent: Tuesday, September 29, 1998 9:30 AM

To: HSC-Announce@Lists.UCHSC.edu

Subject: HSC Identification/Access Control Badges

Reminder To All HSC Employees and Students:

The HSC Identification/Access Control badges should be visibly displayed by all employees and students while on campus.

It is HSC policy that the badges be displayed, and the primary reasons are:

- + Easy identification of employees and students for security purposes. This is important for the safety and security of our employees, students, visitors, and property, and to assist our police/security personnel with the identification of people on campus.

- + To provide easy access for authorized persons to buildings/facilities after regular hours.

Displaying the ID/Access Control badge is particularly important for employees and students who have relocated their offices, labs, etc. It enables everyone to become familiar with who is authorized to be in the area.

It is easy for us to become lax in our security precautions. However, it is important that we recognize the importance of maintaining adequate safety and security measures for our employees, students, visitors, and property. One method of doing this is to prominently display the ID/Access Control badges while on campus. Your cooperation in this security measure, and others, is appreciated.

Employees and students that have not been issued an ID/Access Control badge, or may have lost their badge, should contact the UCDHSC Police Department, ID/Access Office, at 303-724-0399, to make an appointment to obtain, or replace, an ID/Access Control badge.

Appendix C Glossary

Biological Agent

Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing death, disease or other biological malfunction in a human, an animal, a plant or another living organism; deterioration of food, water, equipment supplies or material of any kind; or deleterious alteration of the environment.

Entity

Any government agency (Federal, state or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship or other legal entity.

HHS Select Agent or toxin

A biological agent or toxin listed by the Department of Health and Human Services and/or the CDC in 42 CFR Part 73.4

High consequence livestock pathogens

A biological agent or toxin listed by the USDA in 9 CFR Part 121

Overlap Select Agent or toxin

A biological agent or toxin listed by both the HHS and USDA

Principal Investigator

The one individual who is designated by an entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that program or project.

Select Agent

All of those select agents, toxins and high consequence livestock pathogens included in 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331 (plant pathogens)

Toxin

The toxic material or product of plant, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or a recombinant or synthesized molecule, whatever their origin and method of production and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homology or derivative of such a substance

APPENDIX D

Submission Requirements for Use of Select Agents

1. Request for Select Agents Registration
 - a. Research proposals involving the possession, use and disposal of any materials on the federal list of Select Agents must be submitted to, and considered through a review process, involving the UCDHSC Institutional Biosafety Committee (IBC), and the UCHSC Responsible Official (RO) and the appropriate federal agencies (CDC, USDA, etc).
 - b. The Principal Investigator(s) for the study must submit their relevant information on the proposed Select Agents experiments through the department chair, to the UCHSC Biosafety Office, for distribution to the IBC and the Responsible Official (RO).
 - c. Upon review of the relevant information the IBC will make a recommendation to approve, require modifications in (to secure approval), or disapprove biomedical research involving SA, and forward that information to the RO for final action.
 - d. The RO will make the final approval, sign and submit the application packet to the appropriate federal agency on behalf of the PI and the UCHSC.
 - e. Once approved by the RO and the appropriate federal agency, all laboratories and related SA documents must be ready and available for federal inspection (the CDC or designee) at all times.
2. Routing and documentation requirements
 - a. Submission to the UCHSC IBC and RO
 - b. Submission of protocols for concurrent IBC and RO review will be on the CDC Application for Laboratory Registration and the UCHSC Biosafety Authorization Form (BSF-001) and Appendix A for Use of Select Agents (BSF-002)
 - c. All submissions for possession and use must provide answers to all of the questions posed in UCDHSC forms and any federal agency forms.
 - d. All submissions for possession and use must be accompanied by a statement of support from the department/division chair. (see Appendix E for sample letter)
 - e. Submissions must include the CV of the Principal Investigator, the CV of any other individuals to be authorized access to Select Agents and evidence of the adequate training of all members of the research team. **Background investigations, as required by federal regulation will also be required.** (See Personnel Qualifications Statement, Appendix F)
 - f. These documents will be submitted to the Biosafety Office, Mailstop F484, for distribution to the IBC and RO.
3. Institutional Review
 - a. A minimum of two reviewers will be assigned by the IBC. The IBC requires that *four* complete copies of the protocol, the CDC form and the appropriate UCHSC forms be submitted for review.

- b. Inspection of and acceptance of the physical facility, biosafety containment, training of personnel and other safety features in conjunction with the federal regulations must be documented by the committee and the RO.
- c. Upon review by the UCHSC IBC and the RO, letters of approval and authorization to apply with the CDC will be issued. Application with the CDC will be through the RO office.
- d. Only upon notification of approval by the CDC may work begin. Evidence of approval by the CDC will be submitted to the RO.
- e. To conduct research at facilities other than the Anschutz Medical Campus, e.g., at one of the other UCDHSC campuses or affiliates, requires separate submission of and approval of registration by the administration of that institution. Inspection of and acceptance of the physical facility, biosafety containment, training of personnel and other safety features in conjunction with the federal regulations must be documented by that facility.
- f. No shipment of Select Agents materials shall be permitted, per the federal regulations until the following documentation has been submitted to the RO:
 - i. Institutional Biosafety Committee approval;
 - ii. IBC inspection of and acceptance of physical containment and security measures;
 - iii. Curriculum Vitae of the principal investigator(s) (no more than two pages in biographical sketch format);
 - iv. Department/Division chair letter of support
 - v. RO approval
 - vi. CDC and/or USDA and other federal approvals as necessary.

Appendix E
Letter of Department/Division Support

1. All requests/applications to use Select Agents must be routed through the Department chair to the campus Responsible Official and the Institutional Biosafety Committee.
2. A letter from the department chair (and division head as appropriate) will be required for all Principal Investigators who wish to apply to use Select Agents or SA Toxins, as part of their request for Select Agents Registration.
3. The letter must be on department letterhead, include the information as outlined in this sample letter, and have an original signature.

For work with Select Agents organisms, on department letterhead

MEMORANDUM

TO UCDHSC Responsible Official
Institutional Biosafety Committee

FROM *Insert title, name, etc., of Chair*
Department/Division, Mailstop

DATE *Insert date*

SUBJECT Request for Authorization for Use of Select Agent

Attached you will find *insert Principal Investigator name(s)* submission to the UCHSC Responsible Official and Institutional Biosafety Committee for authorization to conduct research using the following Select Agent, governed under federal regulations.

*Insert the name of the specific agent(s) to be used in the research
The proposed use of the agent(s);and
the location (building and room numbers)of the proposed work*

I have reviewed the UCHSC Select Agents policies, with respect to possession, use, transfer disposal and security of these materials. I am aware of the federal requirements for laboratory registration with the RO, the IBC and the appropriate federal agency for possession and use of Select Agents organisms.

I am aware of the requirements for increased biological safety containment and security for these materials. I support the use of these materials in the proposed research and I will support the requirements for enhanced biological containment and security, including additional costs for security measures as deemed necessary and appropriate for the proposed research

Department Chair, Signature block

cc Insert title, name, etc. of Principal Investigator requesting authorization

For work with Select Agents Toxins, on department letterhead

MEMORANDUM

TO UCDHSC Responsible Official
Institutional Biosafety Committee

FROM *Insert title, name, etc., of Chair*
Department/Division, Mailstop

DATE *Insert date*

SUBJECT Request for Authorization for Use of Select Agent Toxin

Attached you will find *insert Principal Investigator name(s)* submission to the UCHSC Responsible Official and Institutional Biosafety Committee for authorization to conduct research using the following Select Agent Toxin, as governed under federal regulations.

*Insert the name of the specific agent(s) toxin to be used in the research
The proposed use of the agent(s);and
the location (building and room numbers)of the proposed work*

The Principal Investigator and I understand the federal limits on possession of this SA Toxin and will inform the Responsible Official and the IBC should this laboratory anticipate the need to exceed those limits at any time in the future.

I am aware of the federal requirements for laboratory registration with the RO, the IBC and the appropriate federal agency for possession and use of SA/Toxins, exceeding federal limits. I understand there is a need for increased security for these materials, should the possession and use of this material exceed those federal limits.

I support the use of these materials in the proposed research and I will support the requirements for enhanced security, including additional costs for security measures as deemed necessary and appropriate for the proposed research should those circumstances arise.

Department Chair, Signature block

cc Insert title, name, etc. of Principal Investigator requesting authorization

Appendix F

Personnel Qualifications Statement

Please complete one form for **EACH INDIVIDUAL** who will have any direct access to or contact with Select Agents in your laboratory.

Federal law requires that personnel handling and/or conducting procedures with Select Agents and disposing of SA waste, must be appropriately qualified and trained. Such personnel are subject to background investigations per federal regulations.

It is the Principal Investigator's responsibility to assure only trained personnel work with Select Agents. It is the Institution's responsibility to document that training.

If you (or your staff) require training in Select Agents use, storage, or disposal procedures, please contact the Biosafety Office, Health and Safety Division at (303) 724-0235.

**UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER
SELECT AGENTS
PERSONNEL QUALIFICATIONS STATEMENT**

EMPLOYEE NAME (PRINTED)	MAIL STOP	PHONE	SA USE LOCATION (Bldg, rooms)
PRINCIPLE INVESTIGATOR (PRINTED)	MAIL STOP	PHONE	DEPARTMENT/DIVISION AFFILIATION

Select Agent(s) to be used in your work e.g. the specific toxin or toxin subunit, infectious agent or rDNA materials

FORMAL EDUCATION AND / TRAINING:

Degree(s) Earned/Date(s):

Institution(s):

Other Related Training:

CAMPUS MANDATORY TRAINING (DATES)

UCHSC Bloodborne Pathogens Training _____

UCHSC Hazardous Waste Generator Training _____

Other (List with Dates)

Provide complete information for the procedures you will perform with Select Agents. (e.g. weighing, making solutions, serial dilutions, adding to cell culture, use in animals, etc). Use as many pages as required to describe in detail. Failure to provide sufficient detail may delay your approval process. **Please put your name at the top of each page.**

If experienced in these procedures, describe the frequency with which performed. (e.g., performed once or twice, a few times, numerous times, 5 years, etc.).

If not experienced in these procedures, identify who will train you and what method(s) of training will be employed (e.g., Dr. X will give hands on training, I'll use training videos, laboratory staff will train me, etc.). **Please be brief, but specific.**

I certify that I am qualified to perform the procedures listed, or if not currently qualified, I will get appropriate training and become competent in the procedures before I perform them.

Employee Signature

Date

I certify that I will ensure the above individual is competent with the procedures before allowing him/her to perform these manipulations.

Principal Investigator's Signature

Date

