According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control numbers for these information collections are 0579-0213 for APHIS and 0920-0576 for CDC. The time required to complete the information collection for APHIS ranges from 3.75 to 19.5 hours per response, and the time required to complete the information collection for CDC ranges from 4 to 31 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 1)

FORM APPROVED OMB NO. 0579-0213 OMB NO. 0920-0576 EXP DATE XX/XX/XXXX

	Section 1A – Entity	/ Informati	on		
This submission is:	☐ An update to an existing	g registration	☐ A renewal	Dat	e:
	ENTITY INFOR	MATION			
Entity Application Number (e.g., CDC0300	01):				
Current Registration Number (e.g., A00000	0000-0000):				
Entity Name:					
Physical Address (NOT a post office box):		City:		State:	Zip Code:
Additional Physical Address(es):				l	
Type of Entity:	☐ Academic (Sta		Comme		ofit)
One of the control of	Government (State/Lo)	
Lact Namo:		L IIVI OKIVI		1 1	Date of
Last Name:	First Name:		DOJ Number:		Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Offi	cer):	1		Tier 1 Access
Business Telephone #:	Business Fax #:		Emergency Tel	ephone #	t :
Mailing Address (NOT a post office box):		City:		State:	Zip Code:
ALTE	RNATE RESPONSIBLE O	FFICIAL IN	FORMATION	!	
Last Name:	First Name:		DOJ Number:		Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Offi	icer):			Tier 1 Access
Business Telephone #:	Business Fax #:		Emergency Tel	ephone #	! :
Mailing Address (NOT a post office box):		City:		State:	Zip Code:
Last Name:	First Name:	!	DOJ Number:		Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Offi	icer):			Tier 1 Access
Business Telephone #:	Business Fax #:		Emergency Tel	ephone #	t:
Mailing Address (NOT a post office box):	L	City:	1	State:	Zip Code:
OWN	ER / CONTROLLER INFOR	RMATION (I	f Applicable)		
Last Name:	First Name:				
DOJ Number:	Date of Birth:		Tier 1 Access	6	
Last Name:	First Name:				
DOJ Number:	Date of Birth:		Tier 1 Access	5 <u> </u>	
This submission is:	n	e to an existir	ng registration		☐ A renewal
Entity Name:					Date:

Section 1B - Certification of Responsibility

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official(s) for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is, to the best of my knowledge, accurate and truthful. The institution/organization listed above meets the requirements specified in 42 CFR Part 73 and/or 7 CFR Part 331 and/or 9 CFR Part 121, is equipped and capable of safely and securely handling the agent(s), and will use or transfer these agents solely for purposes authorized by 42 CFR Part 73 and/or 7 CFR Part 331 and/or 9 CFR Part 121.

I understand that submission of a false statement and/or failure to comply with the provisions of the applicable regulations (42 CFR Part 73 and/or 7 CFR Part 331 and/or 9 CFR Part 121) may result in the immediate revocation of this entity's registration, a civil penalty of up to \$500,000 for each violation, and a criminal penalty and/or imprisonment up to five years for each violation. (7 USC 8401; 18 USC 175, 175B, 1001, 3559, 3571; 42 USC 262a).

Responsible Official Signature	Date	Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name
Alternate Responsible Official Signature	 Date	Alternate Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name

This submission is:	☐ A new registration	$\ \square$ An update to an existing registration	☐ A renewal
Entity Name:			Date:
			-
		Section 1C – Entity Abstract	
general es laboratorio research, structure o of the sele	stimated number of employes, overall scope of resear education, or expertise ca of the institution related to ect agent and toxin work at	stitution mission, functions, and size. This info yees, square footage of entire campus or facil ch, and any international collaborations. Spe n be highlighted. Include a brief description of oversight of the select agent facility/facilities. the entity including mission, function, and siz will be required in later sections of this applica	ity, number of cialized areas of f the management Provide a brief summary e. Note: information

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:
			110 6 11 111
	·	ficial Certification of Personnel and Fac	
		are in effect and contain all information rec 21, and 42 CFR 73] (initial each line):	quired by the Select
Security, I	Biosafety and Incident Res	<u>ponse</u>	
ass		security plan designed according to a site ded protection in accordance with the risl	
the		ic, and site-specific biosafety plan comm t contains sufficient information and docunedures.	
sele loss	ect agent and/or toxin that full	incident response plan commensurate with ly describe the entity's response procedure and/or toxin, inventory discrepancies, sec	es to include the theft,
		ent response plans are reviewed annually rill or exercise and after any incident.	and revised as
		cises are conducted at least annually to va safety and incident response plans.	alidate or test the
<u>Training</u>			
on :	safety, security, and incident	, authorized visitors, and escorted personr response for select agents and/or toxins, a 1.15, 9 CFR 121.15, and 42 CFR 73.15.	
Records			
Cor	an accurate, current inventinformation about all entries	d for at least 3 years that include but are nory for each select agent and/or toxin posses into areas containing select agent and/or toxin been granted access approvals that have been granted access approvals.	sessed, r toxin, and
	ole Official Duties & APHIS/ onsible Official will:	CDC Program Notification	
	n are stored or used to asses	ed for each laboratory and storage area what compliance with the requirements of the	
but not limi	ted to: adding or removing in nt and/or toxin and any chang	n circumstances to the certificate of regist dividuals, addition of a suite/room prior to ges to Responsible or Alternate Responsib	use or storage of
		prior to an individual or entity conducting a 1.13, 9 CFR Part 121.13 or 42 CFR Part 7	
Ensure inv		as defined in 7 CFR Part 331.11, 9 CFR P	art 121.11 or 42
This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:

Section 2 - Responsible Official Certification of Personnel and Facility Activities (Continued)

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7 CFR 331, 9 CFR 121, and 42 CFR 73] (initial each line):

Responsible Official Duties & APHIS	S/CDC Program N	otification (Continued)
The Responsible Official will:		
		ent Program using APHIS/CDC Form 2 prior to as put forth within Section 16 of the Select Agent
appropriate Federal, State, or I required upon discovery of a rerelease of a select agent and/o	ocal law enforcement elease of a select a for toxin outside the submitted to the Fec	ify the Federal Select Agent Program and ent agencies. Immediate notification is also gent or toxin causing occupational exposure or a primary barriers of the containment area. An deral Select Agent Program within seven calendar
identification of any Tier 1 sele- appropriate authorities when re for the identification and final d presented for diagnosis or veri	ct agent and/or tox equired by Federal, isposition of any se fication within seve	S select agent as defined in 9 CFR 121.5, or the in, to the Federal Select Agent Program and other State, or local law. Submit APHIS/CDC Form 4 elect agent or toxin contained in a specimen n calendar days of identification and/or in a 90 calendar days of receipt of the sample.
Responsible Official Signature	Date	Responsible Official Name (Typed or Printed)

This submission is:	☐ A new registration	$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $	☐ A renewal
Entity Name:			Date:
	Soci	there Co. Coloot Amente and Toying	
		tion 3 – Select Agents and Toxins	
HHS Ac	gents and Toxins	Overlap Agents and Toxins	USDA Agents and Toxins
(Chec	k if possessed)	(Check if possessed)	(Check if possessed)

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:

Section 4A – Laboratorians and Animal Care Staff							
Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator	
been or wi address th refresher t	at information and trai Il be provided to the in the needs of the individual raining will be provided the training will be n Signature:	ndividuals listed abo lual, the work being ed for these individu	ove before they hav performed, and risl als. Written records	e access to select ks posed by the se	agents and tox elect agents and sed to verify tha	ns. Training will /or toxins. Annual	

This submission is:	egistration	n update to an existing regis	stration	☐ A renewal	
Entity Name:				Date:	-
					_
	Section	n 4B – Support Staff			
Tier 1 Access Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	
I certify that information and traing role, has been or will be provided address the needs of the individuals be provided for these individuals maintained for at least three yea RO/ARO Signature:	d to the individuals listed ab ual, the work they do, and ri s. Written records and the m	ove before they have acc isks posed by the select a leans used to verify that th	ess to select agents agents agents and/or toxins.	and toxins. Training will Annual refresher training wil	I
-					_
This submission is:	egistration	n update to an existing regis	stration	☐ A renewal	
Entity Name:				Date:	

		Section 4C - 0	nescorted Visite	ors		
For guidance and instructions on Visitors, please see <u>www.selectagents.gov</u>						
Tier 1 Access	Last Name	First Name	HOME ENTITY DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Supervising Principal Investigator	
I certify that information and training on safety, security, and incident response for working with select agents and toxins has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work being performed, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years. RO/ARO Signature: Date: Date:						
Duto.						
This submiss		n 📗 An upd	ate to an existing reg	jistration	☐ A renewal	
Entity Name:					Date:	

Section 5A – Entity-Wide Security Assessment and Incident Response

1. The facility is: (check all that apply)

☐ Government owned ☐ Rented/leased ☐ Shared with and ☐ Other program						
2.		the entity have a security officer or	other individual(s) ide	ntified to assist the	Yes□	No□
	RO ir	n security matters? If yes, does the security plan contain the RO and the entity's security pro		dination between	Yes□	No□
3.	A throa.	eat assessment has been conducted Were local law enforcement or fede threat assessment?		d in developing the	Yes□ Yes□	No□ No□
	b. c.	Has there been a break-in at the er Have there been any direct threats last three years?			Yes □ Yes □	No□ No□
	d.	Have there been protests at the ent If yes to any of the above, describe needed.			Yes□	No□
4.	Inside a.	er risk assessment As a condition of granting unescorte organization on behalf of the entity, Educational background Previous work references Criminal history (beyond the se Agent Program) Other None	verifies (check all tha	t apply):	Federal Sele	ect
	b. c.	Does the entity have policies and p Does the entity have additional requ retain access to select agents or to	uirements for personn		Yes □ Yes □	No□ No□
5.	Natuı a.	ral hazards Is the entity located in any of the fol Is flood/flood zone In Hurricane In Tornado In Other	llowing hazard zones?	Earthquake (as de Wildfire Tsunami	efined by US	GGS)
	b.	In the event of a natural disaster wi apply): Secure the select agent and/or Transfer the select agent and/or Destroy the select agent and/or Other	toxin in place. In toxin to an alternate toxin.	`	or entity.	
This submission	on is:	☐ A new registration ☐ An	update to an existing regis	tration	☐ A renewal	
Entity Name:					Date:	
		Section 5A – Entity-Wide Security A	ssessment and Incider	nt Response (Contir	nued)	
6.		here electronic records and databas t and/or toxin? If yes, indicate the means to contro			Yes□	No□
	a. b.	Is a stand-alone (non-networked) of Are there area external connection	computer employed?		Yes□ Yes□	No□ No□

		facility (remote log in, work from home)?		
	C.	Is access to files or equipment containing select agent and/or toxin related information granted to users only when necessary to fulfill their roles and	Yes□	No□
	d.	responsibilities? Is user access modified when roles and responsibilities change or when their access to select agent and/or toxin is suspended or revoked?	Yes□	No□
	e. f.	Are anti-virus and anti-malware programs employed?	Yes□ Yes□	No□ No□
7.	Ship	ping/Receiving		
	a. b.	Does the entity have a centralized receiving area? Are all personnel who ship or receive select agent and/or toxin shipments Security Risk Assessment (SRA) approved?	Yes□ Yes□	No□ No□
	C.	Are select agent and/or toxin shipments stored in a registered and secured area prior to distribution to the Principal Investigators (PIs)?	Yes□	No□
8.	Does	s the entity transport select agent and/or toxin outside of registered area(s)? If yes, does the security plan address transport of select agent and/or toxin material	Yes□	No□
		a. through non-registered areas?b. during intra-entity transfers using chain of custody documentation?	Yes□ Yes□	No□ No□
9.		a response time for local law, guard force or other designated responders determined?	Yes□	No□
10.		ermission required to conduct select agent and/or toxin work after established hours? If yes, who grants permission? RO/ARO	Yes□	No□
		□ PI □ Other		

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:

	Section 5B – Entity-Wide Biosafety/Biocontainment		
1.	Describe the program or expertise used to develop and implement the biosafety and procedures described in the site-specific biosafety or biocontainment plan. Add add needed.		
2.	Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins.	Yes□	No□
3.	Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required.	Yes□	No□
4.	Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program.	Yes□	No□
5.	Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate.	Yes□	No□
6.	There are policies for the safe handling of sharps.	Yes□	No□
7.	There is a spill protocol in place appropriate to the select agent and/or toxin risk.	Yes□	No□
8.	There is an effective, integrated pest management program in place.	Yes□	No□

nis submissio	n is: A new registration	☐ An update to an existing registration	☐ A renewal	
tity Name:			Date:	
	Section 5C – Entry Reg	uirements for Federal Select Agent Program Ins	pectors	
			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	•	cility, such as gate location, visitor reception area, a visit. Add additional sheets as needed.	and	
Identifica	tion requirements:			
	Government ID			
	Other ID (describe)			
Are there	security clearance requireme	nts?	Yes□	No□
If ye	es, check all that apply.			
	hange of security clearance do Describe			
	npletion of entity specific secu			
•	tory protection required?		Yes□	No□
		nce for respirator use required.	Yes□	No□
	required respirators (check all	that apply):		
	N95			
	N100			
	PAPR: If required, will the ent		Yes□	No□
	Other	-		
List other as neede	nd	will be provided by the entity). Add additional shee	ts	
	documentation required:		Yes□	No□
	nunizations		Yes□	No□
	Recommended (specify)		· -	—
	D skin test (e.g. for animal cle	arance)	Yes□	No□
	In past 6 months?			
	In the past 12 months?			
-	specific training required?	ding the estimated time to complete all entry training	Yes□	No□
	es, provide a description (incluing nspectors). Add additional sh	ding the estimated time to complete all entry trainin	y	
101 11	nspectors). Aud auditional Sh	ceis as needed.		
Describe	any additional entry requirem	ents for inspectors. Add additional sheets as need	ed.	
This submis	ssion is: \square A new registration	\Box An update to an existing registration	□ A renew	al

Entity Name:		Date:				
	Building/Suite or Room:					
Building/Suite of	ROUII:					
	Section 6A – Building and Suite/Room Specific Security					
1. Will t	his suite/room be used for Tier 1 select agent and/or toxin?	Yes□	No□			
2. Perir	neter security measures outside the building (check all that apply): Security lighting Bars/security film on windows Exterior intrusion detection system Perimeter fence Roving guards Video surveillance of all access points Vehicle screening Other None					
	ss to building(s) or other area(s) housing the suite/room is controlled by k all that apply): Lock and key Biometric system Other None Guards					
agen □ □	ional security measures present in the interior of the building where select t and/or toxin is stored or used (check all that apply): Additional locked doors Card access system Card access system with PIN Biometric System Intrusion detection system a. What triggers the alarm? b. Is the alarm contracted to an outside company? c. Who does the alarm notify? d. Are any emergency exits equipped with the same kind of intrusion detection system as the customary entrances? Video surveillance	Yes□ Yes□	No□ No□			
	 a. Does the video surveillance observe select agent and/or toxin work? b. Does the video surveillance observe select agent and/or toxin storage? c. Does the video surveillance observe access to the registered room? d. Is the video monitored by security personnel? e. Is the video reviewed by laboratory personnel? Other	Yes Yes	No□ No□ No□ No□			

This subn	nission is:	□ A □	new registration	☐ An update to an exi	isting registration	☐ A renewa	al
Entity Nan	ne:					Date:	
Building	/Suite or	Room:				•	
			On the second Desired			IV	
			Section 6A - Buildi	ng and Suite/Room Sp	pecific Security (Contin	uea)	
	5.	control Lo	led by (check all that a ock and key ard access system ard access system with ometric System				
	6.	control No Lo Ca Bi	led by (check all that a b access control on the ock and key ard access system ard access system with ometric System	storage unit(s)			
	7.		e a pass through autoc yes, are the doors inte	lave in the suite/room? rlocked?		Yes□ Yes□	No□ No□
	8.	agent a	and/or toxin waste?	suite/room used for de	econtamination of select	Yes□	No□
	9.		e a pass through windo yes, is it secured?	w or box at the perimet	ter of the suite/room?	Yes□ Yes□	No□ No□

Is there a dunk tank at the perimeter of the suite/room? If yes, is it secured?

10.

Yes No No No

This su	ıbmission is:	☐ A new registration	☐ An update to a	an existing registration		renewal	
Entity N	lame:				Dat	e:	
Buildir	ng/Suite or Ro	oom:			'		
		Secti	on 6B – Room/Suite F	Physical Information			
-	For each re		ea, laboratory suite or				
	Include a fle plan for each locations of drains, show including ty	oor plan for the suite of suite or room should fequipment [including wers, incubator, centrige (e.g., Class II, Type	r room where select ag d include as applicable: but not limited to]: sink, fuge, animal caging, au e A2; Class III)], Heating	ent and/or toxin is to be u points of entry and/or eg eyewash, fume hood, fre toclave, Biological Safety g Ventilation and Air Cond floor plan specifying airflo	gress for peezer, refri Cabinet (ditioning (F	ersonnel, gerator, fl BSC) HVAC) su	oor
	For storag	e only area(s), proce	ed to Section 7.				
	Answer the	e following questions	s for each laboratory s	suite or room:			
	questions a and Biomed Involving R	apply to each biosafety dical Laboratories (BM ecombinant DNA Mole	level according to the (BL), the National Instituctules, and the America	vels. The accompanying current edition of the Bios utes of Health (NIH) Guide an Society of Tropical Mean to apply to the laborator	afety in M elines for F dicine and	icrobiolog Research Hygiene	ical
1.			check all that apply): NIHBL2 NIHBL3 NIHBL4 NIHBL2N NIHBL3N NIHBL3N NIHBL4N	☐ NIHBL2-LS ☐ NIHBL3-LS ☐ NIHBL4-LS		ACL3 ACL4	
	List the	resources/references ι	used				
2.	BSCs ar years.	nd fume hoods are cer	tified at least annually a	and records kept for at lea	st three	Yes□	No□
3.		present in the laborat res, the hand washing	ory for hand washing. sink is hands-free or au	utomatically operated.		Yes□ Yes□	No□ No□
4.	An eyew	vash station is readily a	available.			Yes□	No□
5.				lected and heat or chemic og a public sewage systen		Yes□	No□
	a. Are	•	om the containment sho	ower areas similarly treate	ed for	Yes□	No□
		rility? the effluent decontamin	nation system validated	monthly with a bio-indica	ator?	Yes□	No□
If E	BSL3Ag, BS	SL4 or ABSL4 is sele	cted, proceed to Secti	on 7.			
6.			ough two self-closing do nteroom open inward to			Yes□ Yes□	No□ No□

 $\hfill \square$ An update to an existing registration $\ \square$ A renewal

Entity Name:	Date:
Building/Suite or Room:	

	Section 6B – Room/Suite Physical Information (Continued)		
7.	The ventilation system provides sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas.	Yes□	No□
8.	The laboratory is designed such that under failure conditions the airflow will not be reversed.	Yes□	No□
9.	Laboratory design and operational parameters are re-verified at least annually.	Yes□	No□
10.	A visual monitoring device, which confirms directional airflow, is provided at the laboratory entry.	Yes□	No□
11.	Laboratory exhaust is not re-circulated to other areas of the building.	Yes□	No□
12.	 Exhaust air is HEPA filtered. a. If yes, the HEPA filter housing has decontamination and test ports. i. If this laboratory is a suite, please list rooms with HEPA filtered exhaust: ii. HEPA filters and housings are certified at least annually. b. If no, exhaust air is dispersed away from occupied areas and building air intake locations. 	Yes Yes Yes Yes	No No No
13.	Emergency shower is readily available.	Yes□	No□
14.	Floor drains are present.	Yes□	No□
15.	Sink traps and any floor drains are filled with water and/or appropriate liquid to prevent the migration of vermin and gases.	Yes□	No□
16.	Mechanical cage washer is present. If yes, cage washer has a final rinse temperature of at least 180°F.	Yes□ Yes□	No□ No□
17.	The laboratory has a shower-out capability with a change room.	Yes□	No□

submission i	is: A new registration		An update to an exis	sting registration		☐ A renewal
Name:						Date:
Sec	ction 7A – Principal Inve	stigator (PI) Information a	nd Select Ag	ent and T	oxin Locations
A complete	ete Section 7 must be submitt ed, multiple PI's can be listed	ed for eac in the head	h PI. If separate PI' der.	s would result i	n an identic	al Section 7 being
					DOJ Num	ber:
PI	Last Name:	F	First Name:		Date of Bi	rth:
					Tier 1 Acc	ess
Select Ag	jent/Toxin/Regulated Nucleic Acid		Location	Laboratory o	or Storage or both)	Laboratory Safety Level (Leave blank if storage
		Bldg	Suite/Room	Lab	Storage	only)
Suite Lege (If Applicab	nd: Suite A = Rooms 1, 2, 3	3, 4				
submission i	is: A new registration		An update to an exis	sting registration		☐ A renewal
Name:			_ ·			Date:

PI(s):							
	Section 7B – Strain or Serotype Designation Information						
Select Agent/To:	Select Agent/Toxin/ Regulated Nucleic Acid Strain or Serotype Designations						
Regulated Nucleic	Acid	Strain or Serotype Designations					
Agent							
Toxin							
Regulated Nucleic	Acid						
-							
This submission is: \[\] A new registration \[\] An update to an existing registration \[\] A renewal							

Date:

Entity Name:

PI(s):

Section 7C - D	Description	of	Work
----------------	-------------	----	------

1.	containn used. In appropri	ment level(s nclude any vi iate for the), includir work invo work desc	rk for each select agent and/ong a description of the metho lving animals, arthropods or peribed. If no work is being pernal sheets as needed.	dologies or laboratory p plants. Attachments A-G	rocedures that must be com	it will be ipleted if
	Agent/Toxi	in BSL	Object	tive of Work			
2	and conce	entration of	each org	ximum quantities (e.g., number anism grown at a given time (ndicate "no propagation of ager	e.g., 2 - 250 ml flasks c	of 10 ⁵ cfu/ml). eets if needed.	If select
			Agen	· ·	Maximum Quant	ity/Concentra	llion
3				kimum quantity of functional tox ditional sheets if needed. 1		one time (e.g.,	500 mg,
4	flow cyton exhaust a	neter, cell s	orter, plate IEPA filtra	nfectious agent or toxin aerosole e washer) is contained in prima ation or other equivalent techno	ary barrier devices that	Yes□	No□
5	Name(s)	of Individual	(s) respor	nsible for inventory of select ag	ent(s) and/or toxin(s):		
							1
	Inventory	record is re	conciled:	☐ Annually ☐ Other (specify	y frequency)		
6		d nucleic ac are held in		ined in 7 CFR 331.3, 9 CFR 12 n storage.	21.3, 42 CFR 73.3 or 42	Yes□	No□
his sı	ubmission is:	A new reg	gistration	☐ An update to an exis	ting registration	☐ A renewal	
ntity N	Name:					Date:	
	PI(s):					1	
			Se	ction 7C – Description of Wo	rk (Continued)		

7	All cu	ultures, stocks and other regulated wastes are decontaminated prior to disposal.	Yes□	No□
•		s, describe method: Autoclaved Chemical (disinfectant, concentration, and time) ncineration rradiation Other		
8	toxin	en records that would allow someone the ability to gain access to select agent and/or are controlled by: Lock and key Locked filing cabinet, drawer, cabinet, etc. Card access system Other		
9.	Will	work be performed with:		
	a.	agents that will be propagated and produce regulated amounts of toxins or with registered toxins at or below the regulated amount? If yes, complete Attachment A – Work With Toxins	Yes□	No□
	b.	regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms? If yes, complete Attachment 2 – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms	Yes□	No□
	C.	animals? If yes, complete Attachment C – Work with Animals	Yes□	No□
	d.	plants? If yes, complete Attachment D – Work with Plants	Yes□	No□
	e.	arthropods? If yes, complete Attachment E – Work with Arthropods	Yes□	No□
10.	Will	work be performed in:		
	a.	BSL3Ag laboratory? If yes, complete Attachment F – BSL3Ag Laboratories	Yes□	No□
	b.	BSL4/ABSL4 laboratory? If yes, complete Attachment G – BSL4/ABSL4 Laboratories	Yes□	No□

This submission is:		☐ A new registration	☐ An update to an existing registration	☐ A renewal	
Entity Na	me:			Date:	
Pl	(s):		Laboratory Safety Level:		
			Attachment A –Work with Toxins		
			Attachment A - Work With Toxins		
1.	A toxin- toxins.	specific Chemical Hygie	ene Plan is available for the laboratory using select	Yes□	No□
2.		ry forms quid forms entrifugation	eduction in the laboratory includes (check all that apply)):	
3.	a. If	s are exposed to select tyes, toxin exposure pro yes, complete relevant	coxins. cedure(s) is performed in registered laboratories. questions in Attachment C - Work with Animals .	Yes□ Yes□	No□ No□
4.	If		s). scription of the method and an estimate of the maxim nd concentration. Add additional sheets as needed.	Yes □ um quantities	No□ s during
5.	A hazaı	rd sign is posted when s	elect toxins are in use	Yes□	No□
				_	
6.	regulate	ed wastes are appropria f yes, describe method:] Autoclaved	, materials coming into contact with toxins, and other tely inactivated prior to disposal. ant, concentration, and time)	Yes □	No□
7.	perform	ed. yes, conducted in: Fume hood Biological Safety C Outside of a BSC o		Yes□	No□
8.	outside If yes, i □ A			Yes□	No□
9.		oxins are transferred to entity transfer).	other entities in quantities below the aggregate amoun	t Yes□	No□
This sub	mission is:	☐ A new registration	☐ An update to an existing registration	☐ A Renewal	
Entity Na	me.			Date:	

PI(s):		Lak	boratory Safety Level:		
		Attachment A –Work with Toxins (Co	ontinued)		
10.	the toxii	oxins are commercially distributed/shipped outside of the n. yes, is there a hazard communication plan?		Yes□ Yes□	No□ No□
11.	acids th 73.3 or If N	rk involve possession, use or transfer of recombinant and at encode for the functional form(s) of any select toxins a 42 CFR 73.13? yes, complete Attachment 2 – Work with Regulated Nodification of Select Agents and Toxins, Recombinations or Recombinant/Synthetic Organisms.	as defined in 42 CFR Nucleic Acids, Genetic	Yes□	No□

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:
PI(s):		Laboratory Safety Level:	

Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms

1.	Will a. b.	work involve possession, use, or transfer of the following? Nucleic acids that can produce infectious forms of select agent viruses. Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in	Yes□ Yes□	No□ No□
	c.	vitro. Select agent viruses, bacteria, fungi or toxins that have been genetically modified.	Yes□	No□
2.	Will a. b. c. d.	work involve the following with select agents and/or toxins: Introduction and/or modification of genetic elements. Recombinant or synthetic nucleic acids. Recombinant or synthetic organisms. Reverse genetics system to produce infectious forms of select agent viruses, or any complete set of reagents that would allow rescue of infectious virus available for use by a PI at the entity.	Yes□ Yes□ Yes□ Yes□	No No No No
3.		a restricted experiment be performed as defined in 42 CFR 73.13, 7 CFR 331.13 or FR 121.13? If yes, please indicate the type of restricted experiment: The introduction of, or selection for, drug resistance trait(s) into select agent orgonized the agent(s) and the drug resistance trait(s): Select Agent Select Agent Drug Resistance Trait Select Agent Drug Resistance Trait The deliberate formation of DNA containing genes for the biosynthesis of toxin livertebrates at an LD ₅₀ < 100 ng/kg body weight. List toxins		No□
	b.	Has this PI received approval from the APHIS Administrator or HHS Secretary for this restricted experiment?	Yes□	No□
4.	Will a.	work involve possession, use or transfer of <u>a product of</u> a restricted experiment? If yes, please indicate the type of restricted experiment product: □ Drug resistance trait(s) in select agent organisms. List the select agent(s) and the drug resistance trait(s) □ DNA containing genes for the biosynthesis of toxin lethal for vertebrates at an LD ₅₀ < 100 ng/kg body weight. List toxin(s)	Yes □	No□
	b.	Has this PI received approval from the APHIS Administrator or HHS Secretary for this product of a restricted experiment?	Yes□	No□
5.	resi	experiments involve the acquisition of increased/restored virulence (e.g., drug stance, increased host range, enhanced transmissibility, infectivity, environmental bility) in select agents or toxins?	Yes□	No□

This submi	ssion is:	☐ A new registration	☐ An update to an existin	g registration	\square A renewal	
Entity Name	e:				Date:	
PI(s)):			Laboratory Safety Level:		
Attac			ed Nucleic Acids, Genetic Neic Acids, or Recombinant			•
	-	question 1-5 above answ itional sheets as needed.	ered "yes", provide a brief de	escription of the work.		
	ecombii If y	nant work with select age es, has the IBC approved	tee (IBC) reviews and appronts and toxins at this facility. the work described above? anation. Add additional sheet		m Yes□ Yes□	No□ No□

This submission is	A new registration	An update to an existing registration	<u> </u>	☐ A renewal	
Entity Name:				Date:	
PI(s):		Laboratory	Safety Level:		
		Attachment C. Werle with Animals			
		Attachment C – Work with Animals			
1. Provide th	e select agent/toxin and	species of animal to be used:			
Select	Agent / Toxin	Species of Animal	Route(s) of Administr	ation
If ye	s, is the aerosol exposu	ents or toxins by the aerosol route? re equipment used within a primary conta	inment device	Yes□ ? Yes□	No□ No□
a. Are disp □	Are animal carcasses, cages, and waste (e.g., sewage, bedding) treated prior to Yes No disposal by an approved method? (check all that apply): Autoclaved. Describe validation procedures that account for variables such as time and temperature of autoclave run cycles, as well as temperature and weight of carcass at initiation of autoclave cycle. Add additional sheets as needed.				
b. Was	Incineration Tissue Digester Other te Handling Procedures Waste decontaminated animal facility). Waste outside of the co	concentration, and time) inside the containment area (e.g., pass-tlentainment area for decontamination. Des	cribe when an	d how waste is	
irradiation biosafety	of samples collected fr	rmalin fixation, lysis of cells for nucleic aci om infected animals that will be manipula tion or dosage and contact/exposure time	ted at a lower		
approve p If ye	rotocols prior to work wi s, the proposed work wi	ional Animal Care and Use Committee (IA th animals at this entity. th select agents and toxins in animals has n. Add additional sheets as needed.	•		No□ No□
This submission is	☐ A new registration	☐ An update to an existing registration	<u> </u>	☐ A renewal	
Entity Name:		2 1 2 2 3 3 3		Date:	
PI(s):		Laboratory	Safety Level:		

	Attachment C – Work with Animals (Continued)						
6.	The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). If yes, give most recent (re)accreditation date	Yes□	No□				
7.	There is a system in place for recording the number of animals infected, the number animals disposed of, and the records are reviewed frequently.	of Yes□	No□				
	If yes, describe. Add additional sheets as needed.						
8.	Are animals restrained for experimental manipulation? If no, explain.	Yes □	No □				
9.	Are experimentally infected animals monitored (e.g., daily checks)? If no, explain.	Yes □	No 🗆				
10.	Describe animal housing for each species, including whether cages provide primary containment and a brief description (e.g. cage or cage rack is HEPA filtered, active or passive ventilation of the cages, non-containment caging housed within inward flow ventilated enclosure).						
1		ne cages, non-conta	ainment				
	caging housed within inward flow ventilated enclosure).	ne cages, non-conta	ainment				
	caging housed within inward flow ventilated enclosure).		ainment				
	caging housed within inward flow ventilated enclosure).		ainment				
	caging housed within inward flow ventilated enclosure).		ainment				
11.	caging housed within inward flow ventilated enclosure).		ainment				
11. 12.	caging housed within inward flow ventilated enclosure). Species Anim		No□				
	Species Anim Describe how animals will be euthanized. Add additional sheets as needed. Are animals euthanized?	nal Housing					
	Species Anim Describe how animals will be euthanized. Add additional sheets as needed. Are animals euthanized?	nal Housing Yes□					
12.	Species Anim Describe how animals will be euthanized. Add additional sheets as needed. Are animals euthanized? If no, explain. Describe how animal carcasses are secured prior to decontamination. Locked freezers, coolers Not secured, immediately decontaminated (e.g., autoclave, tissue digester, inci	nal Housing Yes□					
12. 13.	Species Anim Describe how animals will be euthanized. Add additional sheets as needed. Are animals euthanized? If no, explain. Describe how animal carcasses are secured prior to decontamination. Locked freezers, coolers Not secured, immediately decontaminated (e.g., autoclave, tissue digester, inci Other	Yes —					

Attachment D – Work with Plants

1. Provide the select agent and species of plant to be used:

Select Agent	Species of Plant	Route(s) of Inoculation
plants or samples) by an approve ☐ Autoclaved	entration, and time)	
 c. Please describe vector spec 	I to observe potential escapes?	Yes
	ent E - Work with Arthropods.	165 140
a. Is the glass house attachedb. Is the glass house separatedc. Is pest monitoring conducted	from the laboratory? within the glass house? between areas such as glass house to laboratory'	Yes No No Yes No
a. Is the greenhouse attachedb. Is the greenhouse separatedc. Is pest monitoring conducted	from the laboratory? within the greenhouse? between areas such as greenhouse to laboratory?	Yes No No Yes No
This submission is: A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:		Date:
PI(s):	Laboratory Safety Leve	el:
Attac	hment D – Work with Plants (Continued)	

6.	Wil	I plants exposed to select agents be housed or manipulated in a screenhouse ?	Yes□	No□
	a.	Is the screenhouse attached to the laboratory?	Yes□	No□
	b.	Is the screenhouse separated from the laboratory?	Yes□	No□
	C.	Is pest monitoring conducted within the screenhouse?	Yes□	No□
	d.	Are inoculated plants moved between areas such as screenhouse to laboratory?	Yes□	No□
	e.	If yes, provide a description of the screenhouse materials (including screen mesh		
		size)		
	f.	Structure is reinforced.	Yes□	No□
	g.	Floor is constructed of:		
		□ Concrete		
		☐ Tile or other floor covering		
		☐ Dirt or gravel		
7.	Wil	I plants exposed to select agents be housed or manipulated in a growth chamber ?	Yes□	No□
•	a.	Is the growth chamber located in or attached to the laboratory?	Yes□	No□
	b.	Is the growth chamber separated from the laboratory?	Yes□	No□
	C.	Is pest monitoring conducted within the growth chamber?	Yes□	No□
	d.	Are inoculated plants moved between areas such as growth chamber to laboratory?	Yes□	No□
	f.	Structure is reinforced.	Yes□	No□
	g.	Floor is constructed of:		- —
	3	□ Concrete		
		☐ Tile or other floor covering		
		☐ Dirt or gravel		
	h.	Manufacturer name Model number		
	i.	Access to growth chamber is controlled (e.g., lock and key, card access system,	Yes□	No□
		biometrics).		
	j.	Is the growth chamber located at a reasonable distance from other growth chambers	Yes□	No□
		with healthy plants, insectaries and outside doors?		
8.	\\/il	I work be performed with regulated nucleic acids, genetic modification of select agents	Yes□	No□
0.		oxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms?	165	140
	Oi t	If yes, complete Attachment B – Work with Regulated Nucleic Acids, Genetic		
		Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids		
		or Recombinant/Synthetic Organisms.		
		or recombinate synthetic Organisms.		

This submiss	sion is:	☐ A new registration	☐ An updat	te to an existir	ng registration	☐ A renewal	
Entity Name:						Date:	
PI(s):					Laboratory Safety Level:		
		•		1 21 4			
		Atta	achment E – W	ork with Ai	thropods		
		erformed with field-collec on of select agents.	ted arthropods	in a <u>diagno</u>	estic capacity only for	Yes□	No□
	ect age	erformed to experimentally ents. , complete questions 3-16		fect arthrop	ods (any stages) with	Yes□	No□
3. Prov	vide th	e select agent and specie	s of arthropod ເ	ısed:			
		Select Agent			Species of Arthr	opod	
a.	Inject Infect	experimental exposure ro ed with select agent. ed with select agent via bl , indicate the blood meal s Animal species	ood meal.			Yes □ Yes □	No□ No□
		If vertebrate hosts are us this objective of work? If yes, complete Attachm If no, explain. Add addition	ient C - Work w	ith Animal		Yes□	No□
c. d.	If yes	Collected blood (describe ed with select agent via in , complete Attachment D (Describe)	sect feeding on	ŭ	nt infected plants.	Yes	No□
		description of the procedu darthropods. Add addition			inment and any transfer((s)	
	nber of	system in place for record farthropods disposed of, a describe. Add additiona	and the records	are reviewe		Yes□	No□
impl Con	lemen Itainm	containment laboratory de ted in accordance with gui ent Guidelines, a project o can Society of Tropical Me	idance found in of the American	the current Committee	edition of the Arthropod		No□

This submission is:	☐ A new registration	stration An update to an existing registration			
Entity Name:			Date:		
PI(s): Laboratory Safety Level:					
Attachment E – Work with Arthropods (Continued)					

	Attachment E – Work with Arthropods (Continued)		
8.	An Institutional Biosafety Committee (IBC) reviews and approves arthropod work with select agents at this facility. If yes,	Yes□	No□
	a. has the IBC approved the arthropod containment laboratory design and operational procedures?	Yes□	No□
	b. has the IBC approved the work described in this objective of work? If no, explain. Add additional sheets as necessary.	Yes□	No□
9.	Arthropods are prevented from release into suite/room. If yes, do procedures include protocol for accidental escape?	Yes□ Yes□	No□ No□
10.	Experimentally infected arthropods are housed and manipulated in a suite/room such that accidental contact and release is prevented.	Yes□	No□
11.	Ventilation filters/barriers are installed to prevent arthropod escape.	Yes□	No□
12.	Floor drains are present in the laboratory. If yes, floor drains are modified to prevent accidental release of arthropods and agents.	Yes□ Yes□	No□ No□
13.	Suite/room plumbing is suitable to prevent arthropod escape.	Yes□	No□
14.	All stages of arthropods are killed before disposal.	Yes□	No□
15.	All wastes from the arthropod containment laboratory are treated for disposal using an approved method. If yes, describe method: Autoclaved Chemical (disinfectant, concentration, and time) Incineration Other	Yes□	No□
16.	Animals or plants are permitted in the arthropod containment laboratory. If yes,	Yes□	No□
	a. are animals or plants associated with the work being performed? b. are animals or plants accessible to escaped arthropods?	Yes□ Yes□	No□ No□

This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal
Entity Name:			Date:
PI(s):			

	Attachment F – BSL3Ag Laboratories						
1.	Supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, an interlocked and double-door autoclave, or shower. For materials which are temperature sensitive, a gas sterilizer, pass-through liquid dunk tank, or a cold gas decontamination chamber are provided.	Yes□ Yes□	No□ No□				
2.	Is a shower required when leaving the containment boundary	Yes□	No□				
3.	Disposable materials are decontaminated by a verified method (check all that apply): Autoclaved Chemical (disinfectant, concentration, and time) Incineration Other	Yes □	No□				
4.	All containment areas are designed, constructed and verified to function as a primary containment barrier. All walls are constructed slab-to-slab and walls, floors, and ceilings are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination.	Yes□	No□				
5.	Differential pressures/directional airflow are monitored and alarmed to indicate system failure.	Yes□	No□				
6.	There is HEPA filtration of all supply and exhaust air to and from the containment space. If yes, all HEPA filters are certified annually.	Yes□ Yes□	No□ No□				
7.	 Laboratory procedure and design features include: a. Personnel ingress and egress only through a series of rooms which includes a ventilated vestibule. b. A clean change room outside of containment. c. Doors that define a containment boundary have compressible or inflatable gaskets with airtight hinges and latch/knob areas. d. A shower room at the non-containment/containment boundary. e. A dirty change room within containment. 	Yes Yes	No No No No No No				
8.	A second shower is required at the facility access control point before donning street clothing.	Yes□	No□				

This submission is:		☐ A new registration	☐ An update to an existing registration	□ A ı	enewal	
Entity	Name:			Date	:	
	PI(s):			·		
		Attachme	ent F – BSL3Ag Laboratories (Continued)			
9.		estraining devices are pro cribe. Add additional she	ovided in large animal rooms. ets as needed.		Yes□	No□
10.		rooms are sized and equi cribe. Add additional she	pped to accommodate large animals. ets as needed.		Yes□	No□

his submission is:		☐ A new registration	new registration		
ntity Name:				Date:	
	PI(s):				
		Λtta	chment G – BSL4/ABSL4 Laboratories		
		Atta	Chillent G - B3L4/AB3L4 Laboratories		
	BSL4 LAB	ORATORY			
1.		e performed in a BSL4/, complete questions 2 -	ABSL4 Cabinet Laboratory? 8	Yes□ No□	
2.	Describe th	ne type of personal prote	ective equipment that will be used. Add add	ditional sheets as needed.	
3.	Describe the as needed		hods for materials/equipment in the Class I	II cabinet. Add additional sheets	
4.	Describe what liquid effluents are decontaminated and how they are decontaminated. Add additional sheets as needed.				
5.	Describe the supply and exhaust components of the ventilation system, including how the ventilation system of the Class III cabinet is manifolded to the room ventilation. Add additional sheets as needed.				
6.		nt of a ventilation failure, sheets as needed.	describe what measures are used to preve	ent reversal of airflow. Add	
7 .	Describe how differential pressures and directional airflow are monitored and analyzed. Add additional sheets as needed.				
8.	Describe h	ow containment parame	eters are monitored daily. Add additional sh	neets as needed.	
9.		e performed in a BSL4// complete questions 10	ABSL4 Suit Laboratory? - 16	Yes□ No□	
10.	Describe t	he type of personal prot	tective equipment that will be used. Add ad	ditional sheets as needed.	
11.	Describe sheets as		decontaminated and what measures are us	sed to do so. Add additional	

This submission is:		☐ A new registration	☐ An update to an existing registration	☐ A renewal	
Entity Name:				Date:	
	PI(s):			·	
		Attachmen	t G – BSL4/ABSL4 Laboratories (Continued	(1)	
12.			omponents of the ventilation system, including supply and exhaust air. Add additional sheets		
13.	 In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow. Adaptitional sheets as needed. 				
14.	4. Describe how differential pressures and directional airflow are monitored and analyzed. Add additional sheets as needed.				
15.	In the event of a breathing air failure, describe what facility redundancies are in place. Add additional sheets as needed.				
16.	Describe h	ow containment parame	eters are monitored daily. Add additional shee	ets as needed.	