How to Create Appendices and Attach to an IRB Protocol

1. Go to RASCAL: www.rascal.columbia.edu. Login with your UNI and password.

Logout | Help |

- 2. Go to Hazmats. Create an Appendix. Click on Dropdown to choose your Appendix.
- 3. For Each Appendix, see tips and instructions below. Starting on Page 11 are instructions on how to attach to IRB protocol.
- 4. **NOTE**: For Human Gene Therapy Trials-**DO NOT SUBMIT AN APPENDIX A**. See separate instructions on submitting an Appendix M to the IBC.



Human Subjects | Animal Care | Process | Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

10000000	READ AND PRINT GENERAL INSTRUCTIONS	
Haz Mats		
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	Radiation Safety - Approval Queue	
	Radiation Safety - Committee Queue	
	IRB Human Materials Attestation Search	
	Contact Us @ Columbia University	
	Rascal, Research Administration and Compliance Application Columbia University Information Technology 615 West 131st Street, 5th Floor	

For Appendix A

<u>**Tips**</u>: There are multiple sections to this Appendix. Fill Form in order and always save when section is completed. Each page must be filled in its entirety to save. If cannot fill out Appendix A in one session, fill out remaining section you are working on, and return back to the Appendix later to complete the remaining sections.

- 1. Fill out Appendix A. Fill out First Section "General". Click Save.
- 2. Fill out Microorganism Section next. Click Save.
- 3. Fill out "Human Tissue and Cell Culture" Section. Click Save.
- 4. Fill out "Safety Equipment and Practices" Section. Click Save.
- 5. If attaching documents, use the Attachments section in the Left hand side.
- 6. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be imported to the Appendix in the IRB submission process.
- 7. Navigate to your IRB protocol to attach the Appendix A.



RASCAL Hazardous Materials

Logout Help Human Subjects Anir	nal Care Proposal Tracking Consent Forms HIPAA Forms Haz Mats Ad	ministration Training Center Conflict of Interest My Rascel	
APA-AAAD8750	MULTIPLE SECTIONS: Comple	ete in	
Status: Creating	order	safety (Appendix A)	
Appendix Content		Subject Species N/A	
General	Title		
Microorganism Information	Creation Date 04/09/2019 09:23:38	Initiator Aderemi Dosunmu (ad3241)	
Human Tissue and Cell	You are Aderemi Dosunmu (ad3241)	Appendix Submitted	
Culture Section		General Instructions @ General instructions ex	volain how to fill
Safety Equipment and			
Practices	I. General Information	out appendix appropria	ately.
Personnel			
Attachments	*The appendix will be: ~Select~ -		
Protocol/Proposal	*Project Title:		0 / 255
Appendix Action	*Describe methodologies/manipulations of the work per	rformed. In brief describe the lab's research goals and the methodologies involved to accon	nplish these
Conv Annendix	goals. If applicable, include any recombinant DNA gene	e manipulations such as gene editing (e.g., CRISPR, TALENs, zinc fingers):	0 / 500
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	*Are there any relevant vaccinations or work restriction	s/considerations that should be acknowledged in regards to work with the biological materi	ial? 😮
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	Company/Core Facility/Repository:	armasonnoa spoeniencen meroarer microorganism) be procared nom: 🥹	
	Collaborator (Name/University):		
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	*Will this project be a research collaboration where rec Ves ON0	combinant DNA or infectious material is shared between different institutions?	

*III. Dual Use Research of Concern (DURC) 🥹

Dual Use Research of Concern (DURC) is defined as: life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

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IV. Laboratory Location

*Laboratory Locations 🕖

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V. Recombinant DNA

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Columbia University Information Technology 615 West 131st Street, 5th Floor		•

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For Appendix D

<u>**Tips**</u>: Laser Registration is a form provided by the Laser Safety Officer. Approval number is found at the bottom of the laser registration form. Laser approval number is provided by EH&S. To inquire what the approval number is, contact <u>lasersafety@columbia.edu</u>.

If Laser registration form is needed, fill out the form in the link and attach in the Attachments Section of the Appendix D.

- 1. Fill out Appendix D.
- 2. Save
- 3. If attaching documents, use the Attachments section in the Left hand side.
- 4. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be imported to the Appendix in the IRB submission process.
- 5. Navigate to your IRB protocol to attach the Appendix D.

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Adding Attachments to Appendix D:

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Contact Us © Columbia University @ Rascal, Research Administration and Columbia University Information Tech 615 West 131st Street, 8th Floor New York, NY 10027	Compliance Application cology			

New York, NY 10027 Phone: (212) 851-0213

For Appendix E

Tips: Do not include isoflurane or formaldehyde; They have been moved to their own Appendix.

You may use the Attachments Section of the Appendix to provide information on Safety Data Sheets (SDS) or chemical specific SOPs

Under Emergency Response, add information, as applicable for each chemical. For example:

*Acute symptoms of exposure: For Chemical A symptoms are xyz; for Chemical B symptoms are xzy;

Instructions:

- 1. Fill out Appendix E.
- 2. Save

w rasta)

- 3. If attaching documents, use the Attachments section in the Left hand side.
- 4. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be imported to the Appendix in the IRB submission process.
- 5. Navigate to your IRB protocol to attach the Appendix E.

Logout | Help | Human Subjects | Animal Care | Procesal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

	APE-AAAG4600 Status: Creating		Hazardous Chen	nicals (Appendix E)		
	Appendix Content	Appendix Number	AAAG4600	Subject Species	N/A	
	General	Title				
	Personnel	Creation Date	04/09/2019 16:34:44	Initiator	Aderemi Dosunmu (ad3241)	
_	Attachments	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted		
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То	attach	VI. Emergency Response				
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		*Location of Spill Kit: *Actions taken in event of cont	amination/spill: 🥝			
		*Methods for detecting contam	ination of skin, clothing, apparatus, etc.:			
		*Is a biological toxin used?	O Yes ● No			
		Describe the excretion pathway	s and metabolic products of the compounds, if app	icable: 😗		
		*What is the biological 1/2 life	of the administered compounds?			
		what is the toxicity (if any) of	excreted metabolites :			
		If special waste containers mus	t be used or specific waste instructions are to be gi	ven, please email <u>hazmat@co</u>	olumbia.edu.	
		The OSHA regulation Occupation Safety and Chemical Hygiene Ori important to note that these initial	al Exposures to Hazardous Chemicals in Laboratories (entation (LSCHO) Session INITIALLY. These sessions a trainings do expire and refresher trainings must be take	29 CFR1910.1450) requires tha re offered twice monthly by EH n online through RASCAL.	t persons working with chemical(s) attend a Laboratory &S and can be scheduled locally if desired. It is also	
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Adding Attachments to Appendix E:

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For Appendix E1

<u>**Tips</u>**: This Appendix is for Isoflurane. As long as there are no modifications to the Appendix or personnel changes, the Appendix remains approved for the life of the IRB protocol.</u>

- 1. Fill out Appendix E1.
- 2. Save
- 3. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be imported to the Appendix in the IRB submission process.
- 4. Navigate to your IRB protocol to attach the Appendix E1.

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IV. Hazard Control The laboratory is utilizing at least one of the engineering controls listed while working with isoflurane. (Check all that apply): Certified Chemical Fume Hood Ducted Biological Safety Cabinet (Class II, Type B1 or B2) Active Engineering Control (Vacuum Pump w(Charcoal Canister) Pessive Engineering Control (Vacuum Pump w(Charcoal Canister) Ducted Biological Safety cabinet to provide the engineering controls and has been assessed by Environmental Health and Safety Cother: The laboratory will be implementing one or all of the below administrative controls during work with isoflurane. (Check all that apply): Utilization of a digital vaporizer Dutted biological safety from an outside vendor Dutted will be writehe are diversible transmitted before name.		*Laboratory Locations 🕑 Campus	N I -	Building	1	Room	Modify Delete
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*The laboratory is utilizing at least one of the engineering controls listed while working with isoflurane. (Check all that apply): Certified Chemical Fume Hood Ducted Biological Safety Cabinet (Class II, Type B1 or B2) Active Engineering Control (Vacuum Pump w/Charcoal Canister) Passive Engineering Control (Vacuum Pump w/Charcoal Canister) Laboratory works on an open bench top without any engineering controls and has been assessed by Environmental Health and Safety ? Other: *The laboratory will be implementing one or all of the below administrative controls during work with isoflurane. (Check all that apply): Utilization of a digital vaporizer Lab will calibrate their isoflurane vaporizer from an outside vendor		IV. Hazard Control					
Calificates will be weighted and the weights recorded before the soft state and table teach use Calificates will be weighted and one-site storage to amounts used Calificates will be disposed of as hazardous waste The laboratory will be utilizing the appropriate personal protective equipment including nitrile gloves, lab coat, and safety glasses or goggles: Lab Coat Disposable Gloves: Nitrile Latex Vinyl Calificate Gloves: Nitrile Latex Vinyl		The laboratory is utilizing a Certified Chemical Fume H Ducted Biological Safety C Active Engineering Contro Passive Engineering Contro Dassive Engineering Contro Dassive Engineering Contro Cother: The laboratory will be impl Utilization of a digital vapo Lab will calibrate their isoft Canisters will be weighed Follow time limit guidelines Lab will limit ordering and Canisters will be disposed The laboratory will be utilizity Canisters will be disposed The laboratory will be utilizity	It least one of the engineering controls li food vabinet (Class II, Type B1 or B2) (Vacuum Pump w(Charcoal Canister) vol (Charcoal Canister) en bench top without any engineering contr ementing one or all of the below adminis rizer urane vaporizer from an outside vendor and the weights recorded before and after et as recommended by EH&S to minimize isc on-site storage to amounts used of as hazardous waste ing the appropriate personal protective et	sted while working with isoflura ols and has been assessed by Er trative controls during work wit ach use flurane exposure.	ane. (Check all that nvironmental Health th isoflurane. (Chec res, lab coat, and sa	apply): and Safety 🥡 :k all that apply): afety glasses or goggles:	
Safety Glasses/Goggles Respirator		*Disposable Gloves: Nitrile	Latex Vinyl				

For Appendix E2

<u>**Tips</u>**: This Appendix is for Formaldehyde/Formalin/Paraformaldehyde. As long as there are no modifications to the Appendix or personnel changes, the Appendix remains approved for the life of the IRB protocol.</u>

Instructions:

- 1. Fill out Appendix E2.
- 2. Save
- 3. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be imported to the Appendix in the IRB submission process.
- 4. Navigate to your IRB protocol to attach the Appendix E2.



RASCAL Hazardous Materials

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

APE2-AAAA0050		Formaldehyde	(Appendix E2)						
Status: Creating	Appendix Number	AAA0050	Subject Species	N/A					
Appendix Content	Title								
General	Creation Date	04/09/2019 17:31:05	Initiator	Aderemi Dosunmu (ad3241)					
Personnel	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted						
Attachments		General Ins	tructions @ Ger	neral instructions explain how	<i>w</i> to fill				
Protocol/Proposal	Formaldehyde is a hazardous	chemical with a regulatory permissible exposure limit,	ished by the	annendix annronriately					
Appendix Action	submitting this appendix, the	Principal Investigator/Initiator confirms awareness of t	he zardous natu	appendix appropriately.					
Copy Appendix	I. General Information								
Delete Appendix					_				
Appondix View	*The appendix will be: ~Se	elect~							
View History		0/255							
View Detechant	*Project Title:								
View Datasileet									
Haz Mats	II. Chemical Used For:								
Haz Mats Menu					1				
[RASCAL Menu]	OHuman Subject Research	∂OAnimal Subject Research OIn vitro Research							
					1				
	III. Type of Formalin/Form	aldehyde:							
	Formalin/Formaldehyde]				
	Paraformaldehyde (PFA)								
					1				
	IV. Laboratory Location								
	*Laboratory Locations 🕖								
	V Hazard Control								
	V. Huzuru control				1				
	*The laboratory is utilizing at	least one of the engineering controls listed while work	ing with formaldehyde. (Che	ck all that apply):					
	Certified Chemical Fume Ho	od							
	Downdraft Table								
	Ducted Biological Safety Cal Laboratory works on an oper	binet (Class II, Type B1 or B2) n bench top without any engineering controls and has cont	acted Environmental Health an	nd Safety at occusafety@columbia.edu					
	Other:								
	*The Jaboratony will be implen	centing one or all of the below administrative controls	during work with formaldeby	rde (Check all that apply):					
	Lab will limit ordering and on	-site storage to amounts used	during work with formatieny	ue. (check an that appry).					
	Work on an open bench top	of chemicals and hazardous waste 🥝 with amounts smaller than 0.1 mL							
	Work on an open bench top	with amounts larger than 0.1 mL and have contacted Envi	ronmental Health and Safety at	t occusafety@columbia.edu					
	*The laboratory will be utilizin Lab Coat	g the appropriate personal protective equipment inclu	ding:						
	*Disposable Gloves: Nitrile	Latex Vinvl							
	Respirator								
		SAVE: Work will be de	leted if not		1				
	Save	saved after each section	on						
	Contact Us © Columbia University 🗗			J					

How to Attach to IRB protocol

- 1. Go to the Human Subjects Section in Rascal. Either "Create a Protocol" for a new Protocol or find existing protocol under "My Protocols" (May also find your protocols under "My RASCAL")
- 2. Under Attachments, Go to HazMats on the left hand side.
- 3. Based on title and/or Appendix Number, find the relevant Appendices you want to attach to IRB protocol and click "Attach"
- 4. A pop up box will appear in order to add personnel. If personnel will handle hazardous material, they are to be selected.
 - Note: All "included" protocol staff must complete or renew all required training before Appendix approval. Note that incomplete or expired training will result in a "Hold" and may prolong the approval process. Please ensure all training records are up to date before attachment and submission to expedite timely review.
 - b. Once you have attached the protocol, you can view the Appendix to view that the personnel tab is populated. Click The Appendix Number and a new tab will open to show the datasheet. If personnel have expired training (Expired) or never had training (incomplete), this datasheet can be printed out or emailed to the relevant personnel so they can expediently update their required safety trainings.
- 5. Under Protocol Action, Go to Notify Approvers. Click to Notify Approvers. The PI will be notified to sign the Attestation Piece
- 6. After the Protocol has been approved by the PI and the other approvers if necessary, Submit the Protocol.
- 7. Under Protocol Action, click submit. If there is anything missing from the IRB protocol or the Appendix, the validation check occurs here. If there is a problem, follow the instructions on the screen to navigate back to the problem areas. If there are no problems proceed with IRB protocol submission.



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RASCAL Human Subjects





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Status: Creating	Abbreviated upe	EUS Environ Lingth Oct Dark (9211402)	Dr.	stocol Initiator	Adarami Dosunmu (1432)/11	
Protocol Content	Protocol Year	1 Modification (0)		Data Created	07/11/2019 12:10:56	
General Information	Principal Investigator	Aderemi Dosunnu (ad3241)		You are	Aderemi Dosunmu (ad3241)	
Attributes	Hazmats	Total and a second s				
Funding	Helpful Information:					
Personnel	Laser (Appendix D): ġ					
Departmental Approvers	Formaldehyde (Appendix E2): 0					
Research Aims & Abstracts	Radiation Safety (Appendix H): Use of Recombinant DNA (rDNA) Molecules in	Human Gene Transfer (Appendix M): 🥹			Find A	ppendix relevant to
Attachments	Attached Appendices					ppendix relevant to
Hazmats	Туре	Title Appendix Number	Date Created Initiator		A Protoc	ol and click "attach"
HIPAA Forms			No data to display			
Documents						
Consent Form	All released Appendices to which you have ac	cess and are not currently attached to a protocol.				
	Attach Type	Title	Number		Date Created	Initiator
	Laser(Appendix U)	test 123	APD-AAAA/100	94/12/2019		Aderemi Dosunmu (adu241)
Notify Approvers	Use of Hazardous Chemicals in Animal	s(Appendix E) Differentiating Radiosensitivities and Niche Factors among Intestinal Stem Cell Pools	APE-AAAG4460 0	03/27/2019		Aderemi Dosunmu (ad3241)
Submit Protocol	Use of Hazardous Chemicals in Animal	s(Appendix E)	APE-AAAG4378	03/15/2019		Aderemi Dosunmu (ad3241)
Delete Protocol	Infectious Agents(Appendix B)		APB-AAAE7153 0	01/14/2019		Aderemi Dosunmu (ad3241)
Drotocol View	Use of Hazardous Chemicals in Animal	s(Appendix E)	APE-AAAG3727 1	11/21/2018		Aderemi Dosunmu (ad3241)
Print Menu	Use of Hazardous Chemicals in Animal	is(Appendix E)	APE-AAAG3055 0	06/30/2018		Aderemi Dosunmu (ad3241)
View Datasheet	Use of Hazardous Chemicals in Animal	s(Appendix E) dsfasdf	APE-AAAG2962 0	08/21/2018		Aderemi Dosunmu (ad3241)
View History	Recompinant DNA(Appendix A1)		APA1-AAAD6705	07/11/2018		Aderemi Dosunmu (ad3241)
Human Subjects	Use of Hazardous Chemicals in Animal	s(Appendix E)	APE-AAAG2609 0	06/13/2018		Aderemi Dosunmu (ad3241)
Protocol Overview	Laser(Appendix D)		APD-AAAA6101 0	04/25/2018		Aderemi Dosunmu (ad3241)

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RASCAL Human Subjects

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IRB-AAAR9905	Abbreviated title discificiant			Protocol Numb	ir AAAR9905		
Status: creating	Originating Department EHS Envi	on Health Sci Rsch (8211402)		Protocol Initiat	w Aderemi Dosunmu (ad3241)		
Protocol Contant	Protocol Year 1 Modifica	bon 00		Date Created 07/11/2018 12:19:56			
General Information	Principal Investigator Aderemi (losunmu (ad3241)		You a	e Aderemi Dosunmu (ad3241)		
Attributes	Hazmats						
Funding	Helpful Information: 💮						
Personnel	Biosafety (Appendix A):						
Departmental Approvers	Hazardous Chemicals (Appendix E): 🤕			6			
Research Aims & Abstracts	Radiation Safety (Appendix H): Use of Recombinant DNA (rDNA) Molecules in Human	Hazardous Materia	Is Appendix Sta	aff Check-Off			
Attachments	Attached Appendices	Check staff to be included in appendix APD-AAAA7100	2		-		
Hazmats	Type Ti	Select	Name	Rote	Appendix Letter	Action Staff Replace with a copy	
HIPAA Forme		🕼 Aderemi Dos	sunmu (ad3241)	Principal Investigator			
Documents							
Consent Form	All released Appendices to which you have access an Attach Type	17			Date Created	* Iniliator	
Protocol Actions	S Laser(Appendix D)	A	alach Appendix			Aderemi Dosunmu (ad3241)	
Notity Approvers	Use of Hazardous Chemicals in Animals(Appendix	E) Differentiating Radiosensitivities and Niche Factore among Intestinal Stem Cell Pools	APE-AAAG4460	03/27/2019		Aderemi Dosunmu (ad3241).	
Submit Protocol	Use of Hazardous Chemicals in Animais(Appendix	E)	APE-AAAG4378	03/15/2019		Aderemi Dosunmu (ad3241)	
Copy Protocol Ontete Protocol	(%) Infectious Agents(Appendix B)		APB-AAAE7153	01/14/2019		Aderemi Dosunmu (ad3241)	
Bendered Marrie	Use of Hazardous Chemicals in Animals(Appendix	E)	APE-AAAG3727	11/21/2018		Aderemi Dosunmu (ad3241)	
Print Menu	Use of Hazardous Chemicals in Animals(Appendix	E) //	APE-AAA03055	08/30/2018		Aderemi Dosunmu (ad3241)	
View Datasheet	Use of Hazardous Chemicals in Animals(Appendix	E) dsfasdf	APE-AAA32982	09/21/2018		Aderemi Doşunmu (ad3241)	
View History	Recombinant DNA(Appendix A1)		APA1-AAAD6708	07/11/2018		Aderemi Dosunmu (ad3241)	
Human Subjects	Use of Hazardous Chemicals in Animas(Appendix	E)	APE-AAAG2609	05/13/2018		Aderemi Doslinmu (ad3241)	
Protocol Overview	- Laser(Appendix D)		APD-AAAA6101	04/25/2018		Aderemi Dosunmu (ad3241)	

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RASCAL Human Subjects

RB-AAAR9905 Itatus: Creating Protocol Context General Information Antibutos Funding Personnel Departmential Approvers Research Ams & Abstracts	AAR9905 I: Creating d Content al Information tes 19 annel Earth Appendix (3): @ Earth Appendix (4): @ Ear		Health Sci Risch (8211402) 100 Innmu (ad3241) Transfer (Append)7	with the imported on the Appendix. provided to staff to training requireme delay of the appro		rted pers dix. This aff to infor rements to pproval p	ted personnel, click ix. This can be iff to inform them of ements to prevent proval process.					
Attachments	Attach	ed Appendices	Title	Appendix Numb	er.	Date Created	Initi	tor	Appendix Letter	Action	Staff	Replace with a copy
Hazmats	Laser(Appendix D) test 12:	1.	APD-AAAA7100	04/	04/12/2019 Aderemi Dosunmu		(ad3241)	N/A	v	- Start	(uplace min a cop)
HIPAA Forms				2						<u>^</u>	1.80	13.
Documents												
Consent Form	All rele	ased Appendices to which you have h Type	access and are	not currently attached to a protocol. Title		Nom	ber		Date Created			Initiator
		Infectious Agents(Appendix B)		rwgerwar		APB-AAAE1801		01/26/2016		Aderemi Dosunmu (ad3241)		
Protocol Actions		Lise of Hazardous Chemicals in Anim	als(Annendix F)			APF-AAAF2R17		04/28/2016		Arterer	ni Dasuar	mu (ad3241)
Notity Approvers	30					14 E 1444 (617)						
Submit Protocol	S	Infectious Agents(Appendix B)		Determination of Cancer Genetics in Te	g Mice	APB-AAAE2256		04/27/2016	14/27/2016		Aderemi Dosunmu (ad3241)	
Copy Protocol	1	Use of Hazardous Chemicals in Anim	as(Appendix E)	sdafsaf		APE-AAAF9069		07/13/2016		Adeter	ni Dosuni	mu (ad3241)
Delete Protocol	2	Infectious Agents(Appendix B)		waefadf		APB-AAAE2960		11/10/2016		Aderer	ni Dosuni	mu (ad3241)
Protocol View	100	Recombinant DNA(Appendix A1)		Test Project		APA1-AAAD3004		04/27/2016		Aderen	ni Dosuni	mu (ad3241)
Print Menu		Decembinant DNA/Annandiy &1)		artanut		AD41.44403367		0000000		Advantation (Providence of the State)		
View Datasheet	2	Reconcinant Unixe(appendix A1)		enerwi		APA INANALI 3357		09/14/2016		Aderer	ni Dosoni	mu (ad3241)
View History	51	Recombinant DNA(Appendix A1)				APA1-AAAD3005		04/28/2016		Aderer	ni Dosuni	mu (ad3241)
Denne Deblede	-	Infectious Agents(Appendix B)				APB-AAAE7153		01/14/2019		Aderer	ni Dosun	mu (ad3241)
Protocol Overview	(9)	Use of Hazardous Chemicals in Anim	als(Appendix E)	dsfasdf		APE-AAAG2962		08/21/2018		Aderer	ni Dosuni	mu (ad3241)
- reserve a res right												

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Notify Approvers

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RB-AAAR9600	Abbreviated title	test	Protocol Number	AAARHOO
status: Creating	Originating Department	EHS Environment Health Science (821100K)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Content	Protocol Year	1 Modification 00	Date Created	04/12/2019 14:34:21
General Information	Principal Investigator	Aderemi Dosuninu (ad3241)	You are	Aderemi Dosunmu (ad3241)
Attributes	Approve Protocol			
Background	Contraction Contraction Contraction			
Exempt and Expedited	Click Here To Approve Protocol			
Funding	Contact Us (@ Columbia University BP			
Locations	Please contact the Human Research Protection Office If you have o CUMC Campus	uestions about submitting to the IRB, or whether this study requires review.		
Personnel	CT3: 305-5031 intoffice@solumbia.edu CU-MS and LDEO Campue (CT3) 851-70401 aslum@polumbia.edu			
Departmental Approvers				
Privacy & Data Security				
Procedures				
Recruitment And Consent				
Research Aims & Abstracts				
Risks, Benefits & Monitoring				
Subjects				
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r Ja	sia)	RASCAL Human Subjects	
pout <u>Help</u>	Human Subjects Animal Care Proposal Tr	king I Consent Forms I HPAA Forms I Haz Mass I Administration I Taning Canter I Conflict of Interest I Mv.Rescal	Complete HazMats
ASCAL Menu) IB Menul	Information Message Because this protocol has indicated to Appendix Attestation:	e use of human materials or other potentially infectious materials, the PI must complete an attestation of compliance to proper procedures. Please complete the attestation by clicking on the	Attestation before protocol submission
	Appendix D :		
	Laser Safety Signs will be por Appropriate Laser Safety Gog Written Standard Operating P Users are trained on the laser		
		Hit CERTIFY button only ONCE to complete attestation.	
		Cancel CERTIFY	
	Contract Lin L @ Columbia Linium rity I	Please Confirm	0
	Please contact the Human Research Prote CUMC Campus: (212) 305-5883 irboffice@columbia.edu CU-MS and LDEO Campus: (212) 881-7040 aski/ib@columbia.edu	Read the attestation carefully. Also, make sure all of the Hazardous Materials appendix information has been completed. If any changes are made to the attached appendices a Cancel OK	after this attestation, the protocol will need to be approved again.
		1	

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RASCAL Animal Care

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Status: Still Creating	Information Message
AC-AAAY7455	
General	Because this protocol has indicated the use of hazardous materials or other potentially infectious materials. the PI must complete an attestation of complete the attestation by circling on the button below.
Funding	
Pain Categorization	Appendix Attestation:
Personnel	Appendix A :
Locations .	
Drugs	 Personnel with exposure to human blood, united issues or cell ines will be informed that CU offers all stats the Hepatite 9 vaccine. The Vorcinal Investment set tails in the Associated contract of the Associated
Objectives .	The Principal investigation and the laboratory staff have taken the appropriate safety trainings on Rascal convided by EHAS (to determine trainings required, see
Animal Use	thes insearch columbs adulties before to test ST-STraining Catemining four Safey (raining Sequence), of P and for training scheduling see they insearch columbs equipments adult presser to columbs equipments
Surgery	Research staff must observe the following Regulated Medical Waste disposal procedures
Endpoint Criteria	Depose of symperineous (who we specified), service(a) specified update or places, place a molecular down single in a practice control in a practice c
Hazardoon Materiani	Please Confirm O
Standard Procedure Description	Read the attestation carefully. Also, make sure all of the Hazardous Materials appendix information has been completed. If any changes are made to the attached appendices after this attestation, the protocol will need to be approved again.
Attach Documents	Carceli DK
Protocol View	(a) For spitsmeleases, these the contaminated area with 10% household bleach solution (fresh) precared daily) for 20 minutes and their blean it (g). Dispose of all solid waske its neo bag waste.
Frint Meno	Accendix E1 :
Vew Datasneet	
Protocol History	 All engineering control devices used in conjunction with the protocol, including, but not limited to cherical turne hoods, are currently certified and properly maintained.
Copy Protocol	 Manageode spin are categorate as a chemical or biological release that is capable or being cleaned up by uporatory statt pased on their knowledge, solit, abilities, and the resource a variable to their as the time of the resiste. Chemical spin must be obtained up promptly, efficiently and protection.
	All staff are to be trained in the appropriate response to release of, or exposure to, protocol-related hazardous materials.
Protocol Action	All manageable chemical splits will be cleaned using the chemical specific split kit.
HazMats Atlestation	 All strahmangebile chemical spills should be immediately reported to E-MSE at <u>Immediately reported to E-MSE at Immediately reported to E-MSE at Immedia</u>
Submit Protocol	Medical attention we be sought in the event of an exposure at Wooldarce Health and Ballety of the NY Prestyletian Holpital Emergéncy Room
Delete Protocor	Personal protective equipment will be made available and used at all times during protocol activities involving potential exposure to hazandous chemicae. At a minimum, PPE will include goves, tao coats and protective eyewear.
	 Laboratione may not employated by a chemical and a ch
Animal Care	 Elementaria en escale cabacitación en escale en constructiva de la escale cabacitación en escale en escale escale en escale en esca escale en escale en escal
Protocol Overview	HIT CERTIFY button only ONCE to complete attestation
1ACUC Menu	(power 1 presented)
Previous List	URGB LEDITY
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RASCAL Animal Care

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Researcher Profile Page: Information can be auto-populated to your Appendix.

Instructions: On the HazMats Page click on "Researcher Profile.

A new page will open where Lab locations, Assets (Biosafety Cabinets, Fume Hoods, and Lasers), RAM permit Number, and Controlled Substance License can be added. When creating a new Appendix this information will auto-populate to the form.

Note: Researcher is responsible to occasionally check-in and update this information. So if the lab moves or obtains new engineering control certification dates, go into the Research Profile Page to update the information here so information in the Appendix will be accurate.

łaz Mats	READ AND PRINT GENERAL INSTRUCTIONS
Haz Mats Menu	Create an Appendix: ~Select~ Create
RASCAL Menu]	Researcher Profile
	Hepatitis B Vaccine Notification Form
	Human Subjects - JRSC Application
	Human Subjects - RDRC Application
	Retrieve an Appendix AP ~Select~ : XXXX0000 Retrieve
	Search for an Appendix
	Hazmats Reports
	Notification Queue
	Edit Personal Information
	<u>Safety Officer Approval Queue</u>
	Radiation Safety - Preliminary Review Queue
	 <u>Radiation Safety - Assign Primary Reviewer Queue</u>
	<u>Radiation Safety - Approval Queue</u>
	<u>Radiation Safety - Committee Queue</u>
	IRB Human Materials Attestation Search
	Contact Us @ Columbia University 앱
	Rascal, Research Administration and Compliance Application
	Columbia University Information Technology 615 West 131st Street, 5th Floor
	New York, NY 10027 Phone: (212) 851-0213

Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal

Haz Mats	The Researcher Profile page centralizes various items experience expedited and accurate Appendix completed	s of demographic information and other dat tion by including as much information in thi	a points for transfer and automated input into Haz N s profile as possible. Once complete, information wil	fats Appendices. Researchers ca I be added into any new
ridz widts wienu	Appendices that are created. Fields that have more the	an one entry will be available for selection	when completing an Appendix, and updated inform	ation will be available for input into
[RASCAL Menu]	new Appendices when the information is changed in t	he Profile page.		
	ab ocation(s)			
		0.11		
	Campus	Building	Room	Modify Delete
		No data to	display	
	II. Asset(s)			
	Assets 🕐			
	Asset	Certification Date	Registration Number	Modify Delete
		No data to	display	
	III. RAM Permit			
	RAM Permit Number:	Save RAM Permit N	umber	
	IV. Controlled Substances License(s)			
	Document Identifier:			
	Document Type: Controlled Substances License			
	File (max file size is 75 MB): Choose File N	o file chosen		
	Save Cancel			
	View Document File Name	Document Type	Date Created Edit	Detach
	The work occurrent File Marile	No data ta	diaplay	Detach
		no data to	uispiay	
	0 - 0 of 0 results			« <1 > » 50 ▼

EH&S Review & Correspondence

EH&S will review. If the Safety Officer has comments, this will be communicated when the protocol is returned by IRB. An Email notice will also go out via the Correspondence feature within RASCAL. The email sent via RASCAL will direct you to a link within RASCAL. Follow the link which will return you to the Protocol History. Open View your Correspondence under Safety Officer Hazmats Correspondence.

If there is a training deficiency and it is remedied, RASCAL will automatically update the training table. For other changes that need to be completed by editing the Appendix: Under Hazmats, click on the Appendix link in blue under "Attached Appendices" A new tab will open with the appendix. Make changes where relevant and select "Save" at the bottom of the form. Once the form has been saved successfully, the changes are synced to the IRB protocol. The tab can be closed. The Attestation will also need to be re-certified by the PI.

	🗄 ୭୦ 🕈	Ų ≑	Rascal Haz Mats Co	orrespondence for APD-AAA	A4250 attached to IRB-A	AAR9600 - Message (Pla				
	File Messag	ge Adobe PDF 🛛 🛛 Tell me what	you want to do							
	ि Ignore X Sunk ∗ Delete	Reply Reply Forward I More *	 Permanently de Stewardship Team Email Create New 	C To Manager C Reply & Delete ⊽	Move Actions	Assign Mark Categ				
	Delete	Respond	Quick Steps	5	Move	Tags				
	Fr	i 4/12/2019 3:42 PM								
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Fo	llow link	ond	for APD-AAAA4250 attached to IRB	-AAAR9600						
	Follow link ond the for APD-AAAA4250 attached to IRB-AAAR9600 10 ad5241@columbia.edu THIS IS A TEST OF RASCAL. PLEASE DISREGARD. Dear Aderemi Dosunmu, A correspondence has been sent to you in Rascal from Environmental Health and Safety in regards to your appendix. To view this correspondence, please click on the following link: https://test.rascal.columbia.edu/irb/protocol/AAAR9600/193650/history If you have any questions, please contact the Rascal Help Line at 212.851.0213 or rascal@columbia.edu . Please do not "reply" to this email. Research Administration System									

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IRB-AAAR9600	·		Assigned To. IRB 1	
Status: Returned Protocol Content General Information	Logged In Submitted Creating 1 - 4 of 4 results	View Corres	pondence	×
Attributes Background Exempt and Expedited	Researcher Hazmats Correspond	From To	Aderemi Dosunmu (sd3241) Aderemi Dosunmu (sd3241)	
Funding Locations Personnel	Filter keyword	* Subject	Rascal HazMats Correspondence for APO-AAAA42S0 attached to IRB-AAAR9600	
Departmental Approvers Privacy & Data Security Procedures	Safety Officer Hazmats Correspo	Hello, EH&S has rev appendix in H	iewed and returned your appendix. Please respond to the following concerns, and if necessary, make the requested changes to the Rascal.	:
Recruitment And Consent Research Aims & Abstracts Risks, Benefits & Monitoring		Notes/Message When resubmi specific char	e:Add another laser ting the appendix through Rascal, please also use the "correspondence" function in Rascal to send BH&S a message indicating th mase made or comments/ouestions/clarifications for the Safety Officer to review.	ie
Subjects Attachments	From: Aderemi Dosunmu From: Aderemi Dosunmu	For EH&S que reviewed the	stions, including questions about this correspondence, please contact EH&S at 212-305-6780 and ask for the Safety Officer who specific Appendix.	
Hazmats HIPAA Forms	Hazardous Materials History Hazard	Thank you, Columbia Uni	versity Environmental Health & Safety Office	
Documents Consent Form	Laser (Class 3b or 4) 1 - 1 of 1 results			i Dosunm
Protocol Actions	Department and Personnel Approval History	Approver	Approval Role	
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Departmental Approvers	Attached Appendices	Title	Appendix Number	Date Created	Initiator	Approval Letter Acti	ion Staff Rep	lace wit	h a co	py				
Privacy & Data Security	Recombinant DNA (rDNA) Molecules in Human Gene		APM-AAAA9050	06/19/2019	Aderemi Dosunmu (ad3241) N	/A 🗙	· 🔊 📍							
Procedures	Transfer(Appendix M)													
Biological Specimens	All released Appendices to which you	have access and	are not currently attached to	a protocol.										
Drugs/Biologics	Attach Type		Title	Num	iber	Date Created	Initi	ator						
Existing Data	Use of Hazardous Chemicals i Animals(Appendix E)	n		APE-AAAG5127	05/10/2019	,	Aderemi Dosunmu (a	3241)						
Recruitment And Consent	Biosafety(Appendix A)			APA-AAVA3788	05/24/2019	,	Aderemi Dosunmu (a	3241)						
Research Aims & Abstracts	Recombinant DNA (rDNA) Mol Human Gene Transfer(Append	lecules in fix M)		APM-AAAA7050	06/06/2019	,	Aderemi Dosunmu (a	3241)						
Risks, Benefits & Monitoring	Use of Hazardous Chemicals i	n		APE-AAAG5767	06/10/2019		Aderemi Dosunmu (a	3241)						
Subjects	Biosafety(Appendix A)			APA-AADD3757	05/01/2019		Aderemi Dosunmu (a	3241)						
Attachments	Formaldehyde(Appendix E2)			APE2-AAAB2073	06/13/2019		Aderemi Dosunmu (a	3241)						
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	*Department Affiliation: N/ *IRB Number: A/	A AR5960					
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py Appendix	*Describe briefly the vector/gene insert construct and provide a description of the cells in which it is produced.		
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nandix Maw	"If the vector is designed to be replication incompetent, note how this was accomplished. Copy relevant information from investigators' brochure here.		
ew History	test		
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ew Correspondence	4/2000		
z Mats	Identify and summarize any biosafety concerns for patients administered this therapy. These could be (1) hypothetical concerns based on the nature of the therapy.		
az Mats Menu	(2) concerns based on preclinical data, or (3) anticipated adverse events from past clinical studies, 4/2000		
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EH&S Approval and Correspondence

When EH&S has approved the Appendix, a notification will also be sent via IRB notification. If an approval letter is desired, please ask EH&S Safety Officer. A letter can be generated within RASCAL and a correspondence will be sent from RASCAL. to the PI and the initiator in an email sent via RASCAL. Follow the Link in the email to view your correspondence. DO NOT REPLY to email, this will not go to EH&S.

If EH&S generated an approval letter, you will also receive an email with a link to the letter.

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HazMats Approval Letter Finalize	ed for Appendix Laser(Appendix D)	
To ad3241@columbia.edu		
Obtain Approval letter by following Link To: Aderemi Dosunmu and Aderemi Dosunmu		
Subject: Rascal Haz Mats Appendix AAAA3150	Approval Letter	
Hello,	4	
EH&S has generated an approval letter for your H2. To view the approval letter, please click on the follo	dous Materials appendix. wing link: <u>https://test.rascal.columbia.edu/hazma</u>	ts/appendix/D/AAAA3150/approvalLetter/pdf
Thank you, Columbia University Environmental Health & Safety	Office	

Approval letter

April 11, 2019 TO: Aderemi Dosumu FROM: Environmental Health and Safety RE: APD-AAAA3150 Protocol Title: test 123 Approval Date: 04/11/2019 Expiration Date: 04/09/2021 Thank you for your submission of D for using hazardous materials for research work. Please accept this letter as an indication of approval by Columbia University's Environmental Health and Safety. As a reminder, the laboratory must comply with Columbia University Policy and all applicable regulations concerning laboratory safety and handling of hazardous materials. This includes, but is not limited to, EPA, OSHA, DEA, New York State and City regulations. Thank you, Aderemi Dosumu		COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
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