# How to Create Appendices and Attach to an IRB Protocol

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

- 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.



laz 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~      Select~	Retrieve
	Search for an Appendix	
	<u>Reports</u>	
	Notification Queue	
	Edit Personal Information	
	<u>Safety Officer Approval Queue</u>	
	Radiation Safety - Preliminary Review Queue	
	Radiation Safety - Assign Primary Reviewer Queue	
	<ul> <li>Radiation Safety - Approval Queue</li> </ul>	
	Radiation Safety - Committee Queue	
	IRB Human Materials Attestation Search	
	Contact Us j @ Columbia University 앱	
	Rascal, Research Administration and Compliance Application Columbia University Information Technology 615 West 131 at Street, 5th Floor New York, NY 10227 Phone (131) 855-021	

# 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**

PA-AAAD8750 Status: Creating	MULTIPLE SECTIONS: Complete in order	safety (Appendix A	.)	
Appendix Content		Sut	ject Species N/A	
General	Title			
Microorganism Information	Creation Date 04/09/2019 09:23:38		Initiator Aderemi Dosunmu (ad3241)	
luman Tissue and Cell	You are Aderemi Dosunmu (ad3241)	Append	ix Submitted	
Culture Section Safety Equipment and Practices	I. General Information	General Instructions 🥹	General instructions ex out appendix appropria	-
rersonnel	*The appendix will be: ~Select~   👻			
Protocol/Proposal	*Project Title:			0 / 255
ppendix Action	*Describe methodologies/manipulations of the work performed. In b goals. If applicable, include any recombinant DNA gene manipulation			nplish these
opy Appendix				0 / 500
)elete Appendix	*Are there any relevant vaccinations or work restrictions/considerat	tions that should be acknowle	dged in regards to work with the biological mater	ial? 🥹
ppendix View	Hepatitis B Vaccination     Rabies Virus Vaccination			
/iew History	Immunocompromised Status			
iew Datasheet	Pregnancy			
	Non-Applicable			
az Mats	Other: 🕜			
laz Mats Menu	*If a lab acquired infection were to occur, what therapy is available?	': 🕜		
RASCAL Menu]				0 / 200
	*II. Collaborations/Procurement 💡			
	*Where will the biological materials (viral vector/bacteria/virus/clini	ical specimen/cell line/other n	icroorganism) be procured from? 💡	
	Company/Core Facility/Repository:			
	Collaborator (Name/University):			
	Other:	NA or infectious material is a	and between different computers of Columbia	
	*Will this project be a research collaboration where recombinant DI Yes No			
		MA an infection or stanial is all		

"Will this project be a research collaboration where recombinant DNA or infectious material is shared between different institutions? O Yes O No

#### \*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.

*Does the research in question meet the definition of dual use research of concern? $\bigcirc$ Yes $\bigcirc$ No
--

#### IV. Laboratory Location

#### \*Laboratory Locations 🜔

Campus	Building	Room	Modify	Delete
	No data to disp	lay		

#### V. Recombinant DNA

*Is Recombinant DNA being used? 🥹	⊖Yes ⊖No	
Save Contact Us   © Columbia University \$7 Rascal, Research Administration and Compliance Appl	SAVE: Work will be deleted if not saved after each section	
Columbia University Information Technology 615 West 131st Street, 5th Floor		-

PA-AAAD8751 tatus: Creating		Bio	safety <mark>(</mark> Appendix A)		
Appendix Content	Appendix Number	AAAD8751	Subject Species	N/A	
General	Title				
dicroorganism Information	Creation Date	04/09/2019 10:40:31	Initiato	Aderemi Dosunmu (ad3241)	
dicroorganism in Animals	You are	Aderemi Dosunmu (ad3241)	Appendix Submittee		
	*Document Type ~Select~ + *File (max file size is 75 MB):	Choose File No file chosen			
Practices Personnel Attachments					
Practices Dersonnel Attachments Protocol/Proposal	*File (max file size is 75 MB):	Choose File No file chosen File Name Document Type	Date Attached Attached	By Edit	Detach
Practices Personnel Attachments Protocol/Proposal ppendix Action	*File (max file size is 75 MB):	Choose File No file chosen File Name Document Type		By Edit	Detach
Safety Equipment and Practices Personnel Attachments Protocol/Proposal Appendix Action Copy Appendix Delete Appendix	*File (max file size is 75 MB):	Choose File No file chosen File Name Document Type	Date Attached Attached ata to display	By Edit	Detach

## 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.

Logout   Help   Human Subjects   Animal Care		AL Hazardous	Materials		
	e   <u>Proposal Tracking</u>   <u>Consent Forms</u>		raining Center   Conflict of Interest   My Rascal		
PD-AAAA7100 tatus: Creating			Laser (Appendix D)		
Appendix Content	Appendix Number AAA	A7100	Subject Spec	ies N/A	
General	Title				
Personnel	Creation Date 04/0			Aderemi Dosunmu (ad3241)	
Attachments	You are Ade	remi Dosunmu (ad3241)	Appendix Submit	ted	
Protocol/Proposal				General instructions ex	-
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laz Mats	5	( )			
Li	st the EH&S Approval number is link and attach to the Apper	r(s) of the Laser System(s) used in render, using the Attachments tab: htt	elation to this Laser Appendix. If a new re ps://finance.columbia.edu/files/gateway/f	egistration form needs to be created, fill ou forms/LaserRegistrationForm.pdf 🖉 🤬	it the form at
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Pi	ck laser registration number(s	s) from the following or enter anothe	r below:		0 ( 100
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ments to	agar Uga				
endix, use	Laser Use				
	Are Laser system(s) service/m	naintenance performed by an author	ized service provider? 🤷		
	⊖Yes ⊖No				
*#	Add Laser(s) 🕖				
	Serial Number	r Maximum Expec	ted Exposure Duration (hours per day)	Description N	Modify Delete
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# Adding Attachments to Appendix D:

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W Jasta) RAS	SCAL Hazardous Materia	als		
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APD-AAAA7100 Status: Creating	Laser (Aj	opendix D)		
Appendix Content Appendix Nu	nber AAAA7100	Subject Species	N/A	
General	Title dfdsa			
Personnel Creation	Date 04/09/2019 09:57:39	Initiator	Aderemi Dosunmu (ad3241)	
Attachments	are Aderemi Dosunmu (ad3241)	Appendix Submitted		
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Contact Us   © Columbia Univers Rascal, Research Administration Columbia University Information 615 West 131st Street, 6th Floor New York, NY 10027	and Compliance Application			,

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.

RASCAL Hazardous Materi	als
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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		
	Protocol/Proposal		General In	structions 😗	General instructions explain	how to fill
	Appendix Action	Note: Do not include Isoflurar	e or Formaldehyde, there is a separate Appendix for	each of those substances.	out appendix appropriately	
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То	attach	VI. Emergency Response				
doo	cuments to	What are the emergency procee	lures in the event of personnel exposure?			
Δn	pendix, use	*Acute symptoms of exposure				
• •	-	*Actions taken in event of expo	osure:			
Αττ	achments Tab		vent of a spill (facility or environmental contaminati	on):		
		*Location of Spill Kit: *Actions taken in event of cont	amination/spill: 🧿			
			ination of skin, clothing, apparatus, etc.:			
		*Is a biological toxin used?	OYes ● No			
			s and metabolic products of the compounds, if app	icable: 🥹		
		*What is the biological 1/2 life *What is the toxicity (if any) of	of the administered compounds?			
			t be used or specific waste instructions are to be gi			
		Safety and Chemical Hygiene Ori	al Exposures to Hazardous Chemicals in Laboratories ( entation (LSCHO) Session INITIALLY. These sessions a trainings do expire and refresher trainings must be take	re offered twice monthly by EH	t persons working with chemical(s) attend a Laboratory &S and can be scheduled locally if desired. It is also	
		Save	SAVE: Work will be delet	ed if not		1
		Contact Us   © Columbia University 🗗	saved after each section			
		Rascal, Research Administration and Complia Columbia University Information Technology 616 West 131st Street, 6th Floor New York, NY 10027 Phone: (21) 861-0213	nce Application			

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# Adding Attachments to Appendix E:

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🗤 Jasia)	RASC	AL Hazardous Materia	ls		
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APE-AAAG4600 Status: Creating		Hazardous Chemi	icals <mark>(</mark> Appendix E)		
Appendix Content	Appendix Number	AAAG4600	Subject Species	N/A	
General	Title		1		
Personnel		04/09/2019 16:34:44	Initiator		
Attachments	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted		
Protocol/Proposal	III. Attachments				
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	Contact Us   © Columbia University Rascal, Research Administration and Co Columbia University Information Technol 615 West 1315 street, 5th Floor New York, NY 10027 Phone: (212) 851-0213	mpliance Application agy			

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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.

: Creating		Isoflurane (Ap	pendix E1)			
lix Content	Appendix Number	AAA0050	-	Species N/A		
I	Title		cubject			
iel	Creation Date	04/09/2019 17:10:37		Initiator Aderem	ni Dosunmu (ad3241)	
ents	You are	Aderemi Dosunmu (ad3241)	Appendix S	ubmitted		
/Proposal		General Instruc	tions 🕜	General	instructions	explain how to fill
Action	Isoflurane is a hazardous che	nical with a regulatory permissible exposure limit establis	hed the Oc		endix approp	-
endix		Principal Investigator/Initiator confirms awareness of the I		ourappe		inatery.
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Menu]	II. Amount and Equipmen	t.				
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	Certified Chemical Fume i Ducted Biological Safety C Active Engineering Contro Passive Engineering Contro Laboratory works on an op Other: "The laboratory will be impl Utilization of a digital vapo Lab will califorate their isof Canisters will be weighed Follow time limit guideline Lab will limit ordering and Canisters will be disposed	abinet (Class II, Type B1 or B2) (Vacuum Pump w/Charcoal Canister) ol (Charcoal Canister) en bench top without any engineering controls and has been menting one or all of the below administrative controls of izer urane vaporizer from an outside vendor and the weights recorded before and after each use as recommended by EH&S to minimize isoflurane exposure. on-site storage to amounts used of as hazardous waste ing the appropriate personal protective equipment includ	uring work with	ronmental Health a	and Safety 🥥 k all that apply):	:

### 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	AAAA0050	Subject Species	N/A				
Appendix Content	Title				-			
General		04/09/2019 17:31:05		Aderemi Dosunmu (ad3241)	-			
Personnel	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted					
Attachments		General Ins	tructions 😗 Ger	neral instructions explain how	w to fill			
Protocol/Proposal	Formaldehyde is a hazardous	chemical with a regulatory permissible exposure limit,		appendix appropriately.				
Appendix Action	submitting this appendix, the	Principal Investigator/Initiator confirms awareness of t	zardous natu					
Copy Appendix	I. General Information							
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Haz Mats	II. Chemical Used For:							
Haz Mats Menu	II. Chemical Used For:				7			
[RASCAL Menu]	OHuman Subject Research	⊙ OAnimal Subject Research OIn vitro Research						
	III. Type of Formalin/Form	aldehyde:						
					1			
	Formalin/Formaldehyde Paraformaldehyde (PFA)							
	IV. Laboratory Location							
	*Laboratory Locations ()							
	Laboratory Eccations							
	V. Hazard Control				_			
	Certified Chemical Fume Ho	least one of the engineering controls listed while work od	ing with formaldehyde. (Che	ck all that apply):				
	Glove Box Downdraft Table							
	Ducted Biological Safety Ca	binet (Class II, Type B1 or B2)						
	Cther:	n bench top without any engineering controls and has cont	acted Environmental Health ar	io Salety at occusatety@columpla.eou				
	*The laboratory will be impler Lab will limit ordering and or	henting one or all of the below administrative controls -site storage to amounts used	during work with formaldehy	yde. (Check all that apply):				
	Proper storage and labeling	of chemicals and hazardous waste  😗						
		with amounts smaller than 0.1 mL with amounts larger than 0.1 mL and have contacted Envir	onmental Health and Safety a	t occusafety@columbia.edu				
	*The laboratory will be utilizin	g the appropriate personal protective equipment inclu	ding:					
	*Disposable Gloves: Nitrile	Latex Vinyl						
	Safety Glasses/Goggles							
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# 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** 





### RASCAL Human Subjects

Logast | Hele | Zenner Kitterkit | Animel Care | Process Techno | Contern Forms | HERA Forms | Haz Mats | Administration | Techno Carder | Contest of Interest | Mr. Resout

AAR9905	Abbreviated title	disdidisal		Protocol Number	AAAR9905		
s: Creating	Originating Department	EHS Environ Health Sci Rsch (8211402)		Protocol Initiator Aderemi Dosunmu (ad3241)			
of Content	Protocol Year	1 Modification 00		Date Created	ed 07/11/2018 12:19:56		
al Information	Principal Investigator	Aderemi Dosunnu (ad3241)		You are	Aderemi Dosunmu (ad3241)		
tes	Hazmats						
19	Helpful Information: 🥹						
nnel	Biosafety (Appendix A); Laser (Appendix D);						
partmental Approvers	Hazardous Chemicals (Appendix E): 🥹						
rch Aims & Abstracts	Formaldehyde (Appendix E2): @ Radiation Safety (Appendix H): @						
Inti Millo a Mostalito	Use of Recombinant DNA (rDNA) Molecules in	Human Gene Transfer (Appendix M): 🥹			Find Apr	pendix relevant to	
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nt Form	All released Appendices to which you have ac	cess and are not currently attached to a protocol.	Later teachers			A-1975	
	Attach Type	Title	Number		Date Created +	Initiator	
	Laser(Appendix D)	test 123	APD-AAAA7100	04/12/2019		Aderemi Dosunmu (ad3241)	
Approvers	Use of Hazardous Chemicals in Animals	(Appendix E) Differentiating Radiosensitivities and Niche Factors among Intestinal Stem Cell Pools	APE-AAAG4460	03/27/2019	,	Aderemi Dosunmu (ad3241)	
12000 B 00	1.00						
t Protocol			APE-AAAG4378	03/15/2019	1	Aderemi Dosuhmu (ad3241)	
t Protocol Protocol	Use of Hazardous Chemicals in Animals		APE-AAAG4378 APB-AAAE7153	03/15/2019			
	Use of Hazardous Chemicals in Animale	(Appendix E)	APB-AAAE7153	01/14/2019	4	Aderemi Dosunmu (ad3241)	
Protocol Protocol	Use of Hazardous Chemicals in Animals	(Appendix E)		and the second sec	4		
Protocol Protocol	Use of Hazardous Chemicals in Animals Use of Hazardous Agents(Appendix B)	(Appendix E) (Appendix E)	APB-AAAE7153	01/14/2019		Aderemi Dosunmu (ad3241)	
Protocol Protocol ol View	Use of Hazardous Chemicals in Animals S Infectous Agents(Appendix B) Use of Hazardous Chemicals in Animals Use of Hazardous Chemicals in Animals Use of Hazardous Chemicals in Animals	(Appendix E) (Appendix E) (Appendix E)	APB-AAAE7153 APE-AAAG3727	01/14/2019 11/21/2018 08/30/2018	, , ,	Aderemi Dosunmu (ad3241) Aderemi Dosunmu (ad3241) Aderemi Dosunmu (ad3241)	
Protocol Protocol	Use of Hazardous Chemicals in Animats Use of Hazardous Chemicals in Animats	(Appendix E) (Appendix E) (Appendix E)	APB-AAAE7153 APE-AAAG3727 APE-AAAG3055 APE-AAAG2062	01/14/2019 11/21/2018 08/30/2018 08/21/2018	2 2 2 2 2	kderem Dosunmu (ad3241) kderem Dosunmu (ad3241) kderem Dosunmu (ad3241) kderem Dosunmu (ad3241)	
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# RASCAL Human Subjects

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rolocol Conlant	Protocol Year 1 Modil	ication 00		Date Created 07/11/2018 12:19:56		
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Attributes	Hazmats					
inding	Helpful Information: 🧑					
tersonnel.	Biosafety (Appendix A): 🤣 Laser (Appendix D): 🥹					
Departmental Approvers	Hazardous Chemicals (Appendix E):			0		
Research Aims & Abstracts	Radiation Safety (Appendix H): 0 Use of Recombinant DNA (rDNA) Molecules in Human		Is Appendix Staff Check	-Off		
Cachments	Attached Appendices	Check staff to be included in appendix APD-AAAA7100	3		-	
lazmats	Type Ti	Select	Name	Role	Appendix Letter	Action Staff Replace with a copy
IPAA Forme		Aderemi Dos	sunmu (ad3241) Principal In	vestigator		
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Donsent Form	All released Appendices to which you have access an Attach Type				Date Created	* Initiator
rotocol Actions	S Laser(Appendix:D)		Itach Appendix			Aderemi Dosunmu (ad3241)
otity Approvens	Use of Hazardous Chemicals in Animals(Append	dx E) Differentiating Radiosensitivities and Niche Factors among Intestinal Stem Cell Pools	APE-AAAG4460	03/27/2019		Aderemi Dosunmu (ad3241)
ubmit Protocol aoy Protocol	Use of Hazardous Chemicals in Animate(Append	SX E)	APE-AAA/34378	03/15/2019		Aderemi Dosunmu (ad3241)
Delete Protocol	Infectious Agents(Appendix B)		APB-AAAE7153	01/14/2019		Aderemi Dosummu (ad3241)
rotocol View	Use of Hazardous Chemicais in Animals(Append	5× E)	APE-AAAG3727	11/21/2018		Aderemi Dosunmu (ad3241)
rint Menu	Use of Hazardous Chemicals in Animals(Append	ax E)	APE-AAA03055	06/36/2018		Aderemi Dosunmu (ad3241)
/ew Datasheet	Use of Hazardous Chemicals in Animals(Appen	3× E) defaedt	APE-AAA32982	05/21/2018		Aderemi Dosunmu (ad3241)
lew History	Recomplinant DNA(Appendik A1)		APA1-AAAD6708	07/11/2018		Aderemi Dosunmu (ad3241)
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## **RASCAL Human Subjects**

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n Ame & Abstracts nents			Appendix Number	Date Created	Initiator Aderemi Dosunmu (ad3241)	Appendix Letter	Action Staff Replace with a copy
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oprovers	Use of Hazardous C	Chemicals in Animals(Appendix E)		APE-AAAF8817	04/28/2016	Ð	Aderemi Dosunmu (ad3241)
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# **Notify Approvers**

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## **RASCAL Human Subjects**



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**RASCAL** Human Subjects

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and the second	Originating Department	EHS Environment Health Science (821100X)	Protocol Initiator	Aderemi Dosunmu (ed3241)
rotocol Content	Protocol Year	1 Modification 00	Date Created	04/12/2019 14:34:21
General Information	Principal Investigator	Aderemi Dosunmu (ad3241)	You are	Aderemi Dosunmu (ad3241)
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unding	Contact Us ( @ Columna University @			
ocationa	Please contact the Human Research Protection Office If you have to CUMC Campus	estions about submitting to the IRB, or whether this study requires revers.		
Personnel	CUNC Carrous (212) 305-5503 / Itonfoc@columbia.adu CUNCS and LDEO Carrous (212) 851-75403 astim@columbia.adu			
Departmental Approvers	(A relieve and the second s			
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	Appendix D :		
	<ul> <li>Appropriate Laser Safety Gog</li> </ul>	ted on the entrance door to the leser use room. gles/Glasses will be used by every person in the leser use room. codures (SCP9) are available for the leser system(s) in use. system specific SOP.	
		Hit CERTIFY button only ONCE to complete attestation.	
		Cancel CERTIFY	
	Contact Us   @ Columbia University t	Please Confirm	0
	Clinet: 09 / 6 Colonials Onversity is Please contact the Human Research Prote CUMC Campus: (212) 305-55831 irboffice@columbia.edu CU-MS and LDEO Campus: (212) 851-70401 askitb@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 Cancell OK	after this attestation, the protocol will need to be approved again.
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#### RASCAL Animal Care

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atus: Still Creating	Information Message
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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.

laz 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
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	Hazmats Reports
	Notification Queue
	Edit Personal Information
	<u>Safety Officer Approval Queue</u>
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	<u>Radiation Safety - Committee Queue</u>
	IRB Human Materials Attestation Search
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	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 Haz Mats Menu	The Researcher Profile page centralizes various item experience expedited and accurate Appendix comple				
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#### **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.

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	Follow link       onder of or APD-AAAA4250 attached to IRB-AAAR9600         10       803241gcoumba.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								

Logout Help	RASCAL I			
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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 t	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		When resubmin	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		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 Notify Approvers		Approver	Approval Role	
Approve Protocol	Aderemi Dosunmu (ad3241) 1 - 1 of 1 results		Principal Investigator HAS NOT A	PPROVED

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Logout   Help   Human Subjects   Anim	al Care   Proposal Tracking   Consent Forms   HIP.	AA Forms   Haz Mats	Administration   Training Center   Co	nflict of Interest   My Rascal						
IRB-AAAR5960	Abbreviated title	tes			Protocol Number	AAAR5960				-
Status: Creating	Originating Department	EHS Research (82	21140X)		Protocol Initiator	Aderemi Dosunmu (ad3241)				
Protocol Content	Protocol Year	1 Modification 00			Date Created	09/21/2017 11:34:18				
General Information	Principal Investigator		Select the	link to	You are	Aderemi Dosunmu (ad3241)				
Attributes	Hazmats									
Background	Helpful Information: @		directly ed	it the						
Exempt and Expedited	Biosafety (Appendix A): 2 Laser (Appendix D): 2		appendix							
Funding	Hazardous Chemicals (Appendix E): Formaldehyde (Appendix E2): 9	0	appendix							- 1
Locations	Radiation Safety (Appendix H): 😗			_	-					
Personnel	Use of Recombinant DNA (rDNA) Mole	ecules in Human (	Transfer (Appendix M):	3						
Departmental Approvers	Attached Appendices Type	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 Animals(Appendix E)	,		APE-AAAG5767	06/10/2019		Aderemi Dosunmu (a	3241)		
Subjects	Biosafety(Appendix A)			APA-AADD3757	05/01/2019		Aderemi Dosunmu (a	3241)		
Attachments Hazmats	Formaldehyde(Appendix E2)			APE2-AAAB2073	06/13/2019		Aderemi Dosunmu (a	3241)		
Documents	Formaldehyde(Appendix E2)			APE2-AAAB2055	06/10/2019		Aderemi Dosunmu (a	3241)		_
Consent Form 👻	Use of Hazardous Chemicals i Animals(Appendix E)	n		APE-AAAG5202	05/13/2019	,	Aderemi Dosunmu (a	13241)		•

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APM-AAAA9050 Status: Creating (Protocol Status)		of Recombinant DNA (rDNA) I			_		Î
Appendix Content	Appendix Number	AAA9050	Subject Species	N/A	_		
General	Title				_		
Personnel		06/19/2019 16:22:24		Aderemi Dosunmu (ad3241)	_		- 1
	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	N/A			- 1
Attachments		G	eneral Instructions 😗				- 1
Protocol/Proposal							- 1
Appendix Action	I. General Information						- 1
Copy Appendix					1		
Delete Appendix	*Principal Investigator: N/						
	*Department Affiliation: N/ *IRB Number: A/	A AAR5960					
Appendix View			4 / 255				
View History	Toject nue.	est					
View Datasheet							
View Correspondence	"Select the recombinant i	material(s)/product(s) to be administered, and	I fill in the specific Trade name:				
	Lentivirus:						
Haz Mats	Adeno-Associated	Virus: AAV9					
Haz Mats Menu	L						
[RASCAL Menu]	Adenovirus:						
	Herpes Simplex Vir	rus:					
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Masta)	RASCAL Hazardous Materials			
	Timere win une material de receiveu, sioneu, prepareu, anu auministereu :			
M-AAAA9050 itus: Creating	4/200			
rotocol Status)	"How will the material be prepared for administration?			
pendix Content	4/2000 -			
eneral	*Describe the procedures in the event of spill:			
ersonnel	4/200			
tachments				
otocol/Proposal	III. Recombinant DNA Information			
opy Appendix	*Describe briefly the vector/gene insert construct and provide a description of the cells in which it is produced.			
elete Appendix	test			
pendix View	"If the vector is designed to be replication incompetent, note how this was accomplished. Copy relevant information from investigators' brochure here.			
ew History	test			
iew Datasheet	*Provide a history of testing for replication competent virus [i applicable to the product, and if any such testing will be done as part of this project? You may copy or cite the relevant page(s) from the clinical investigators' brochure to provide this information.			
ew Correspondence	test			
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.			
iz Mats Menu	(2) concerns based on preclinical data, or (3) anticipated adverse events from past clinical studies.			
ASCAL Menu]	test			
	"Does data on localization and shedding a After editing the			
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	Rascal Research Administration and Compliance Applicatio Columbia University Information Technology 615 Weit 135 Used: 519 Prior New York, NY 10027 Prene: (12) 6542015			

#### **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.

<b>⊟</b> 5 ଓ ↑ ↓ =	HazMats Approval Letter Fi	nalized for Appendix Laser(Appendix D) - Message (Pl
File Message Adobe PDF Q Tell me what	you want to do	
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Rascal <no-reply-rascal@< td=""><td>@columbia.edu&gt;</td><td></td></no-reply-rascal@<>	@columbia.edu>	
HazMats Approval Letter Finalize	d 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	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/hazmats/a</u>	ppendix/D/AAAA3150/approvalLetter/pdf
Thank you, Columbia University Environmental Health & Safety	Office	

### **Approval letter**

TO: Aderemi Dosunmu FROM: Environmental Health and Safety RE: APD-AAAA3150 Protocol Title: test 123 Approval Date: 04/01/2019 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 aboratory 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 Dosunmu		COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
TO: Aderemi Dosunmu FROM: Environmental Health and Safety RE: APD-AAAA3150 Protocol Title: test 123 Approval Date: 04/01/2019 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 aboratory 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 Dosunmu		ENVIRONMENTAL HEALTH AND SAFETY
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 Dosunmu	April 11, 2019	
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 Dosunmu	TO: Aderemi	Dosunmu
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Recording Secretary Environmental Health & Safety		