How to Create an Appendix M-Human Gene Therapy and Attach to 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 menu to choose Appendix M.
- 3. (For Continuations/Modifications that have been previously approved by the IBC, a skeleton Appendix M can be created. Please email <u>Biosafety@columbia.edu</u> for further instruction)
- 4. See tips and instructions below. Starting on Page 5 are instructions on how to attach to IRB protocol.
- 5. <u>NOTE</u>: For Human Gene Therapy Trials-DO NOT SUBMIT AN APPENDIX A. Do not email documents to EH&S, please attach documents to the Appendix M.

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Logout Help Human Subjects Animal Care Prop	osal Tracking Consent Forms HIPAA Forms Haz Mats Administration Training Center Conflict of Interest My Rascal	
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	Contact Us @ Columbia University Project 8JSCAL Councils University Information Technology 653 West 3JSLS Street, 58 R Floor New York, IV 10027 Phone: (212) 851-0213	

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	READ AND PRINT GENERAL INSTRUCTIONS
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	IRB Human Materials Attestation Search
	Contact Us © Columbia University 🛱
	Rascal, Research Administration and Compliance Application CoLumbia University Information Technology 915 West Tables Street, China Page New York, NY 10027

For Appendix M

<u>**Tips</u>**: If the Sponsor assists in answering the questions, you can click on View Datasheet for an empty PDF to send to the Sponsor.</u>

Instructions:

- 1. Fill out Appendix M. Fill out First Section "General". Click Save.
- 2. When attaching the required documents, use the Attachments section in the Left hand side.
- 3. **Do not Add personnel in Appendix**, Personnel from your IRB protocol will be automatically imported to the Appendix during the IRB submission process.
- 4. Navigate to your IRB protocol to attach the Appendix M.

Status: Creating	Use of Re	combinant DNA (rDNA	A) Molecules in Human Ger	ne Transfer (Appendix M)	
Appendix Content	Appendix Number AAAA0	052	Subject Spec		
General	Title				
Personnel	Creation Date 04/15/2	019 11:12:03	Initia	ator Aderemi Dosunmu (ad3241)	_
Attachments	You are Aderen	i Dosunmu (ad3241)	Appendix Submit	ted	
Protocol/Proposal			General Instructions @	General instructions expl	ain how to fil
Appendix Action	I. General Information			out appendix appropriate	ly.
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	Herpes Simplex Virus:	15			
	Glycoprotein-deleted Rabie	s virüs: /irus:			
	Vaccinia:	///105.			
	Plasmid:				
	Other:				
	*Sponsor:				1
	*Company Name:				
	*Address:				
	*Contact Person and Title: *Phone Number:				
	Als the recombinant material com	ing from the Sponsor? Ves	No		1
	*Is this part of a multi-center stur	tv2 OVes ONo	140		
	*If applicable, will the trial be reg	istered with the NIH Office of Scie	ence Policy (OSP)? OYes ONo		
	*How will Safety Data, Serious A	dverse Events, incidents, and oth	er unanticipated events be reported and	who will be responsible for reporting?	
				6/300	
	*Will the following vaccines/pers	onnel limitations be applicable to	those who will handle, administer, or ot	therwise have exposure to the product? (Check all that	
	appiy):				
	III. Recombinant DNA Information	ı			
	*Describe briefly the vector/gene ins	ert construct and provide a desc	ription of the cells in which it is produced	d.	
				0/300	
	*If the vector is designed to be replic	ation incompetent, note how this	was accomplished. You may copy or cit	te the relevant page(s) from the clinical investigators'	
	brochure to provide this information			0/300	
	*Provide a history of testing for repl	cation competent virus if applica	ble to the product, and if any such testin	g will be done as part of this project? You may copy or	
	cite the relevant page(s) from the cli	nical investigators' brochure to p	rovide this information.	0/300	
	*Identify and summarize any biosafe (2) concerns based on preclinical da	ty concerns for patients administ ta, or (3) anticipated adverse even	tered this therapy. These could be (1) hyp nts from past clinical studies.	oothetical concerns based on the nature of the therapy,	
	*Does data on localization and shed	ding exist? •Yes ONo			
	*Will there be any assessment of	shedding as part of this project?	⊖Yes ⊖No		
	*What is the expected persistence	e of recombinant material and ge	ne expression in patients?	0/200	
	*Will it be necessary for patients *What provisions (if any) will be i	to limit their types of personal co n effect to isolate patients from s	ntacts? OYes ONo usceptible individuals who may be prese	nt in clinical areas while viral shedding may be	
	occurring?			0/200	

Adding Attachments to Appendix M:

NOTE! Provide 2 printed hard copies of each attached document to the IBC. Package can be dropped off at Biosafety Office on W168th St. Suite 54.

Required Documents:

- If the Sponsor (not the PI) will be responsible for the reporting requirements, PI must submit a copy of the letter sent to the NIH
 Office of Biotechnology and Activities (OBA) of this delegation.
- The scientific abstract. The abstract from the grant proposal may be used.
- A copy of the Clinical Investigator's Brochure.
- The Informed Consent Document that is currently (or will be) under consideration by the University's Institutional Review Board (IRB).

Suggested Documents (the NIH no longer requires some documents below, so disregard submission of NIH documents if not available):

- (Applicable only if there is RAC review) If the aforementioned response, 'Outcome of the Initial Review by the Recombinant DNA Activities Committee', indicates comments by RAC members, this must be attached.
- Annual Safety Report/Information on Serious Adverse Events/Unanticipated Events (only required upon renewal)
- The Sponsor's NIH submittal as per Appendix M of the rDNA Guidelines, Considerations for Human Gene Therapy.
- A copy of the NIH's response to the Sponsor's Appendix M submittal.



RASCAL Hazardous Materials

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ersonnel	You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	
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rotocol/Proposal	III. Attachments			
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and in Mana	The scientific abstract.	The abstract from the grant proposal may be us	ed.	
pendix view	A copy of the Clinical In	vestigator's Brochure.		u inu Roond (IRR)
ew History	I he informed Consent i	Jocument that is currently (or will be) under cor	isideration by the University's institutional Re	eview board (IRD).
ew Datasheet	Suggested Documents:			
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az Mats Menu	Annual Safety Report/In	iformation on Serious Adverse Events/Unanticip	pated Events (only required upon renewal)	
ASCAL Manual	The Sponsor's NIH sub	mittal as per Appendix M of the rDNA Guideline	es, Considerations for Human Gene Therapy.	
CASCAL Menuj	 A copy of the NIH's rest 	conse to the Sponsor's Appendix M submittal.		
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How to Attach to IRB protocol

Instructions:

- 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 Appendix M 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.
 - a. 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. If Clinical Staff will be trained by PI, please provide documentation attesting to this within the attachments section of the Appendix M.
 - 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 are to take Safety trainings and 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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ation .	Principal Investigator	Aderemi Dosur	nmu (ad3241)		You are	Aderemi Dos	unmu (ad3241)		
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RASCAL Human Subjects

Abbreviated title	test	Protocol Number	AAAR9600
Originating Department	EHS Environment Health Science (821100X)	Protocol Initiator	Aderemi Dosunmu (ad3241)
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	Contact Us © Columbia University E	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	fter this attestation, the protocol will need to be approved again.
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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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Recruitment And Consent	Biosafety(Appendix A)			APA-AAVA3788	05/24/2019	/	Aderemi Dosunmu (ad	3241)		
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Attachments	Formaldehyde(Appendix E2)			APE2-AAAB2073	06/13/2019	4	Aderemi Dosunmu (ad	3241)		
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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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To ad3241@columbia.edu		
Obtain Approval letter by following Link To: Aderemi Dosunmu and Aderemi Dosunmu		
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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/appen</u>	dix/D/AAAA3150/approvalLetter/pdf
Thank you, Columbia University Environmental Health & Safety	Office	

Approval letter

	COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
	ENVIRONMENTAL HEALTH AND SAFETY
April 11, 201	9
TO: Ade	eremi Dosunmu
FROM: E	invironmental Health and Safety
RE: APD-	AAAA3150
Protocol T	itle: test 123
Approval I	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 remin	der, the laboratory must comply with Columbia University Policy and all applicable regulations concerning
laboratory sa	fety and handling of hazardous materials. This includes, but is not limited to, EPA, OSHA, DEA, New York
State and Cit	y regulations.
Thank you	
Aderemi D	losunmu
Recording	Secretary
Environme	ntal Health & Safetv