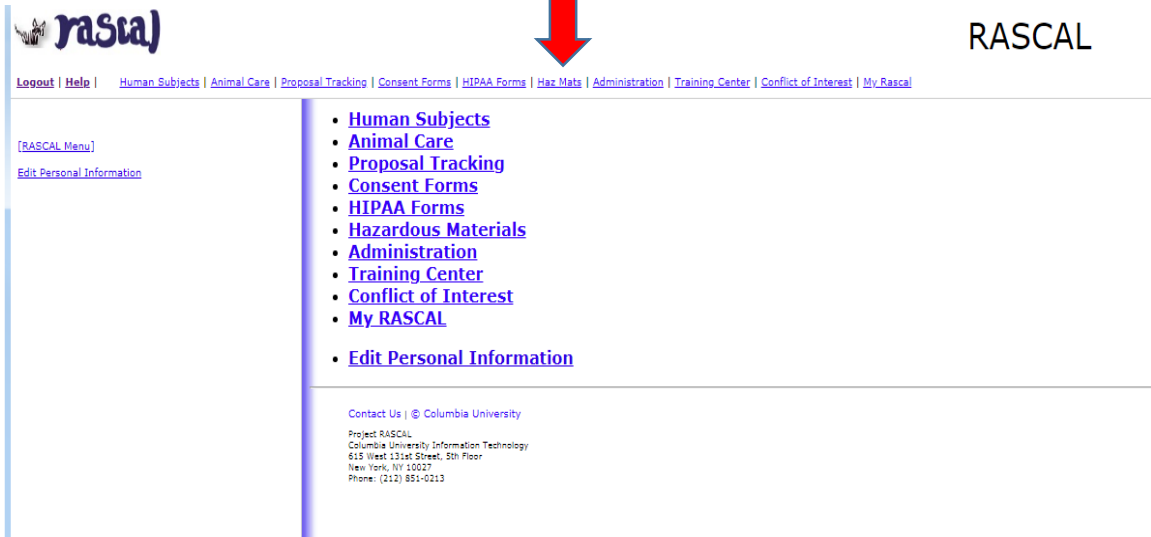
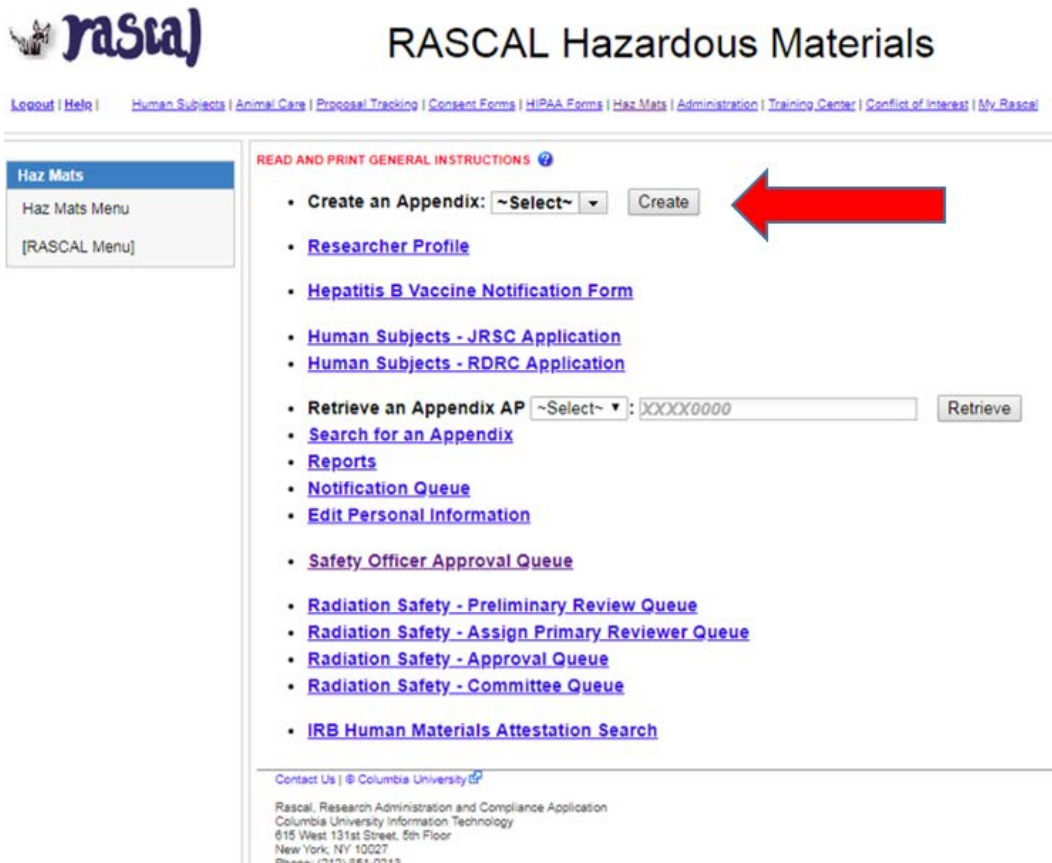


How to Create Appendices and Attach to an IRB Protocol

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.



The screenshot shows the RASCAL homepage. At the top left is the RASCAL logo. Below it is a navigation menu with links: Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal. A red arrow points to the 'Haz Mats' link. On the right side of the page, the word 'RASCAL' is displayed. Below the navigation menu is a list of links: Human Subjects, Animal Care, Proposal Tracking, Consent Forms, HIPAA Forms, Hazardous Materials, Administration, Training Center, Conflict of Interest, My RASCAL, and Edit Personal Information. At the bottom of the page, there is contact information for Columbia University.



The screenshot shows the RASCAL Hazardous Materials page. At the top left is the RASCAL logo. Below it is a navigation menu with links: Logout | Help | Human Subjects | Animal Care | Proposal Tracking | Consent Forms | HIPAA Forms | Haz Mats | Administration | Training Center | Conflict of Interest | My Rascal. A red arrow points to the 'Haz Mats' link. The main heading is 'RASCAL Hazardous Materials'. Below the heading is a section titled 'READ AND PRINT GENERAL INSTRUCTIONS'. In this section, there is a 'Create an Appendix' dropdown menu with a 'Create' button next to it. A red arrow points to the 'Create' button. Below this are several links: Researcher Profile, Hepatitis B Vaccine Notification Form, Human Subjects - JRSC Application, Human Subjects - RDRC Application, Retrieve an Appendix AP (with a dropdown menu and a text input field containing 'XXXXX0000' and a 'Retrieve' button), Search for an Appendix, Reports, Notification Queue, Edit Personal Information, Safety Officer Approval Queue, Radiation Safety - Preliminary Review Queue, Radiation Safety - Assign Primary Reviewer Queue, Radiation Safety - Approval Queue, Radiation Safety - Committee Queue, and IRB Human Materials Attestation Search. At the bottom of the page, there is contact information for Columbia University.

For Appendix A

Tips: 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.

Instructions:

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.

APA-AAAD8750
Status: Creating

Appendix Content

General

Microorganism Information

Human Tissue and Cell Culture Section

Safety Equipment and Practices

Personnel

Attachments

Protocol/Proposal

Appendix Action

Copy Appendix

Delete Appendix

Appendix View

View History

View Datasheet

Haz Mats

Haz Mats Menu

[RASCAL Menu]

MULTIPLE SECTIONS: Complete in order

Appendix A: Biosafety (Appendix A)

Title	Creation Date	You are	Subject Species	Initiator	Appendix Submitted
	04/09/2019 09:23:38	Aderemi Dosunmu (ad3241)	N/A	Aderemi Dosunmu (ad3241)	

General Instructions

General instructions explain how to fill out appendix appropriately.

I. General Information

*The appendix will be:

*Project Title:

*Describe methodologies/manipulations of the work performed. In brief describe the lab's research goals and the methodologies involved to accomplish these goals. If applicable, include any recombinant DNA gene manipulations such as gene editing (e.g., CRISPR, TALENS, zinc fingers):

*Are there any relevant vaccinations or work restrictions/considerations that should be acknowledged in regards to work with the biological material?

Hepatitis B Vaccination
 Rabies Virus Vaccination
 Immunocompromised Status
 Pregnancy
 Non-Applicable
 Other:

*If a lab acquired infection were to occur, what therapy is available?:

II. Collaborations/Procurement

*Where will the biological materials (viral vector/bacteria/virus/clinical specimen/cell line/other microorganism) be procured from?

Company/Core Facility/Repository:
 Collaborator (Name/University):
 Other:

*Will this project be a research collaboration where recombinant DNA or infectious material is shared between different campuses at Columbia?
 Yes No

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

IV. Laboratory Location

*Laboratory Locations

Campus	Building	Room	Modify	Delete
No data to display				

V. Recombinant DNA

*Is Recombinant DNA being used? Yes No

Save

SAVE: Work will be deleted if not saved after each section

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Columbia University Information Technology
615 West 131st Street, 6th Floor

Adding Attachments to Appendix A:



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](#)

APA-AAAD8751
 Status: Creating

Appendix Content

- General
- Microorganism Information
- Microorganism in Animals
- Microorganism in Invertebrates
- Human Tissue and Cell Culture Section
- Safety Equipment and Practices
- Personnel

Attachments

Protocol/Proposal

Appendix Action

- Copy Appendix
- Delete Appendix

Appendix View

- View History
- View Datasheet

Haz Mats

- Haz Mats Menu
- [RASCAL Menu]

Biosafety (Appendix A)

Appendix Number	AAAD8751	Subject Species	N/A
Title			
Creation Date	04/09/2019 10:40:31	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

III. Attachments

*Document Identifier

*Document Type ~Select~ | ▾

*File (max file size is 75 MB): No file chosen

View Document	File Name	Document Type	Date Attached	Attached By	Edit	Detach
No data to display						
0 - 0 of 0 results						

[Contact Us](#) | [Columbia University](#)

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 Columbia University Information Technology
 615 West 131st Street, 5th Floor
 New York, NY 10027
 Phone: (212) 851-0213

For Appendix D

Tips: 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 lasersafety@columbia.edu.

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

Instructions:

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.

Columbia University's RASCAL - F x

https://staging.rascal.columbia.edu/hazmats/appendix/D/AAAA7100/generalInformation

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

APD-AAAA7100
Status: Creating

- Appendix Content
 - General
 - Personnel
 - Attachments
 - Protocol/Proposal
- Appendix Action
 - Copy Appendix
 - Delete Appendix
- Appendix View
 - View History
 - View Datasheet
- Haz Mats
 - Haz Mats Menu
 - [RASCAL Menu]

Laser (Appendix D)

Appendix Number	AAAA7100	Subject Species	N/A
Title			
Creation Date	04/09/2019 09:57:39	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

General Instructions ?

I. General Information

*The appendix will be: 0 / 255

*Project Title:

II. Laser Registration Number(s)

List the EH&S Approval number(s) of the Laser System(s) used in relation to this Laser Appendix. If a new registration form needs to be created, fill out the form at this link and attach to the Appendix, using the Attachments tab: <https://finance.columbia.edu/files/gateway/forms/LaserRegistrationForm.pdf>

Pick laser registration number(s) from the following or enter another below:

 0 / 100

Adding Attachments to Appendix D:

Columbia University's RASCAL - F x

<https://staging.rascal.columbia.edu/hazmats/appendix/D/AAAA7100/attachment>

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](#)

APD-AAAA7100
Status: Creating

Appendix Content

General

Personnel

Attachments

Protocol/Proposal

Appendix Action

Copy Appendix

Delete Appendix

Appendix View

View History

View Datasheet

Haz Mats

Haz Mats Menu

[RASCAL Menu]

Laser (Appendix D)

Appendix Number	AAAA7100	Subject Species	N/A
Title	dfdsa		
Creation Date	D4/09/2019 09:57:39	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

III. Attachments

*Document Identifier

*Document Type ~Select~ ▼

*File (max file size is 75 MB): No file chosen

View Document	File Name	Document Type	Date Attached	Attached By	Edit	Detach
No data to display						
0 - 0 of 0 results « ‹ › » 50 ▼						

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 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
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 Materials

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

APE-AAAG4600
Status: Creating

Appendix Content

General

Personnel

Attachments

Protocol/Proposal

Appendix Action

Copy Appendix

Delete Appendix

Appendix View

View History

View Datasheet

Haz Mats

Haz Mats Menu

[RASCAL Menu]

Hazardous Chemicals (Appendix E)

Appendix Number	AAAG4600	Subject Species	N/A
Title			
Creation Date	04/09/2019 16:34:44	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

General Instructions ?

Note: Do not include Isoflurane or Formaldehyde, there is a separate Appendix for each of those substances.

General instructions explain how to fill out appendix appropriately.

I. General Information

*The appendix will be: ~Select~
*Project Title:

II. Administration:

*Type of administration: Animal Use Human Subjects

To attach documents to Appendix, use Attachments Tab

VI. Emergency Response

What are the emergency procedures in the event of personnel exposure?
*Acute symptoms of exposure:
*Actions taken in event of exposure:
Emergency procedures in the event of a spill (facility or environmental contamination):
*Location of Spill Kit:
*Actions taken in event of contamination/spill:
*Methods for detecting contamination of skin, clothing, apparatus, etc.:
*Is a biological toxin used? Yes No
Describe the excretion pathways and metabolic products of the compounds, if applicable:
*What is the biological 1/2 life of the administered compounds?
*What is the toxicity (if any) of excreted metabolites?
If special waste containers must be used or specific waste instructions are to be given, please email hazmat@columbia.edu.
The OSHA regulation Occupational Exposures to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) requires that persons working with chemical(s) attend a Laboratory Safety and Chemical Hygiene Orientation (LSCHO) Session INITIALLY. These sessions are offered twice monthly by EH&S and can be scheduled locally if desired. It is also important to note that these initial trainings do expire and refresher trainings must be taken online through RASCAL.

Save

SAVE: Work will be deleted if not saved after each section


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

Adding Attachments to Appendix E:

Columbia University's RASCAL - f x +

https://staging.rascal.columbia.edu/hazmats/appendix/E/AAAG4600/attachment



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

APE-AAAG4600
Status: Creating

Appendix Content

- General
- Personnel
- Attachments**
- Protocol/Proposal

Appendix Action

- Copy Appendix
- Delete Appendix

Appendix View

- View History
- View Datasheet

Haz Mats

- Haz Mats Menu
- [RASCAL Menu]

Hazardous Chemicals (Appendix E)

Appendix Number	AAAG4600	Subject Species	N/A
Title			
Creation Date	04/09/2019 16:34:44	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

III. Attachments

*Document Identifier

*Document Type ~Select~ | ▾

*File (max file size is 75 MB): No file chosen

View Document	File Name	Document Type	Date Attached	Attached By	Edit	Detach
No data to display						
0 - 0 of 0 results						


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

For Appendix E1

Tips: 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.

Instructions:

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.



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](#)

APE1-AAAA0050
Status: Creating

- Appendix Content
 - General
 - Personnel
 - Attachments
 - Protocol/Proposal
- Appendix Action
 - Copy Appendix
 - Delete Appendix
- Appendix View
 - View History
 - View Datasheet
- Haz Mats
 - Haz Mats Menu
 - [RASCAL Menu]

Isoflurane (Appendix E1)

Appendix Number	AAAA0050	Subject Species	N/A
Title			
Creation Date	04/09/2019 17:10:37	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

[General Instructions](#)

Isoflurane is a hazardous chemical with a regulatory permissible exposure limit established by the OSHA. When submitting this appendix, the Principal Investigator/Initiator confirms awareness of the hazardous nature of the chemical.

General instructions explain how to fill out appendix appropriately.

I. General Information

*The appendix will be:

*Project Title:

II. Amount and Equipment:

*Isoflurane Amount:

*L/Min of Oxygen:

*Please specify ownership of isoflurane vaporizer: [?](#)

Laboratory Owned Animal Quarters Owned Laboratory Owned/Animal Quarters Managed

III. Laboratory Location

*Laboratory Locations [?](#)

Campus	Building	Room	Modify	Delete
No data to display				

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)
- Passive Engineering Control (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
- Canisters will be weighed and the weights recorded before and after each use
- Follow time limit guidelines as recommended by EH&S to minimize isoflurane exposure. [?](#)
- Lab will limit ordering and on-site storage to amounts used
- Canisters 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

- Safety Glasses/Goggles
- Respirator [?](#)

SAVE: Work will be deleted if not saved after each section

For Appendix E2

Tips: 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.

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
Status: Creating

Appendix Content

General

Personnel

Attachments

Protocol/Proposal

Appendix Action

Copy Appendix

Delete Appendix

Appendix View

View History

View Datasheet

Haz Mats

Haz Mats Menu

[RASCAL Menu]

Formaldehyde (Appendix E2)

Appendix Number	AAAA0050	Subject Species	N/A
Title			
Creation Date	04/09/2019 17:31:05	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	

General Instructions ?

Formaldehyde is a hazardous chemical with a regulatory permissible exposure limit established by the OSHA. By submitting this appendix, the Principal Investigator/Initiator confirms awareness of the hazardous nature of formaldehyde.

General instructions explain how to fill out appendix appropriately.

I. General Information

*The appendix will be:

*Project Title:

II. Chemical Used For:

Human Subject Research Animal Subject Research In vitro Research

III. Type of Formalin/Formaldehyde:

Formalin/Formaldehyde
 Paraformaldehyde (PFA)

IV. Laboratory Location

*Laboratory Locations ?

V. Hazard Control

*The laboratory is utilizing at least one of the engineering controls listed while working with formaldehyde. (Check all that apply):

- Certified Chemical Fume Hood
- Glove Box
- Downdraft Table
- Ducted Biological Safety Cabinet (Class II, Type B1 or B2)
- Laboratory works on an open bench top without any engineering controls and has contacted Environmental Health and Safety at occsafety@columbia.edu
- Other:

*The laboratory will be implementing one or all of the below administrative controls during work with formaldehyde. (Check all that apply):

- Lab will limit ordering and on-site storage to amounts used
- Proper storage and labeling of chemicals and hazardous waste ?
- Work on an open bench top with amounts smaller than 0.1 mL
- Work on an open bench top with amounts larger than 0.1 mL and have contacted Environmental Health and Safety at occsafety@columbia.edu

*The laboratory will be utilizing the appropriate personal protective equipment including:

- Lab Coat
- *Disposable Gloves: Nitrile Latex Vinyl
- Safety Glasses/Goggles
- Respirator ?

Save

SAVE: Work will be deleted if not saved after each section

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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 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.
 - 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.
 - 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.

[RASCAL Menu]

[IRB Menu]

To find existing or in progress protocols

- [Create Protocol](#)
- [Retrieve a Protocol: IRB -](#)
- [My Protocols](#)
- [IRB Protocol Search](#)
- [Search for a Protocol](#)
- [Search for a Protocol \(Admin/Chair only\)](#)
- [Notification Queue](#)
- [Approve Protocols](#)
- [Agenda/Minute Builder](#)
- [Reports](#)
- [Helpful IRB Information](#)
- [Consent Form Templates](#)
- [Helpful HIPAA Information](#)
- [HRPO Homepage](#)
- [Edit Personal Information](#)

For new protocols

Can also use "My Rascal" to find existing protocols

[Contact Us](#) | @ Columbia University

Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.
 CUMC Campus:
 (212) 305-5883 | irboffice@columbia.edu
 CU-MS and LDEO Campus:
 (212) 851-7040 | askirb@columbia.edu

IRB-AAAR9905
Status: Creating

- Protocol Content
- General Information
- Attributes
- Funding
- Personnel
- Departmental Approvers
- Research Aims & Abstracts

Attachments

- Hazmats
- HIPAA Forms
- Documents
- Consent Form

Protocol Actions

- Notify Approvers
- Submit Protocol
- Copy Protocol
- Delete Protocol

Protocol View

- Print Menu
- View Datasheet
- View History

Human Subjects

- Protocol Overview

Abbreviated title	dfscdfsfaf	Protocol Number	AAAR9905
Originating Department	EHS Environ Health Sci Resch (8211402)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Year	1 Modification 00	Date Created	07/11/2018 12:19:56
Principal Investigator	Aderemi Dosunmu (ad3241)	You are	Aderemi Dosunmu (ad3241)

General Information

General Instructions

1. Enter information in each section and be sure to SAVE your work
2. This symbol means help information
3. This symbol means lookup/add information
4. Dotted underline means that hovering the cursor over the text will show a definition
5. *Red asterisks indicate required questions
6. No data on a page is saved until you receive the green save confirmation message. Please remember to save often!
7. Following successful 'Save' of a page, review left hand menu for additional Pages to be completed
8. While each individual page may be considered "complete" upon save, at the time of submission the system may identify additional areas where the information is inconsistent or incomplete between pages.

Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.

CUMC Campus: (212) 305-5883 | irboffice@columbia.edu | <http://www.cumc.columbia.edu/igq/irb>
 CU-MS and LDEO Campus: (212) 851-7040 | askirb@columbia.edu | <http://www.columbia.edu/cu/irb>

*Originating Department Code EHS Environ Health Sci Resch

*From what Columbia campus does this research originate?

*Title (maximum 500 characters)

Protocol Version #

*Abbreviated Title (maximum 60 characters)

*Was this protocol previously assigned a number by an IRB? Yes No

*Is the purpose of this submission to obtain a "Not Human Subjects Research" determination? Yes No



RASCAL Human Subjects

Home | Help | Admin Tools | Animal Care | Research Tools | Consent Forms | HIPAA Forms | Data Mgmt | Administration | Training Center | Conflict of Interest | My RASCAL

IRB-AAAR9905
Status: Creating

Protocol Content

- General Information
- Attributes
- Funding
- Personnel
 - Departmental Approvers
 - Research Arms & Abstracts

Attachments

- Hazmat
- HIPAA Forms
- Documents
- Consent Form

Protocol View

- Print Menu
- View Datasheet
- View History

Human Subjects

- Protocol Overview

Abbreviated title	dfofsoaf	Protocol Number	AAAR9905
Originating Department	EHS Environ Health Sci Resh (0211402)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Year	1 Modification 00	Date Created	07/11/2018 12:19:56
Principal Investigator	Aderemi Dosunmu (ad3241)	You are	Aderemi Dosunmu (ad3241)

Hazmats

Helpful Information: [?](#)

- Biosafety (Appendix A): [?](#)
- Laser (Appendix D): [?](#)
- Hazardous Chemicals (Appendix E): [?](#)
- Formaldehyde (Appendix E2): [?](#)
- Radiation Safety (Appendix H): [?](#)
- Use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix M): [?](#)

Attached Appendices

Type	Title	Appendix Number	Date Created	Initiator
No data to display				

Find Appendix relevant to Protocol and click "attach"

All released Appendices to which you have access and are not currently attached to a protocol.

Attach	Type	Title	Number	Date Created	Initiator
	Laser(Appendix D)	test 123	APD-AAAA7100	04/12/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	Differentiating Radiosensitivities and Niche Factors among Intestinal Stem Cell Pools	APE-AAAQ4460	03/27/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ4378	03/15/2019	Aderemi Dosunmu (ad3241)
	Infectious Agents(Appendix B)		APB-AAAET153	01/14/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ3727	11/21/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ3055	08/30/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	dfofsoaf	APE-AAAQ2962	08/21/2018	Aderemi Dosunmu (ad3241)
	Recombinant DNA(Appendix A1)		APA1-AAAQ6708	07/11/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ2609	06/13/2018	Aderemi Dosunmu (ad3241)
	Laser(Appendix D)		APD-AAAQ6101	04/25/2018	Aderemi Dosunmu (ad3241)



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IRB-AAAR9905
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Abbreviated title	dfofsoaf	Protocol Number	AAAR9905
Originating Department	EHS Environ Health Sci Resh (0211402)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Year	1 Modification 00	Date Created	07/11/2018 12:19:56
Principal Investigator	Aderemi Dosunmu (ad3241)	You are	Aderemi Dosunmu (ad3241)

Hazmats

Helpful Information: [?](#)

- Biosafety (Appendix A): [?](#)
- Laser (Appendix D): [?](#)
- Hazardous Chemicals (Appendix E): [?](#)
- Formaldehyde (Appendix E2): [?](#)
- Radiation Safety (Appendix H): [?](#)
- Use of Recombinant DNA (rDNA) Molecules in Human

Hazardous Materials Appendix Staff Check-Off

Check staff to be included in appendix APD-AAAA7100

Select	Name	Role
<input checked="" type="checkbox"/>	Aderemi Dosunmu (ad3241)	Principal Investigator

Attached Appendices

Type	Title	Appendix Number	Date Created	Initiator
No data to display				

All released Appendices to which you have access and are not currently attached to a protocol.

Attach	Type	Title	Number	Date Created	Initiator
	Laser(Appendix D)		APD-AAAA7100	04/25/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	Differentiating Radiosensitivities and Niche Factors among Intestinal Stem Cell Pools	APE-AAAQ4460	03/27/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ4378	03/15/2019	Aderemi Dosunmu (ad3241)
	Infectious Agents(Appendix B)		APB-AAAET153	01/14/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ3727	11/21/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ3055	08/30/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	dfofsoaf	APE-AAAQ2962	08/21/2018	Aderemi Dosunmu (ad3241)
	Recombinant DNA(Appendix A1)		APA1-AAAQ6708	07/11/2018	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAQ2609	06/13/2018	Aderemi Dosunmu (ad3241)
	Laser(Appendix D)		APD-AAAQ6101	04/25/2018	Aderemi Dosunmu (ad3241)



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Abbreviated title	dfsdfsf
Originating Department	EHS Environ Health Sci Rsch (8211402)
Protocol Year	1 Modification 00
Principal Investigator	Aderemi Dosunmu (ad3241)

- Hazmats**
- Helpful Information:
- Biosafety (Appendix A):
 - Laser (Appendix D):
 - Hazardous Chemicals (Appendix E):
 - Formaldehyde (Appendix E2):
 - Radiation Safety (Appendix H):
 - Use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix I):

To view the Appendix datasheet, with the imported personnel, click on the Appendix. This can be provided to staff to inform them of training requirements to **prevent** delay of the approval process.

Attached Appendices

Type	Title	Appendix Number	Date Created	Initiator	Appendix Letter	Action	Staff	Replace with a copy
Laser(Appendix D)	test 123	APD-AAAAT100	04/12/2019	Aderemi Dosunmu (ad3241)	N/A			

All released Appendices to which you have access and are not currently attached to a protocol.

Attach	Type	Title	Number	Date Created	Initiator
	Infectious Agents(Appendix B)	nwoenwar	APB-AAAE1801	01/26/2016	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)		APE-AAAF9817	04/28/2016	Aderemi Dosunmu (ad3241)
	Infectious Agents(Appendix B)	Determination of Cancer Genetics in Tg Mice	APB-AAAE2256	04/27/2016	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	sdfsf	APE-AAAF9069	07/13/2016	Aderemi Dosunmu (ad3241)
	Infectious Agents(Appendix B)	waefact	APB-AAAE2960	11/10/2016	Aderemi Dosunmu (ad3241)
	Recombinant DNA(Appendix A1)	Test Project	APA1-AAAD3004	04/27/2016	Aderemi Dosunmu (ad3241)
	Recombinant DNA(Appendix A1)	ertert	APA1-AAAD3357	09/14/2016	Aderemi Dosunmu (ad3241)
	Recombinant DNA(Appendix A1)		APA1-AAAD3005	04/28/2016	Aderemi Dosunmu (ad3241)
	Infectious Agents(Appendix B)		APB-AAAE7153	01/14/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals(Appendix E)	dfsdf	APE-AAAG2962	09/21/2018	Aderemi Dosunmu (ad3241)

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Abbreviated title	test	Protocol Number	AAAR9600
Originating Department	EHS Environment Health Science (821100X)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Year	1 Modification 00	Date Created	04/12/2019 14:34:21
Principal Investigator	Aderemi Dosunmu (ad3241)	You are	Aderemi Dosunmu (ad3241)

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Click on one of the buttons below to Notify Approvers.

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 Portland, OR 97239
 (503) 318-1000 | hrp@ohsu.edu
 OHSU and OHSU Center
 (503) 318-1000 | hrp@ohsu.edu



IRB-AAAR9600

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Abbreviated title	test	Protocol Number	AAAR9600
Originating Department	EH&S Environment Health Science (621100X)	Protocol Initiator	Aderemi Dosunmu (a33241)
Protocol Year	1 Modification 00	Date Created	04/12/2019 14:24:21
Principal Investigator	Aderemi Dosunmu (a33241)	You are	Aderemi Dosunmu (a33241)

Approve Protocol

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CUIMS and LDEO Campus: (212) 861-7040 | esim@cumc.columbia.edu

(RASCAL Menu)

(IRB Menu)

Information Message

Because this protocol has indicated the 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

Appendix Attestation:

Appendix D :

- Laser Safety Signs will be posted on the entrance door to the laser use room.
- Appropriate Laser Safety Goggles/Glasses will be used by every person in the laser use room.
- Written Standard Operating Procedures (SOP's) are available for the laser system(s) in use.
- Users are trained on the laser system specific SOP.

Hit CERTIFY button only ONCE to complete attestation.

[Cancel](#) [CERTIFY](#)

Please Confirm

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.

[Cancel](#) [OK](#)



Complete HazMats
Attestation before
protocol submission

RASCAL Animal Care

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Status: Still Creating...
AC-AAAY7455

Information Message
Because this protocol has indicated the use of hazardous 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 button below.

Appendix Attestation:
Appendix A:

- Personnel with exposure to human blood, unfixed tissues or cell lines will be informed that CU offers all staff the Hepatitis B vaccine.
- The Principal Investigator and the laboratory staff (s) will be adequately trained on procedures for the proposed research.
- The Principal Investigator and the laboratory staff have taken the appropriate safety trainings on Rascal provided by EH&S (to determine trainings required, see <https://research.columbia.edu/sites/default/files/content/CIU-6-Training-Calendar-Your-Safety-Training-Requirements.pdf>) and for training scheduling see: <https://research.columbia.edu/content/safety-training.pdf>.
- Research staff must observe the following Regulated Medical Waste disposal procedures:
 - Dispose of syringes/needles (without separation), serological pipettes (glass or plastic), glass Pasteur pipettes, and other sharps in a sharps container.
 - Dispose of all other potentially infectious materials in seal break. All infectious material from seal break bins, BSL-2 research, B. anthracis, etc.

Please Confirm
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.

Cancel OK

For spills/releases, treat the contaminated area with 10% household bleach solution (freshly prepared daily) for 20 minutes and then clean it up. Dispose of all solid waste as red bag waste.

Appendix E1:

- All engineering control devices used in conjunction with the protocol, including, but not limited to chemical fume hoods, are currently certified and properly maintained.
- Manageable Spills are categorized as a chemical or biological release that is capable of being cleaned up by laboratory staff based on their knowledge, skills, abilities, and the resources available to them at the time of the release. Chemical spills must be cleaned up promptly, efficiently, and properly.
- All staff are to be trained in the appropriate response to release of, or exposure to, protocol-related hazardous materials.
 - All manageable chemical spills will be cleaned using the chemical specific spill kit.
 - All unmanageable chemical spills should be immediately reported to EH&S at labafety@columbia.edu or call 212-305-0780.
 - All biological spills will be treated/cleaned with a freshly-prepared bleach solution or other appropriate disinfectant.
- Medical attention will be sought in the event of an exposure at Workforce Health and Safety or the NY Presbyterian Hospital Emergency Room.
- Personal protective equipment will be made available and used at all times during protocol activities involving potential exposure to hazardous chemicals. At a minimum, PPE will include gloves, lab coats and protective eyewear.
- Laboratories may not ship hazardous chemicals. Reach out to EH&S at labafety@columbia.edu or call 212-305-0780.
- I acknowledge and accept responsibility for the safe conduct of research involving the aforementioned hazardous materials.

Hit CERTIFY button only ONCE to complete attestation.

Cancel CERTIFY

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HazMats Attestation
HazMats attestation has been completed.

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

Continue on to Protocol Submission. Data Validation checks are completed here. If there are problems with either the Protocol or the Appendix, the

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.

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READ AND PRINT GENERAL INSTRUCTIONS

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- Human Subjects - RDRC Application
- Retrieve an Appendix AP ~Select~ : XXXX0000 Retrieve
- Search for an Appendix
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- Edit Personal Information
- Safety Officer Approval Queue
- Radiation Safety - Preliminary Review Queue
- Radiation Safety - Assign Primary Reviewer Queue
- Radiation Safety - Approval Queue
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- IRB Human Materials Attestation Search

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The Researcher Profile page centralizes various items of demographic information and other data points for transfer and automated input into Haz Mats Appendices. Researchers can experience expedited and accurate Appendix completion by including as much information in this profile as possible. Once complete, information will be added into any new Appendices that are created. Fields that have more than one entry will be available for selection when completing an Appendix, and updated information will be available for input into new Appendices when the information is changed in the Profile page.

I. Lab Location(s)

Laboratory Locations

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 Number

IV. Controlled Substances License(s)

Document Identifier:

Document Type: Controlled Substances License

File (max file size is 75 MB): No file chosen

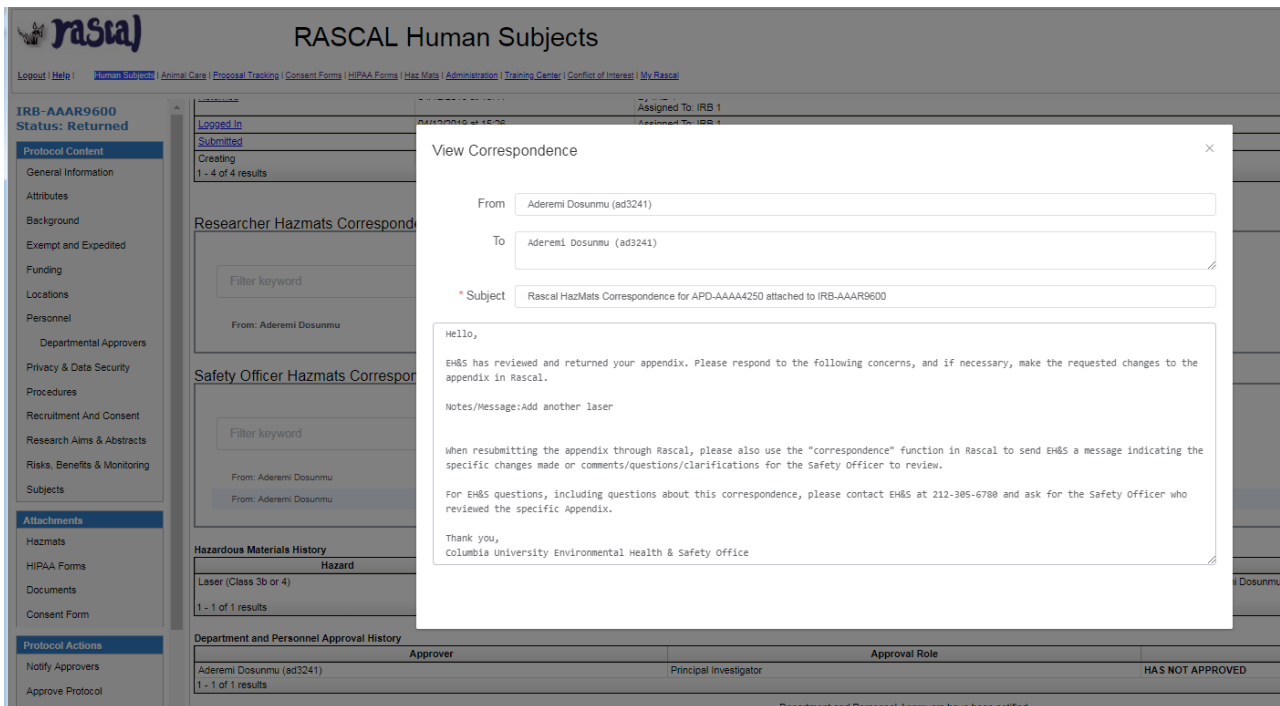
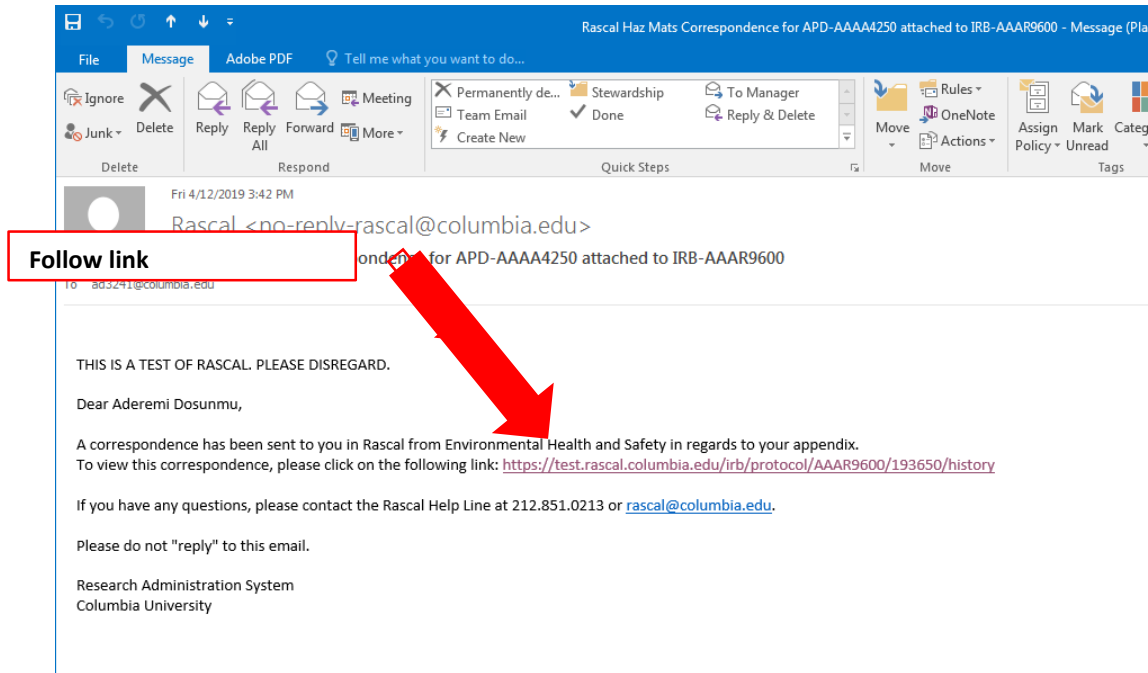
View Document	File Name	Document Type	Date Created	Edit	Detach
No data to display					

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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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https://www.rascal.columbia.edu/irb/protocol/AAAR5960/269440/hazmats

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Abbreviated title	tes	Protocol Number	AAAR5960
Originating Department	EHS Research (821140X)	Protocol Initiator	Aderemi Dosunmu (ad3241)
Protocol Year	1 Modification 00	Date Created	09/21/2017 11:34:18
Principal Investigator		You are	Aderemi Dosunmu (ad3241)

Hazmats

Helpful Information: ?
 Biosafety (Appendix A): ?
 Laser (Appendix D): ?
 Hazardous Chemicals (Appendix E): ?
 Formaldehyde (Appendix E2): ?
 Radiation Safety (Appendix H): ?
 Use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix M): ?

Attached Appendices

Type	Title	Appendix Number	Date Created	Initiator	Approval Letter	Action	Staff	Replace with a copy
Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix M)		APM-AAAA9050	06/19/2019	Aderemi Dosunmu (ad3241)	N/A	X		

All released Appendices to which you have access and are not currently attached to a protocol.

Attach	Type	Title	Number	Date Created	Initiator
	Use of Hazardous Chemicals in Animals (Appendix E)		APE-AAA65127	05/10/2019	Aderemi Dosunmu (ad3241)
	Biosafety (Appendix A)		APA-AAVA3788	05/24/2019	Aderemi Dosunmu (ad3241)
	Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix M)		APM-AAAA7050	06/06/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals (Appendix E)		APE-AAA65767	06/10/2019	Aderemi Dosunmu (ad3241)
	Biosafety (Appendix A)		APA-AADD3757	05/01/2019	Aderemi Dosunmu (ad3241)
	Formaldehyde (Appendix E2)		APE2-AAAB2073	06/13/2019	Aderemi Dosunmu (ad3241)
	Formaldehyde (Appendix E2)		APE2-AAAB2055	06/10/2019	Aderemi Dosunmu (ad3241)
	Use of Hazardous Chemicals in Animals (Appendix E)		APE-AAA65202	05/13/2019	Aderemi Dosunmu (ad3241)

Select the link to directly edit the appendix



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Use of Recombinant DNA (rDNA) Molecules in Human Gene Transfer (Appendix M)

Appendix Number	AAAA9050	Subject Species	N/A
Title			
Creation Date	06/19/2019 16:22:24	Initiator	Aderemi Dosunmu (ad3241)
You are	Aderemi Dosunmu (ad3241)	Appendix Submitted	N/A

General Instructions ?

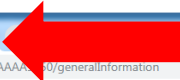
I. General Information

*Principal Investigator: N/A
 *Department Affiliation: N/A
 *IRB Number: AAAR5960
 *Project Title: 4 / 255

*Select the recombinant material(s)/product(s) to be administered, and fill in the specific Trade name:

- Lentivirus:
- Adeno-Associated Virus:
- Adenovirus:
- Herpes Simplex Virus:
- Glycoprotein-deleted Rabies Virus:
- Murine Moloney Leukemia Virus:
- Vaccinia:
- Plasmid:
- Other:

The appendix will open in a new tab



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https://www.rascal.columbia.edu/hazmats/appendix/MJ/AAAA9050/generalInformation

rascal RASCAL Hazardous Materials

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******* How will the material be prepared for administration? ******* 4/2000

test

***How will the material be prepared for administration?** 4/2000

test

***Describe the procedures in the event of spill:** 4/2000

test

III. Recombinant DNA Information

***Describe briefly the vector/gene insert construct and provide a description of the cells in which it is produced.** 4/2000

test

***If the vector is designed to be replication incompetent, note how this was accomplished. Copy relevant information from Investigators' brochure here.** 4/2000

test

***Provide a history of testing for replication competent virus if 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.** 4/2000

test

***Identify and summarize any biosafety concerns for patients administered this therapy. These could be (1) hypothetical concerns based on the nature of the therapy, (2) concerns based on preclinical data, or (3) anticipated adverse events from past clinical studies.** 4/2000

test

***Does data on localization and shedding**

Save

After editing the appendix, "Save" the form and close the tab.

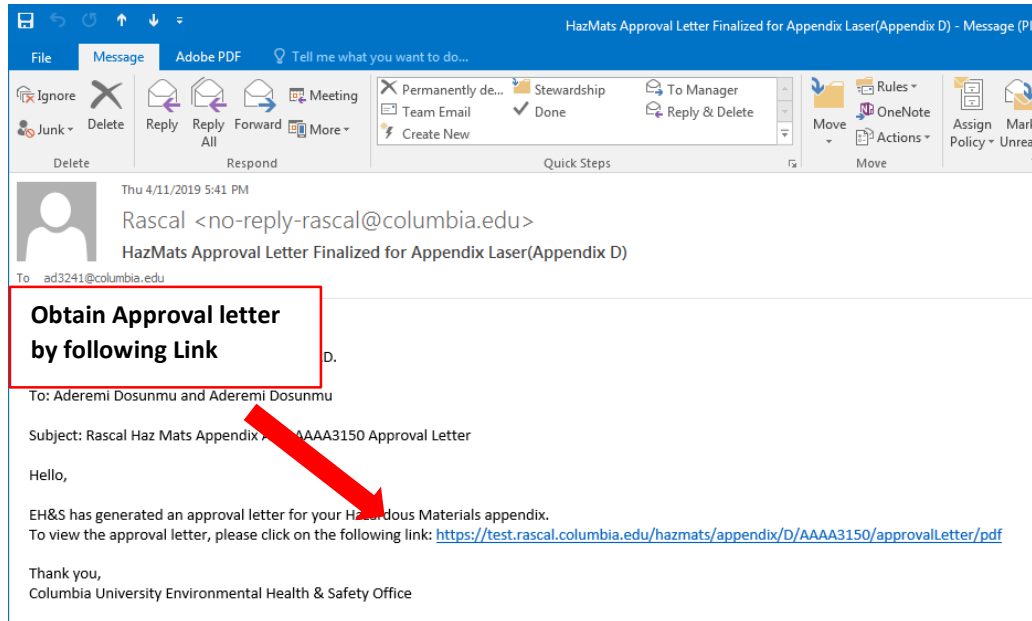
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EH&S Approval and Correspondence

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.



Approval letter

