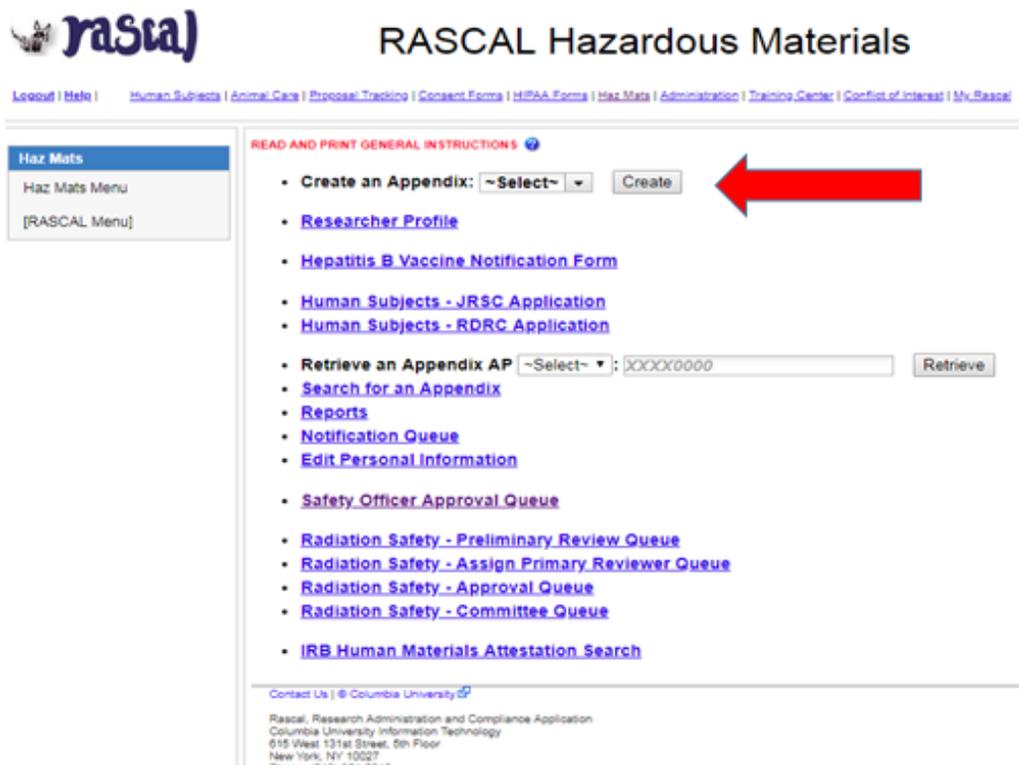
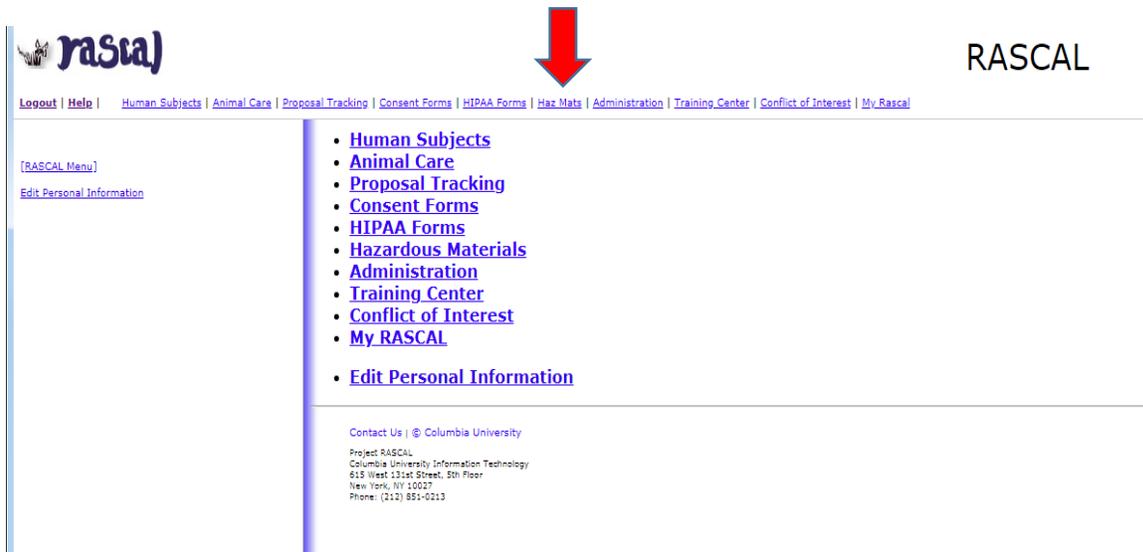


How to Create an Appendix M-Human Gene Therapy and Attach to IRB Protocol

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 Biosafety@columbia.edu for further instruction)
4. See tips and instructions below. Starting on Page 5 are instructions on how to attach to IRB protocol.
5. **NOTE:** 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.



For Appendix M

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

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.

APM-AAAA0052
Status: Creating

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Haz Mats

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

| | | | |
|-----------------|--------------------------|--------------------|--------------------------|
| Appendix Number | AAAA0052 | Subject Species | N/A |
| Title | | | |
| Creation Date | 04/15/2019 11:12:03 | Initiator | Aderemi Dosunmu (ad3241) |
| You are | Aderemi Dosunmu (ad3241) | Appendix Submitted | |

General Instructions

General instructions explain how to fill out appendix appropriately.

I. General Information

*Principal Investigator: N/A

*Department Affiliation: N/A

*IRB Number: N/A

*Project Title:

*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:

*Sponsor:

*Company Name:

*Address:

*Contact Person and Title:

*Phone Number:

*Is the recombinant material coming from the Sponsor? Yes No

*Is this part of a multi-center study? Yes No

*If applicable, will the trial be registered with the NIH Office of Science Policy (OSP)? Yes No

*How will Safety Data, Serious Adverse Events, incidents, and other unanticipated events be reported and who will be responsible for reporting?

*Will the following vaccines/personnel limitations be applicable to those who will handle, administer, or otherwise have exposure to the product? (Check all that apply):

III. Recombinant DNA Information

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

*If the vector is designed to be replication incompetent, note how this was accomplished. You may copy or cite the relevant page(s) from the clinical investigators' brochure to provide this information.

*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.

*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.

*Does data on localization and shedding exist? Yes No

*Will there be any assessment of shedding as part of this project? Yes No

*What is the expected persistence of recombinant material and gene expression in patients?

*Will it be necessary for patients to limit their types of personal contacts? Yes No

*What provisions (if any) will be in effect to isolate patients from susceptible individuals who may be present in clinical areas while viral shedding may be occurring?

Save

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

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.



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

| | | | |
|-----------------|--------------------------|--------------------|--------------------------|
| Appendix Number | AAAA0052 | Subject Species | N/A |
| Title | | | |
| Creation Date | 04/15/2019 11:12:03 | Initiator | Aderemi Dosunmu (ad3241) |
| You are | Aderemi Dosunmu (ad3241) | Appendix Submitted | |

III. Attachments

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:

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- 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.

*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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Rascal, Research Administration and Compliance Application
Columbia University Information Technology

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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Can also use "My Rascal" to find existing protocols

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CU-MS and LDEO Campus:
(212) 851-7040 | askirb@columbia.edu



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|------------------------|---------------------------------------|--------------------|--------------------------|
| Abbreviated title | dfsdfdsaf | Protocol Number | AAAR9905 |
| Originating Department | EHS Environ Health Sci Rsch (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.

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CU-MS and LDEO Campus: (212) 851-7040 askirb@columbia.edu <http://www.columbia.edu/cu/irb>

*Originating Department Code EHS Environ Health Sci Rsch

*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



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|------------------------|---------------------------------------|--------------------|--------------------------|
| Abbreviated title | dlsdlsaf | Protocol Number | AAAR9905 |
| Originating Department | EHS Environ Health Sci Resh (9211402) | 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 | Action |
|--------------------|-------|-----------------|--------------|-----------|--------|
| 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-AAAG4378 | 03/15/2019 | Aderemi Dosunmu (ad3241) |
| | Infectious Agents(Appendix B) | | APB-AAAE7153 | 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) | dlsdlsaf | APE-AAAQ2962 | 08/21/2018 | Aderemi Dosunmu (ad3241) |
| | Recombinant DNA(Appendix A1) | | APA1-AAAD6708 | 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-AAA6101 | 04/25/2018 | Aderemi Dosunmu (ad3241) |



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| Abbreviated title | dlsdlsaf | Protocol Number | AAAR9905 |
| Originating Department | EHS Environ Health Sci Resh (9211402) | 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 |

[Attach Appendix](#)

Attached Appendices

| Type | Title | Appendix Number | Date Created | Initiator | Action |
|------|---|---|---------------|--------------------------|--------------------------|
| | Laser(Appendix D) | | | 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-AAAG4378 | 03/15/2019 | Aderemi Dosunmu (ad3241) |
| | Infectious Agents(Appendix B) | | APB-AAAE7153 | 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) | dlsdlsaf | APE-AAAQ2962 | 08/21/2018 | Aderemi Dosunmu (ad3241) |
| | Recombinant DNA(Appendix A1) | | APA1-AAAD6708 | 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-AAA6101 | 04/25/2018 | Aderemi Dosunmu (ad3241) |



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| Abbreviated title | dstsfhaf |
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| Principal Investigator | Aderemi Dosunmu (ad3241) |

Hazmats

Helpful Information: [?](#)

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- 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-AAAA7100 | 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) | rwqenwar | APB-AAAE1801 | 01/20/2016 | 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) | sdahhaf | APE-AAAF0669 | 07/13/2016 | Aderemi Dosunmu (ad3241) |
| | Infectious Agents(Appendix B) | waefahf | 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) | enterwt | 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) | dstsfaf | APE-AAAG2962 | 09/21/2018 | Aderemi Dosunmu (ad3241) |

Notify Approvers



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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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| Abbreviated title | test | Protocol Number | AAAR9600 |
| Originating Department | EHS Environment Health Science (E21100X) | Protocol Initiator | Aderemi Dosunmu (ad3241) |
| Protocol Year | 1 Modification 02 | Date Created | 04/12/2019 14:34:21 |
| Principal Investigator | Aderemi Dosunmu (ad3241) | You are | Aderemi Dosunmu (ad3241) |

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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.

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Complete HazMats
Attestation before
protocol submission





RASCAL Animal Care

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Status: Still Creating...

AC: AAAY7455

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HazMats Attestation

HazMats attestation has been completed.

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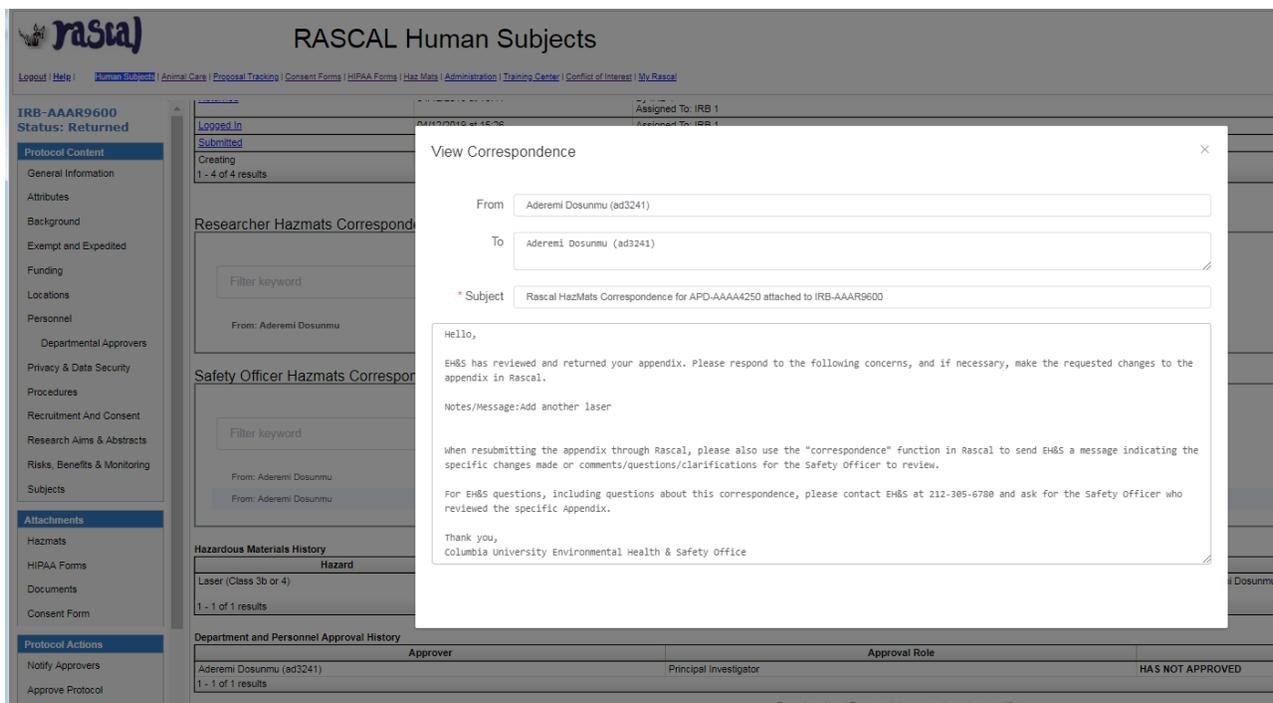
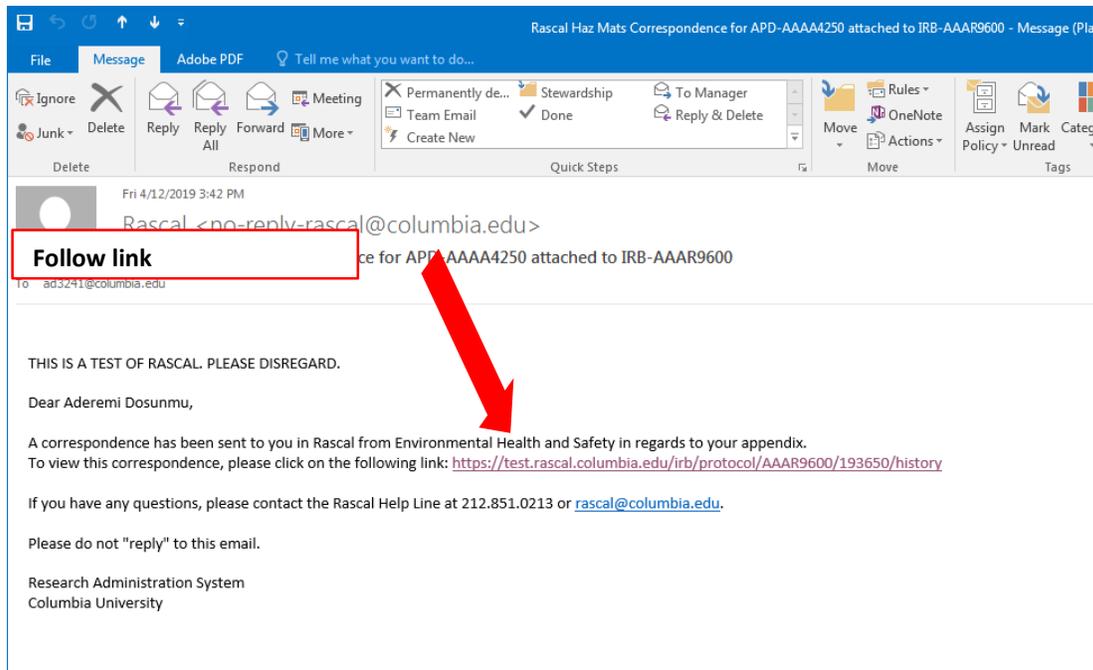
HazMats Attestation is now complete

Continue on to Protocol Submission. Data Validation checks are completed here. If there are problems with either the Protocol or the Appendix, the follow the instructions on the screen to navigate back to the problem areas. Otherwise, you will be allowed to proceed with IACUC protocol submission.

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

RASCAL Human Subjects

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IRB-AAAR5960
Status: Creating

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- Research Aims & Abstracts
- Risks, Benefits & Monitoring
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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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https://www.rascal.columbia.edu/hazmats/appendix/M/AAAA9050/generalInformation

RASCAL Hazardous Materials

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APM-AAAA9050
Status: Creating (Protocol Status)

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| | | | |
|-----------------|--------------------------|--------------------|--------------------------|
| 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

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APM-AAAA9050
Status: Creating
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- [RASCAL Menu]

******* 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

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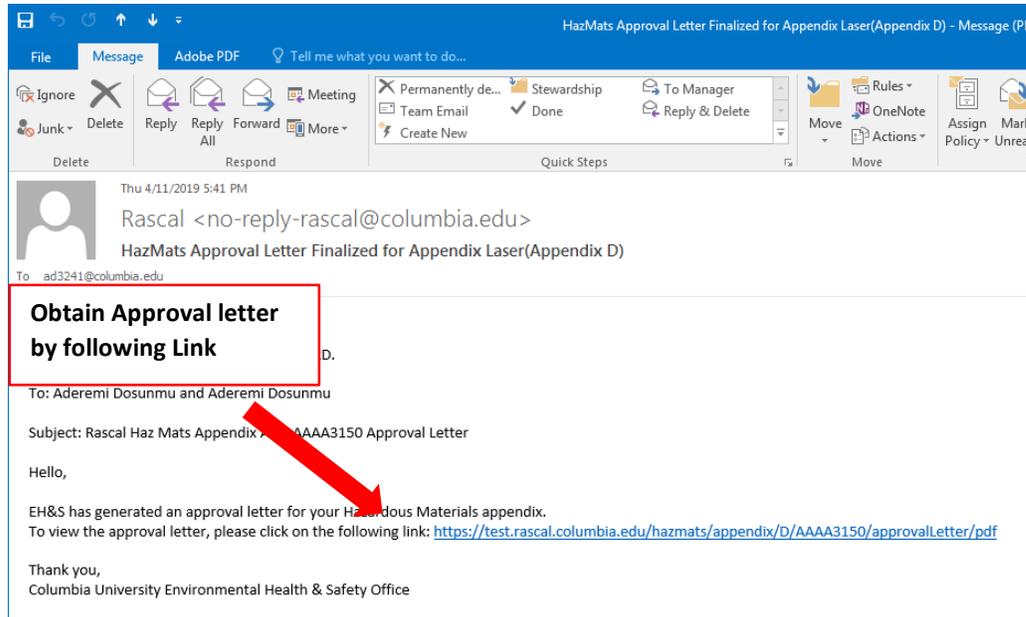
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After editing the appendix, "Save" the form and close the tab.

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

