

NEIS DRUPAL WEBSITE GUIDELINE

Version 2

January 2025

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1 LOGGING INTO THE WEBSITE

The first time you log into the website you will need to create a new password. Select the **Reset your password** option and an email will be sent to you with instructions. If you do not receive the email, please check your spam/junk folder. Please contact neiscpc@emmes.com for login assistance if needed.

Log in screen:

NEIS
National Eye Institute Support

Username *

Password *

Log in

Reset your password

For Login help or information please contact : neiscpc@emmes.com

Welcome to NEIS

Emmes serves as the data coordinating center to assist the National Eye Institute in the development, statistical design, monitoring, and coordination of vision clinical trials and epidemiology research.

National Eye Institute

Emmes
401 N. Washington Street, Ste 700
Rockville, MD 20850

Food and Drug Administration
FDA MedWatch Information
Code of Federal Regulations

2 PROTOCOLS SECTION

Depending on your access, you will see the below main navigation bar. All pages and tabs are access-dependent. If you do not see a category that you believe you should have access to, please contact neiscpc@emmes.com.

NEIS
National Eye Institute Support

 Search My account Log out

Protocols Web Reports OpComs Committees Bibliography Closed Protocols (C) DocuBank Upload Website Help DSMC - Pls Only

Protocols

To navigate to a specific protocol page, click on the **Protocols** tab and the below list will appear (depending on your access to specific protocols). You may search for a specific protocol using the **Protocol Name search field** (using protocol abbreviated title or number) or click on the protocol name on the left side of the screen to open the protocol page.



- Protocols
- Web Reports
- OpComs
- Committees
- Bibliography
- Closed Protocols (C)
- DocuBank
- Upload
- Website Help
- DSMC - Pls Only

Protocols

Protocol Name

Apply

Protocol	Full Protocol Name
AO ORD (000187)	Adaptive Optics Imaging of Outer Retinal Diseases
BioBank (12-EI-0042)	NEI Intramural Biorepository for Retinal Diseases
Coordinating Center	Internal Web Reports ONLY
DA Extension (17-EI-0112)	A Long-term Follow-up Study of Participants Enrolled in 11-EI-0147: Longitudinal Investigation of Dark Adaptation in Participants with Age-Related Macular Degeneration
DA VitA AMD (18-EI-0067)	An Investigation of Vitamin A Palmitate Supplementation in Patients with Age-Related Macular Degeneration (and without reticular pseudodrusen) and Delayed Dark Adaptation

On the specific protocol page you will see the Full Protocol Title, Description of the Protocol, and contact information for the NEI and NEIS study teams. Additionally, if applicable, you can access the Protocol Dashboard and Advantage eClinical link.

DA Extension (17-EI-0112)

View Edit Delete All entities Revisions Members Nodes

A Long-term Follow-up Study of Participants Enrolled in 11-EI-0147: Longitudinal Investigation of Dark Adaptation in Participants with Age-Related Macular Degeneration

Description

The Dark Adaptation Extension study allows us to continue with the follow-up of participants who were enrolled in the clinical trial, 11-EI-0147, *Longitudinal Investigation of Dark Adaptation in Participants with Age-Related Macular Degeneration*, investigating long-term changes in dark adaptation in participants with a range of age-related macular degeneration severity who have already been characterized and followed under that protocol.

DA Extension Dashboard

Contact Information:

NIH

Principal Investigator: Emily Chew echew@nei.nih.gov
Study Coordinator: Angel Garced angel.garced@nih.gov

Coordinating Center

Clinical Study Manager: Sam Chow zchow@emmes.com
Clinical Research Associate: Jessica Stevenson jstevenson@emmes.com
Data Manager: Jonathan Affeltranger jaffeltranger@emmes.com

Advantage eClinical users at the National Eye Institute can view study-specific case report forms and query reports by clicking one of the Advantage eClinical production system links below. A username and password are required to access these systems.

If you have questions or experience problems accessing the Advantage eClinical systems, please contact the Coordinating Center at neisdms@emmes.com.

Advantage eClinical Production System



Click here to enter Advantage eClinical

- [Advantage eClinical User's Guide_NEI](#)

Below that you will see two or three tabs (depending on the protocol) and a search field:

The screenshot shows a navigation bar with three tabs: "Document" (highlighted in green), "Web Reports" (dark blue), and "All" (grey). Below the tabs is a search field with the placeholder text "Enter your keywords" and an "Apply" button (green).

Document

By selecting the **Document** tab, a list of all documents pertaining to the protocol will appear. It is recommended to use the search field to find the document you are looking for. You can also navigate the categories and sub-categories to find the document.

Protocol Documents	
+ Activation Slides	
+ Flowsheets	
+ Modification Summary	
+ Modifications	
+ Protocol	
+ Site Monitoring Plan	
EMR Data Entry Guidelines	
> DA Extension EMR Guidelines	DA Extension EMR Guidelines
Manual of Procedures	
> DA Extension MOP	DA Extension MOP
Numbered Memos	
> DA Extension Numbered Memo 00	DA Extension Numbered Memo 00
> DA Extension Numbered Memo 01	DA Extension Numbered Memo 01
> DA Extension Numbered Memo 02	DA Extension Numbered Memo 02
> DA Extension Numbered Memo 03	DA Extension Numbered Memo 03
> DA Extension Numbered Memo 04	DA Extension Numbered Memo 04
> DA Extension Numbered Memo 05	DA Extension Numbered Memo 05
> DA Extension Numbered Memo 06	DA Extension Numbered Memo 06
> DA Extension Numbered Memo 07	DA Extension Numbered Memo 07

2.1 PROTOCOL DOCUMENTS

Under **Protocol Documents** select the plus sign to expand the category. Click on the title in the second column to open the document:

+ Activation Slides	
- Flowsheets	
> DA Extension Protocol Flowsheet	DA Extension Protocol Flowsheet
+ Modification Summary	
+ Modifications	
- Protocol	
> DA Extension Protocol	DA Extension Protocol

Click here to open document

Web Reports

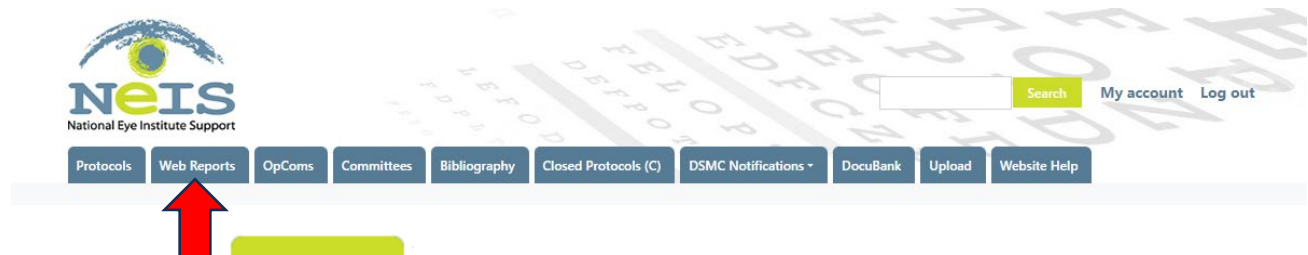
By selecting the **Web Reports** tab (if applicable) all web reports for that specific protocol will display. All Web Reports can also be accessed through the Web Reports tab on the main navigation screen.

Click here to open report

DA Extension

> 1_DA Extension Dashboard	1_DA Extension Dashboard
> DA Extension Accrual (Figure)	DA Extension Accrual (Figure)
> DA Extension Accrual (Table)	DA Extension Accrual (Table)
> DA Extension AE Summary (Table)	DA Extension AE Summary (Table)
> DA Extension AEs (Listing)	DA Extension AEs (Listing)
> DA Extension AEs (New in Last 7 Days) (Listing)	DA Extension AEs (New in Last 7 Days) (Listing)
> DA Extension AEs by MedDRA SOC and PT (Table)	DA Extension AEs by MedDRA SOC and PT (Table)

3 WEB REPORTS (ALL PROTOCOLS)



Web Reports

By selecting the **Web Reports** tab (if applicable) web reports for all protocols will display. It is recommended to use the Search field for a specific report or protocol. Below the **All Protocols** sections, web reports for specific protocols are displayed in alphabetical order. Click on the title in the second column to open the file.

Enter your keywords

Apply

Click here to open report.



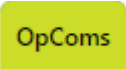
All Protocols

> 1_All Protocols Dashboard	1_All Protocols Dashboard
> All Protocols Accrual (Table)	All Protocols Accrual (Table)
> All Protocols AE Summary (Table)	All Protocols AE Summary (Table)
> All Protocols AEs (Listing)	All Protocols AEs (Listing)
> All Protocols AEs (New in Last 7 Days) (Listing)	All Protocols AEs (New in Last 7 Days) (Listing)
> All Protocols AEs (Related) (Listing)	All Protocols AEs (Related) (Listing)
> All Protocols AEs (Related) by MedDRA SOC and PT (Table)	All Protocols AEs (Related) by MedDRA SOC and PT (Table)
> All Protocols AEs by MedDRA SOC and PT (Table)	All Protocols AEs by MedDRA SOC and PT (Table)
> All Protocols Demographic Summary (Table)	All Protocols Demographic Summary (Table)

DA Extension

> 1_DA Extension Dashboard	1_DA Extension Dashboard
> DA Extension Accrual (Figure)	DA Extension Accrual (Figure)
> DA Extension Accrual (Table)	DA Extension Accrual (Table)
> DA Extension AE Summary (Table)	DA Extension AE Summary (Table)
> DA Extension AEs (Listing)	DA Extension AEs (Listing)
> DA Extension AEs (New in Last 7 Days) (Listing)	DA Extension AEs (New in Last 7 Days) (Listing)
> DA Extension AEs by MedDRA SOC and PT (Table)	DA Extension AEs by MedDRA SOC and PT (Table)
> DA Extension Demographic Summary (Table)	DA Extension Demographic Summary (Table)
> DA Extension Demographics (Listing)	DA Extension Demographics (Listing)
> DA Extension Disposition (Table)	DA Extension Disposition (Table)
> DA Extension IER (Table)	DA Extension IER (Table)
> DA Extension Natural Progression of Disease Events (Listing)	DA Extension Natural Progression of Disease Events (Listing)

4 OPCOM MEETINGS

To view OpCom meeting materials, select the  tab. This will display all OpCom meetings you have access to:

OpComs

OpCom Name



OpCom	Type
DECA OpCom	OpCom
EMR OpCom	OpCom
Met4 OpCom	OpCom
OGVFB OpCom	OpCom
STEM-RPE OpCom	OpCom
Topical GA Metformin OpCom	OpCom
Cukras OpCom	Archived OpCom
LI OpCom	Archived OpCom
Pharmacy OpCom	Archived OpCom

Click on the OpCom name on the left to display the schedule and links to each meeting per calendar year. The Search field can also be used to find a specific meeting date or document:

Enter your keywords

[Apply](#)

Schedule

> DECA OpCom Schedule 2024	DECA OpCom Schedule 2024
----------------------------	--------------------------

2021 - 2025

+ 2024
+ 2023
+ 2022
+ 2021

Select the year to display the agenda and minutes from each meeting held that year. Click on the title in the second column to open a pdf of the document.

[Click here to open document](#)

- 2024	
> April 11, 2024 DECA OpCom agenda	April 11, 2024 DECA OpCom agenda
> April 11, 2024 DECA OpCom Minutes	April 11, 2024 DECA OpCom Minutes
> February 1, 2024 DECA OpCom agenda	February 1, 2024 DECA OpCom agenda
> February 1, 2024 DECA OpCom minutes	February 1, 2024 DECA OpCom minutes
> June 6, 2024 DECA OpCom Agenda	June 6, 2024 DECA OpCom Agenda
> June 6, 2024 DECA OpCom Minutes	June 6, 2024 DECA OpCom Minutes

5 COMMITTEES

The DSMC, ICRRC and SAE Review Committee meeting information is found under the

[Committees](#)

tab. Select the committee (if applicable) in the left column to open the page.

Committees

Committee Name

Apply

Committee	
Dr Musch NEI DSMC	edit
DSMC	edit
ICRRC	edit
ICRRC Schedule	edit
IRB	edit
SAE Review	edit
STEM-RPE DSMC	edit

Select the item in the second column to display the document. Current meeting materials will be listed under the Current Meeting section and all previous meeting materials will be under the specific year and month.

Click here to open document



Schedule	
> ICRRC 2024 Schedule	ICRRC 2024 Schedule

SOP	
> ICRRC SOP	ICRRC SOP

Roster	
> ICRRC Roster	ICRRC Roster

Current Meeting	
+ eyeGENE 3 DTA	

2024 Meetings	
+ July	
+ May	


To view the meeting materials, select the plus sign to expand the category and select the document title in the second column.

Click here to open document



2024 Meetings	
- July	
> July 10, 2024 ICRRRC Agenda	July 10, 2024 ICRRRC Agenda
> July 10, 2024 ICRRRC Minutes	July 10, 2024 ICRRRC Minutes
> NIH-IIA-NIAID - NEI MD	NIH-IIA-NIAID - NEI MD
> PHS ICT-CRADA - Drug Farm	PHS ICT-CRADA - Drug Farm


6 DOCUBANK

To access the DocuBank files (if applicable) select the  tab and a list of all protocols will display. Click on the protocol and a list of the Maps will display:

DocuBank List
Group Name
ARIS (DocuBank)
BBANK (DocuBank)
DA VitA Studies (DocuBank)
DAAMD (DocuBank)
DAEXT (DocuBank)
ERVHL (DocuBank)
GAMIN (DocuBank)
GANHP (DocuBank)
iBANK (DocuBank)

Click on the protocol and a list of the Maps will display. Click on the document name in the second column to open the Map:

Click here to open map



Maps	
> DA_AMD Map Version 1.0 14FEB2013	DA_AMD Map Version 1.0 14FEB2013
> DA_AMD Map Version 1.1 20JUN2017	DA_AMD Map Version 1.1 20JUN2017
> DA_AMD Map Version 1.2 11OCT2017	DA_AMD Map Version 1.2 11OCT2017
> DA_AMD Map Version 1.3 25OCT2017	DA_AMD Map Version 1.3 25OCT2017
> DA_AMD Map Version 1.4 27OCT2017	DA_AMD Map Version 1.4 27OCT2017
> DA_AMD Map Version 1.5 23JAN2018	DA_AMD Map Version 1.5 23JAN2018
> DA_AMD Map Version 1.6 18JUL2019	DA_AMD Map Version 1.6 18JUL2019

6.1 UPLOAD TO DOCUBANK

To upload to Docubank select the **Upload** tab and the following page will display. Fill in the **Title** field (be sure title includes the specific protocol name), attach the document and select the **Save** button at the bottom of page. **No other information is needed.** The NEIS CPCs will move the document to the appropriate protocol under Docubank.

The screenshot shows a web form for uploading a document to Docubank. The form includes the following elements:

- Title ***: A text input field with a yellow callout box containing the text "Enter title here".
- Attachment**: A section with a dropdown arrow and the text "Add a new file". It contains a "Browse..." button, a text input field with "No files selected.", and a yellow callout box containing the text "Attach document here". Below this, it states "Unlimited number of files can be uploaded to this field. 900 MB limit. Allowed types: txt pdf xlsx csv docx zip jpg png html gif doc."
- Display ***: A dropdown menu with "Yes" selected. Below it, the text reads "Choose whether to display this item on the document listing or not."
- Display Tab ***: A dropdown menu with "Document Tab" selected. Below it, the text reads "Choose which tab this document should appear under when listed on group pages. Contact the Web Dev Team for additional tabs if necessary."
- Buttons**: A "Save" button and a yellow callout box containing the text "Select Save Button".

7 BIBLIOGRAPHY

All publications and manuscripts can be found under the **Bibliography** tab. Select the Title in the second column to open a publication or manuscript as shown below. You may also search by Authors, Publication Type and/or Year of Publication.

Publications

Authors Publication Type Year of Publication

Apply

Click here to open

Authors	Title	Journal	Year	Type
R.B. Nussenblatt; R.R. Buggage; D.J. Thompson; L. Zhuqing; J. Ragheb; T.A. Waldmann	4 Year daclizumab therapy for sight threatening uveitis	Annual Meeting of the Federation of Clinical Immunology Societies, San Francisco, CA, June 28-July 21	2002	Journal Article
R.R. Buggage; G. Levy-Clarke; H.N. Sen; R. Ursea; S.K. Srivastava; E.B. Suhler; C. Altemare; G. Velez; J. Ragheb; C.C. Chan; R.B. Nussenblatt; A.T. Bamji; P. Sran; T. Waldmann; D.J.S. Thompson	A double-masked, randomized study to investigate the safety and efficacy of daclizumab to treat the ocular complications related to Behçet's disease.	Ocul Immunol Inflamm	2007	Journal Article
Human Microbiome Project Consortium (including Simone, G)	A framework for human microbiome research.	Nature	2012	Journal Article

A double-masked, randomized study to investigate the safety and efficacy of daclizumab to treat the ocular complications related to Behçet's disease.

View Edit Delete Revisions

Alternate Title

Ocul. Immunol. Inflamm.

Journal

Ocul Immunol Inflamm

Authors

R.R. Buggage; G. Levy-Clarke; H.N. Sen; R. Ursea; S.K. Srivastava; E.B. Suhler; C. Altemare; G. Velez; J. Ragheb; C.C. Chan; R.B. Nussenblatt; A.T. Bamji; P. Sran; T. Waldmann; D.J.S. Thompson

Corporate Authors

R.R. Buggage; G. Levy-Clarke; H.N. Sen; R. Ursea; S.K. Srivastava; E.B. Suhler; C. Altemare; G. Velez; J. Ragheb; C.C. Chan; R.B. Nussenblatt; A.T. Bamji; P. Sran; T. Waldmann; D.J.S. Thompson

Pubmed Id

17558830

Abstract

PURPOSE: To investigate the safety and efficacy of daclizumab (Zenapax, humanized anti-Tac, HAT) in controlling the ocular manifestations of Behçet's disease.

DESIGN: Randomized, placebo-controlled, double-masked clinical trial.

8 CLOSED PROTOCOLS

Closed Protocols (C)

The **Closed Protocols (C)** tab (if applicable) is a repository of closed protocols. You may search by PI or Protocol Name. To open a specific closed protocol page, click on the protocol name in the third column.

Closed Protocols (C)

List of Closed Protocols

Associated PI Protocol Name

- All Djallilian
- Amy Turriff
- Brett Jeffrey
- Brian Brooks
- Catherine Cukras
- Catherine Meyerle
- Edmond FitzGibbon
- Elliot Stein
- Emily Chew

[Click here to open protocol page](#)

[Apply](#)

Associated PI	Full Protocol Name	Protocol
Ali Djallilian	Evaluation of the Survival of Donor Corneal Epithelial Cells after Limbal Stem Cell Transplantation	Limbal Cell (XXXXX) (C)
Amy Turriff	People's Expectations When Enrolling in a Phase I/II RS1 Ocular Gene Transfer Clinical Trial	Patient Expectations (15-EI-0041) (C)
Amy Turriff	Mothers Experiences With X-linked Retinoschisis Compared to Fathers Experiences	XLRS Parents (18-EI-0016) (C)

Once protocol page is open, the full title, link to ClinicalTrials.gov, and protocol documents display as shown below.

COLOBOMA_Old (06-EI-0230) (C)

[View](#) [Edit](#) [Delete](#) [All entities](#) [Revisions](#) [Revisions](#) [Members](#) [Nodes](#)

Family Studies of Uveal Coloboma

Description
National Library of Medicine - ClinicalTrials.gov [Click here to access ClinicalTrials.gov](#)

Associated PI
Brian Brooks

[Document](#) [All](#)

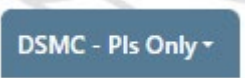
Enter your keywords

[Apply](#)

Protocol Documents
+ **Protocol**

Consents/Assents
+ **Assents**
+ **Consents**

9 DSMC PIs ONLY ACCESS

The  tab is for PIs ONLY to access DSMC Notifications and meeting materials.