

UMDNJ

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION FOR EXEMPT REVIEW

Clearly type all portions of this form.

For IRB Office Use Only:

IRB# _____

STUDY TITLE

NANOS/NOVEL DATA STEWARDSHIP PROJECT- AUTOIMMUNE MEDIATED OPTIC
NEUROPATHY

1. Personnel

All personnel listed (PI, co-investigators and study personnel) must attach a copy of their completed Investigator Financial & Other Personal Interests Disclosure Form http://www.umdnj.edu/opmweb/Policies/HTML/AcademicAff/00-01-20-89_00.html.

Principal Investigator (PI) (last name, first name, MI, highest degree earned) Larry Frohman, MD	<input checked="" type="checkbox"/> UMDNJ Paid Faculty <input type="checkbox"/> UMDNJ Staff <input type="checkbox"/> UMDNJ Student (SHRP, SN & SPH only) Other: _____	Required education in human subjects protection completed: <input checked="" type="checkbox"/> CITI <input checked="" type="checkbox"/> HIPAA Other: _____
Academic Title(s) Professor of Ophthalmology & Neurosciences		
School & Department, Patient-care Unit or Administrative Office NJMS, Ophthalmology	Phone 2-2026	
UMDNJ Institute/Center IOVS	Pager or Cell 973-421-0733	
Mailing address 90 Bergen Street Newark, NJ 07103	Fax 973-972-2068	
	E-mail frohman@umdnj.edu	

Contact person for IRB matters, if other than the PI. This person must be listed under Study Personnel in the box below.

Name	Phone
E-mail	Fax

STUDY PERSONNEL: All individuals responsible for or working on this study for whom a UMDNJ IRB is the IRB of record must be listed below, including individuals who will have responsibility for the consent process, interactions or interventions with subjects, data collection, etc., or who will have access to identifiable private information for research purposes.

Study Personnel (Name/Degree/Title) Attach separate page if more room is needed.	Role in Study Identify as co-investigator or other personnel.		School/Department	Phone	E-mail	Month/Year of completion for Human Subjects Protection and HIPAA training Required for all study personnel.	
	Co-I	Other				CITI	HIPAA
	<input type="checkbox"/>	<input type="checkbox"/>					

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2. Sponsor

Is this study funded? Yes No

If yes, complete the following:

Name of Funding Agency: _____

Title of proposal, if different from IRB study application title: _____

Identification number: _____ Grant/Project number: _____

Dates of funding are/will be: from _____ to _____

If funded, attach a complete copy of grant application/contract as submitted to the sponsor. Salary information (not % effort) may be redacted.

3. Research performance sites (location of subjects, records, specimens and data)

<i>Site(s) (Name and Address)</i>
Department of Ophthalmology DOC private practice
Department of Ophthalmology Roseland private practice (556 Eagle Rocek Ave. Roseland, NJ 07068)
University Hospital Eye Clinic

4. Subject Population

Age range: 0 to 105

Vulnerable Populations: Check all populations below that might be enrolled, even if not target group:

- Non-English speaking
- Pregnant women
- Diminished decision-making capacity
- Specify: **all**
- Minorities
- Fetuses
- Prisoners
- Wards of the state or foster children
- Economically or educationally disadvantaged

5. Research Plan

a. Purpose of the study (provide a brief description)

The North American Neuro-ophthalmology Society (NANOS) has built an educational library (the Neuro-ophthalmology Virtual Education Library, or NOVEL) that received about two million hits a year from 99 countries. We are going to use the website and its popularity with neuro-ophthalmologists and other physicians over the world to disseminate information about our efforts to collect de-identified data on rare neuro-ophthalmic conditions. We wish to use the website to establish a "registry of rare visual diseases" under study. These will be conditions that are so unusual that a neuro-ophthalmologist might never see one in his/her career, so no natural history and treatment data can be developed. But by developing standard data collection forms, and advertising who will be the "data steward" for each disease, we should be able to collaboratively develop natural history and treatment data. Although my efforts to do this AIMONS effort

data collection are unfunded, NANOS does have an unretricted grant from Pfizer to maintain the website and add academic materials. We will have five initial rare conditions, I will be data steward for one of them, Autoimmune Immune Mediated Optic Neuropathy (AIMON, also known as Autoimmune Optic Neuropathy). The project will be to post my name and contact information on the website, with instructions and a deidentified standard data collection form that anyone seeing one of these patients can fill out and send to me. I will collect the clinical material on these cases. We envision having society sponsored publications if enough data is collected (hopefully, we can collect data for three years and then will have enough information to analyze and publish). Once we see if the data collection for the five initial disease states that are piloted work, we will likely set up disease registries for additional rare diseases. It is understood that anyone submitting data will inquire if their IRB first requires obtaining approval for doing so; my IRB application will be posted with the data collection form so that they might modify this for their IRB's needs as required.

- b. Provide background information, including references to any prior studies, to support your project.

See Appendix one for lecture given by PI at NANOS annual meeting in 2007 on this disease entity

- c. Describe the expected medical, scientific and research benefits of the project.

Obtaining natural history data and clinical therapy data on AIMON

- d. What are the potential risks (including breach of confidentiality) and/or benefits to subjects or society?

None

- e. How will data be obtained? *Check all that apply.*

Commercial Cell Lines

Name of the Provider: _____

Existing Databanks

Paper

Epic

Logician

PACs

Other, *specify* **current and future patients seen with AIMON**

will have their records deidentified and extracted

- f. Is there an existing link to the identifiers?

Yes

No

6. Privacy/Confidentiality

Data that are coded, where the key to the code is accessible to researchers, are considered protected health information (PHI) and subject to HIPAA regulations. When PHI is collected by the investigator, HIPAA mandates that the research data be maintained by the PI for 6 years following the close of the study. However, the code linking individual subjects to their research data may be destroyed as soon as it is no longer needed for the conduct of the study. UMDNJ requires that study data be kept for a minimum of six years after termination of study or publication of the data, whichever occurs later, but preferably indefinitely.

- a. Will you be collecting Protected Health Information as defined by HIPAA?

Yes (if yes, then this study does not qualify for exempt review) No

- b. How long will you keep the research data? *State in terms which relate to the study timeline, e.g., six years after the closure of the study. State indefinitely if the data will never be destroyed.*

indefinitely

- c. Describe how the data will be stored and protected:

- (i) For paper-based information include the following information: where the data will be stored, who has access to the storage area, and how access will be monitored:

Larry Frohman, in his password protected computer or in locked office in DOC

- (ii) For electronic information include the following information: how electronic security will be maintained, what password protection and virus software are enabled, and how the system will be audited:

Larry Frohman, in his password protected computer or locked office in DOC

- d. Is your computer authenticated within the UMDNJ IST System? Yes No

If not, list computer, its use, and location: _____

- e. Is your computer password protected? Yes No

- f. Is the PI the data steward? Yes No

(A data steward is any individual who creates, maintains or stores a file, which contains protected health information and is responsible for that database.) *Note that the data steward must be listed on page 1 of the application under personnel.*

If not, indicate who will be responsible _____

7. Signatures

Investigator Assurance:

- I agree to accept responsibility for the scientific conduct of the protocol and to comply with Federal, State and UMDNJ policies relative to the protection of the rights and welfare of human subjects.
- I will submit to the IRB for review any changes in the protocol before their implementation. I also agree to provide the required final progress report at the end of the study and/or progress report for continuing review in time to have this study approved before the expiration date as directed by the IRB.
- I will promptly inform the IRB of any and all protocol deviations/violations or unanticipated problems.
- My signature below also provides written assurance that identifiable information will not be reused or disclosed except as required by law; or for other research only if that research has been reviewed and approved by a UMDNJ IRB with specific attention to and approval of the issue of access to this identifiable information.

Department Chairperson Approval: I have reviewed this protocol and approve its submission to the IRB. The investigator is credentialed, has appropriate training to conduct the research and has adequate resources and staff to perform procedures outlined in this study.

Signature of Principal Investigator (<i>designee's signature NOT acceptable</i>) _____ Date _____	Signature of Department Chair (<i>designee's signature NOT acceptable</i>) _____ Date _____
Signature of Co-investigator (<i>designee's signature NOT acceptable</i>) _____ Date _____	Signature of Department Chair (<i>designee's signature NOT acceptable</i>) _____ Date _____
Signature of Co-investigator (<i>designee's signature NOT acceptable</i>) _____ Date _____	Signature of Department Chair (<i>designee's signature NOT acceptable</i>) _____ Date _____
Signature of Co-investigator (<i>designee's signature NOT acceptable</i>) _____ Date _____	Signature of Department Chair (<i>designee's signature NOT acceptable</i>) _____ Date _____

Please include a copy of the following with your submission:

- Certificate of Completion for HSP/CITI training for all study personnel on this project. (For assistance, contact the HSP office at: 973-972-1149).
- UMDNJ Investigator Financial & Other Personal Interests Disclosure Form for all investigators on this project. http://www.umdj.edu/oppmweb/Policies/HTML/AcademicAff/00-01-20-89_00.html
- For studies conducted at UMDNJ-University Hospital, the University Hospital (UH) Research Protocol Pre-Registration Form. <http://ocr.umdj.edu/3steps.cfm>
- For studies conducted at Robert Wood Johnson University Hospital, the RWJUH RUG Allocation of Resources Form.
- For studies conducted at University Behavioral Health Care, the UBHC Human Research Form. <http://www.umdj.edu/irbnweb/forms/UBHC%20Human%20Research%20Form.doc>
- For studies conducted at the Cancer Institute of New Jersey, the Scientific Review Board Approval Letter.
- For studies conducted at Kennedy Memorial Hospitals, the required GAFA Form along with the signature of the Vice President Graduate Medical Education.